Pharmacy Purchasing Outlook

Member-Publication of the National Pharmacy Purchasing Association (NPPA)

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New Bulk Drug Substances Added To 503B Bulks Compounding List

On January 27, 2022, the FDA announced they have added the first four (4) bulk drug substances to the list of bulk drug substances that may be used in compounding by outsourcing facilities, titled 503B Bulks List. The FDA's efforts helps to ensure that Americans have access to compounded medicines when a patient's medical needs cannot be met by an FDA-approved drug.

The 4 newly added bulk drug substances include the following (all of which are not components of currently FDA-approved drugs):

1) Diphenylcyclopropenone (DPCP) for Topical Use;
2) Glycolic Acid for Topical Use, in concentrations up to 70%;
3) Squaric Acid Dibutyl Ester (SADBE) for Topical Use;
4) Trichloroacetic Acid (TCA) for Topical Use.

The FDA's dedicated clinicians and researchers have implemented a careful and deliberative process to consider whether a bulk drug substance should be included in the 503B Bulks List. This process is also informed by external research partners, feedback from industry stakeholders, and other public commenters. As development of the 503B Bulks List progresses, nominations of bulk drug substances that are adequately supported will continue to undergo the thorough FDA vetting necessary to protect patients while balancing access to compounded drugs to meet patient needs.

To mitigate patient access concerns, the FDA's Interim Policy on Compounding Using Bulk Drug Substances is set forth in guidance, and addresses compounding from certain bulk drug substances, during which time they conduct clinical need evaluations.

Federal law places conditions on compounded drugs that qualify for the exemptions in section 503B of the Federal Food, Drug & Cosmetic Act. One of these conditions is that a drug must be compounded by an outsourcing facility that only compounds drugs using bulk drug substances for which

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Biosimilar Drug Approvals

Byooviz™ Injection - First Biosimilar To Treat Macular Degeneration Disease & Other Eye Conditions

On September 20, 2021, Samsung Bioepis Co., Ltd. of Incheon, Korea and Biogen Inc. of Cambridge, Massachusetts jointly announced that the FDA has approved Byooviz™ (ranibizumab-nuna) Injection for intravitreal use (delivered into the vitreous humor of the eye), indicated for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization.

Byooviz is the first ophthalmology biosimilar drug to be approved in the United States. It compares to Lucentis® (ranibizumab) by Genentech, Inc.

Age-related macular degeneration (AMD) is the current leading cause of irreversible blindness in adults over 50. Approximately 11 million individuals are affected with AMD in the U.S. alone. Wet AMD is responsible for 80% to 90% of all AMD-related blindness.

Central retinal vein occlusion (RVO) is a common cause of retinal disease that can cause vision loss. Vision loss from CRVO is commonly caused by macular edema, which occurs when fluid leaks into the macula (center of the retina) as a result of blocked blood vessel.

Myopia is one of the most common causes of vision impairment, and one of the most feared complications of myopia is the development of choroidal neovascularization (CNV). Myopic CNV can occur in patients with any degree of myopia, even in the absence of characteristic degenerative retinal changes.

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Highlights Inside This Edition

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Join Us For The 25th Annual NPPA Conference This August 2022!

Be sure to plan ahead and mark your calendars for the ***next*** NPPA Conference, at Bally's Las Vegas over August 9-11, 2022.

2022 NPPA: Tuesday, August 9 through Thursday, August 11

Pre-Conference 340B University: Monday, August 8

Registration for Attendees is now open. Look for regular updates by email and on our NPPA website's Home Page on the right, under "NPPA Conference News."

In addition, an optional **340B University event is being offered** by the 340B Prime Vendor Program Managed By Apexus, on Monday August 8th, the day before our NPPA Conference begins, with no additional fee as sponsored by Apexus. To register, see the link on the NPPA website.

Bally's hotel room rates for our 2022 NPPA Group Room Block are $99+Tax per night plus a $35+Tax Resort Fee, which expires after July 5th.

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NPPA Membership Rates: $90, 1-year; $170, 2-years (comes with 7 editions/year of *Pharmacy Purchasing Outlook*, the member-publication of NPPA). Issues are distributed via First Class U.S. Mail, by the end of the first week of the month after the publication issue month. See details on our website.

Within This Edition

Editorial

By Amy Empson
NPPA Office & Event Assistant

In March 1994, NPPA Founder **Dale Kroll** wrote and published his first *Pharmacy Purchasing Outlook* publication. It was 8 pages long and contained information that Dale believed in. The mission statement in that first publication states: *"Pharmacy Purchasing Outlook is created by, for, and about pharmacy purchasing professionals, published in a timely manner, for the immediate benefit, education, and career growth of its subscribers and those in the pharmaceutical industry. In looking out for and to others in our profession, we highlight the positive achievements of colleagues and discover that, as a result, we all become better at what we do."*

While reading the first year's start of the *PPO* editions, Dale wrote passionately about helping pharmacy purchasing professionals. The articles in the beginning concentrated on inventory control issues, wholesalers and manufacturing issues, pricing issues, generic drugs, new drugs, and other things he thought were important to the industry.

Dale believed in education to help others within the pharmacy industry as well. He believed in helping so much, that in June of 1994, he did his first *PPO* "mini-tour," driving cross country to visit subscribers' directly at their jobs in hospital pharmacies. He drove across cities to meet with the most Pharmacy Buyers as he could, in an effort to learn more and help others spread their respective knowledge from what they shared and what Dale learned about them in those visits. For the second mini-tour the following year (in 1995), Dale again set out in his car once more, to interview and write about his Subscriber-Buyers. He drove 8,600 miles just to speak to 18 members for the *PPO*. Dale wanted so badly to connect with his readers, to make them feel they were a significant part of it all, and to share their feedback with the rest of the readers.

Then on March 13, 1997, the first NPPA Conference began in Las Vegas. It was a 1-day event, with meeting topics such as: "Inventory Control Systems That Can Save You Money," and "The Future of Wholesaler Distribution & How it Will Affect the Pharmacy Buyer." After the educational program, attendees were able to network with 17 vendor companies at table-top displays. Attendees received a Certificate of Participation for their 6 educational program hours, although this was before NPPA started using an ACPE-accredited continuing education provider.

1997 was also the first year NPPA's Outstanding Buyer of the Year Award was handed out in person. In 1998, the second year of the NPPA Conference, it grew from 1 day to 2, and doubled in size for both the Buyer-Attendees and Vendor-Exhibitors and Sponsors.

Since the beginning, with the help of **Francine Morgano,** as Editor of *PPO* and then-company Vice-President, NPPA's vision has grown into what it is now. Francine has worked tirelessly over the last 27 years to help fulfill Dale's vision. As I have read countless older issues of the *PPO* and articles about the Annual NPPA Conference, I am truly in awe of what Dale and Francine have been able to do. The NPPA Conference now has over 100 vendors with 7 hours of Exhibit Hall time, more continuing education credits, and a chance to meet up with an average of 300+ fellow pharmacy staff from all over the United States. In addition, Apexus now partners with the NPPA Conference for a 340B University training they offer/sponsor on the day prior.

The *PPO* has grown from 8 pages to the average of 68 to 80 pages. The information now provided in the current *PPO* includes Generic Approvals, New Drugs, Discontinued Drugs, Biosimilar Drugs and more; along with the more recent updates on the pandemic with various news about COVID-19 treatments, vaccines, and tests.

Dale said: *"This is your publication, so we encourage your participation."* He always wanted to ensure the members had a voice. In every edition of *PPO* towards the back, you can find a column about how to contribute by sending articles and any feedback or messages (Board@pharmacypurchasing.com). NPPA also has a Membership Incentive Program in place with various ways to help our members (www.pharmacypurchasing.com/member-incentive-programs).

We want to encourage everyone to use their voice to share and collaborate in order to help fellow members as best we can, as Dale genuinely wanted and worked for. The staff at the NPPA is honored to carry on the vision that Dale and Francine have worked countless hours on throughout the years to keep the *PPO* and the Annual NPPA Conference going.

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NPPA Mission

The Mission of NPPA is to:

- Promote the Profession of Pharmacy Purchasing.
- Provide Specific and Enhanced Educational Opportunities for the Pharmacy Buyer.
- Provide a Unified Voice for the Professional Pharmacy Buyer.
- Affirm Pharmacy Purchasing as a unique and important specialty within the Pharmacy Profession.
- Affirm that Pharmacy Purchasing is an important aspect of Total Patient Care.

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Generic Approvals & News

Amantadine HCl Softgel Capsules - Strides Pharma

On February 21, Strides Pharma Inc. of East Brunswick, New Jersey announced they received final FDA approval for Amantadine HCl Softgel Capsules 100mg.

This product compares to Symmetrel® Capsules 100mg by Endo Pharmaceuticals, Inc. It is indicated for the prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus; and for the treatment of parkinsonism and drug-induced extrapyramidal reactions.

In 2021, U.S. sales of the product in this strength were $11 million, according to IQVIA™.

Arformoterol Tartrate Inhalation Solution - Lupin

On February 8, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they have received final FDA approval to market their Abbreviated New Drug Application (ANDA) for Arformoterol Tartrate Inhalation Solution 15mcg/2mL Unit-Dose Vials.

This product compares to Brovana® Inhalation Solution 15mcg/2mL by Sunovion Pharmaceuticals Inc. It is indicated for nebulization use only, for long-term maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

In 2021, U.S. sales of the product in this strength were $251 million, according to IQVIA.

Azacitidine For Injection - Amneal Pharmaceuticals

On February 17, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they received final FDA approval of their Abbreviated New Drug Application (ANDA) for Azacitidine for Injection 100mg.

This product compares to Vidaza® for Injection in this strength by Celgene Corporation, which had U.S. sales in 2021 of $61 million, according to IQVIA. It is indicated to treat certain types of bone marrow cancers and blood cell disorders.

This antineoplastic drug is currently on the FDA drug shortage list.

Brimonidine Tartrate Ophthalmic Solution Launch - Apotex

On January 31, Apotex Corp. of Weston, Florida announced their ***launch*** of Brimonidine Tartrate Ophthalmic Solution 0.15%, as detailed below:

- **5mL bottles:** NDC #60505-0564-01;
- **10mL bottles:** NDC #60505-0564-02;
- **15mL bottles:** NDC #60505-0564-03.

This product compares to Alphagan® P Ophthalmic Solution by Allergan (an AbbVie company). It is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Bupivacaine HCl Injection Launch - Hikma Pharmaceuticals

On December 20, 2021, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Bupivacaine HCl Injection in the following strengths: 0.25%, 0.5%, and 0.75% in 10mL and 30mL doses.

This product is indicated in adults for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures.

Recent annual U.S. sales (ending October 2021) of the product in these strengths were $64 million, according to IQVIA.

Carboprost Tromethamine Injection - Amneal Pharmaceuticals

On February 17, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they have received final FDA approval of their Abbreviated New Drug Application (ANDA) for Carboprost Tromethamine Injection 250mcg/mL.

This product compares to Hemabate® Injection by Pfizer, Inc., which had 2021 U.S. sales of $57 million, according to IQVIA. It is a form of prostaglandin that is indicated to treat severe postpartum bleeding for women (after childbirth).

Cisatracurium Besylate Injection Launch - Sagent Pharmaceuticals

On January 7, Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois announced their ***launch*** of Cisatracurium Besylate Injection, available preservative-free as detailed below.

- **10mg per 5mL single-dose vials:** NDC #25021-668-05.
- **20mg per 10mL multi-dose vials:** NDC #25021-670-10.
- **200mg per 20mL single-dose vials:** NDC #25021-669-20.

This product compares to Nimbex® Injection by GlaxoSmithKline LLC. It is indicated for the following:

1) As an adjunct to general anesthesia to facilitate tracheal intubation in adults and in pediatric patients 1 month to 12 years of age;

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Generic Approvals & News

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2) To provide skeletal muscle relaxation during surgery in adults and pediatric patients 2 to 12 years of age, as a bolus or infusion maintenance;
3) For mechanical ventilation in the ICU (intensive-care unit) in adults.

These products all come with Sagent's PreventIV Measures® features: easy-to-read drug name and dosage strength to aid in identifying the right product; barcodes included on the vial and carton for ease of scanning; unique label design to help products stand out on the shelf; and enhanced packaging and labeling designed to promote safety and help reduce the risk of medication errors.

Cyanocobalamin Injection - Zydus Pharmaceuticals

On April 18, Zydus Pharmaceuticals, Inc. of Pennington, New Jersey announced they received final FDA approval to market Cyanocobalamin Injection in the following strengths: 1,000mcg/mL, 10,000mcg/10mL, and 30,000mcg/30mL Multiple-Dose Vials.

This product is indicated to treat and prevent lack of vitamin B12 that may be caused due to pernicious anemia (lack of a natural substance needed to absorb vitamin B12 from the intestine), certain diseases, infections, or medications that decrease the amount of vitamin B12 absorbed from food.

Cyclosporine Ophthalmic Emulsion Launch - Apotex

On February 7, Apotex Corp. of Weston, Florida announced their ***launch*** of Cyclosporine Ophthalmic Emulsion 0.05% in 0.04mL vials, available in 30-count (NDC #60505-6202-01) and 60-count (NDC #60505-6202-02) packs.

This product compares to Restasis® Ophthalmic Emulsion 0.05% by Allergan (an AbbVie company). It is indicated to increase tear production in those who it is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Dapagliflozin Tablets - Zydus Pharmaceuticals

On February 23, Zydus Pharmaceuticals, Inc. of Pennington, New Jersey announced they received final FDA approval to market Dapagliflozin Tablets in the strengths of 5mg and 10mg.

This product compares to Farxiga® Tablets in these strengths by AstraZeneca. It is indicated along with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes. Dapagliflozin also lowers the risk of heart failure in adults with type 2 diabetes with heart disease. It is also used to lower the risk of further worsening of kidney disease, end-stage kidney disease, death due to cardiovascular disease, and hospitalization for heart failure in adults with chronic kidney disease. Dapagliflozin works by increasing the removal of sugar by kidneys.

Daptomycin For Injection Launch - Apotex

On February 7, Apotex Corp. of Weston, Florida announced their ***launch*** of Daptomycin Powder for Injection 500mg; available in 10mL vials (NDC #60505-6229-04).

This product compares to Cubicin® for Injection by Merck & Co., Inc. It is an antibiotic indicated to treat bacterial infections of the skin and underlying tissues and infections that have entered the bloodstream, including complicated infections such as Methicillin-resistant *Staphylococcus aureus* (MRSA).

Dexamethasone Sodium Phosphate Injection - Amneal Pharmaceuticals

On February 17, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they have received final FDA approval of their Abbreviated New Drug Application (ANDA) for Dexamethasone Sodium Phosphate Injection 10mg/mL.

Dexamethasone is currently on the FDA drug shortage list. It is a corticosteroid that prevents the release of substances in the body that cause inflammation and is indicated to treat many different inflammatory conditions such as allergic disorders, skin conditions, ulcerative colitis, arthritis, lupus, psoriasis, and breathing disorders.

2021 U.S. sales for the medication in this same strength were $66 million.

Dexlansoprazole DR Caps (AG Dexilant®) Launch - TWi Pharmaceuticals

On January 3, TWi Pharmaceuticals USA, Inc. of Paramus, New Jersey announced the ***launch*** and immediate availability of Dexlansoprazole Delayed-Release (DR) Capsules.

This product is an Authorized Generic (AG) of Dexilant® DR Capsules from Takeda Pharmaceuticals U.S.A., Inc. It is indicated for the treatment of heartburn caused by gastroesophageal reflux disease (GERD) and to heal erosive esophagitis (damage to the esophagus from stomach acid).

Recent annual U.S. sales (ending November 2021) of both brand and generics were $1.1 billion, according to IQVIA.

Generic Approvals & News

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Diazepam Injection In Single-Dose Prefilled Syringe (C-IV) Launch - Hikma Pharmaceuticals

On January 21, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Diazepam Injection Single-Dose Prefilled Syringe in the strength of 5mg/mL in 2mL dose.

Diazepam has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance. It is indicated for the management of anxiety, convulsive seizures, and alcohol withdrawals.

Recent annual U.S. sales (ending November 2021) for Diazepam Injection in this strength were $31 million, according to IQVIA.

Riad Mishlawi, President of Hikma Injectables, said: "We are excited to announce the launch of Diazepam Injection, our second product in prefilled syringe form, which may help treat patients faster, more easily and with reduced risk, particularly in time-sensitive situations."

Erythromycin Lactobionate For Injection Single-Dose Vials - Nexus Pharmaceuticals

On February 17, Nexus Pharmaceuticals, Inc. of Lincolnshire, Illinois announced they received final FDA approval for Erythromycin Lactobionate for Injection 500mg in single-dose vials; available in cartons of 5 single-dose vials.

This product compares to Erythrocin™ for Injection by Pfizer, Inc. It is indicated in the treatment of bacterial infections when oral administration is not possible or when the severity of the infection requires immediate high serum levels of erythromycin.

Febuxostat Tablets Launch – Dr. Reddy's Laboratories

On January 11, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey announced the ***launch*** of Febuxostat Tablets in the strengths of 40mg and 80mg, available in 30-count bottles.

This product compares to Uloric® Tablets by Takeda Pharmaceuticals U.S.A., Inc., which had recent annual U.S. sales (ending October 2021) of both brand and generics of $108 million, according to IQVIA. It is indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.

Metronidazole Vaginal Gel – Glenmark Pharmaceuticals

On January 28, Glenmark Pharmaceuticals Inc., USA of Mahwah, New Jersey announced they received final FDA approval for Metronidazole Vaginal Gel 0.75%.

This product compares to MetroGel-Vaginal® Gel 0.75% by Bausch Health U.S., LLC. It is indicated to treat bacterial vaginosis.

Recent annual U.S. sales (ending November 2021) of both brand and generics were $60.4 million, according to IQVIA.

Oseltamivir Phosphate For Oral Suspension - Strides Pharma

On January 17, Strides Pharma Inc. of East Brunswick, New Jersey announced they received final FDA approval for Oseltamivir Phosphate for Oral Suspension 6mg/mL.

This product compares to Tamiflu® for Oral Suspension in this strength by Hoffmann-La Roche, Inc., which had recent annual U.S. sales (ending November 2020) of $132 million, according to IQVIA.

It is indicated for the following: 1) treatment of acute, uncomplicated influenza A and B in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours, and 2) prophylaxis of influenza A and B in patients 1 year and older.

Posaconazole DR Tablets Approval & Launch - Lupin Pharmaceuticals

On February 17, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced the ***launch*** of Posaconazole DR (delayed-release) Tablets 100mg, after its alliance partner AET Pharma US Inc. (part of the Tiefenbacher Group) received an approval from the FDA.

The product has been developed by and is manufactured at Tiefenbacher Laboratories in Hyderabad, India, and is being distributed by Lupin Pharmaceuticals.

Posaconazole DR compares to Noxafil® DR Tablets by Merck Sharp & Dohme Corporation, which had U.S. sales in 2020 of $186 million, according to IQVIA. It is indicated for prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with graft-versus-host disease or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prochlorperazine Edisylate Injection Launch - Sagent Pharmaceuticals

On January 14, Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois announced their ***launch*** of Prochlorperazine Edisylate Injection 10mg per 2mL multi-dose vials, available in 10-count (NDC #25021-790-02) and 25-count packs (NDC #25021-790-03).

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This product is indicated for the treatment of schizophrenia and to control severe nausea and vomiting.

Prochlorperazine Edisylate Injection comes with Sagent's PreventIV Measures® features: easy-to-read drug name and dosage strength to aid in identifying the right product; barcodes included on the vial and carton for ease of scanning; unique label design to help products stand out on the shelf; and enhanced packaging and labeling designed to promote safety and help reduce the risk of medication errors.

Rifabutin Capsules - ANI Pharmaceuticals

On December 21, 2021, ANI Pharmaceuticals, Inc. of Baudette, Minnesota announced they have received final FDA approval for the Abbreviated New Drug Application (ANDA) for Rifabutin Capsules 150mg; and product will be available immediately.

Rifabutin Capsules compare to Mycobutin® Capsules by Pfizer, Inc., which had recent annual U.S. sales of $16.6 million, according to IQVIA. It is indicated for the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in patients with advanced HIV (human immunodeficiency virus) infection.

Sevelamer Carbonate For Oral Suspension - Lupin

On December 25, 2021, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval to market their Abbreviated New Drug Application (ANDA) for Sevelamer Carbonate for Oral Suspension in the strengths of 0.8Gm and 2.4Gm, both available in packets.

This product compares to Renvela® for Oral Suspension by Genzyme (a Sanofi Company), which had recent annual U.S. sales (ending September 2021) of $51.7 million, according to IQVIA. It is a phosphate binder indicated for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease on dialysis.

Succinylcholine Chloride Injection Launch - Sagent

On January 28, Sagent Pharmaceuticals, Inc. of Schaumburg, Illinois announced their ***launch*** of Succinylcholine Chloride Injection 200mg per 10mL multi-dose vials, available in 25-count packs (NDC #25021-677-10).

This product compares to Quelicin® Injection by Hospira/Pfizer, Inc. It is a depolarizing neuromuscular blocker indicated in adults and pediatric patients for the following: 1) as an adjunct to general anesthesia, 2) to facilitate tracheal intubation, and 3) to provide skeletal muscle relaxation during surgery or mechanical ventilation.

These products all come with Sagent's PreventIV Measures® features: easy-to-read drug name and dosage strength to aid in identifying the right product; barcodes included on the vial and carton for ease of scanning; unique label design to help products stand out on the shelf; and enhanced packaging and labeling designed to promote safety and help reduce the risk of medication errors.

Tavaborole Topical Solution - Lupin

On February 9, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they have received final FDA approval to market Tavaborole Topical Solution 5%.

This product compares to Kerydin® Topical Solution 5% by Anacor Pharmaceuticals, Inc., which has U.S. sales in 2020 of $76 million, according to IQVIA. It is an oxaborole antifungal drug that is indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes.*

Valsartan Tablets Launch - Dr. Reddy's

On December 9, 2021, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey announced their ***launch*** of Valsartan Tablets, available as detailed below.

- **30-count bottles:** 40mg.
- **90-count bottles:** 80mg, 160mg, and 320mg.

This product compares to Diovan® Tablets by Novartis Pharmaceuticals Corporation, which had recent annual U.S. sales (ending October 2021) of both brand and generics of $150 million, according to IQVIA.

It is an angiotensin II receptor blocker (ARB) drug that is indicated for the following: 1) hypertension in adults and children 6 years and older; 2) to reduce hospitalization for heart failure in adults; and 3) for the reduction of cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction in adults.

Vasopressin Injection Launches - Multiple Companies

On January 18 & February 9, Vasopressin Injection was approved by the FDA for multiple companies and are also all ***now available*** for order, as follows.

- On January 18, Eagle Pharmaceuticals, Inc. of Woodcliff Lake, New Jersey announced their launch of Vasopressin Injection, after previous receipt of final FDA approval of their Abbreviated New Drug Application (ANDA) in mid-December 2021.

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Diphenhydramine HCl Liquid	10 mL	25 mg / 10 mL	100 UD	60687-0267-56
Diphenhydramine HCl Liquid	10 mL	25 mg / 10 mL	30 UD	60687-0267-08
Hydrocodone Bitartrate & APAP Oral Solution (CII)	15 mL	7.25 mg / 325 mg / 15 mL	50 UD	60687-0417-71
Hydromorphone HCl Oral Solution (CII)	5 mL	5 mg / 5 mL	30 UD	60687-0566-86
Midazolam HCl Syrup (CIV)	2.5 mL	5 mg / 2.5 mL	30 UD	60687-0576-10
Midazolam HCl Syrup (CIV)	5 mL	10 mg /5 mL	30 UD	60687-0576-86
Phenobarbital Elixir (CIV)	5 mL	20 mg /5 mL	50 UD	60687-0448-67
Theophylline Oral Solution	15 mL	80 mg / 15 mL	50 UD	60687-0258-71

The NDC shown is in the 11-digit format required for the Centers for Medicare & Medicaid Services (CMS) processing, 42 CFR § 447.502 – Definitions.

*Product contains 10% alcohol

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AD202204-0134

Generic Approvals & News

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- On February 9, American Regent, Inc. of Melville, New York announced their launch of Vasopressin Injection 20 units per mL, as single-dose 1mL vials, in shelf packs of 25 (NDC# 0517-1020-25).
- On February 9, Dr. Reddy's announced the launch of an Authorized Generic (AG) version of Vasostrict® Injection (as approved by the FDA), which is available in a carton of 25 single-dose vials each containing vasopressin 1mL at 20 units/mL.

This product compares to Vasostrict Injection by Par Pharmaceutical, Inc., which had recent annual U.S. sales (ending September 2021) of $890 million, according to IQVIA. It is indicated for use to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

This approval follows the recent U.S. District Court of Delaware decision holding that Eagle's proposed vasopressin product does not infringe any of the patents Par Pharmaceutical, Inc.

Venlafaxine ER Tablets Launch - Dr. Reddy's Laboratories

On December 10, 2021, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey announced their ***launch*** of Venlafaxine ER (extended-release) Tablets in the strengths of 150mg and 225mg; both available in 30-count and 90-count bottles.

This product compares to Venlafaxine ER Tablets by Osmotica Pharmaceutical US LLC. It is indicated to treat major depressive disorder and social anxiety disorder.

Recent annual U.S. sales (ending October 2021) of the product in these strengths were $51 million, according to IQVIA.

Vigabatrin Tablets - Dr. Reddy's & Zydus Pharmaceuticals

On January 20 & February 2, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey and Zydus Pharmaceuticals, Inc. of Pennington, New Jersey each announced they have received final FDA approval for Vigabatrin Tablets, as detailed below.

1) Dr. Reddy's: 500mg Tablets available in 100-count bottles.

2) Zydus Pharmaceuticals: 500mg Tablets.

This product compares to Sabril® Tablets by Lundbeck, which had 2020 U.S. sales of both brand and generics of $141 million, according to IQVIA. It is indicated to treat children between 1 month to 2 years old with infantile spasms. It is also used in combination with other medications to treat seizure disorders for the treatment of epilepsy.

Vigabatrin decreases the number of seizures in adults and children who have not been able to control their seizures with other treatment. Vigabatrin is an anticonvulsant. It is known to work by stopping the breakdown of a natural calming substance (GABA) in the brain.

Dr. Reddy's Laboratories is the "first approved applicant" for a Competitive Generic Therapy Designation (CGT), and is therefore eligible for 180 days of CGT exclusivity.

First Generics

Adapalene/Benzoyl Peroxide Gel (Generic Epiduo® Forte Gel) Launch - Teva

On December 1, 2021, Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey announced the ***launch*** of Adapalene 0.3%/Benzoyl Peroxide 2.5% Gel.

This product is a first generic and Authorized Generic (AG) of Epiduo® Forte Gel by Galderma Laboratories, L.P., which had recent annual U.S. sales (ending September 2021) of $253 million, according to IQVIA. It is a topical prescription medicine used to treat acne vulgaris.

Generic Approvals & News

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Atropine Sulfate Injection - Amneal Pharmaceuticals

On February 17, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they received final FDA approval of their Abbreviated New Drug Application (ANDA) for Atropine Sulfate Injection 0.5mg/5mL, available in a pre-filled single-dose syringe.

This product compares to Atropine Sulfate Injection by Hospira, Inc., which has 2021 U.S. sales of $1 million, according to IQVIA. It is a muscarinic antagonist indicated for temporary blockade of severe or life-threatening muscarinic effects.

Amneal Pharmaceuticals is the "first approved applicant" for a Competitive Generic Therapy Designation (CGT), and is therefore eligible for 180 days of CGT exclusivity.

Betaine Anhydrous Powder For Oral Solution (Generic Cystadane®) - ANI & Oakrum Pharma

On February 14, ANI Pharmaceuticals of Baudette, Minnesota and Oakrum Pharma, LLC of St. Louis, Missouri jointly announced that the FDA has approved the Abbreviated New Drug Application (ANDA) for Betaine Anhydrous for Oral Solution Powder in a 180Gm bottle. Product is also ***now available.***

This is the first generic version of Cystadane® by Recordati Rare Diseases Inc., and it was also granted Competitive Generic Therapy (CGT) designation by the FDA, with 180 days of exclusivity.

Nikhil Lalwani, CEO of ANI Pharmaceuticals, said: "Rare diseases are often overlooked, and we are especially pleased to continue identifying patient populations that are underserved and medicines that can help them."

Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution (Generic Combigan®) Launch - Apotex

On January 9, PRNewswire.com reported that Apotex Corp. of Weston, Florida announced the ***launch*** of Brimonidine Tartrate/Timolol Maleate 0.2%/0.5% Ophthalmic Solution in a 5mL bottle, available with Apotex NDC #60505-6225-00.

This is a first generic and Authorized Generic (AG) of Combigan® by AbbVie, Inc. It is indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension.

Peter Hardwick, President of Apotex, said: "We are proud to provide American patients with cost savings by bringing the first generic version of Combigan to patients, allowing for a low-cost, high-quality solution."

Cyclosporine Ophthalmic Emulsion 0.05% (Generic Restasis®) - Viatris/Mylan Pharmaceuticals

On February 2, Viatris, Inc. of Canonsburg, Pennsylvania announced that its subsidiary Mylan Pharmaceuticals Inc. has received final FDA approval of its Abbreviated New Drug Application (ANDA) for Cyclosporine Ophthalmic Emulsion 0.05% in single-use vials. Product is also ***now available.***

This is the first generic version of Restasis® by Allergan. Also note there are no remaining legal or regulatory barriers holding this generic product back from market.

Cyclosporine Ophthalmic Emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, also known as dry eye. Dry eye disease is a common condition that occurs when a patient's tears are unable to provide adequate lubrication for their eyes. Tears can be inadequate and unstable for many reasons, but the instability can lead to discomfort, inflammation, and potential damage of the eye's surface.

Sally Choe, Ph.D., Director of the Office of Generic Drugs in FDA's Center for Drug Evaluation & Research, stated: "Restasis has been approved for use in the U.S. for nearly 20 years, but until now, there was no approved generic product of this drug that can help the millions of Americans who suffer from dry eyes. This approval reflects the FDA's continued commitment to advancing patient access to lower-cost, high-quality generic drug products that are as safe and effective as their brand name counterparts. Supporting development and expanding opportunities to bring complex generic drugs to the market is a major focus of our efforts to help improve competition and help lower drug prices."

Glycopyrrolate Oral Solution (Generic Cuvposa®) Launch - Par Pharmaceutical

On January 4, Endo Pharmaceuticals, Inc. of Irvine, California announced that one of its operating companies Par Pharmaceutical, Inc., has ***launched*** Glycopyrrolate Oral Solution 1mg/5mL; following its recent final FDA approval of the Abbreviated New Drug Application (ANDA) on the product.

This is the first generic version of Cuvposa® by Merz Pharmaceuticals, LLC, which had recent annual sales (ending October 2021) of $27 million, according to IQVIA. It is an anticholinergic drug that is indicated to reduce chronic severe drooling in patients 3 to 16 years old with neurologic conditions that are associated with cerebral palsy.

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Generic Approvals & News

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Mupirocin Cream 2%
(Generic Bactroban®) - Alembic

On November 17, 2021, Alembic Pharmaceuticals Inc. of Bridgewater, New Jersey (and parent company in India) and its joint venture company Aleor Dermaceuticals Ltd. of Gujurat, India announced they received final FDA approval for an Abbreviated New Drug Application (ANDA) for Mupirocin Cream 2%.

This product is a first generic of Bactroban® Cream 2% by GlaxoSmithKline (*now discontinued*). It is indicated for the treatment of secondarily infected traumatic skin lesions (up to 10cm in length) due to susceptible strains of *S. aureus* and *S. pyogenes*.

Recent annual U.S. sales (ending June 2021) of the product in this strength were $28 million, according to IQVIA.

Aleor Dermaceuticals is the "first approved applicant" for a Competitive Generic Therapy Designation (CGT), and is therefore eligible for 180 days of CGT exclusivity.

Naloxone HCl Nasal Spray (Generic Narcan®) Launches - Sandoz & Teva Pharmaceuticals

On December 22, 2021, Sandoz, Inc. of Princeton, New Jersey and Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey announced their ***launch*** of Naloxone HCl Nasal Spray 4mg, both now immediately available.

Sandoz's is an Authorized Generic (AG) version of the product. And Teva's is the first generic version of the product.

Naloxone HCl Nasal Spray compares to Narcan® Nasal Spray 4mg by Emergent BioSolutions Inc. It is indicated to treat an opioid emergency such as an overdose (or a possible opioid overdose) with signs of breathing problems and severe sleepiness or not being able to respond. Product is to be given right away, does not take the place of emergency medical care, and is safe and effective in children.

Approximately every 8 minutes in the U.S. a life is lost to an opioid overdose. Opioid dependency and accidental opioid overdoses are a serious national crisis affecting public health and social and economic welfare. Opioid overdose death rates have been continuously increasing in the U.S. for over 2 decades.

During the COVID-19 pandemic, increased stressors (such as isolation, unemployment, and illness), along with disruptions in healthcare and obstacles obtaining treatment, have put people at increased risk of opioid overdose. Of the 49 million patients prescribed opioids in the U.S., more than 18 million are considered at-risk, but only 5% received a prescription for naloxone.

According to data from the U.S. Centers for Disease Control & Prevention (CDC), opioid overdoses accounted for more than 73,000 deaths in the U.S. in one year (most recently through April 2021). Opioid overdose deaths increased almost 40% during the COVID-19 pandemic (June 2019 versus May 2020), highlighting the need for more people to have access to overdose-reversing medicine during this evolving national crisis.

Discontinued Drugs

Ambrisentan Tablets By Par

On December 23, 2021, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manu-facture of Ambrisentan Tablets (with product labeling as Par Pharmaceutical, an Endo subsidiary), in the following presentations.

- **5mg:** 10-count bottle (NDC #49884-353-62); and 30-count bottle (NDC #49884-353-11).
- **10mg:** 10-count bottle (NDC #49884-354-62); and 30-count bottle (NDC #49884-354-11).

Ambrisentan Tablets are indicated to treat pulmonary arterial hypertension in adults.

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In July 2020, the FDA issued recommendations to healthcare professionals (HCP's) encouraging them to discuss the availability of naloxone with patients at increased risk of opioid overdose, which includes certain patients taking opioid pain relievers or medicines to treat opioid use disorder. The FDA has also identified situations in which an HCP may give strong consideration to prescribing naloxone, such as for patients prescribed medications for opioid use disorder or if the patient's household has members at risk for accidental opioid ingestion or overdose. Family and friends are often in the best position to administer this potentially lifesaving drug to those who overdose.

All 50 U.S. States allow for access to the 4mg naloxone HCl nasal spray either directly from a pharmacist without a prescription under a Statewide Standing Order, a Collaborative Practice Agreement between pharmacists and other healthcare providers, or through a third-party prescription that allows someone other than the patient to obtain naloxone nasal spray to assist an at-risk individual. However, State laws vary for eligibility and distribution.

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Discontinued Drugs

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Amitriptyline HCl Tablets By Par

On December 16, 2021, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manufacture of Amitriptyline HCl Tablets (with product labeling as Par Pharmaceutical), in the following presentations.

- **10mg:** 30-count bottle (NDC #0603-2212-16); 90-count bottle (NDC #0603-2212-02); 100-count bottle (NDC #0603-2212-21); and 1,000-count bottle (NDC #0603-2212-32).
- **25mg:** 90-count bottle (NDC #0603-2213-02); 100-count bottle (NDC #0603-2213-21); 1,000-count bottle (NDC #0603-2213-32); and 2,500-count bottle (NDC #0603-2213-30).
- **50mg:** 100-count bottle (NDC #0603-2214-21); and 1,000-count bottle (NDC #0603-2214-32).
- **75mg:** 100-count bottle (NDC #0603-2215-21); and 300-count bottle (NDC #0603-2215-25).
- **100mg:** 100-count bottle (NDC #0603-2216-21); and 300-count bottle (NDC #0603-2216-25).
- **150mg:** 100-count bottle (NDC #0603-2217-21).

This product is indicated to treat symptoms of depression.

Betamethasone Valerate Topical Foam By Ingenus

On November 30, 2021, the FDA announced that Ingenus Pharmaceuticals, LLC of Orlando, Florida will discontinue the manufacture of Betamethasone Valerate Topical Foam 0.12%, as follows.

- **50Gm Can:** NDC #50742-315-50.
- **100Gm Can:** NDC #50742-315-01.

This product is a steroid drug that is indicated to treat the inflammation and itching caused by a number of skin conditions, such as eczema or psoriasis.

Clobetasol Propionate Topical Foam By Ingenus Pharmaceuticals

On November 16, 2021, the FDA announced that Ingenus Pharmaceuticals, LLC of Orlando, Florida will discontinue the manufacture of Clobetasol Propionate Topical Foam 0.05%, as follows.

- **50Gm Can:** NDC #50742-304-50.
- **100Gm Can:** NDC #50742-304-01.

This product is a highly potent corticosteroid indicated to treat inflammation and itching caused by plaque psoriasis and skin conditions that respond to corticosteroid medication.

Clobetasol Propionate Topical Solution By Tolmar

On November 1, 2021, the FDA announced that Tolmar Pharmaceuticals, Inc. of Fort Collins, Colorado will discontinue the manufacture of Clobetasol Propionate Topical Solution 0.05%, as follows.

- **25mL:** NDC #63646-500-25.
- **50mL:** NDC #63646-500-50.

This product is a corticosteroid indicated to treat inflammation and itching caused by plaque psoriasis and skin conditions that respond to corticosteroid medication.

Clonidine HCl ER Tablets By Par

On November 30, 2021, the FDA announced that Par Pharmaceutical, Inc. of Chestnut Ridge, New York will discontinue the manufacture of Clonidine HCl ER (extended-release) Tablets 0.1mg, in 60-count bottles (NDC #10370-257-02).

This product is indicated to treat hypertension (high blood pressure).

Cubicin® Injection

On October 8, 2021, the FDA announced that Merck Sharp & Dohme Corp. of Kenilworth, New Jersey will discontinue the manufacture of Cubicin® (daptomycin) Injection 500mg, in single-use vials (NDC #67919-011-01).

This product is an antibiotic drug that is indicated to treat bacterial infections of the skin and underlying tissues, and infections that have entered the bloodstream.

Diazepam (C-IV) Oral Solution Concentrate By Lannett

On January 5, the FDA announced that Lannett Company, Inc. of Philadelphia, Pennsylvania has made a business decision to discontinue the manufacture of Diazepam Oral Solution Concentrate 25mg/5mL (5mg/mL), in a 30mL bottle (NDC #0527-1768-36).

This product has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance. It is a benzodiazepine indicated to treat anxiety disorders or alcohol withdrawal symptoms.

Doxycycline Capsules By Par

On January 31, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manufacture of Doxycycline Capsules (labeled as a Par Pharmaceutical product), as follows.

- **50mg:** 100-count bottle (NDC #49884-726-01).
- **100mg:** 50-count bottle (NDC #49884-727-03); and 250-count bottle (NDC #49884-727-04).
- **150mg:** 60-count bottle (NDC #49884-305-02).

Discontinued Drugs

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This product is an antibiotic indicated to treat many different bacterial infections, such as acne, urinary tract infections, intestinal infections, respiratory infections, eye infections, gonorrhea, chlamydia, syphilis, periodontitis (gum disease), and others.

Efavirenz Tablets By Viatris

On November 2, 2021, the FDA announced that Viatris Inc. of Canonsburg, Pennsylvania will discontinue the manufacture of Efavirenz Tablets 600mg, in 30-count bottles (NDC #0378-2233-93).

This product is indicated to treat HIV (human immunodeficiency virus) infection, the virus that can cause acquired immunodeficiency syndrome (AIDS).

Note: this product was originally manufactured by Mylan Pharmaceuticals, Inc. (now a Viatris Inc. company).

Febuxostat Tablets By Dr. Reddy's

On November 30, 2021, the FDA announced that Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey will discontinue the manufacture of Febuxostat Tablets, in the following strengths.

- **40mg:** 30-count bottle (NDC #55111-796-30).
- **80mg:** 30-count bottle (NDC #55111-797-30).

This product is indicated to keep uric acid levels from getting too high in people with gout.

Flagyl® Tablets

On October 13, 2021, the FDA announced that Pfizer, Inc. of New York City will discontinue the manufacture of Flagyl® (metronidazole) Tablets, in the following strengths and presentations.

- **250mg:** 50-count bottle (NDC #0025-1831-50); and 100-count bottle (NDC #0025-1831-31).
- **500mg:** 50-count bottle (NDC #0025-1821-50); and 100-count bottle (NDC #0025-1821-31).

This product is an antibiotic indicated to treat bacterial infections of the vagina, stomach, liver, skin, joints, brain and spinal cord, lungs, heart, or bloodstream.

Glipizide Extended-Release Tablets By Par

On February 9, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania has made a business decision to discontinue the manufacture of Glipizide Extended-Release Tablets (labeled as a Par Pharmaceutical product), in the following presentations.

- **5mg:** 100-count (NDC #10370-745-01); and 500-count (NDC #10370-745-05).
- **10mg:** 100-count (NDC #10370-746-01); and 500-count (NDC #10370-746-05).

This product is indicated to help control blood sugar levels by helping the pancreas produce insulin.

Imipramine Tablets By Sandoz

On February 25, the FDA announced that Sandoz Inc. of Princeton, New Jersey will discontinue the manufacture of Imipramine Tablets, in the following presentations.

- **10mg:** 100-count bottle (NDC #0781-1762-01).
- **25mg:** 100-count bottle (NDC #0781-1764-01); and 1,000-count bottle (NDC #0781-1764-10).
- **50mg:** 100-count bottle (NDC #0781-1766-01); and 1,000-count bottle (NDC #0781-1766-10).

This product is an antidepressant indicated to treat symptoms of depression.

Levoleucovorin Calcium Pentahydrate Injection By Ingenus

On December 10, 2021, the FDA announced that Ingenus Pharmaceuticals, LLC of Orlando, Florida will discontinue the manufacture of Levoleucovorin Calcium Pentahydrate Injection, as follows.

- **175mg/17.5mL (10mg/1mL):** 17.5mL vial (NDC #50742-494-17).
- **250mg/25mL (10mg/1mL):** 25mL vial (NDC #50742-495-25).

This product is indicated to treat or prevent toxic effects of methotrexate in people who have received the drug to treat bone cancer.

Megestrol Acetate Suspension By Par

On December 1, 2021, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania has made a business decision to discontinue the manufacture of Megestrol Acetate Suspension 625mg/5mL (125mg/1ml), in 150ml bottles (NDC #49884-230-69), which is labeled as a Par Pharmaceutical product.

This product is indicated to treat loss of appetite and wasting syndrome in people with acquired immunodeficiency syndrome (AIDS).

Meloxicam Tablets By Boehringer Ingelheim

On November 1, 2021, the FDA announced that Boehringer Ingelheim Pharmaceuticals, Inc. of Ridgefield, Connecticut will discontinue the manufacture of Meloxicam Tablets, in the following presentations.

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Discontinued Drugs

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- **7.5mg:** 10-count bottle (NDC #0597-0029-94); and 100-count bottle (NDC #0597-0029-01).
- **15mg:** 10-count bottle (NDC #0597-0030-56); and 100-count bottle (NDC #0597-0030-01).

This product is an NSAID (nonsteroidal anti-inflammatory drug), indicated to treat pain or inflammation caused by rheumatoid arthritis and osteoarthritis in adults.

Nafcillin Injection By Pfizer

On October 20, 2021, the FDA announced that Pfizer, Inc. of New York City will discontinue the manufacture of Nafcillin Injection Powder (labeled as a Hospira product), as follows.

- **1Gm:** single-dose vial (NDC #0409-3713-01).
- **2Gm:** single-dose vial (NDC #0409-3714-01).
- **10Gm:** bulk-package vial (NDC #0409-3715-01).

This product is a penicillin antibiotic indicated to treat many different types of infections, especially those caused by *staphylococcus* bacteria ("staph" infections).

Omeprazole/Sodium Bicarbonate Powder By Par

On February 2, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manufacture of Omeprazole/Sodium Bicarbonate Powder for Suspension (with product labeling as Par Pharmaceutical), in the following presentations.

- **20mg/1680mg:** 1-count pouch (NDC #49884-268-52); and 30-count pouches (NDC #49884-268-11).
- **40mg/1680mg:** 1-count pouch (NDC #49884-269-52); and 30-count pouches (NDC #49884-269-11).

This product is indicated to treat heartburn and other symptoms of gastroesophageal reflux disease (GERD). It is also used to treat certain types of ulcers, or to promote healing of erosive esophagitis (damage to your esophagus caused by stomach acid).

Pioglitazone HCl Tablets By Sandoz

On January 10, the FDA announced that Sandoz, Inc. of Princeton, New Jersey will discontinue the manufacture of Pioglitazone HCl Tablets, in the following presentations.

- **15mg:** 30 unit-dose blister pack (NDC #0781-5420-64).
- **30mg:** 1,000-count bottle (NDC #0781-5421-10).
- **45mg:** 1,000-count bottle (NDC #0781-5422-10).

This product, when used together with diet and exercise, is indicated for the improvement of blood sugar control in adults with type 2 diabetes mellitus.

Pramipexole Dihydrochloride ER Tablets By Par

On December 16, 2021, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manufacture of Pramipexole Dihydrochloride ER (extended-release) Tablets in 30-count bottles (with product labeling as Par Pharmaceutical), in the following strengths.

- **0.375mg:** NDC #10370-251-11.
- **0.75mg:** NDC #10370-252-11.
- **1.5mg:** NDC #10370-253-11.
- **2.25mg:** NDC #10370-305-11.
- **3mg:** NDC #10370-254-11.
- **3.75mg:** NDC #10370-306-11.

Pramipexole Dihydrochloride ER is indicated to treat restless legs syndrome (RLS) and symptoms of Parkinson's disease including stiffness, tremors, muscle spasms, and poor muscle control.

Propafenone HCL Tablets By Par

On February 2, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manufacture of Propafenone HCL Tablets (with labeling by Par Pharmaceutical), as follows.

- **150mg:** 100-count bottle (NDC #0603-5448-21); and 300-count bottle (NDC #0603-5448-25).
- **225mg:** 100-count bottle (NDC #0603-5449-21); and 300-count bottle (NDC #0603-5449-25).
- **300mg:** 100-count bottle (NDC #0603-5450-21).

This product is an anti-arrhythmic drug indicated to treat certain types of irregular heartbeats (such as paroxysmal supraventricular tachycardia and atrial fibrillation).

Quadramet® Injection

On October 28, 2021, the FDA announced that Lantheus Medical Imaging, Inc. of North Billerica, Massachusetts will discontinue the manufacture of Quadramet® (samarium Sm 153 lexidronam) Injection 150mCi, in single-dose 3mL vials (NDC #11994-016-01).

This product is indicated to treat bone pain caused by cancer.

Skelaxin® Tablets

On February 25, the FDA announced that Pfizer Inc. of New York City will discontinue the manufacture of Skelaxin® (metaxalone) 800mg Tablets, in 100-count bottles (NDC #60793-136-01) and 500-count bottles (NDC #60793-136-05).

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CHILDREN'S ACETAMINOPHEN ORAL SUSPENSION

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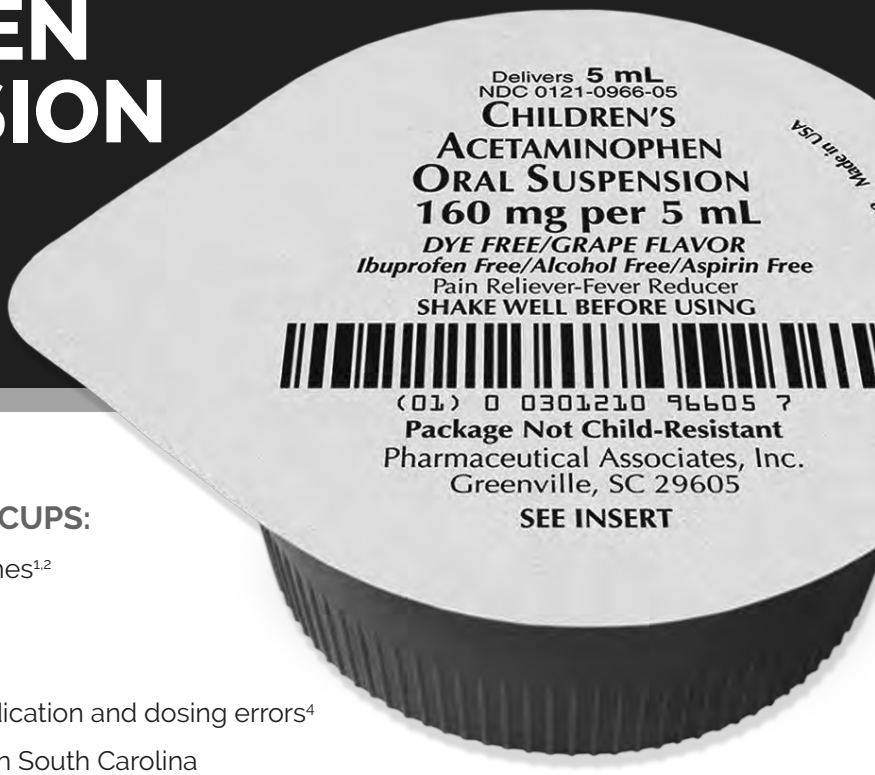

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NDC# 00121	Name	Amerisource Bergen	Cardinal	McKesson	Morris Dickson
-0966-94	Children's Acetaminophen Oral Suspension 160 mg/5 mL cups OTC 30/cs	10266991	5779582	2608701	212738
-0966-00	Children's Acetaminophen Oral Suspension 160 mg/5 mL cups OTC 100/cs	10267137	5779590	2608677	212761

References: 1. U.S. Food & Drug Administration. Working to reduce medication errors. https://www.fda.gov/drugs/drug-information-consumers/working-reduce-medication-errors. Accessed March 2, 2022. **2.** American Society of Hospital Pharmacists. ASHP guidelines on preventing medication errors in hospitals. *Am J Hosp Pharm.* 2018;75:1493-1517. **3.** Doraci B. Maximize use of pre-packaged unit dose products. Pharmacy Purchasing & Products. 2014;89(11):30. https://www.pppmag.com/article/1513. Accessed March 2, 2022. **4.** American Society of Hospital Pharmacists. ASHP statement on unit dose drug distribution. *Am J Hosp Pharm.* 1989;46:2345-2346.

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Biosimilar Drugs

Continued from Page 1

Ranibizumab is an anti-vascular endothelial growth factor (VEGF) therapy that prevents vision loss in patients with retinal vascular disorders which can cause irreversible blindness or visual impairments in adults in the United States.

Ian Henshaw, Senior VP & Global Head of Biosimilars at Biogen, said: "We are very excited to be able to open a new chapter with the approval of Byooviz in the United States. This approval represents a great step toward the advancement of a new therapeutic option addressing debilitating disease progression of patients with retinal vascular disorders in the United States. Biosimilars could help broaden patient access to more affordable treatments and generate healthcare savings to offset rising costs of these complex diseases while ensuring sustainability of healthcare systems."

Biosimilars are products that have been demonstrated to be similar in efficacy and safety to the originator's reference product, with the advantage that they offer cost savings and promote sustainable access to therapies. Savings in the United States over the next years from 2020 to 2024 as a result of biosimilars are projected to exceed $100 billion.

Discontinued Drugs

Continued from Page 18

This product is a muscle relaxant indicated to treat skeletal muscle conditions such as pain or injury, when used together with rest and physical therapy.

Tapazole® Tablets

On November 5, 2021, the FDA announced that Pfizer Inc. of New York City will discontinue the manufacture of Tapazole® (methimazole) Tablets, in the following strengths.

- **5mg:** 100-count bottle (NDC #60793-104-01).
- **10mg:** 100-count bottle (NDC #60793-105-01).

This product is indicated for the treatment of hyperthyroidism (overactive thyroid).

Tekturna HCT® Tablets

On December 16, 2021, the FDA announced that Noden Pharma USA, Inc. of Boston, Massachusetts will discontinue the manufacture of Tekturna HCT® Tablets in 30-count bottles, as follows.

- **150mg/12.5mg:** NDC #70839-112-30.
- **150mg/25mg:** NDC #70839-125-30.
- **300mg/12.5mg:** NDC #70839-312-30.
- **300mg/25mg:** NDC #70839-325-30.

This product is a combination medicine indicated to treat hypertension (high blood pressure).

Temixys™ Tablets

On September 1, 2021, the FDA announced that Celltrion USA Inc. of Jersey City, New Jersey will discontinue the manufacture of Temixys™ (lamivudine and tenofovir disoproxil fumarate) Tablets 300mg/300mg, in 30-count bottles (NDC #72606-002-01).

This product is indicated to treat HIV (human immunodeficiency virus) infection.

Trimethobenzamide HCl Capsules By Sun Pharma

On October 26, 2021, the FDA announced that, due to non-availability of the active ingredient, Sun Pharmaceutical Industries, Inc. of Princeton, New Jersey will discontinue the manufacture of Trimethobenzamide HCl Capsules 300mg, in 100-count bottles (NDC #53489-376-01).

This product is indicated to treat nausea and vomiting as related to surgery or when caused by stomach flu.

Vibramycin® Suspension

On November 16, 2021, the FDA announced that Pfizer Inc. of New York City will discontinue the manufacture of Vibramycin® (doxycycline hyclate) Oral Suspension 25mg/5mL, in 60mL bottles (NDC #0069-0970-65).

This product is indicated for the treatment or prevention of bacterial infections, acne, malaria, and periodontitis (swelling of the tissue around the teeth).

Viramune® Oral Suspension

On October 1, 2021, the FDA announced that Boehringer Ingelheim Pharmaceuticals, Inc. of Ridgefield, Connecticut will discontinue the manufacture of Viramune® (nevirapine) Oral Suspension 50mg/5mL, in 240mL bottles (NDC #0597-0047-24).

This product is an antiviral medicine indicated to treat HIV (human immunodeficiency virus) infection.

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Biosimilar Drugs

Continued from Page 20

Sarah Yim, M.D., Director of the Office of Therapeutic Biologics & Biosimilars in the FDA's Center for Drug Evaluation & Research, said: "This approval provides another treatment option for millions of people whose vision is impaired and is another step forward in our commitment to provide access to safe, effective, and high-quality biological products. Continuing to grow the number of biosimilar approvals is a key part of our efforts to provide greater access to treatment options for patients, increase competition, and potentially lower costs."

Yusimry™ For Multiple Arthritics & More - Biosimilar To Humira®

On December 20, 2021, Coherus BioSciences, Inc. of Redwood City, California announced that the FDA approved Yusimry™ (adalimumab-aqvh), a tumor necrosis factor (TNF) blocker drug indicated to reduce the signs and symptoms of plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, Crohn's disease, and ulcerative colitis.

Product is expected to be available in mid-2023, on or after July 1 (2023).

Yusimry is a biosimilar to the brand drug Humira® (adalimumab) by AbbVie, Inc., which in 2020 had net revenues of $16.1 billion.

Approval was based on a comprehensive data package that demonstrated the biosimilarity of Yusimry to the reference product, Humira.

Barbara Finck, M.D., Chief Medical Officer of Coherus, said: "The approval of Yusimry brings a new offering to healthcare practitioners and their patients with certain inflammatory diseases. We believe high-quality biosimilars provide important alternatives that expand the use of safe and effective medicines to more patients in need. This approval was supported by a comprehensive analytical similarity package, as well as comparative pharmacokinetic, efficacy, and immunogenicity studies enrolling patients with moderate to severe chronic plaque psoriasis as well as healthy subjects."

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New Drugs/Indications

Adbry™ For Moderate-To-Severe Atopic Dermatitis Specifically Targeting IL-13

On December 27, 2021, Leo Pharma Inc. of Madison, New Jersey announced that the FDA approved Adbry™ (tralokinumab-ldrm) Injection for subcutaneous use, indicated for the treatment of moderate-to-severe atopic dermatitis in adults 18 years or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Product will be available in a 150mg/mL prefilled syringe for subcutaneous injection with an initial dose of 600mg followed by 300mg every other week. It can be used with or without topical corticosteroids. A dosage of 300mg every 4 weeks may be considered for patients below 100kg who achieve clear or almost clear skin after 16 weeks of treatment.

Adbry is the first and only FDA approved biologic that specifically binds to and inhibits the IL-13 cytokine, a key driver of atopic dermatitis signs and symptoms.

Jonathan Silverberg, M.D., Ph.D., M.P.H., Associate Professor of Dermatology at George Washington University School of Medicine and Health Sciences in Washington, D.C. (and clinical drug trial investigator), explained: "Atopic dermatitis can be severe and unpredictable, which makes it not only challenging for patients to achieve long-term disease control, but also for clinicians to treat, since there are limited treatment options for this burdensome chronic skin disease. Adbry will be an important addition to our therapeutic armamentarium as a treatment designed to specifically target and neutralize the IL-13 cytokine, thereby, helping patients manage their atopic dermatitis."

Apretude - First & Only Long-Acting Injectable Option For HIV Prevention

On December 20, 2021, ViiV Healthcare of Research Triangle, North Carolina announced the FDA approval of Apretude (cabotegravir extended-release) Injectable Suspension, which is the ***first and only*** long-acting injectable pre-exposure prophylaxis (PrEP) option indicated to reduce the risk of sexually acquired HIV-1 (human immunodeficiency virus infection) in adults and adolescents weighing at least 77 pounds who are at risk of sexually acquiring HIV and who have a negative test for it prior to initiation; regardless of gender.

Apretude is provided as an injection given as few as 6 times per year and is initiated with a single 600mg (3mL) intramuscular injection in the buttocks, given 1 month apart for 2 consecutive months. After the second initiation injection, the recommended continuation dose is a single 600mg (3mL) injection given every 2 months. In addition, another ViiV product, Vocabria (cabotegravir) Tablets, may be administered for approximately 1 month before initiating the first injection to assess the tolerability of the medicine.

Continued on Page 24

VASOSTRICT® READY-TO-USE BOTTLES

Vasostrict®
(Vasopressin Injection, USP)
READY-TO-USE BOTTLES
Available in Two Concentrations
20 units/100 mL
40 units/100 mL

FIRST AND ONLY MANUFACTURER PREPARED READY-TO-USE VASOPRESSIN

Note: Images are for illustration purposes only and do not represent actual size

- ☑ Two-year shelf life,[1] with up to 12 months at room temperature,[2]* may offer enhanced inventory management
- ☑ Available through your wholesaler
- ☑ Does not require compounding, diluting, mixing, or transferring, which may reduce waste and chance of preparation error
- ☑ Compatible with most Automated Dispensing Machines

1. Data on File. Vasostrict® Stability Summary Report. Par Sterile Products, LLC; December 8, 2021.
2. Vasostrict® Prescribing Information 04/2021.
*Room temperature (68°F to 77°F) upon removal from refrigeration. Recommended storage is under refrigerated conditions (36°F and 46°F).

NDC	Strength	Fill Volume	Pack Size	ABC	Cardinal	McKesson	M&D	Barcode
42023-237-10	20 Units/100 mL (0.2 units/mL)	100 mL SDV*	10 vials	10264700	5766159	2388502	148007	
42023-219-10	40 Units/100 mL (0.4 units/mL)	100 mL SDV*	10 vials	10264671	5766142	2388544	148031	

*Single-Dose Vial

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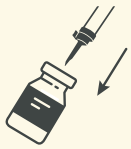
 PSP-VS-05007/February 2022

SIMPLIFYING YOUR PHARMACY WORKFLOW PREPARATION

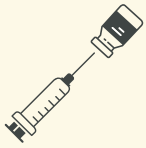
NO STEPS PRIOR TO SPIKING WITH READY-TO-USE BOTTLE



Spike

VS.

3 STEPS PRIOR TO SPIKING TO PREPARE A 20 UNITS PER 100 ML IV-BAG



Draw medication from vial into syringe

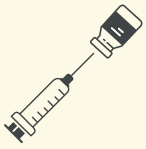
Express medication into diluent bag

Roll to mix solution until completely mixed

Spike

VS.

4 STEPS PRIOR TO SPIKING TO PREPARE A 40 UNITS PER 100 ML IV-BAG



Draw first dose of medication* from vial into syringe

Draw second dose of medication* from vial into syringe

Express medication into diluent bag

Roll to mix solution until completely mixed

Spike

*Illustration depicts 20 units

Vasostrict®

(Vasopressin Injection, USP)

FIRST AND ONLY MANUFACTURER PREPARED READY-TO-USE VASOPRESSIN

PAR PHARMACEUTICAL
an endo international company

New Drugs/Indications

Continued from Page 21

HIV continues to be a global public health crisis, with an estimated 38 million people living with HIV worldwide and 1.7 million new cases annually. PrEP represents an effective tool to reduce new cases of HIV, which in addition to successful HIV antiretroviral treatment, will help efforts to end the HIV epidemic. However, fewer than 25% of the people who could benefit from PrEP in the U.S. are currently taking it. Despite the wide availability of daily oral PrEP, it can be limited by inconsistent adherence as well as structural and cultural barriers that lead to underutilization in key populations.

Apretude is an integrase strand transfer inhibitor of HIV replication, by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic disease.

Gabriel Maldonado, MBA, Executive Director & CEO of TruEvolution of Riverside, California, remarked: "Many people who are vulnerable to HIV have complex lives that can make taking a daily pill to prevent HIV a burden. This can include stigma, fears about accidental disclosure of their medicine, as well as general complications from daily living. Together, these issues may contribute to low rates of PrEP usage and the expansion of the HIV epidemic. Our community has been in dire need of additional HIV prevention options that may address their evolving needs, and cabotegravir long-acting for PrEP represents an exciting new option to help them reduce their risk of acquiring HIV."

The FDA granted Apretude with Priority Review and Breakthrough Therapy designation.

Debra Birnkrant, M.D., Director of the Division of Antivirals in the FDA's Center for Drug Evaluation & Research, said: "This approval adds an important tool in the effort to end the HIV epidemic by providing the first option to prevent HIV that does not involve taking a daily pill. This injection, given every 2 months, will be critical to addressing the HIV epidemic in the U.S., including helping high-risk individuals and certain groups where adherence to daily medication has been a major challenge or not a realistic option."

Carvykti™ For Patients With Relapsed Or Refractory Multiple Myeloma

On February 28, the Janssen Pharmaceutical Companies of Johnson & Johnson of Horsham, Pennsylvania and Legend Biotech USA, Inc. of Somerset, New Jersey jointly announced that the FDA approved Carvykti™ (ciltacabtagene autoleucel; cilta-cel) Suspension for intravenous (IV) infusion, indicated for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

The recommended dose range for Carvykti is 0.5-1.0×106 CAR-positive viable T-cells per kg of body weight, with a maximum dose of 1×108 CAR-positive viable T-cells per single infusion.

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow. Despite the development of additional treatment options in recent years, most people living with the disease face poor prognoses after experiencing progression following treatment with three major therapy classes. When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow with tumors. In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the United States. While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems, or infections.

Carvykti is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express the B-cell maturation antigen (BCMA). BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells. The Carvykti CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA, which promotes T-cell activation, expansion, and elimination of target cells.

Note: Carvykti treatment requires extensive training, preparation, and certification to ensure a positive experience for patients. Through a phased approach, Janssen and Legend Biotech will activate a limited network of certified treatment centers as the company works to scale its production capacity and increase the availability of Carvykti throughout the U.S. in 2022 and beyond, to ensure providing treatment to oncologists and their patients in a reliable and timely manner. Carvykti is ***only*** available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Carvykti REMS Program.

Sundar Jagannath, M.D., Director of the Center of Excellence for Multiple Myeloma and

New Drugs/Indications

Continued from Page 24

Professor of Medicine, Hematology & Medical Oncology at The Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai in New York (and principal study investigator), stated: "The responses in the clinical drug study showed durability over time and resulted in the majority of heavily pretreated patients achieving deep responses after 18-month follow-up. The approval of cilta-cel provides physicians an immunotherapy treatment option that offers patients an opportunity to be free from anti-myeloma therapies for a period of time."

Cibinqo® For Moderate-To-Severe Atopic Dermatitis

On January 3, Pfizer Inc. of New York announced that the FDA has approved Cibinqo® (abrocitinib) Tablets, indicated for once-daily treatment of adults living with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Cibinqo is approved at the recommended doses of 100mg and 200mg, with the 200mg dose being recommended for patients who are not responding to the 100mg dose. Additionally, a 50mg dose was approved to treat moderate-to-severe atopic dermatitis specifically in patients with moderate renal impairment (kidney failure), certain patients receiving treatment with inhibitors of cytochrome P450 (CYP) 2C19, or patients who are known or suspected to be poor metabolizers of CYP2C19. For patients with moderate renal impairment who are not responding to 50mg once daily, 100mg once daily may also be prescribed.

Moderate-to-severe atopic dermatitis (AD) is one of the most common inflammatory skin diseases, affecting approximately 5% to 10% of adults in the United States. AD is a chronic skin disease characterized by inflammation of the skin and skin barrier defects. Most people know it's a skin condition, but many don't realize it can be caused in part by an abnormal immune response beneath the skin. This dysregulated immune response is thought to contribute to inflammation within the skin and the signs of AD on the surface.

Jonathan Silverberg, M.D., PhD, M.P.H., Department of Dermatology with The George Washington University School of Medicine & Health Sciences in Washington, D.C., explained: "The reality for patients living with chronic inflammatory skin disease such as moderate-to-severe atopic dermatitis is that many experience debilitating symptoms that are not managed by current treatment options. This approval of Cibinqo will provide an important new oral option that could help those who have yet to find relief. In multiple large-scale clinical trials, Cibinqo demonstrated strong efficacy at clearing skin, improving itch, and managing the extent and severity of eczema, offering a benefit-risk profile that supports the use of this treatment in the FDA-approved patient population."

Note: women are advised not to breastfeed during treatment with Cibinqo and for one day after the last dose.

Dartisla ODT For Peptic Ulcers

On February 28, Edenbridge Pharmaceuticals, LLC of Parsippany, New Jersey and Phil, Inc. of San Francisco, California jointly announced the availability and recent FDA approval in late December 2021, for Dartisla (glycopyrrolate) Orally Disintegrating Tablets (ODT), indicated to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.

Product is ***now available*** through Phil, Inc., the product's commercialization partner for Edenbridge; as well as in retail pharmacies throughout the country.

Patients receiving the 2mg dosage strength of another oral tablet dosage form of glycopyrrolate may be switched to the 1.7mg dosage strength of Dartisla ODT. This product is not recommended for patients initiating treatment or receiving maintenance treatment with a lower dosage strength of another oral glycopyrrolate product (e.g., tablet strength of 1mg).

Daniel G. Worley Jr., Edenbridge's VP of Business Development & General Counsel, noted: "Dartisla ODT is the first and only FDA-approved orally disintegrating tablet of glycopyrrolate, and we are excited to introduce this novel formulation of glycopyrrolate to patients and healthcare providers."

Deepak Thomas, Founder & CEO of Phil, said: "Phil is proud to support Edenbridge's commitment to providing broad access to this innovative therapy by simplifying the patient onboarding process allowing affordable, fast, broad-based distribution of Dartisla ODT."

Dartisla ODT is manufactured by Catalent, Inc. of Somerset, New Jersey, using their proprietary Zydis® ODT delivery technology to create a freeze-dried tablet that disperses almost instantly in the mouth without water.

Enjaymo™ - First Treatment For Patients With Cold Agglutinin Disease

On February 4, Sanofi of Bridgewater, New Jersey announced that the FDA approved Enjaymo™ (sutimlimab-jome) Injection for intravenous (IV) use, indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease. Enjaymo is the first and only approved treatment for people with CAD and works by inhibiting the destruction of red blood cells (hemolysis).

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New Drugs/Indications

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The recommended dose of Enjaymo is based on body weight (6,500mg for people 39kg to 75kg and 7,500mg for people >75kg). Enjaymo is administered intravenously weekly for the first 2 weeks with administration every 2 weeks thereafter.

Cold agglutinin disease (CAD), a rare autoimmune hemolytic anemia, is caused by antibodies called cold agglutinins binding to the surface of red blood cells, which starts a process that causes the body's immune system to mistakenly attack healthy red blood cells and cause their rupture (hemolysis). As red blood cells have the vital job of carrying oxygen throughout the body, patients with CAD may experience severe anemia, which can result in fatigue, weakness, shortness of breath, light-headedness, chest pain, irregular heartbeat, and other potential complications. CAD is a chronic and rare blood disorder that impacts the lives of an estimated 5,000 people in the United States or just 1 person per million each year globally, and mostly develops in individuals between ages 40 and 80 years.

Enjaymo is a humanized monoclonal antibody that is designed to selectively target and inhibit C1's in the classical complement pathway, which is part of the innate immune system. By blocking C1's, Enjaymo inhibits the activation of the complement cascade in the immune system and inhibits C1-activated hemolysis in CAD to prevent the abnormal destruction of healthy red blood cells. Enjaymo does not inhibit the lectin and alternative pathways.

Bill Sibold, Executive VP & Head of Specialty Care with Sanofi, stated: "Until now, people living with cold agglutinin disease haven't had an approved treatment option to manage the constant destruction of red blood cells. Without healthy, viable red blood cells, a chain reaction of debilitating signs and symptoms can be triggered, starting with severe anemia. Enjaymo is the only approved treatment to inhibit red blood cell destruction in CAD and help stop the chain reaction from the start."

The FDA granted Enjaymo with Orphan Drug designation, Breakthrough Therapy designation, and Priority Review.

Note: Enjaymo affects your immune system, lowering the ability to fight infections. People who take Enjaymo may have an increased risk of getting infections caused by certain kinds of bacteria such as *Neisseria meningitides*, *Streptococcus pneumoniae*, and *Haemophilus influenzae*, which may quickly become life-threatening or cause death if not recognized and treated early.

Fleqsuvy™ Suspension For Spasticity From MS Or Spinal Cord Injuries

On February 7, Azurity Pharmaceuticals, Inc. of Woburn, Massachusetts announced the FDA approval of Fleqsuvy™ (baclofen) Oral Suspension, 25mg per 5mL (5mg/mL) concentrated formulation, indicated for the treatment of spasticity from multiple sclerosis or in patients with spinal cord injuries and other spinal cord diseases.

Fleqsuvy is available in a grape-flavor, and is supplied in bottles of either 120mL or 300mL.

Nearly 1 million people are living with multiple sclerosis (MS) in the United States. Spasticity is a commonly reported symptom for MS, with an estimated prevalence of spasticity of 67%. Due to the severity of spasticity resulting from MS, or patients with spinal cord injuries and other spinal cord diseases, dosing becomes paramount to providing appropriate relief. Furthermore, dysphagia is commonly experienced, affecting approximately 43% of multiple sclerosis patients and 16% to 30% of patients with spinal cord injuries. Fleqsuvy provides an option as a baclofen oral liquid medication at an effective dose for patients who have trouble swallowing pills or prefer a liquid formulation. As the most concentrated FDA-approved oral liquid baclofen formulation, Fleqsuvy allows for the lowest volume to be prescribed for patients, which can be an important consideration for those suffering from dysphagia.

Amit Patel, Chairman & CEO of Azurity Pharmaceuticals, commented: "The approval of Fleqsuvy represents our commitment to providing innovative alternative formulations that address individualized patient needs. The clinical profile of Fleqsuvy allows for a tailored and flexible approach to dosing for patients suffering from spasticity, a debilitating symptom that may impact daily functioning."

Jardiance® Now For Wider Range Of Patients With Heart Failure

On February 24, Boehringer Ingelheim Pharmaceuticals, Inc. of Ridgefield, Connecticut and Eli Lilly & Company of Indianapolis, Indiana jointly announced that the FDA approved a ***new indication*** for Jardiance® (empagliflozin) 10mg Tablets, now also to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.

Jardiance can be initiated in adults with heart failure with an estimated glomerular filtration rate (eGFR) as low as 20mL/min/1.73m2.

Affecting more than 6 million people in the U.S., heart failure is a leading cause of hospitalization and is becoming increasingly prevalent due to the aging population, affecting more than 650,000 people in the U.S. each year. It is a syndrome in which the heart is not meeting the needs of the body. Despite therapies in multiple drug classes, mortality remains high

Continued on Page 28

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†Vial closure is not made with natural rubber latex

New Drugs/Indications

Continued from Page 26

and treatment options for a broader range of patients are needed. Symptoms of heart failure vary but can include shortness of breath, fatigue, and swelling in the legs.

Javed Butler, M.D., Chairman for the Department of Medicine at the University of Mississippi in Jackson, said: "This approval means these demonstrated benefits can now help to address a significant unmet need for the approximately 3 million adults in the U.S. with preserved ejection fraction, a form of heart failure that has very limited treatment options."

Mohamed Eid, M.D., M.P.H., M.H.A., Vice President of Clinical Development & Medical Affairs, Cardio-Metabolism & Respiratory Medicine with Boehringer Ingelheim, remarked: "With this news, Jardiance becomes the first and only heart failure treatment to show a statistically significant risk reduction in cardiovascular death and hospitalization for heart failure in adults with heart failure, regardless of ejection fraction."

Leqvio® Injection To Lower Cholesterol & Keep Low With 2 Doses A Year

On December 22, 2021, Novartis Pharmaceuticals Corporation of East Hanover, New Jersey announced that the FDA has approved Leqvio® (inclisiran) Injection for subcutaneous use, indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of low-density lipoprotein cholesterol (LCL-C, bad cholesterol).

This is the first and only small interfering RNA therapy treatment to lower low-density lipoprotein cholesterol with 2 doses a year, after an initial dose and one at 3 months, and then every 6 months thereafter. It is to be administered by a healthcare provider, which may help those who have trouble sticking to medicines that are self-administered and have more frequent dosing frequency.

Cardiovascular (CV), renal, and metabolic diseases are a global health crisis. These chronic, complex and often hereditary diseases are frequently inter-related, come with healthcare and treatment barriers and a lack of transformative medicines, and almost always lead to the same outcome: death due to CV disease. CV disease is currently the #1 killer in the world. Taking more lives than all cancers combined, it contributes to 1 in every 3 deaths globally. Of all CV events, 80% can be prevented.

Leqvio works to reduce the amount of LDL-C in the bloodstream, by improving the liver's natural ability to prevent the production of a protein that plays a role in keeping circulating cholesterol levels high.

Vas Narasimhan, CEO of Novartis, said: "As a first-of-its-kind siRNA therapy, Leqvio works differently than other cholesterol treatments, with twice-yearly dosing that makes it a compelling option for the millions of people with ASCVD already on cholesterol-lowering medications struggling to reach their LDL-C target. Leqvio is a revolutionary approach to lower LDL-C, and creates new possibilities for how healthcare systems can impact cardiovascular disease, a defining public health challenge of our time."

Novartis has obtained global rights to develop, manufacture and commercialize Leqvio under a license and collaboration agreement with Alnylam Pharmaceuticals.

Nucala Prefilled Syringe For Kids With Severe Asthma - Now At-Home Administration

On January 24, GlaxoSmithKline (GSK) of Philadelphia, Pennsylvania announced that the FDA approved Nucala (mepolizumab) Injection for subcutaneous use in a 40mg prefilled syringe for appropriate children aged 6 to 11 years old who have severe eosinophilic asthma, now ***for at-home administration*** by a child's healthcare provider or as administered by a caregiver at the patient's home after proper training has been provided.

Nucala is available as a solution in a prefilled syringe, prefilled autoinjector, and as a lyophilized powder that comes in a vial and is reconstituted for injection.

Previously, children aged 6 to 11 years old received a dose of 40mg Nucala using a solution that was mixed and administered in a physician's office. Now, a child's healthcare provider will determine if at-home administration is appropriate, and if so, will provide instruction to a patient's caregiver on how to properly administer and monitor for any allergic reactions. Nucala will be administered every 4 weeks whether at home or in the physician's office.

Severe eosinophilic asthma (SEA) is characterized by having an increase of eosinophils, a type of white blood cell that helps fight disease and infections. However, in some people, a high number of eosinophils can have a negative effect and is associated with inflammation of the airways, potentially resulting in asthma symptoms.

Asthma is the most common chronic disease in children. It is estimated that 6 million children in the U.S. are living with asthma. Approximately 2.5% to 5% of these cases are characterized as severe. Severe asthma is defined as asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or

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New Drugs/Indications

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systemic corticosteroids) to prevent it from becoming uncontrolled or which remains uncontrolled despite this therapy. It can have an impact on a patient's quality of life, as their asthma symptoms can remain uncontrolled, despite high-dose standard treatments.

Tonya Winders, CEO & President of Allergy & Asthma Network of Vienna, Virginia and President of Global Allergy & Airways Patient Platform, stated: "The younger population with severe eosinophilic asthma often has more symptoms, less control over those symptoms, and experiences more frequent exacerbations, making childhood activities challenging. For many, going to the doctor's office to receive a biologic can be challenging, so having the possibility for children to receive Nucala at home, provides a bit more flexibility for the child's and caregiver's lives."

Pemfexy™ For Injection In Ready-To-Dilute Formulation For Metastatic Non-Small Cell Lung Cancer

On February 1, Eagle Pharmaceuticals, Inc. of Woodcliff Lake, New Jersey announced the ***availability*** of its novel product Pemfexy™ (pemetrexed) Injection for Intravenous (IV) use, indicated to treat locally advanced or metastatic nonsquamous non-small cell lung cancer and mesothelioma.

The product is a branded alternative to Alimta® by Eli Lilly & Company.

Pemfexy is a pemetrexed injection ready-to-dilute liquid formulation that is indicated for locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin; locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, as maintenance treatment; locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy as a single agent; and malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin.

In February 2020, Eagle received final FDA approval of its New Drug Application for Pemfexy, following the settlement agreement of patent litigation with Eli Lilly & Company. The agreement provided for a release of all claims by the parties and allows for an initial entry of Pemfexy into the market on February 1, 2022.

Pyrukynd® - First Disease-Modifying Therapy For Rare Hemolytic Anemia Disorder

On February 17, Agios Pharmaceuticals, Inc. of Cambridge, Massachusetts announced that the FDA has approved Pyrukynd® (mitapivat) Tablets, indicated for the treatment of hemolytic anemia in adults with pyruvate kinase deficiency.

Hemolytic anemia is a disorder in which red blood cells are destroyed faster than they can be made. Pyruvate kinase (PK) deficiency is an inherited disease. It is a rare, debilitating, lifelong hemolytic anemia disease that presents as chronic hemolytic anemia, which is the accelerated destruction of red blood cells.

PK deficiency is associated with serious complications, including gallstones, pulmonary hypertension, extramedullary hematopoiesis, osteoporosis, iron overload and its sequelae, which can occur regardless of the degree of anemia or transfusion burden. Patients can also develop gallstones and an enlarged spleen caused by too much iron in their blood from repeated blood transfusions. It can also cause quality of life problems, including challenges with work and school activities, social life, and emotional health. Current management strategies for PK deficiency, including red blood cell transfusions and splenectomy, are associated with both short and long-term risks.

Pyrukynd is a first-in-class, oral pyruvate kinase activator and the first approved disease-modifying therapy for PK deficiency.

Hanny Al-Samkari, M.D., Hematologist & Clinical Investigator at the Mass General Cancer Center & Harvard Medical School in Boston (and an investigator in the clinical drug studies), commented: "The successful clinical studies demonstrate the impact of Pyrukynd in significantly improving hemolysis and anemia in PK deficiency. The FDA approval of mitapivat, a targeted agent and first disease-modifying medication in PK deficiency, is an encouraging step forward for these patients that addresses a significant unmet need."

Kim Hall, who was diagnosed with PK deficiency in 1969 and is also a mother of 2 adult daughters with the disorder, said: "I am so grateful that Pyrukynd has been approved for PK deficiency. As both patient and caregiver, I have spent the majority of my life feeling alone in this disease, and never thought I would see a medicine approved."

The FDA granted Pyrukynd with Orphan Drug designation, Fast Track and Priority Reviews.

Ryaltris™ Nasal Spray For Symptoms Of Seasonal Allergic Rhinitis

On January 14, Glenmark Pharmaceuticals Inc., USA of Mahwah, New Jersey announced that the FDA has approved Ryaltris™ Nasal Spray (mometasone furoate 25mcg/spray; olopatadine HCl 665mcg/spray), indicated for the treatment of

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symptoms of seasonal allergic rhinitis in adults and pediatric patients 12 years of age and older.

The recommended daily dose for Ryaltris is 2 sprays in each nostril twice daily. It is a metered, fixed-dose, aqueous suspension, prescription nasal spray. Each unit of Ryaltris nasal spray contains 665mcg of olopatadine HCl, a histamine-1(H1)-receptor inhibitor, and 25mcg of mometasone furoate, a corticosteroid.

This product will be marketed and distributed in the United States by Hikma Specialty U.S.A., Inc. of Memphis, Tennessee, as part of its exclusive licensing agreement with Glenmark Specialty S.A in Switzerland.

Tarpeyo™ To Reduce Proteinuria In IgA Nephropathy

On December 15, 2021, Calliditas Therapeutics AB of Stockholm, Sweden (with U.S. headquarters in New York City) announced that the FDA approved Tarpeyo™ (budesonide) Delayed Release Capsules, the first and only corticosteroid drug that is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression, generally a urine protein-to-creatinine ratio =1.5Gm/Gm.

Immunoglobulin A nephropathy (IgAN) is a rare, progressive autoimmune disease which has a high unmet need, with more than 50% of patients potentially progressing to end-stage renal disease.

Tarpeyo is an oral, delayed release formulation of budesonide, a corticosteroid drug with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism.

Richard Lafayette, M.D., Professor of Medicine at Stanford University and the Director of the Stanford Glomerular Disease Center in California, remarked: "IgAN is a tough diagnosis for many patients, and it can progressively lead to the need for dialysis and/or kidney transplantation. The FDA approval of Tarpeyo now offers disease-specific treatment for patients with this complicated disease."

Bonnie Schneider, Director & Co-Founder of the IGA Nephropathy Foundation of America in Belmar, New Jersey, commented: "It has been a difficult journey not only for our family, but for all the IgA nephropathy patients we serve. Having this disease specific option has our community very excited."

Tezspire™ For Severe Asthma

On December 17, 2021, AstraZeneca USA of Wilmington, Delaware and Amgen Inc. of Thousand Oaks, California jointly announced the FDA approval and launch of Tezspire™ (tezepelumab-ekko) Injection (subcutaneous), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older, to improve severe asthma symptoms that are not controlled by their current asthma medications.

Product is administered once every 4 weeks by a healthcare professional through a subcutaneous (under the skin) injection.

Approximately 5% to 10% of Americans with asthma have severe asthma. Asthma is a long-term inflammatory disease that causes the airways of the lungs to become swollen or inflamed, triggered by several factors including allergen or irritant exposure and viral infections. Severe attacks can be intense, last for long periods of time, impact daily activities, and don't usually get better with use of short-term treatments.

Tezspire is the first asthma treatment targeting thymic stromal lymphopoietin, a molecule involved in airway inflammation. It is also the first treatment for severe asthma that is not limited to a specific type of severe asthma.

Professor Andrew Menzies-Gow, Director of the Lung Division at Royal Brompton Hospital in London, England (and principal investigator of the clinical trial), stated: "Due to the complex and heterogeneous nature of severe asthma and despite recent advances, many patients continue to experience frequent exacerbations, an increased risk of hospitalization, and a significantly reduced quality of life. Tezspire represents a much-needed new treatment for the many patients who remain underserved and continue to struggle with severe, uncontrolled asthma."

The FDA granted Tezspire with Priority Review and Breakthrough Therapy designation.

Vabysmo™ Injection For 2 Leading Causes Of Vision Loss

On January 28, Genentech of South San Francisco, California, a member of the Roche Group, announced that the FDA approved Vabysmo™ (faricimab-svoa) Intravitreal Injection, indicated for the treatment of neovascular age-related macular degeneration and diabetic macular edema.

Product is expected to be available in approximately 6 weeks after this announcement date.

Neovascular or "wet" age-related macular degeneration (nAMD) and diabetic macular edema (DME) are 2 leading causes of vision loss, around the world.

Vabysmo is the first and only FDA-approved injectable eye medicine for nAMD and DME that improves and maintains vision with treatments from 1 to 4 months apart in the first year

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following 4 initial monthly doses, based on evaluation of the patient's anatomy and vision outcomes.

People with nAMD initially receive 4 monthly treatments of Vabysmo. Based on anatomical and vision outcomes, they may receive subsequent treatments every 2, 3, or 4 months. People with DME are initially given 4 monthly treatments. Subsequently, their treatment may be extended or reduced based on anatomical and vision outcomes, with a range of 1 to 4 months between doses. A second approved treatment regimen for DME involves 6 monthly loading doses, followed by treatment every 2 months.

Charles Wykoff, M.D., Ph.D., Director of Research at Retina Consultants of Texas in Houston (and study investigator), stated: "Vabysmo represents an important step forward for ophthalmology. It is the first bispecific antibody approved for the eye and a major advance in treating retinal conditions such as neovascular AMD and diabetic macular edema. With Vabysmo, we now have the opportunity to offer patients a medicine that could improve their vision, potentially lowering treatment burden with fewer injections over time."

Vonjo™ For Myelofibrosis & Thrombocytopenia

On February 28, CTI BioPharma Corporation of Seattle, Washington announced that the FDA approved Vonjo™ (pacritinib) Capsules, indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L.

The recommended dosage is 200mg orally twice daily.

Myelofibrosis is bone marrow cancer that results in formation of fibrous scar tissue and can lead to thrombocytopenia and anemia, weakness, fatigue, and an enlarged spleen and liver. Within the U.S., there are approximately 21,000 patients with myelofibrosis, 7,000 of which have severe thrombocytopenia (defined as blood platelet counts below 50 × 109/L). Severe thrombocytopenia is associated with poor survival and high symptom burden and can occur as a result of disease progression or from drug toxicity with other JAK2 inhibitors, such as Jakafi® and Inrebic®.

Vonjo is the first approved therapy that specifically addresses the needs of patients with cytopenic myelofibrosis.

John Mascarenhas, M.D., Associate Professor of Medicine, Hematology & Medical Oncology at the Tisch Cancer Institute and Icahn School of Medicine at Mount Sinai in New York City, explained: "The approval of Vonjo establishes a new standard of care for myelofibrosis patients suffering from cytopenic myelofibrosis. Those with severe thrombocytopenia have been shown to result in poor survival outcomes coupled with debilitating symptoms. Limited treatment options have rendered this disease as an area of urgent unmet medical need. I am pleased to see that a new, efficacious, and safe treatment option is now available for these patients."

The FDA granted Vonjo with Accelerated Approval and Priority Review.

Vyvgart™ For Generalized Myasthenia Gravis

On December 17, 2021, Argenx US, Inc. of Boston, Massachusetts announced the FDA approval of Vyvgart™ (efgartigimod alfa-fcab) Injection for intravenous (IV) use, indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive.

Generalized myasthenia gravis (gMG) is a rare and chronic neuromuscular autoimmune disease that is characterized by debilitating and potentially life-threatening muscle weakness, when IgG autoantibodies disrupt communication between nerves and muscles. It affects voluntary muscles, especially those that are responsible for controlling the eyes, face, mouth, throat, and limbs. Severe attacks of weakness can cause breathing and swallowing problems that can be life-threatening. Approximately 85% of people with initial myasthenia gravis (MG) progress to gMG within 24 months.

Vyvgart is the first approval of a new class of medication. It is an antibody fragment that binds to the neonatal Fc receptor (FcRn), preventing FcRn from recycling immunoglobulin G (IgG) back into the blood. The medication causes a reduction in overall levels of IgG, including the abnormal AChR antibodies that are present in MG. Vyvgart is the first-and-only FDA-approved neonatal FcRn blocker.

Samantha Masterson, President & CEO of the Myasthenia Gravis Foundation of America, Inc. of Hopkinton, Massachusetts, said: "The gMG community has long-awaited the FDA approval of Vyvgart, especially for those patients who struggle with basic personal tasks such as speaking, chewing and swallowing food, brushing teeth and hair, and in some severe cases, breathing."

James F. Howard Jr., M.D., Professor of Neurology, Medicine & Allied Health in Department of Neurology with the University of North Carolina at Chapel Hill School of Medicine (and principal investigator for the clinical trial), stated: "People living with gMG have been in need of new treatment options that are targeted to the underlying pathogenesis of the disease and supported by clinical data. This approval represents

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an important new advance for gMG patients and families affected by this debilitating disease. This therapy has the potential to reduce the disease burden of gMG and transform the way we treat this disease."

Steve Miller, M.D., Executive VP & Chief Clinical Officer at Cigna Corp., explained: "Generalized myasthenia gravis imposes a significant lifestyle and treatment burden on patients, families, and the overall healthcare system. This autoimmune disease affects each patient differently which can create variability in dosing and the resulting cost per patient. The approval of Vyvgart promises to address a treatment gap for patients suffering from this disease."

The FDA granted Vyvgart with Fast Track Review and Orphan Drug designation.

New Indications

Rexulti® Now For Schizophrenia In Adolescent Patients

On January 7, Otsuka America Pharmaceutical, Inc. of Princeton, New Jersey and Lundbeck, Inc. of Deerfield, Illinois jointly announced that the FDA approved an ***expanded indication*** for the supplemental new drug application (sNDA) of Rexulti® (brexpiprazole) Tablets, now also for the treatment of schizophrenia in adolescent patients 13 to 17 years of age.

Before this, Rexulti was only FDA-approved in 2015 for adult patients to treat schizophrenia and major depressive disorder.

Johan Luthman, Executive VP of R&D for Lundbeck, said: "We are proud to offer a treatment option for adolescents with schizophrenia who are navigating the complexities of their health during a transitional time in their lives, we hope this will help make a meaningful difference in reducing their schizophrenia symptoms so they can be their best."

The FDA granted Rexulti with Priority Review for this new sNDA indication.

Rexulti was discovered by Otsuka and is being co-developed by Otsuka and Lundbeck.

Note: this product contains a Boxed Warning regarding the risk of increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.

Rinvoq® For 12 Years & Older With Refractory, Moderate To Severe Atopic Dermatitis

On January 14, AbbVie, Inc. of North Chicago, Illinois announced that the FDA approved an ***expanded indication*** for Rinvoq® (upadacitinib) extended-release 15mg Tablets, now also for the treatment of moderate to severe atopic dermatitis in adults and children 12 years of age and older whose disease did not respond to previous treatment and is not well controlled with other pills or injections, including biologic medicines, or when use of other pills or injections is not recommended.

Once daily Rinvoq can be initiated in adults and children 12 years of age and older weighing at least 40kg. In these children and adults less than 65 years of age who do not achieve an adequate response, the dose may be increased to 30mg once daily.

Atopic dermatitis is a chronic, relapsing inflammatory condition characterized by a cycle of intense itching and scratching that leads to cracked, scaly and oozing skin. It affects an estimated 7% of adults and 12% of adolescents in the U.S., with approximately 40% of adults experiencing moderate to severe disease. It manifests differently for all, with symptoms posing significant physical, psychological, and economic burdens.

Thomas Hudson, M.D., Senior VP of Research & Development and Chief Scientific Officer of AbbVie, noted: "Early in my career as an allergist, I saw how relentless the itch and rash could be for my patients with moderate to severe atopic dermatitis yet had limited options to offer those whose disease could not be adequately controlled with systemic therapy. This additional approval for Rinvoq provides a once-daily oral option that can significantly improve the debilitating itch and skin symptoms of atopic dermatitis."

Emma Guttman-Yassky, M.D., Ph.D., Waldman Professor & System Chair of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City, said: "Despite available therapies, many people with moderate to severe atopic dermatitis are caught in an endless cycle of itching and scratching. In clinical trials, upadacitinib showed a robust response across skin and itch symptoms that may help evolve treatment goals for those who have not achieved adequate control of their disease. And as an oral pill with two dose strengths, upadacitinib is a welcome addition to the toolbox of clinicians who are striving to make a significant difference."

Note: women are advised to use effective birth control to avoid becoming pregnant during treatment with Rinvoq and for 4 weeks after the last dose; and should not breastfeed during treatment and for 6 days after the last dose.

Skyrizi® For Active Psoriatic Arthritis

On January 21, AbbVie, Inc. of North Chicago, Illinois announced the FDA has approved a ***new indication*** for Skyrizi® (risankizumab-rzaa) Injection for subcutaneous use, now also for the

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treatment of adults with active psoriatic arthritis, a systemic inflammatory disease that affects the skin and joints and impacts approximately 30% of patients with psoriasis.

Skyrizi maintains a dosing regimen for active psoriatic arthritis (PsA) that is consistent with the existing regimen for moderate to severe plaque psoriasis patients, a single 150mg subcutaneous injection (one 150mg pre-filled pen or pre-filled syringe) administered 4 times a year (after 2 starter doses at weeks 0 and 4). It can either be administered alone or in combination with disease-modifying antirheumatic drugs (DMARD).

Skyrizi is part of a collaboration between Boehringer Ingelheim and AbbVie, with AbbVie leading development and commercialization of Skyrizi globally.

Solosec® For Bacterial Vaginosis & Trichomoniasis In Adolescent Females

On February 17, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced that the FDA approved an ***expanded indication*** for Solosec® (secnidazole) Oral Granules 2Gm, now also for the treatment of bacterial vaginosis and trichomoniasis for all patients 12 years of age and older.

Solosec is a single oral dose therapy that is designed to be easy to take. The entire contents of Solosec packet should be sprinkled onto applesauce, yogurt, or pudding and consumed once within 30 minutes without chewing or crunching the granules. It is not intended to be dissolved in any liquid. Avoid consumption of alcoholic beverages and preparations containing ethanol or propylene glycol during treatment with Solosec, and for at least 2 days after completing therapy.

Bacterial vaginosis (BV) is a common vaginal infection, and trichomoniasis is the most common non-viral, curable sexually transmitted infection in the United States. This is the first and only single-dose oral prescription antimicrobial agent approved to treat both, in patients 12 years of age and older.

Tom Merriam, Executive Director of Lupin Specialty, said: "The FDA's approval expands the indication for Solosec to treat adolescents brings to healthcare professionals a treatment option for both BV and trichomoniasis in adolescents which provides a complete course of therapy in a single dose, one which helps to address gaps in care related to adherence, and may reduce risk factors associated with BV and trichomoniasis, such as other sexually transmitted diseases (STI's). We are optimistic about this new treatment option for both healthcare practitioners and their adolescent patients."

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Government News

CDC Reports Increase In Human Rabies Cases Linked To Bats

On January 6, the U.S. Centers for Disease Control & Prevention (CDC) announced it is raising awareness of the risks of rabies from bats in the U.S. after 3 people–including 1 child, died from rabies between late September and early November 2021.

Those cases bring the number of cases in year 2021 to 5 total as of this announcement date, as compared to ***no*** reported rabies cases during all of 2019 and 2020.

Over a 5-week period between September 28 and November 3, 2021, 3 people, one each in Idaho, Illinois, and Texas, were confirmed to have rabies after direct contact with bats in or around their homes and died. Two of the bat-associated cases were considered avoidable exposures; one was attributed to a bat roost in the patient's home, the other to the patient picking up the bat with bare hands. Two patients released the bat, rather than capturing it for testing. None of the 3 individuals received post-exposure prophylaxis (PEP) shots that can prevent rabies from developing if received before symptoms start.

Ryan Wallace, D.V.M., M.P.H., Veterinarian & Rabies Expert in the CDC's Division of High-Consequence Pathogens & Pathology, said: "We have come a long way in the United States towards reducing the number of people who become infected each year with rabies, but this recent spate of cases is a sobering reminder that contact with bats poses a real health risk."

Exposure to rabid bats is the leading cause of rabies in humans in the U.S., accounting for 70% of people who become infected. The number of rabid bats reported to the National Rabies Surveillance System has been stable since 2007, which suggests that this uptick in cases of rabies in people may be due to a lack of awareness about of the risks of rabies, and that getting PEP is a life-or-death matter.

Bat bites do not always cause a visible mark yet can still spread rabies virus through infected saliva, so any direct contact with a bat should be assessed by a clinical or public health provider. It typically takes anywhere

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between 3 weeks to 3 months, though sometimes more or less time, for people to develop symptoms if infected. PEP is effective in preventing rabies until symptoms develop. Once symptoms begin, rabies is nearly always fatal.

The CDC is urging people to take the following measures to prevent or lessen the risk of infection with rabies.

Avoid direct contact with bats. If you come into contact with a bat, or if someone possibly had contact with a bat, do the following.

- Call your state or local health department or animal control to help trap the bat for testing or safely trap the bat yourself. Testing a bat to determine if it is rabid can help to determine whether you need PEP.
- Contact your doctor or a local public health official to assess whether PEP is needed.

These steps are important even if contact with a bat takes place through clothing and bite or scratch marks are not visible. Sometimes it is not clear whether someone may have had contact with a bat, such as when a bat is found in a room with someone who is sleeping or where a child has been left unattended.

If potentially exposed to a rabid animal, receiving PEP soon after exposure and before symptoms begin is critical. While rabies deaths in people in the United States are not common, the CDC estimates that approximately 60,000 people receive PEP each year to prevent becoming ill with rabies. PEP is nearly 100% effective at preventing rabies if received before symptoms start.

For more information about rabies, visit: www.cdc.gov/rabies/index.html

Flu Vaccination Prevents Severe Flu Illness In U.S. Children

On January 13, the U.S. Centers for Disease Control & Prevention (CDC) announced the results of a new CDC study indicating that flu vaccination protected children against serious flu illness even when they were infected with a flu virus that was antigenically different from the vaccine virus. This reinforces the benefit of flu vaccination, even when circulating flu viruses have drifted and are different from the virus used in vaccine production.

Rochelle P. Walensky, M.D., M.P.H, Director of the CDC, explained: "This study highlights that flu can cause serious illness in children, but flu vaccines can be lifesaving. This is very good news. It's especially important that children get a flu vaccine in addition to their recommended COVID-19 vaccines this season. Flu season has started and currently flu vaccination is down in children, so now is the best time to get your child vaccinated, if you have not already."

A hallmark of flu viruses is that they are constantly changing through a process called antigenic drift, especially H3N2 viruses, which are often associated with more severe flu seasons. How well flu vaccines work is determined in part by the similarity between the viruses chosen for vaccine production and viruses circulating in populations. While the composition of flu vaccines is reviewed annually and updated to match evolving viruses, even then, changes in the virus can outpace vaccine production.

The CDC study reports that flu vaccination reduced the risk of severe flu in children by 78% against similar flu A viruses, and 47% against flu A viruses that had drifted from the vaccine virus. Further, the vaccine was 76% effective at preventing life-threatening influenza, which included invasive mechanical ventilation, CPR, and other severe complications including death. This study adds to evidence showing that some people who are vaccinated still get sick, but the vaccination can decrease illness severity.

This large CDC study summarizes findings from a CDC vaccine effectiveness network that looks at how well flu vaccines work at preventing serious flu illness in children. This network is now called the Overcoming COVID-19 Network and will investigate how well COVID-19 vaccines work to prevent COVID-19 hospitalizations in children in addition to how well flu vaccines protect children against flu hospitalization during 2022.

Researchers looked at data from the 2019-2020 flu season, during which a record-breaking 199 flu deaths in children were reported to the CDC and when most flu activity was caused by 2 viruses that were antigenically different from their corresponding vaccine viruses.

According to CDC flu surveillance systems, flu season has started in many parts of the country with continued flu activity expected over the coming weeks. Most flu detected so far has been H3N2 flu found in children and young adults. These circulating H3N2 flu viruses are genetically closely related to the H3N2 vaccine virus but have some differences that may result in reduced protection against those viruses from the vaccine. As this study highlights, however, vaccination can still have important benefits even when this happens. It is also important to note that usually many flu viruses spread over any one season and flu vaccines protect against four different viruses.

Flu illness can be dangerous for children. Each year, millions of children get sick with seasonal flu, thousands of children are hospitalized, and some children die from flu. Two flu deaths in children have been reported to the CDC already

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this season. Flu can be especially dangerous for children younger than 5 years old because they are at higher risk of getting very sick from flu because of their age.

With flu activity just getting started, that means there's still time to benefit from flu vaccination this season. It takes about two weeks after vaccination for antibodies to develop in the body and provide protection against influenza virus infection. The U.S. Advisory Committee on Immunization Practices (ACIP) has recommended annual vaccination for all persons aged 6 months or older since 2010. Despite this recommendation, during the 2020-2021 flu season U.S. flu vaccination coverage remained between 50.8% to 68% for children younger than 18 years old.

CDC Releases Updated Maps Of America's High Levels Of Physical Inactivity

On January 20, the U.S. Centers for Disease Control & Prevention (CDC) announced that according to new state maps of adult physical inactivity prevalence, more than 1 in 5 adults is inactive, in all but 4 states.

For these maps, physical inactivity for adults is defined as not participating in any physical activities outside of work over the last month, such as running, walking for exercise, or gardening.

State and territory-level estimates of physical inactivity range from 17.7% of people in Colorado to 49.4% in Puerto Rico. In 7 states and 1 territory (Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Oklahoma, West Virginia, and Puerto Rico), 30% or more of adults were physically inactive. By region, the South had the highest prevalence of physical inactivity (27.5%), followed by the Midwest (25.2%), Northeast (24.7%), and the West (21.0%).

Ruth Petersen, M.D., Director of the CDC's Division of Nutrition, Physical Activity & Obesity, said: "Getting enough physical activity could prevent 1 in 10 premature deaths. Too many people are missing out on the health benefits of physical activity such as improved sleep, reduced blood pressure and anxiety, lowered risk for heart disease, several cancers, and dementia (including Alzheimer's disease)."

The new maps are based on combined 2017-2020 data from the Behavioral Risk Factor Surveillance System (BRFSS), an on-going state-based telephone interview survey conducted by the CDC and state health departments. This is the first time that the CDC has created state maps of physical inactivity for non-Hispanic American Indian/Alaskan Native and non-Hispanic Asian adults.

The demographics of physical inactivity: The maps point to notable differences in physical inactivity levels by race and ethnicity. Overall, Hispanic adults (32.1%) had the highest prevalence of physical inactivity outside of work, followed by non-Hispanic Black (30.0%), non-Hispanic American Indian/ Alaskan Native (29.1%), non-Hispanic White (23.0%), and non-Hispanic Asian adults (20.1%). The maps also show the following data.

- 2 states (Alaska and Montana) and Guam had a physical inactivity prevalence of 30% or higher among non-Hispanic Asian adults.
- 5 states (Arkansas, Kentucky, Mississippi, Oklahoma, and West Virginia) had a physical inactivity prevalence of 30% or higher among non-Hispanic White adults.
- 27 states had a physical inactivity prevalence of 30% or higher among non-Hispanic American Indian/Alaska Native adults.
- 23 states and the District of Columbia had a physical inactivity prevalence of 30% or higher among non-Hispanic Black adults.
- 25 states and Puerto Rico had a physical inactivity prevalence of 30% or higher among Hispanic adults.

Physical activity can benefit everyone. Lack of access to safe and convenient places to be physically active may contribute to the observed racial and ethnic disparities.

What more can be done? The CDC is working with communities and partners across the country as part of the Active People, Healthy Nation initiative, to make it easier, safer, and more convenient for people to be active where they live, learn, work, and play. The overall goal of the initiative is to help

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27 million Americans become more physically active by 2027 to improve overall health and quality of life and to reduce healthcare costs. The initiative helps community leaders take advantage of proven strategies to make physical activity safe and enjoyable for people of all ages and abilities. Building active and walkable communities may also help support local economies and create more cohesive communities.

The *Physical Activity Guidelines for Americans, 2nd edition*, recommends that adults get at least 150 minutes of moderate-intensity physical activity each week. This can be broken into smaller amounts such as 22 minutes every day or 30 minutes/5 times a week. Individuals and families are encouraged to build physical activity into their day by going for a brisk walk or a hike, walking the dog, choosing the stairs instead of the elevator or escalator, parking further away in the parking lot and walking the rest of the way, walking or cycling to run errands, and getting off the bus one stop early and walking the rest of the way. The key is to move more and sit less.

Community leaders can also encourage school and youth physical activity programs, educate, and support families and individuals to be more active. They can create activity-friendly routes to everyday destinations such as home, work, school, and grocery stores. Together, leaders and community members can work with various populations to design and implement culturally relevant solutions to reduce disparities in physical inactivity.

To learn more about physical activity, visit the CDC website, at: www.cdc.gov/physicalactivity/index.html

Maps and data tables are available at: www.cdc.gov/physicalactivity/data/inactivity-prevalence-maps/index.html

New Reports On Health & Well-Being Of Children During COVID-19 Pandemic

On February 18, the U.S. Centers for Disease Control & Prevention (CDC) announced the results of two new reports that provide important insights on the health and well-being of children and adolescents during the COVID-19 pandemic.

The first report looked at pediatric Emergency Department (ED) visits. The study found that overall pediatric ED visits decreased in 2020, 2021, and in January 2022 compared with visits in 2019, while COVID-19-related ED visits increased across all pandemic years and among pediatric age groups. There were also increases in the weekly number and proportion of ED visits for certain types of injuries, some chronic diseases, and visits related to behavioral health concerns, especially among older children (5 to 11 years) and adolescents (12 to 17 years).

Factors affecting caregivers during the pandemic, including unavailable or unpredictable childcare, illness, financial hardship, and mental health concerns, might increase a child's vulnerabilities. Loss of a parent or caregiver, increases in other challenges, and disruptions in daily routine due to the COVID-19 pandemic might have also increased a child's behavioral health concerns and unhealthy coping behaviors.

The second report examined changes in pediatric ED visits for mental health conditions and found that adolescent girls (12 to 17 years) accounted for the largest increases in the number and proportion of ED visits for mental health conditions in 2020, 2021, and in January 2022 compared with 2019. Weekly visits for eating and tic disorders increased for females, and particularly adolescent females (12 to 17 years), during 2020, 2021, and in January 2022.

The highly complex nature of individual experiences makes it difficult to identify a single reason for changes in mental health conditions during the pandemic. While extended time at home could increase familial support for some youth, it may have increased challenges and stressors, among others. These factors, as well as other pandemic-related stressors that impact families (e.g., increases in parental mental health problems, parental substance use, financial strain, and loss of a parent or caregiver), could have created or increased the risk for mental health conditions.

Early identification and expanded evidence-based prevention and intervention strategies are critical to improving children's mental health, especially among adolescent females who might have increased need. The CDC recommends increased awareness for health concerns among children and adolescents that could arise due to delayed medical care and heightened emotional distress.

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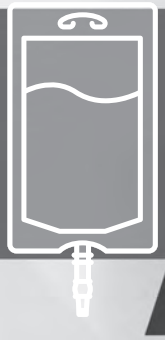
Baxter

Myxredlin
INSULIN INFUSION

MYXREDLIN

(Insulin Human) in 0.9%
Sodium Chloride Injection
100 units per 100 mL (1 unit/mL)



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INSULIN
INFUSION

Myxredlin (insulin human) in 0.9% Sodium Chloride Injection is now available for purchase through your Baxter representative or wholesaler.

PRODUCT CODE	STRENGTH/VOLUME	NDC#	PACK FACTOR
2G3322	100 units/100 mL	0338-0126-12	12

Myxredlin Insulin Human in 0.9% Sodium Chloride Injection
100 units per 100 mL (1 unit/mL)

IMPORTANT RISK INFORMATION

Indication

Myxredlin is a short-acting human insulin indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

Contraindications

- During episodes of hypoglycemia
- Hypersensitivity to insulin human or any of the excipients in **Myxredlin**

Warnings and Precautions

- *Hyper- or Hypoglycemia with Changes in Insulin Regimen:* Carry out under close medical supervision and increase frequency of blood glucose monitoring.
- Administer **Myxredlin** intravenously ONLY under medical supervision with close monitoring of blood glucose and potassium levels. Hypokalemia may be life-threatening if not treated.
- Individualize dose based on metabolic needs, blood glucose monitoring results, and glycemic control goal. Dosage adjustments may be needed with changes in nutrition, renal, or hepatic function or during acute illness.
- Adverse reactions observed with insulin human injection include hypoglycemia, allergic reactions, weight gain and edema.
- Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.

Dosage and Administration

- Inspect **Myxredlin** visually before use. It should appear clear and colorless. Do not use **Myxredlin** if particulate matter or coloration is seen.
- Do not add supplementary medication or additives.
- Do not use in series connections.
- Do not shake or freeze. Discard unused portion.

Please see Brief Summary of Prescribing Information for Myxredlin adjacent to this ad.

MAKE **MYXREDLIN** PART OF YOUR RISK REDUCTION STRATEGY

Help reduce insulin compounding errors with **Myxredlin**, the first and only commercially-prepared IV insulin.

ISMP and ASHP guidelines recommend using a commercially-prepared product instead of compounding as a risk reduction strategy for high-alert medications.[1,2]

BRIEF SUMMARY OF PRESCRIBING INFORMATION
See Package Insert for Full Prescribing Information.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Myxredlin safely and effectively. See full prescribing information for Myxredlin.

Myxredlin (insulin human) in sodium chloride injection, for intravenous use.
Initial U.S. Approval: 2019

INDICATIONS AND USAGE
Myxredlin is a short-acting human insulin indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

DOSAGE AND ADMINISTRATION
– Inspect **Myxredlin** visually before use. It should appear clear and colorless. Do not use **Myxredlin** if particulate matter or coloration is seen.
– Administer **Myxredlin** intravenously ONLY under medical supervision with close monitoring of blood glucose and potassium levels.
– Do not add supplementary medication or additives.
– Do not use in series connections.
– Do not shake or freeze. Discard unused portion.
– Individualize dose based on metabolic needs, blood glucose monitoring results, and glycemic control goal.
– Dosage adjustments may be needed with changes in nutrition, renal, or hepatic function or during acute illness.

DOSAGE FORMS AND STRENGTHS
Injection: 100 units insulin human in 100 mL of 0.9% sodium chloride (1 unit/mL) in a single-dose container

CONTRAINDICATIONS
– During episodes of hypoglycemia
– Hypersensitivity to insulin human or any of the excipients in **Myxredlin**

WARNINGS AND PRECAUTIONS
– *Hyper- or Hypoglycemia with Changes in Insulin Regimen:* Carry out under close medical supervision and increase frequency of blood glucose monitoring.
– *Hypoglycemia:* May be life-threatening. Factors which may increase the risk include changes in nutrition and co-administered medication and patients with renal or hepatic impairment. Increased frequency of blood glucose monitoring is recommended in patients at increased risk.
– *Hypersensitivity Reactions:* Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue **Myxredlin**, monitor, and treat if indicated.
– *Hypokalemia:* May be life-threatening. Monitor potassium levels and treat if indicated.
– *Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs):* Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.

ADVERSE REACTIONS
Adverse reactions observed with insulin human injection include hypoglycemia, allergic reactions, weight gain and edema.

To report SUSPECTED ADVERSE REACTIONS, contact Baxter Healthcare at 1-866-888-2472 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS
– *Drugs that may increase the risk of hypoglycemia:* antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics.

– *Drugs that may decrease the blood glucose lowering effect:* atypical antipsychotics, corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g., in oral contraceptives), protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, terbutaline), and thyroid hormones.

– *Drugs that may increase or decrease the blood glucose lowering effect:* Alcohol, beta-blockers, clonidine, lithium salts, and pentamidine.

– *Drugs that may blunt the signs and symptoms of hypoglycemia:* beta-blockers, clonidine, guanethidine, and reserpine.

Please visit www.baxterpi.com for Full Prescribing Information

Baxter Healthcare Corporation Deerfield, IL 60015 USA

References
1. American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors in hospitals. Am J Health-Syst Pharm. 2018;75:1493-1517.
2. Institute for Safe Medication Practices (ISMP). ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations; 2016.

USMP/MYX/20-0004(1) 07/20

Outstanding Buyer Nominee - Irma Flores

Nominee name & facility: **Irma Romo Flores,** CPhT, Pharmacy Buyer, Moore County Hospital District (MCHD), Dumas, Texas.

Are you certified, licensed, and/or registered, as a Pharmacy Technician in your city/state? Yes, I am a Certified Technician.

Are you a current NPPA member, and will be an active member through August 2022? Yes.

What is your facility's bed size, and what type of facility is it? We are a general medical and surgical hospital with 30 beds.

Approximately how many dollars of pharmaceutical related expenditures do you purchase or supervise the purchasing of, at your facility per year? $579,699.

What is the dollar amount of the average inventory that you control throughout the year? $210,706.

Provide the current Inventory "Turns" you/your Pharmacy Department currently have: 2.75.

How long have you been a Pharmacy Buyer? 15 years.

What are the main responsibilities you have in your position (as Buyer and if otherwise in addition)? I am the Lead Pharmacy Tech and Buyer.

Additional Comments by Irma's supervisor, Elise Heil, RPh, Director of Pharmacy: Irma is not only the Buyer but also the lead Pharmacy Tech, so she performs double duty. Irma's dedication and hard work makes her excel in both roles allowing her to keep an eye on the pulse of the organization. Irma also mentors and trains new pharmacy technicians and her positive and motivated personality is infused into the team.

What is unique about your facility? We are a new hospital and still building on.

Additional Comments by Ms. Heil: We are a Critical Access Hospital so our community as well as the surrounding communities depend on MCHD to provide care in all facets including stabilizing patients prior for transfer to rehabilitation for a patient to return home strong. The range of medications we provide is diverse like our patient population and Irma does a fantastic job managing the inventory. Irma ensures the right medication in the right quantity which saves money and waste.

List any accomplishments or projects that you may have instituted, which has either saved your department/facility money, or helped to make your job or the department run more efficiently. Managing stock and back-order items to keep the facility running, and rotating stock to cut back on waste.

Additional Comments by Ms. Heil: Irma is very well adept to where medication will move faster in the facility. Stock rotation for Irma includes moving the medication to another department of the hospital and not just the soonest expiration dates first.

How has your job changed over the years? It has gotten better and better, as I learn through conferences and the education provided there.

Additional Comments by Ms. Heil: With the addition and renovation of the hospital, Irma's job has gotten busier and more difficult. The patient treatment areas are much further now than before so she has become very efficient at stock delivery, moving and merging stock in the automated dispensing cabinets.

What do you like about your job? Making sure stock is rotated and filled, and that everything runs smoothly.

Additional Comments by Ms. Heil: Irma has a positive and uplifting attitude so I would say she likes everything about her job. Actually, I don't know if it is the job or her motivation to do any and all jobs well.

What are your dislikes about your job? There is nothing to dislike; every day is a new day to learn and make work better.

What would be your advice to vendors? Drug companies send good information through emails.

What kind of specific challenges do you have? Challenges in having better inventory turns.

How has your membership to NPPA/subscription to PPO helped? With the educational information that is provided within the NPPA member-publication.

Has your ever attended an NPPA Conference? If so, how did that help in your job after the event? Yes, I have attended the NPPA Conference in the past, and it helped with the education that was provided at there, then coming back to work and actually being able to put it to good use.

If you were one of the top 2 placing winners for this Award, would you be able to attend the upcoming NPPA Conference? Yes.

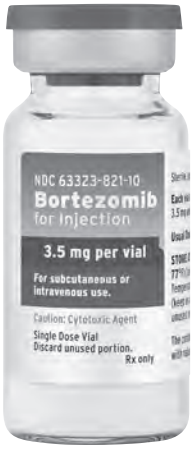
Do you belong to any other professional organizations besides NPPA? No.

List any other qualifications you may have for this award (such as being honored by your facility; having an article published; organizing buyer meetings; doing public speaking;

Continued on Page 44

FRESENIUS KABI
caring for life

Bortezomib for Injection



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Strength	3.5 mg per vial
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[1] 2021 - 2022 Data on file.

Please see package insert for full prescribing information.

Outstanding Buyer, Flores

Continued from Page 42

volunteer work). I have received two Service Excellence Awards from my facility, first in 2014 and again in 2015; as well as an Outstanding Recognition Award in 2008. In my personal time, I do a lot of volunteer work in the community, to help serve meals to those in need.

Additional Comments by Ms. Heil: Irma is a star at our facility and everyone in the hospital appreciates her hard work and great attitude.

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Editorial Note: NPPA was happy to see the nominations come in for our **2022 Outstanding Pharmacy Buyer Award Program,** after 2 years of not receiving any nominations (from 2020 to 2021).

Although the nomination deadline has now ***already ended*** for this current year's program, we hope you will enjoy reading about your fellow colleagues' accomplishments and innovations in this edition of NPPA's member-publication *PPO,* and more to follow.

Qualified NPPA-member nominees have the chance to win one of the following 3 distinctions and educational prize awards, as sponsored by NPPA.

1st Place: $1,000 Award for Education/Travel
2nd Place: $500 Award for Education/Travel
3rd Place: $250 Award for Education/Travel

Nominations by a third party as well as self-nominations are both considered. Completed nominations will be submitted to our neutral panel of judges, who will determine the top 3 awardees. Winners will be recognized at the 2022 NPPA Conference in August, and results included in a post-conference *PPO* edition.

For more information on this program, see the NPPA website "Outstanding Buyer Award" page, listed under the main "Membership" navigation menu.

Good luck to all nominees! If you missed the deadline this year, we hope you take the time to enter it for 2023's Outstanding Buyer of Year.

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Medication Safety News

New Best Practices Added To Hospital Medication Safety List By ISMP 2022-2023

On February 10, The Institute for Safe Medication Practices (ISMP) of Horsham, Pennsylvania announced they have issued its 2022-2023 List of Medication Safety Best Practices for Hospitals, which was established to help identify, inspire, and mobilize widespread national action to address recurring problems that continue to cause fatal and harmful errors. ISMP is the country's first 501c (3) nonprofit organization devoted entirely to preventing medication errors.

In addition, three (3) new Best Practices have been added to the list, such as preventing errors with both oxytocin and high-alert medications, and maximizing the use of barcode verification by expanding beyond inpatient areas. Details of the new Best Practices are listed here below.

Oxytocin Best Practice (to safeguard against errors):

- Require the use of standard order sets for prescribing oxytocin antepartum and/or postpartum that reflect a standardized clinical approach to labor induction/augmentation and control of postpartum bleeding.
- Standardize to a single concentration/bag size for both antepartum and postpartum oxytocin infusions (e.g., 30 units in 500mL Lactated Ringers).
- Standardize how oxytocin doses, concentration, and rates are expressed. Communicate orders for oxytocin infusions in terms of the dose rate (e.g., milliunits/minute) and align with the smart infusion pump dose error-reduction system (DERS).
- Provide oxytocin in a ready-to-use (RTU) form. Boldly label both sides of the infusion bag to differentiate oxytocin bags from plain hydrating solutions and magnesium infusions.
- Avoid bringing oxytocin infusion bags to the patient's bedside until it is prescribed and needed.

Barcode Verification Best Practice (to maximize the use of barcode verification prior to medication and vaccine administration by expanding use beyond inpatient care areas):

- Specifically target clinical areas with an increased likelihood of a short or limited patient stay (e.g., emergency department, perioperative areas, infusion clinics, dialysis centers, radiology, labor and delivery areas, catheterization laboratory, outpatient areas).
- Regularly review compliance and other metric data to assess utilization and effectiveness of this safety technology (e.g., scanning compliance rates; bypassed or acknowledged alerts).

Continued on Page 46

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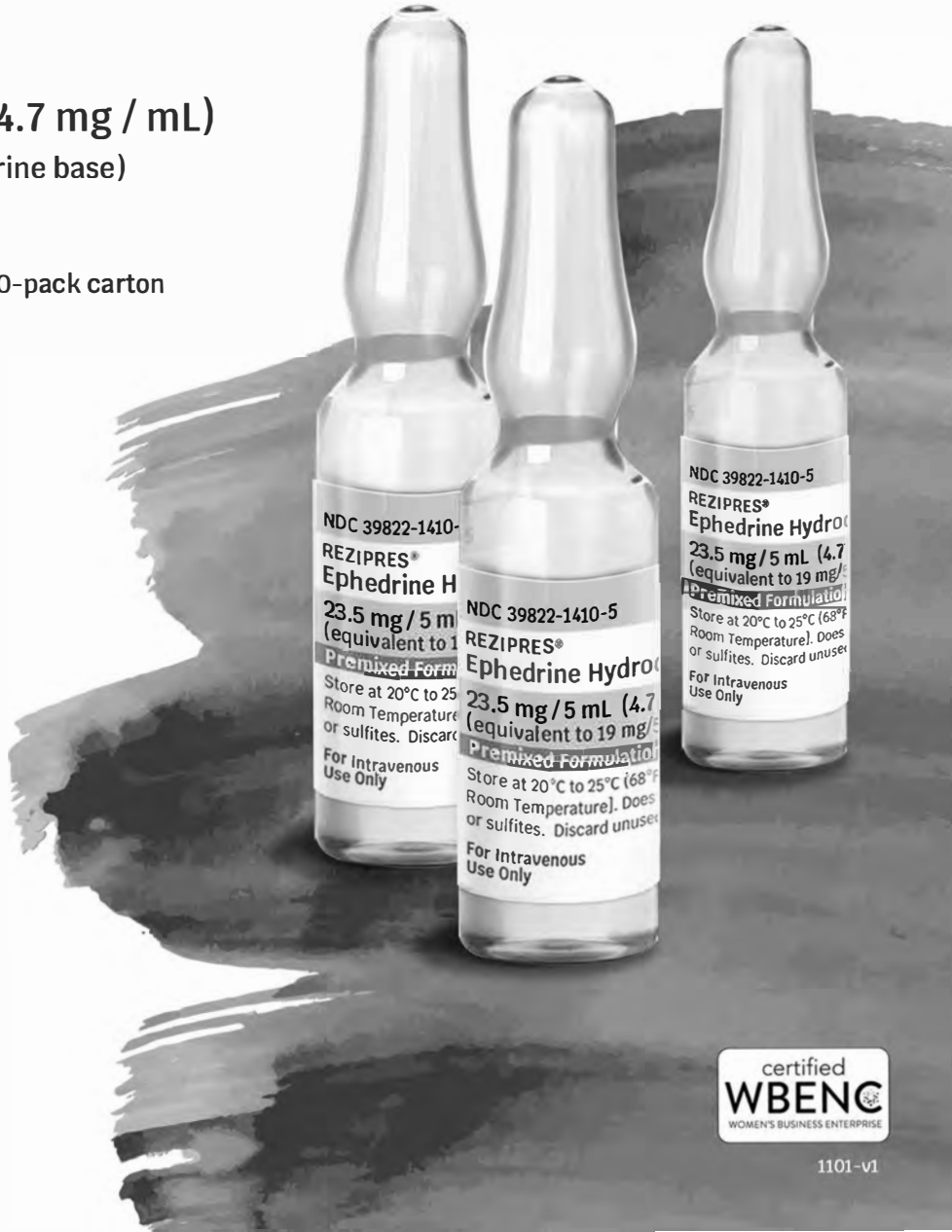
10 DIGIT NDC **39822-1410-6**

11 DIGIT NDC **39822-1410-06**

STRENGTH **23.5 mg / 5 mL** (4.7 mg / mL)
(equivalent to 19 mg/5 mL ephedrine base)

SIZE **5 mL** single-dose ampules in 10-pack carton



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Medication Safety News

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High-Alert Medication Safety Best Practice (to layer numerous strategies throughout the medication-use process to improve safety with high-alert medications):

- For each medication on the facility's high-alert medication list, outline a robust set of processes for managing risk, impacting as many steps of the medication-use process as feasible.
- Ensure that the strategies address system vulnerabilities in each stage of the medication-use process (i.e., prescribing, dispensing, administering, and monitoring) and apply to prescribers, pharmacists, nurses, and other practitioners involved in the medication-use process.
- Avoid reliance on low-leverage risk-reduction strategies (e.g., applying high-alert medication labels on pharmacy storage bins, providing education) to prevent errors, and instead bundle these with mid- and high-leverage strategies.
- Limit the use of independent double checks to select high-alert medications with the greatest risk for error within the organization (e.g., chemotherapy, opioid infusions, intravenous insulin, heparin infusions).
- Regularly assess for risk in the systems and practices used to support the safe use of medications by using information from internal and external sources (e.g., FDA, The Joint Commission, ISMP).
- Establish outcome and process measures to monitor safety and routinely collect data to determine the effectiveness of risk-reduction strategies.

ISMP's Top 10 Medication Safety Concerns

On January 27, the Institute for Safe Medication Practices (ISMP) of Horsham, Pennsylvania announced they have released a list of the Top 10 Medication Errors & Hazards from 2021, which focuses on safety problems that are frequently reported, have caused serious harm to patients, and could be avoided or minimized with system and practice changes attainable by all healthcare providers. Errors related to COVID-19 vaccines involve 4 out of the 10 categories.

Below follows the list of the top concerns, which ISMP hopes become a part of healthcare organizations' future medication safety improvement plans.

1) **Mix-ups between different formulations of the Pfizer-BioNTech COVID-19 vaccine.** ISMP has received ongoing reports of mix-ups between the age 5 to 11 formulation and the formulation for individuals 12 years or older or 16 years or older. Although the caps and label borders are different colors, once caps are removed the difference is less apparent and the labels do not prominently indicate age ranges. Other mistakes have been due to syringe mix-ups or healthcare providers mistakenly thinking it was acceptable to administer a smaller or diluted dose of the vaccine for individuals 12 or older to children ages 5 through 11.
2) **Mix-ups between COVID-19 vaccines or boosters and influenza (flu) vaccine.** Health authorities recommended administering both the flu and COVID-19 vaccines or boosters together at the same visit, unfortunately, this has led to mix-ups, especially in outpatient pharmacies. Mix-ups have been associated with unlabeled syringes, labeled syringes sitting next to each other in the vaccination area, interruptions or distractions during preparation and administration, and staffing shortages.
3) **EPINEPHrine administered instead of COVID-19 vaccine.** Numerous mix-ups between EPINEPHrine injection and COVID-19 vaccines have been reported, as EPINEPHrine should be readily available to treat anaphylactic reactions. Most mix-ups have occurred between look-alike, pre-drawn syringes, both labeled but within arm's length of the vaccinator. Also, ADRENALIN vials from Par Pharmaceutical look similar to the Pfizer-BioNTech vaccine with the purple cap and could be easily confused.
4) **Preparation errors with Pfizer-BioNTech COVID-19 vaccine.** ISMP has published reports of dilution errors with the Pfizer-BioNTech vaccine that resulted in administering too much or too little. In many cases, practitioners used the wrong volume of diluent or diluted the vaccine vial twice. If too much diluent is used, doses may be ineffective; if too little diluent is used, doses may invoke stronger adverse effects. In several cases, the vaccine was administered using the wrong diluent or using air in a syringe to "dilute" it.
5) **Errors & delays with hypertonic sodium chloride (Cl).** Using hypertonic sodium Cl has become the standard of care to manage elevated intracranial pressure or reduce cerebral edema in patients with certain neurological injuries. In 2021, most errors with hypertonic sodium chloride reported to ISMP were associated with mix-ups between 0.9% sodium chloride and hypertonic sodium chloride, often when compounding, stocking, or prescribing, or when programming infusion pumps.

Continued on Page 48

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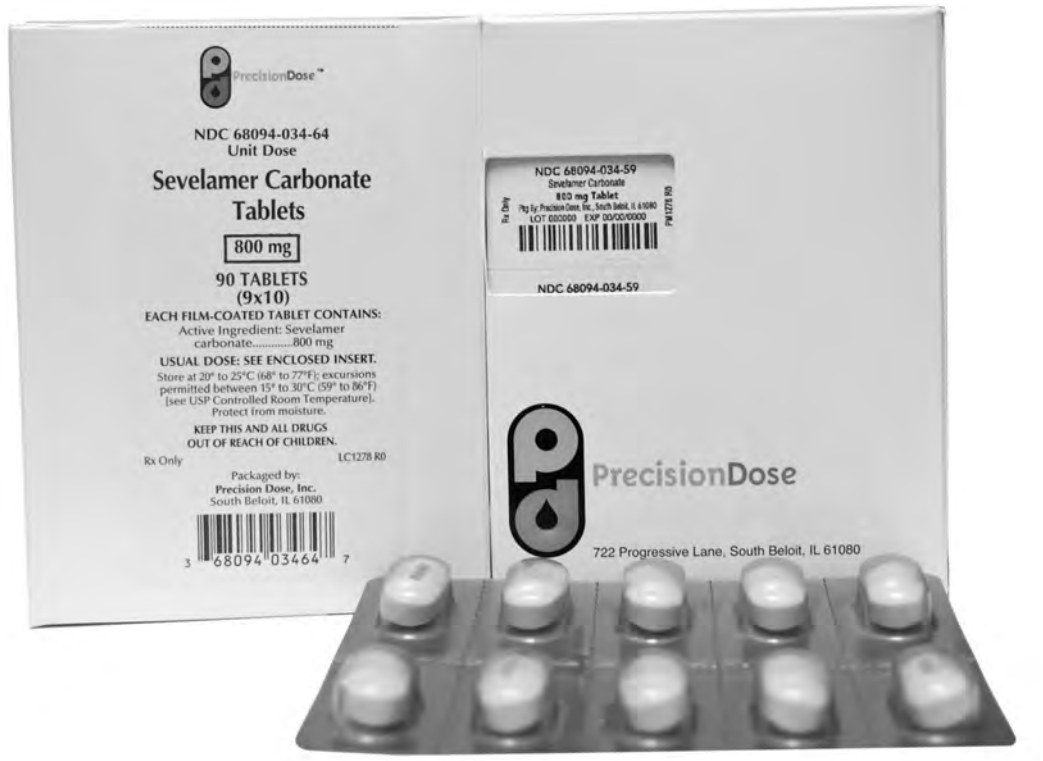

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07-21

Medication Safety News

Continued from Page 46

6) **Errors with discontinued or paused infusions.** In 2021, ISMP published harmful errors involving discontinued high-alert medication infusions that had not been disconnected from patients and were inadvertently restarted, often requiring medical treatment or causing death. While a discontinued or paused medication infusion may be needed again later and keeping the same medication bag may save time and resources, safety should come first.
7) **Infection transmission with shared glucometers, fingerstick devices, and insulin pens.** Increasingly, unsafe practices such as using devices for more than one person have led to outbreaks caused by transmission of hepatitis B virus, hepatitis C virus, HIV (human immunodeficiency virus), and other infectious diseases during assisted blood glucose monitoring and insulin administration.
8) **Adverse glycemic event errors.** ECRI and the ISMP Patient Safety Organization analyzed 100 harmful adverse glycemic events that led to or occurred during a medical emergency and identified key contributing factors, including delays in initiating management protocols or monitoring, mixups between insulin names or vials, communication breakdowns, inaccurate home medication lists, and untimely medication reconciliation.
9) **Organizations lacking a medication safety officer (MSO).** Continuous changes in healthcare constantly introduce new challenges that compromise medication safety. An MSO is a dedicated clinical advocate who can serve as an organization's expert in safe medication use and reduce patient harm. Unfortunately, as of 2018, only about half of U.S. hospitals had created an MSO position to ensure high-leverage strategies are being implemented to reduce risks.
10) **Failure to increase error reporting.** Error-reporting systems are an important tool for learning about medication hazards, errors, and prevention strategies. But barriers to effective reporting still remain in some healthcare organizations due to leadership inaction, unnecessary complexity, or staff misperceptions that it may lead to punitive action.

For more details, visit: www.ismp.org/resources/start-year-right-addressing-these-top-10-medication-safety-concerns-2021

Editorial Note: at the upcoming August 2022 NPPA Conference, one of the lectures on the educational program will be on the topic of ***"Medication Safety & The P&T Committee In Hospital Pharmacies"*** *presented by* ***Cynthia E. Gunn,*** *BS, CPhT, Pharmacy Inventory & Automation Specialist of the Continental Division for HealthTrust Purchasing Group (HCA) in Denver, Colorado.*

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Legal News

Hetlioz® Patent Litigation Settled

On January 14, Vanda Pharmaceuticals Inc. of Washington, D.C. announced it has entered into a License Agreement with MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., and Impax Laboratories LLC, to resolve Vanda's patent litigation against MSN regarding MSN's Abbreviated New Drug Application (ANDA) seeking approval of its generic version of Hetlioz® (tasimelteon) Capsules by Vanda.

Under the agreement, Vanda granted MSN and Impax a non-exclusive license to manufacture and commercialize MSN's version of Hetlioz in the U.S. effective March 13, 2035. Unless prior to that date Vanda obtains pediatric exclusivity for Hetlioz; in which case, the license will be effective July 27, 2035. (MSN and Impax may enter the market earlier under certain circumstances.)

The agreement provides for a full settlement and release by Vanda, MSN, and Impax of all claims that are the subject of the litigation. It is still subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

Hetlioz is a melatonin receptor agonist that is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

Opioid Cases & Claims Settlement Agreement

On January 18, Endo International plc of Dublin, Ireland announced that it and its wholly-owned subsidiaries Endo Pharmaceuticals Inc. of Malvern, Pennsylvania and Endo Health Solutions Inc. have entered into a statewide settlement agreement intended to resolve all government-related opioid claims in the state of Florida.

The settlement, which is subject to certain conditions and contingencies, provides a framework through which Endo and its subsidiaries can fully and finally resolve the opioid-related claims of Florida and its subdivisions. The settlement includes no admission of wrongdoing, fault, or liability of any kind by Endo or its subsidiaries; and resolves among other things, claims against Endo's subsidiaries which were set for trial in Florida state court in April 2022. The settlement value should not be extrapolated to any other opioid-related cases or claims.

Continued on Page 50

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Injection, USP, Synthetic

AP Rated to Miacalcin®

Does Not Contain Natural Rubber Latex

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Product Information

NDC	Strength	Concentration	Fill Volume	Container Size	Closure	Unit of Sale
24201-400-02	400 USP Units/2 mL	200 USP Units/mL	2 mL	2 mL Vial	13 mm	1

Wholesaler Item Numbers

AmerisourceBergen	Cardinal	McKesson	Morris & Dickson
10258223	5722459	1594258	101931

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Legal News

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Endo is continuing to litigate opioid claims not covered by its settlements and to pursue settlements that it believes are in its best interests while remaining focused on its primary goal of achieving a global settlement. At the same time, they are exploring other strategic alternatives, and may seek to implement one or more of those alternatives in the event it is unable to achieve a global settlement.

Texas State Opioid-Related Claims Settled

On February 7, Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey announced it has reached an agreement with the Attorney General of Texas that settles the state's and its subdivisions opioid-related claims.

Under the terms of the settlement, Teva will pay Texas $150 million over a 15-year time period and will provide the recently launched, lifesaving medicine generic Narcan® (naloxone HCl) Nasal Spray, valued at $75 million (wholesale acquisition cost) over 10 years.

Kåre Schultz, Teva President & CEO, said: "Expanding access to lifesaving medicines is at the core of Teva's mission. The Texas Attorney General is taking steps to address the opioid epidemic in the State by negotiating a settlement that includes critical medicines as part of their solution. While the settlement includes no admission of wrongdoing by Teva or its affiliates, it remains in the best interest of Teva to put these cases behind us and continue to focus on the patients we serve every day."

Naloxone is a life-saving medication that can reverse an overdose from opioids. As of December 2021, Teva has made available the first generic version of this critical medicine and has included this product in the company's ongoing pursuit of a national or narrower settlement with individual states, such as the deal announced here.

Teva will continue to defend itself in court in states where they have not yet reached terms of a settlement agreement. The company believes this settlement with the state of Texas is a critical step forward in getting life-saving treatments to people suffering from opioid addiction.

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Outstanding Buyer Nominee - Angela Westdorp

Nominee name & facility: **Angela Westdorp,** CPhT, RPhT, Pharmacy Tech Distribution Specialist, Sarasota Memorial Hospital, North Venice, Florida.

If you are nominating another, provide your own name, title, facility, and relationship to the nominee: Maureen Christoph, CPhT, RPhT, Pharmacy Tech Distribution Specialist, Sarasota Memorial Hospital, Sarasota, Florida; one of Angie's co-worker colleagues.

Is the nominee certified, licensed, and/or registered, as a Pharmacy Technician in their city/state? Nominee is both a Certified & Licensed Tech.

Is the nominee a current NPPA member, and will be an active member through August 2022? Yes, she is a current NPPA member, active through August 2022.

What is the nominee facility's bed size, and what type of facility is it? 135 bed, not-for-profit public institution.

Additional Nominee Comments: 110 beds, but with a census of 130-140 all the time.

Approximately how many dollars of pharmaceutical related expenditures does the nominee purchase or supervise the purchasing of, at the nominee's facility per year? $7 million.

Additional Nominee Comments: Note this amount is an estimate for now, since this facility just opened in November 2021.

What is the dollar amount of the average inventory that the nominee controls throughout the year? $1.3 million.

What are the nominee's/Pharmacy Department's current Inventory "Turns"? 5.

How long has the nominee been a Pharmacy Buyer? 30 years.

What are the nominee's main responsibilities? Inventory; storage; stability; invoices; working with finance, billing, and payroll; perpetual inventory system; filling in as a tech when needed; system administrative duties; Pyxis™ optimization; monitoring and adjusting appropriately in our perpetual inventory system so items are ordered, and of course, not running out of medications.

What is unique about the nominee's facility? It is a brand-new facility that is rapidly growing. They opened in November 2021 and have 110 beds, but their census is always more than 110, with an average of 135. They are already starting another 100-bed tower with plans for another 100 beds once that one is finished. Our challenge is we have no purchase history. With all the backorders, this affects allocations provided by wholesaler.

Outstanding Buyer Nominee, Westdorp

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List any accomplishments or projects that the nominee instituted that has either saved their department/facility money, or helped to make their job or the department run more efficiently. Training everyone in Pharmacy Department how to manage logistics. Working with other team members to make sure they are using all systems effectively, so medications cross over from our perpetual inventory system to the wholesaler accurately.

How has the nominee's job changed over the years? Angie started out in our freestanding Emergency Room (ER) opening in September of 2009. After the 2021 NPPA Conference last year, she moved to Venice to prepare for the opening of this hospital. She went from a 21-bed ER purchasing medications and supplies, to a 110 plus-bed hospital.

Additional Nominee Comments: When I first started purchasing, I lived in Michigan purchasing for a retail Pharmacy. Then I moved to purchase for a 100-bed hospital in Michigan, before moving to Florida.

What does the nominee like about their job? Angie enjoys her job. It is a challenge each and every day to make sure we get all the medications needed for patients, which is very rewarding.

Additional Nominee Comments: I love working with all of the departments in the hospital and getting to know employees in the other departments. It really helps to have a good relationship with everyone.

What does the nominee dislike about their job? The challenges of all the backorders and not being able to get medications needed for patients due to the supply chain issues.

Additional Nominee Comments: I really have a hard time with employees that don't give 100% and look for the easy way to do things, even if it is not the correct way, and it makes more work in the end.

What would be the nominee's advice to vendors? Keep your chin up, it is not your fault!

Additional Nominee Comments: I really feel for them. They are the ones that have to listen to us when we are upset there is no product, and even though they are just the messenger of that kind of bad news.

What kind of specific challenges does the nominee have? Backorders, and we are so much busier than expected so we need more help.

How has the nominee's membership to NPPA/subscription to PPO helped? The publication provides us with updated information on new medications being released, medications that are going off patent, when new generics will be available, discontinued products, and the like.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? Yes, Angie has been to the Annual NPPA Conference multiple times. It helps in the networking with other Buyers (and even the Vendors there), and realizing that we all are in the same boat. It really refreshes you and go back with new tools to do your job.

If the nominee were one of the top 2 placing winners for this Award, would they be able to attend the upcoming NPPA Conference? Yes, definitely.

Does the nominee belong to any other professional organizations besides NPPA? The Florida Society of Health-System Pharmacists (FSHP) and the National Association of Boards of Pharmacy (NABP).

List any other qualifications the nominee may have for this award (such as being honored by their facility; having an article published; organizing buyer meetings; doing public speaking; volunteer work). Angie spoke at last year's 2021 NPPA Conference for the first time and really enjoyed it, she will even be speaking again this year (2022). Angie is also part of the quarterly newsletter for our department.

Additional Nominee Comments: When I worked in Michigan, we had quarterly Buyer's Meetings that I was involved with. I also volunteered each week with the Free Clinic that was for people without healthcare insurance. We had a cart for which we stocked a small supply of medications that we would give at no cost, to people visiting the clinic.

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Coronavirus Treatments

Veklury® For Non-Hospitalized Patients At High Risk For COVID-19 Disease Progression - Expanded Uses

On January 21, Gilead Sciences, Inc. of Foster City, California announced that the FDA has granted expedited approval of a supplemental new drug application (sNDA) for the following ***expanded uses*** of Veklury® (remdesivir 100mg) Injection for intravenous (IV) use:

1) Now also indicated for the treatment of non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death;
2) To now include treatment for non-hospitalized pediatric patients younger than 12 years of age who are at high risk of disease progression (expanding its previous pediatric Emergency Use Authorization-EUA).

This provides another treatment option to reduce the risk of hospitalization in high-risk patients. (Previously, the use of Veklury was limited to patients requiring hospitalization.)

Under the expanded indication for Veklury, non-hospitalized adult and pediatric patients (12 years of age and older and weighing at least 40kg) with confirmed SARS-CoV-2 infection who are at high risk for COVID-19 disease progression can be treated in qualified outpatient settings with daily IV infusions over 3 consecutive days, to help prevent hospitalization. For hospitalized patients not on mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO), a 5-day course of treatment is recommended, with the option to extend to a total of 10-days as needed. Critically ill patients who require mechanical ventilation and/or ECMO should receive a 10-day course of treatment.

Veklury targets the highly conserved viral RNA polymerase, thereby retaining activity against existing SARS-CoV-2 variants of concern. In vitro laboratory testing shows that Veklury retains activity against the Omicron variant.

Also of note, on January 18, Johns Hopkins University of Baltimore, Maryland announced results of a new study they helped conduct, supporting that Veklury increases the likelihood of clinical improvement in COVID-19 patients on low-flow oxygen or no oxygen.

The study was conducted by the Johns Hopkins University School of Medicine, the Johns Hopkins Bloomberg School of Public Health, the Hospital Corporation of America (HCA) Healthcare, and Genospace of Boston, Massachusetts.

Researchers analyzed data from over 43,000 patients hospitalized with COVID-19 who were treated by HCA Healthcare. Overall, 74% of remdesivir-receiving patients saw improvement within 28 days (with a median time of 7 days) versus 68.3% of control patients (with a median time of 9 days). In particular, remdesivir patients receiving low-flow oxygen treatment or no treatment with oxygen saw significantly greater clinical improvement than their control patient counterparts. Treatment with remdesivir also significantly reduced mortality in patients on low-flow oxygen, even when accounting for the effects of anti-inflammatory medications, such as dexamethasone.

FDA Limits Use Of Certain Monoclonal Antibodies To Treat COVID-19 Due To Omicron Variant

On January 24, the FDA announced they are limiting the use of certain monoclonal antibodies to treat COVID-19 due to the Omicron variant; as explained in the below statement by **Patrizia Cavazzoni,** M.D., Director of the FDA's Center for Drug Evaluation & Research (CDER).

"As we have throughout the COVID-19 pandemic, the FDA has used the best available science as the virus has evolved to make informed decisions with the health and safety of the American public in mind. Ensuring that healthcare providers on the frontlines have the best tools available to treat patients is a top priority for the agency.

In light of the most recent information and data available, the FDA revised the authorizations for two (2) monoclonal antibody treatments: bamlanivimab and etesevimab (administered together), and REGEN-COV® (casirivimab and imdevimab) by Regeneron Pharmaceuticals, Inc.; to limit their use to only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.

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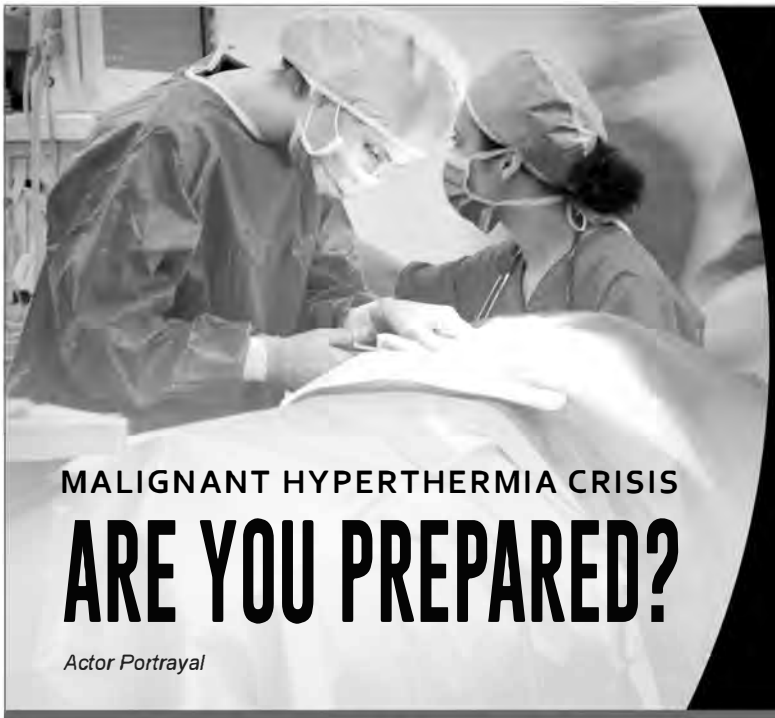

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The use of Revonto in the management of malignant hyperthermia crisis is not a substitute for previously known supportive measures. These measures must be individualized, but it will usually be necessary to discontinue the suspect triggering agents, attend to increased oxygen requirements, manage the metabolic acidosis, institute cooling when necessary, monitor urinary output, and monitor for electrolyte imbalance. Patients who receive i.v. dantrolene sodium preoperatively should have vital signs monitored.

If patients judged malignant hyperthermia susceptible are administered dantrolene sodium preoperatively, anesthetic preparation must still follow a standard malignant hyperthermia susceptible regimen, including the avoidance of known triggering agents. Monitoring for early clinical and metabolic signs of malignant hyperthermia is indicated because attenuation of malignant hyperthermia, rather than prevention, is possible.

Despite initial satisfactory response to i.v. dantrolene there have been reports of fatality, which involve patients who could not be weaned from dantrolene after initial treatment. The administration of i.v. dantrolene is associated with loss of grip strength and weakness in the legs, as well as drowsiness and dizziness. There have been reports of thrombophlebitis following administration of intravenous dantrolene. Tissue necrosis secondary to extravasation has been reported. Injection site reactions (pain, erythema, swelling), commonly due to extravasation, have been reported. Fatal and non-fatal liver disorders of an idiosyncratic or hypersensitivity type may occur with dantrolene sodium therapy.

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Revonto®
(dantrolene sodium for injection)

Coronavirus Treatments

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Because data show these treatments are highly unlikely to be active against the Omicron variant, which is circulating at a very high frequency throughout the United States, these treatments are not authorized for use in any U.S. state, territory, and jurisdiction at this time. In the future, if patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to these treatments, then use of these treatments may be authorized in these regions.

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses, like SARS-CoV-2. And like other infectious organisms, SARS-CoV-2 can mutate over time, resulting in certain treatments not working against certain variants such as Omicron. This is the case with these two treatments for which we're making changes.

Based on the U.S. Centers for Disease Control & Prevention (CDC) data, the Omicron variant of SARS-CoV-2 is estimated to account for more than 99% of cases in the United States (as of January 15, 2022). Therefore, it's highly unlikely that COVID-19 patients seeking care in the U.S. at this time are infected with a variant other than Omicron, and these treatments are not authorized to be used at this time. This avoids exposing patients to side effects, such as injection site reactions or allergic reactions, which can be potentially serious, from specific treatment agents that are not expected to provide benefit to patients who have been infected with or exposed to the Omicron variant.

The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel, an independent panel of national experts, recently recommended against the use of bamlanivimab and etesevimab (administered together) and REGEN-COV (casirivimab and imdevimab) because of markedly reduced activity against the Omicron variant and because real-time testing to identify rare, non-Omicron variants is not routinely available.

Importantly, there are several other therapies: Paxlovid™ (by Pfizer Inc.), sotrovimab, Veklury® (remdesivir) by Gilead Sciences, Inc., and molnupiravir; that are expected to work against the Omicron variant, and that are authorized or approved to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death. Healthcare providers should consult the NIH panel's COVID-19 treatment guidelines and assess whether these treatments are right for their patients.

While it's critical that we have ways to treat those who contract COVID-19, the authorized treatments are not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. Data has clearly demonstrated that the available, safe, and effective vaccines can lower your risk of developing COVID-19 and experiencing the potential associated serious disease progression, including hospitalization, and death.

The FDA is committed to continuing to review emerging data on all COVID-19 therapies related to the potential impact of variants and revise the authorizations further as appropriate to ensure healthcare providers have an effective arsenal of treatments for patients."

Bebtelovimab Injection For Mild-To-Moderate COVID-19

On February 11, Eli Lilly & Company of Indianapolis, Indiana announced that the FDA has issued an Emergency Use Authorization (EUA) for Bebtelovimab Injection for intravenous use, indicated for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

Bebtelovimab is an antibody that demonstrates neutralization against the Omicron variant of COVID-19, which has shown a benefit in reducing the risk of hospitalization or death.

The authorized dose is 175mg, given as an intravenous injection over at least 30 seconds.

Patrizia Cavazzoni, M.D., Director of the FDA's Center for Drug Evaluation & Research, commented: "This action makes available another monoclonal antibody that shows activity against omicron, at a time when we are seeking to further increase supply. This authorization is an important step in meeting the need for more tools to treat patients as new variants of the virus continue to emerge."

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Outstanding Buyer Nominee - Sonya Stone

Nominee name & facility: **Sonya Stone,** CPhT, Inpatient Pharmacy Buyer, Cook Children's Medical Center, Fort Worth, Texas.

If you are nominating another, provide your own name, title, facility, and relationship to the nominee. I am Sonya's direct manager: **Matthew Ridge,** Manager of Pharmacy Business Operations, Cook Children's Medical Center, Fort Worth, Texas.

Is the nominee certified, licensed, and/or registered, as a Pharmacy Technician in their city/state? Sonya is both a Certified & Licensed Tech.

Is the nominee a current NPPA member, and will be an active member through August 2021? Yes, she is a current NPPA member, and will be through August 2022.

What is the nominee facility's bed size, and what type of facility is it? 430-bed, Non-Profit Children's Hospital.

Approximately how many annual dollars of pharmaceutical related expenditures does the nominee purchase or supervise the purchasing of, at the nominee's facility? $45 million per year.

What is the dollar amount of the average inventory that the nominee controls throughout the year? $3.35+ million per year.

What are the nominee's/Pharmacy Department's current Inventory "Turns"? 13.42

How long has the nominee been a Pharmacy Buyer? 3 years.

What are the nominee's main responsibilities? Overseeing inventory, assisting in contracts, and reducing inventory turns.

Additional Comments by Co-Worker Christine Atwell, RPh, Retail Pharmacy Manager (at same facility as nominee): Sonya is the primary buyer for the entire hospital, as well as a Specialty Clinic Pharmacy and the Operating Room Pharmacy. She also helps with keeping track of 340B medication usage and orders drop ship items. Sonya is always available to help when we have trouble obtaining medications.

Additional Comments by Co-Worker Rhonda Carlton, RPh, Pharmacy Supervisor for Perioperative & Surgical Services (at same facility as nominee): Sonya is a member of our buyer Drug Shortage Task Force, and co-teaches IV certification courses.

Additional Comments by Co-Worker Ashlee Hubbard, 340B Program Manager (at same facility as nominee): Sonya handles all the inpatient buying for the medical center, along with assisting the outpatient Pharmacy Buyer when needed. She works with the manufacturers to determine what products are on long-term or short-term backorder. She also develops and works with the vendors to ensure that the hospital has what it needs.

Additional Comments by Co-Worker Haydee Madrigal, 340B Coordinator (at same facility as nominee): Sonya does the ordering for outpatient facilities throughout the hospital, receiving orders, putting up orders, managing backorders, doing direct orders, drop ships, and specialty orders. She has helped implement a lot of new policies and procedures in our IV room as well as to help staff the IV room. She walks satellites before ordering, and does a million other things that probably go unnoticed.

Additional Comments by Co-Worker Eddie Woodall, Pharmacy Inventory Specialist (at same facility as nominee): Sonya is responsible for ordering items for the main Pharmacy Department as well as for the Emergency Room Pharmacy and Operating Room Pharmacy.

What is unique about the nominee's facility? We are a pediatric facility.

Additional Comments by Ms. Atwell: We are a pediatric hospital and order specialized pediatric medications as well as compounding of quite a few medications.

Additional Comments by Ms. Carlton: It's a pediatric facility, and sometimes due to backorders or patient need we have to compound our own product for the patient since there is no commercially available product. Sonya helps get all needed supplies to do this.

Additional Comments by Ms. Hubbard: Pediatrics is nothing like adult hospitals. Dosing is more complicated and the medications needed (such as nutrition) can be life or death for a child. And a lot of oral medications that are available through tablets/capsules are not able to be dispensed to a child, and instead have to be compounded to a liquid.

Additional Comments by Ms. Madrigal: It's a children's hospital, so at times it's hard when certain things go on backorder, because for some kids there are no alternatives. I know Sonya has had to get real creative in the past with how she gets meds in, whether its begging far and wide, going to the P&T Committee for suggestions, or just good old hustling.

Additional Comments by Mr. Woodall: Indeed, pediatric facilities are very unique and present a lot more challenges and needs. The formulary is much larger, and there are many more presentations of each drug, including unique compounds.

List any accomplishments or projects that the nominee instituted that has either saved their department/facility money, or helped to make their job or the department run more efficiently. Sonya is our hospital's "Peak Performer," constantly saving money by reaching failure-to-supply

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Outstanding Buyer, Stone

Continued from Page 55

goals. She also utilizes alternative vendor companies to find less expensive high-use drugs, such as MedShorts.

Additional Comments by Ms. Atwell: Sonya constantly monitors for cost saving alternatives.

Additional Comments by Ms. Carlton: Sonya reaches out to all areas affected when something goes on backorder and works to find substitutes or emergency stock as she can. She actively works to decrease med inventory on items not used that much, as well as maintaining a backstock of items we use a lot to help when backorders do occur. She helps to get creative with leadership to stretch out stock in dire backorders.

Additional Comments by Ms. Hubbard: Sonya has worked closely with the 340B team to ensure that we are using our GPO/340B accumulations effectively in order to save money. She has been vital to identifying medications that are being used as single dose, and making sure that the 340B team has identified these so that the item is rounded and we can order more on the 340B account. She ensures that we are purchasing items that are preferred by our GPO, which helps ensure that the company gets rebates at the end of the quarter.

Additional Comments by Ms. Madrigal: The IV room has pass-through shelves, so when Sonya put in bins she implemented a new procedure so that when the techs were out of something they'd "turn the bin." So now instead of the buyers having to dig through the shelves and see what they're out of, when the bin is simply turned, Sonya knows that they are out and they need to be ordered. This is how Sonya is. She has really great solutions to problems that don't actually need to be problems. She is very smart and resourceful.

How has the nominee's job changed over the years? Sonya has expanded the role into utilizing more reports very well; and in managing Satellite pharmacies vs. our controlling main pharmacy.

Additional Comments by Ms. Atwell: Sonya's job has expanded over the last 3 years. She started out by managing inventory for just one pharmacy and now handles 3 pharmacies.

Additional Comments by Ms. Carlton: Sonya began as an IV technician. She then helped maintain our IV software for doses with the IV Pharmacist. She helps test new items before moved to production to ensure the build works before going live. Then she moved into the buyer role. She understands roles in various areas and helps to know who to talk to about backorders, new products, etc. She also helps setup vendors during "Pharmacy Week."

Additional Comments by Ms. Hubbard: Sonya's job has gotten more complicated over the past few years due to the increase of backorders, and has been one of the leaders in the team that was created internally to address them. COVID has also changed her job, as she now works with vendors to ensure the hospital has all the medications needed for prevention; along with the infusion center we had next door that was open to the community.

Additional Comments by Ms. Madrigal: Over the years, her tasks and areas that she covers have only grown. Everything is getting bigger and more time-consuming, but Sonya handles it like a champ. She doesn't stumble, she picks up the ball and keeps running with it.

Additional Comments by Mr. Woodall: Sonya has grown in her role and taken on additional pharmacies. She has also built many daily reports to run on Epic based on usage to ensure we are lean, but have the items we need.

What does the nominee like about their job? Sonya is providing service to all the children in the hospital; and even takes time to work with them on an individual basis.

Additional Comments by Ms. Atwell: Sonya is enthusiastic about helping people. She loves to help to make the families of sick children feel better by facilitating the medications they need to receive.

Additional Comments by Ms. Carlton: It's like a puzzle to solve when items aren't available from the wholesaler. She likes talking to vendors, pharmacists, leaders, and other facilities to brainstorm how to solve the puzzle. She is good at it, too!

Additional Comments by Ms. Hubbard: Sonya comes off as someone who enjoys every aspect of her job. She enjoys the challenges of ensuring that there is enough product in stock to get through the day. She never complains and always walks in with a smile on her face.

Additional Comments by Ms. Madrigal: I think Sonya loves her job. You can tell when a person is really passionate about what they do, and that person is Sonya. She loves learning about drugs and what they're for, and learning new and creative ways to acquire drugs. She is constantly expanding her knowledge. Sonya really loves her job, as you can tell by the joy she emits and the positivity she radiates.

Additional Comments by Mr. Woodall: She seems to like everything! Her heart is in it!

What does the nominee dislike about their job? Backorders!

Additional Comments by Ms. Atwell: I am not aware of anything that Sonya dislikes about her job!

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Outstanding Buyer, Stone

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Additional Comments by Ms. Madrigal: Other than backorders, I can truly say there is nothing Sonya doesn't love about her job. She is the most positive ray of sunshine person I've ever met.

What would be the nominee's advice to vendors? Be prepared for the worst, and prioritize the kids over adults.

Additional Comments by Ms. Carlton: Communication! If an item is on shortage or they know something may be coming up (new product or drug they are unable to supply), communicate to facilities so they can start figuring out backup plans before the last minute.

Additional Comments by Ms. Hubbard: Communication with the hospitals. If they know stock is getting low, or if a new product is coming, having that dialect and discussing with the buyers can help ward off any issues.

Additional Comments by Mr. Woodall: Be transparent about drug shortages and provide realistic timelines about availability when able.

What kind of specific challenges does the nominee have? Sonya has to be the Buyer and Inventory Tech both, in order to keep our inventory at a manageable amount.

Additional Comments by Ms. Atwell: Finding alternatives for backordered drugs is one of the greatest challenges at the present time.

Additional Comments by Ms. Hubbard: Trying to get ahead of backorders. Sometimes a backorder can be fatal in the pediatric world if a substitute is not available, and Sonya never loses sight of the reason we go to work each day–for the babies.

Additional Comments by Ms. Madrigal: A lot of pediatric doctors are very specific when they prescribe something and are unwilling to compromise. When there is a formulary in place, that can make it really hard to order something. Sonya constantly works with providers to keep them satisfied as well as going above and beyond to get the drug that the child needs.

Additional Comments by Mr. Woodall: Her heart is in it so much, sometimes I feel it is hard for her to unplug.

How has the nominee's membership to NPPA/subscription to PPO helped? Her membership to NPPA has made her open up her networking abilities, to then better service our hospital and department.

Additional Comments by Ms. Atwell: Sonya is new to NPPA, and is looking forward to the things she will learn at this August's conference.

Additional Comments by Ms. Hubbard: NPPA's publication has helped identify any recall and drug related information. Being a member has also helped further Sonya's buying knowledge, along with increasing her ability to network with her peers.

Additional Comments by Ms. Madrigal: Sonya loves to learn and I know that the NPPA has given her the tools and resources to learn more. For instance, she is already registered to attend the upcoming NPPA Conference to learn and network with other buyers.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? No, Sonya has not yet attended an NPPA Conference.

If the nominee were one of the top 2 placing winners for this Award, would they be able to attend the upcoming NPPA Conference? Yes, she will.

Does the nominee belong to any other professional organizations besides NPPA? Sonya is an active member with the Children's Hospital Association (CHA).

Additional Comments by Ms. Atwell: Sonya is also a member of ASHP.

List any other qualifications the nominee may have for this award (such as being honored by their facility; having an article published; organizing buyer meetings; doing public speaking; volunteer work). As the Buyer, Sonya won the Award for our Medical Center's "Peak Performer" distinction, and has been nominated for it twice in total. This is our version of an "Employee of the Month" award, but for the entire medical center.

Additional Comments by Ms. Atwell: Sonya has been honored by Cook Children's as a Peak Performer. This is a special award given to employees who show exceptional caring and go above and beyond their job requirements.

Additional Comments by Ms. Carlton: Peak Performer winner at our facility; and she's also a coach for a children's sports team.

Additional Comments by Mr. Woodall: Sonya is a 2-time Peak-Performer winner. This is hard to achieve, and she has done it ***twice***! In addition, Sonya helped form and now leads a weekly Drug Shortages Task Force meeting, to plan and combat drug shortage issues that our Medical Center may face.

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Coronavirus Vaccines

FDA Approves EUA For COVID-19 Vaccine For Adolescents & Expands Use Of Booster

On January 3, Pfizer Inc. of New York City and Biopharmaceutical New Technologies (BioNTech) of Mainz, Germany jointly announced that the FDA expanded the Emergency Use Authorization (EUA) of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine, as follows.

1) Expand the use of a single booster dose to include use in individuals 12 through 15 years of age.
2) Shorten the time between the completion of primary vaccination of the Pfizer-BioNTech COVID-19 Vaccine and a booster dose to at least 5 months.
3) Allow for a third primary series dose at least 28 days following the second dose for individuals who are 5 through 11 years of age and have been determined to have certain kinds of immunocompromise.

The booster dose is the same dosage strength (30-µg) as the dose approved in the primary series.

Peter Marks, M.D., Ph.D., Director of the FDA's Center for Biologics Evaluation & Research, said: "Based on the FDA's assessment of currently available data, a booster dose of the currently authorized vaccines may help provide better protection against both the delta and Omicron variants. In particular, the Omicron variant appears to be more resistant to the antibody levels produced in response to the primary series doses from the current vaccines. With this in mind, the FDA has extended the range of individuals eligible to receive a booster, shortened the length of time between the completion of the Pfizer primary series for individuals to receive a booster, and is authorizing a third protective vaccine dose for some of our youngest and most vulnerable individuals."

Spikevax COVID-19 Vaccine Receives Full FDA Approval

On January 31, Moderna, Inc. of Cambridge, Massachusetts announced that the FDA approved the Biologics License Application (BLA) for Spikevax (COVID-19 vaccine, mRNA) Injection for intramuscular use, indicated for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

Spikevax has the same formulation as the Emergency Use Authorization (EUA) Moderna COVID-19 Vaccine that was available in the U.S. since December 2020.

It is administered as a primary series of 2 doses, 1 month apart; and can be used interchangeably with the EUA Moderna COVID-19 Vaccine to provide the COVID-19 vaccination series.

Moderna COVID-19 Vaccine remains available under EUA as: a 2-dose primary series for those 18 years of age and older; as a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise; and as a single booster dose for individuals 18 years of age and older at least 5 months after completing a primary series of the vaccine. It is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID-19 vaccine.

Peter Marks, M.D., Ph.D., Director of the FDA's Center for Biologics Evaluation & Research, said: "The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods, and manufacturing facilities. Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards."

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Heart Health News

New Hospital Certification Evaluates Quality Of Care For Most Complex, Critically Ill Cardiac Patients

On January 19, the American Heart Association (AHA) of Dallas, Texas and The Joint Commission of Oakbrook, Illinois jointly announced they have launched a new Comprehensive Heart Attack Center certification (CHAC) program; and starting July 1, 2022, the new Advanced Disease-Specific Care (DSC) certification for the program will be available to all hospitals.

This new program has been initiated in an effort to promote the most effective care for patients who experience the deadliest type of heart attacks. The CHAC certification is based on clinical practice guidelines and recommendations from the AHA that calls for the implementation of a system of care for all time-sensitive cardiovascular disorders in an effort to minimize delays in patient care, including emergency medical services' routing protocols to transport patients to the most appropriate level of care. Hospitals certified under this program must also meet the characteristics for a Level I STEMI Center (most comprehensive).

Alice K. Jacobs, M.D., Vice Chair for Clinical Affairs at Boston University Medical Center, Volunteer Expert, and past President for the AHA, stated: "The recent recommendations from the AHA provide new guidance on how best to care for patients experiencing the deadliest types of heart attacks. These are the heart attacks where survival is measured in minutes, and rapid delivery of guideline-directed care is essential for survival. Providing evidence-based care that improves the quality of care and outcomes for patients is central to the work of the AHA."

CHAC certified hospitals will be recognized for meeting standards that denote the highest level of commitment to providing consistent and optimal treatment for patients with acute coronary syndrome (ACS), including ST-elevated myocardial infarction (STEMI), non-ST elevated myocardial infarction (NSTEMI), and unstable angina, as well as complications related to ACS, such as cardiac arrest and cardiogenic shock.

In order to qualify for the certification, hospitals must provide 24-hour-a-day, 7-day-a-week on-site coverage for primary percutaneous coronary intervention and cardiac surgical services. Additionally, they must have a multidisciplinary team approach that offers a full range of advanced hemodynamic support for the treatment of the most complex and critically ill patients, including those with cardiogenic shock and cardiac arrest, across the continuum of care.

Performance measure expectations for the new certification program are available on The Joint Commission website. The standards will also be included in the July 1, 2022 version of *E-dition* and hard copy update of the Comprehensive Manual for Hospitals.

To learn more about the certification program, hospitals may send an email inquiry to: certification@jointcommission.org

Oral Penicillin Advised For People With High-Risk Rheumatic Heart Disease

On January 20, the American Heart Association (AHA) of Dallas, Texas announced that a growing body of evidence indicates that some people thought to have an allergic response to injectable penicillin, the standard treatment for rheumatic heart disease, may instead be experiencing a cardiac reaction to the medicine, according to a new AHA presidential advisory.

The advisory, which represents official insights from the AHA, suggests oral penicillin may be a safer option for people with rheumatic heart disease who are at high risk of a cardiac reaction.

More than 39 million people worldwide have rheumatic heart disease (RHD), a condition in which the heart's valves are permanently damaged by rheumatic fever, which can occur if a strep throat infection or scarlet fever are untreated or inadequately treated. Most RHD cases are among people living in low- and middle-income countries, where RHD is often diagnosed after severe valvular heart disease or other cardiovascular complications have already developed, leading to higher rates of death and lower life expectancy.

The recommended treatment for RHD is an intramuscular injection of benzathine penicillin G (BPG) given every 3 to 4 weeks for a prolonged period of time (e.g., 10 years, up to the age of 40 years or lifelong). Treatment with BPG for RHD has been limited in part due to patients' and clinicians' fears of a severe allergic reaction called anaphylaxis, even though the risk of anaphylaxis following BPG injection is low.

Amy E. Sanyahumbi, M.D., Chair of the Presidential Advisory writing group, Pediatric Cardiologist at Texas Children's Hospital and Assistant Professor of Pediatrics at Baylor College of Medicine in Houston, explained: "Until recently, deaths within the minutes and hours after BPG injection have been assumed to be due to anaphylaxis. However, a growing number of reports of BPG-related deaths did not have the features of classic anaphylaxis, and, instead, point to cardiovascular reactions. This distinction is important, as it indicates the need for different strategies to prevent or stop these reactions to BPG."

Signs of a cardiovascular response often occur immediately after administration of BPG, sometimes even during injection. They include low

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blood pressure, which may be corrected by changing physical position, slow heart rate and fainting, all of which may lead to low blood flow to the heart, irregular heart rhythm and sudden cardiac death. On the other hand, signs of anaphylaxis after BPG injection are usually slightly delayed after the injection, even up to an hour later, and include coughing, respiratory distress, rapid heart rate, low blood pressure that doesn't respond to position change, fainting, itching, and redness at the injection site.

The risks of a cardiovascular reaction to BPG are highest among individuals with severe mitral stenosis, aortic stenosis, aortic insufficiency or decreased left ventricular systolic function (ejection fraction < 50%), and those who have active symptoms of RHD.

The advisory suggests that people who are at low risk of cardiovascular reaction and who do not have a history of being allergic to penicillin or anaphylaxis be prescribed BPG for treatment and prevention of RHD. BPG has proven to be the best treatment for prevention of recurrent rheumatic fever. Those with higher cardiovascular risks such as severe valvular heart disease or heart failure, treatment with oral penicillin should be strongly considered.

For all patients receiving BPG, the following standard practices are advised.

- Reducing injection pain and patient anxiety, both of which are known risk factors for injection-related fainting. Methods for pain reduction include applying firm pressure to the site for 10 seconds or application of an ice pack or the use of analgesics such as acetaminophen, ibuprofen, or other non-steroidal anti-inflammatory medications (NSAID's).
- Patients should be well-hydrated prior to injection. Drinking at least 500mL of water before injection has been found to prevent reflexive fainting.
- Eating a small amount of solid food within the hour before injection.
- Receiving the injection while laying down, which may reduce the risk of blood pooling in the extremities.

Providers who administer BPG should be taught how to recognize and quickly treat symptoms such as low blood pressure, low heart rate, or fainting.

Men Who Worry More May Develop Heart Disease & Diabetes At Younger Ages

On January 24, the American Heart Association (AHA) of Dallas, Texas announced that middle-aged men who are anxious and worry more may be at greater biological risk for developing heart disease, stroke, and type 2 diabetes, also called cardiometabolic disease, as they get older.

Lewina Lee, Ph.D., Assistant Professor of Psychiatry at Boston University School of Medicine, an Investigator & Clinical Psychologist at the National Center for Posttraumatic Stress Disorder at the U.S. Department of Veterans Affairs, both in Boston (and lead author of the study), explained: "While the participants were primarily white men, our findings indicate higher levels of anxiousness or worry among men are linked to biological processes that may give rise to heart disease and metabolic conditions, and these associations may be present much earlier in life than is commonly appreciated, potentially during childhood or young adulthood."

To track the relationship between anxiety and cardiometabolic disease risk factors over time, the investigators analyzed data on participants in the Normative Aging Study, which is a longitudinal study of aging processes in men, founded at the U.S. Veterans Affairs outpatient clinic in Boston in 1961. The study includes both veterans and non-veterans. This analysis included 1,561 men (97% white), who were an average age of 53 years in 1975. The men completed baseline assessments of neuroticism and worry and did not have cardiovascular disease or cancer at that time. A personality inventory assessed neuroticism on a scale of 0 to 9. In addition, a worry assessment tool asked how often they worried about each of 20 items, with 0 meaning never and 4 meaning all the time.

Dr. Lee said: "Neuroticism is a personality trait characterized by a tendency to interpret situations as threatening, stressful, and/or overwhelming. Individuals with high levels of neuroticism are prone to experience negative emotions, such as fear, anxiety, sadness, and anger more intensely and more frequently. Worry refers to our attempts at problem-solving around an issue whose future outcome is uncertain and potentially positive or negative. Worry can be adaptive, for example, when it leads us to constructive solutions. However, worry can also be unhealthy, especially when it becomes uncontrollable and interferes with our day-to-day functioning."

After their baseline assessment, the men had physical exams and blood tests every 3 to 5 years until they either died or dropped out of the study. The research team used follow-up data through 2015. During follow-up visits, 7 cardiometabolic risk factors were measured, as folows: 1) systolic (top number) blood pressure; 2) diastolic (bottom number) blood pressure; 3) total cholesterol; 4) triglycerides; 5) obesity (assessed by body mass index); 6) fasting blood sugar levels; and 7) the erythrocyte sedimentation rate (ESR), a marker of inflammation.

A risk factor for cardiometabolic disease was considered in the high-risk range if the test results

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New 503B Bulk Substance

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the FDA has determined there is a clinical need (the 503B Bulks List), unless the compounded drug appears on the FDA's drug shortage list at the time of compounding, distribution, and dispensing. The FDA will continue to balance patient protection and access to compounded drugs for patients who need them.

Editorial Note: at the upcoming August 2022 NPPA Conference, one of the lectures on the educational program will be on the topic of ***"503B Outsourcing Companies Explained,"*** *presented by* ***Pam Shea,*** *CPhT, Retired Pharmacy Buyer, Scripps Green Hospital, La Jolla, California.*

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for the risk factor was higher than the cut-point established by national guidelines, or if the participant was taking any medicines to manage that risk factor (such as cholesterol-lowering medications). Cut points for ESR as a risk factor are not standardized, so the participant was ranked as high-risk if they were in the top 25% of those tested. Each participant was assigned a risk factor count score, 1 point for each of the 7 risk factors classified as high-risk. The men were then stratified based on whether they did or did not develop 6 or more high-risk factors during the follow-up period.

Dr. Lee added: "Having 6 or more high-risk cardiometabolic markers suggests that an individual is very likely to develop or has already developed cardiometabolic disease."

The researchers found the following.

- Between ages 33 to 65, the average number of cardiometabolic high-risk factors increased by about 1 per decade, averaging 3.8 risk-factors by age 65, followed by a slower increase per decade after age 65.
- At all ages, participants with higher levels of neuroticism had a greater number of high-risk cardiometabolic factors.
- Higher neuroticism was associated with a 13% higher likelihood of having 6 or more cardiometabolic disease risk factors, after adjusting for demographic characteristics (such as income and education) and family history of heart disease.
- Higher worry levels were associated with a 10% higher likelihood of having 6 or more cardiometabolic disease risk factors after adjusting for demographic characteristics.

Women 35 & Younger Are 44% More Likely To Have An Ischemic Stroke Than Males

On January 24, the American Heart Association (AHA) of Dallas, Texas announced that according to a new review of more than a dozen international studies on sex differences in stroke occurrence, women ages 35 years and younger were 44% more likely to have an ischemic stroke (caused by blocked blood vessels in the brain) than their male counterparts.

In the article, titled: "Systematic Review of Sex Differences in Ischemic Strokes Among Young Adults–Are Young Women Disproportionately at Risk", researchers looked at the differences in stroke incidence among women and men in various young adult age groups. They reviewed studies from January 2008 to July 2021 published and indexed on PubMed, one of the largest online research databases in the world managed by the National Library of Medicine at National Institutes of Health (NIH). They included original studies that were population-based and focused on young adults 45 years of age and younger.

The studies included data on any stroke type, including ischemic strokes; hemorrhagic strokes (a bleed that occurs when a weakened blood vessel ruptures); TIA, or transient Ischemic attack, also called a mini stroke (caused by a serious, temporary clot); and cryptogenic strokes for which no known cause is identified. Most of the strokes in the review were ischemic strokes, which account for about 87% of all strokes.

The researchers identified 16 studies, including a combined total of 69,793 young adults with stroke (33,775 women and 36,018 men), from more than half a dozen countries, including the U.S., Canada, France, and The Netherlands.

The authors' analysis identified the sex differences in the incidence of ischemic strokes was the greatest and most evident among adults younger than age 35 years, with an estimated 44% more women than men in this age group experiencing ischemic strokes. This sex difference narrowed among adults ages 35 to 45 years. Sex differences in older age groups were more difficult to determine due to wide variability in the way data was presented among the studies in this systemic review. Researchers were also not able to identify specific causes behind the higher prevalence of strokes in young women compared to young men.

Sharon N. Poisson, M.D., M.A.S., Associate Professor of Neurology at the University of Colorado in Denver (and study co-author), said: "Our finding suggests that strokes in young adults may be happening for different reasons than strokes in older adults. This emphasizes the importance of doing more studies of stroke in younger age groups so that we can better understand what puts young women at a higher risk of stroke. Better understanding which young adults are at risk for stroke can help us to do a better job of preventing and treating strokes in young people."

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Mechanical Clot Removal May Restore More Function Than Medication Alone After Severe Stroke

On February 11, the American Heart Association (AHA) of Dallas, Texas announced results of a preliminary research study, which found that stroke patients previously considered unlikely to survive without severe disability may regain far more function if the blood clots (which cause ischemic stroke) are mechanically removed, in addition to standard medical therapy.

In 2018, the AHA's stroke treatment guidelines were updated to recommend endovascular therapy (mechanical clot removal) for select stroke patients to improve the odds of functional recovery. The therapy involves threading a slim catheter through a vessel in the leg to mechanically remove a clot blocking a brain vessel.

A new study in Japan is the first randomized, controlled trial to demonstrate the effectiveness of endovascular therapy in patients who have severe strokes involving clots in one or more large brain arteries, interrupting blood flow to a large area of the brain. Effectiveness of the approach had previously been established for patients whose large-vessel clots disrupted blood flow to fewer areas of the brain, however, clinical experience was mixed for patients with more severe strokes.

Infarction area, or core area, estimates the volume of brain affected and describes the blockage location as seen on a brain computerized tomography (CT). A lower number translates to a stroke affecting more core areas of the brain: 8 to 10=small core, 6 to 7=moderate core, and 0 to 5=large core (larger, more severe strokes). Current U.S. stroke guidelines recommend conducting endovascular therapy for core areas 6 to 9. This study examined blockages that affected more core brain areas, specifically blockages that scored as 3 to 5. Strokes with blockages measuring 0 to 2 core areas are considered too severe and highly unlikely the patient would return to ambulatory independence.

In the study, 203 stroke patients (average age of 76 years; 44% women) were treated at 45 hospitals in Japan. Most (71%) were examined and had magnetic resonance imaging or a CT scan of the brain within 6 hours after stroke symptoms were first noticed, which is the timeframe that patients are generally considered eligible for endovascular therapy. The other patients were seen between 6 to 24 hours after symptoms were noticed, and additional imaging showed areas of the brain that might benefit from prompt treatment.

On imaging, all patients were found to have clots blocking a large artery in the brain, either the internal carotid artery, the proximal middle cerebral artery or both. The strokes were rated as severe (median 22 on the National Institutes of Health [NIH] Stroke Scale, which assesses a patient's ability to perform normal functions such as speaking and moving) and involved disrupted blood flow to large areas of the brain (about 7 out of 10 regions).

After imaging, the patients were randomly selected to receive either standard medical care for stroke (providing intravenous fluids, controlling blood pressure and other risk factors, and administering clot-busting medications for select patients at lower risk of bleeding) or standard medical care plus endovascular therapy performed within an hour after imaging to mechanically remove the clots. Due to bleeding concerns, intravenous clot-busting medications were sparingly administered to select patients in a similar proportion in both treatment groups (27 of those who received endovascular therapy and 29 who received standard care).

Comparing the 100 patients who received endovascular therapy with 102 on standard therapy alone, the analysis found the following.

- Patients who received endovascular therapy were 2.43 times more likely (31% vs. 13%) to be able to walk without assistance and to have a residual disability rated as none to moderate 90 days later.
- After 90 days, more of the patients (14% vs. 6.9%) who received endovascular therapy were considered functionally independent, meaning they were either able to carry out all their pre-stroke activities or to have a slight disability that did not require daily assistance.
- At 48 hours after treatment, more patients (31% vs. 8.8%) who received endovascular therapy had major early neurological improvement (improved ability to talk and move limbs).

Takeshi Morimoto, M.D., Ph.D., M.P.H., Professor of Medicine in the Department of Clinical Epidemiology at Hyogo College of Medicine in Nishinomiya, Japan (and senior author of the study), said: "Our findings confirm that anyone who suffers from stroke should be transferred to a medical facility capable of endovascular therapy as soon as possible. The benefit of endovascular therapy is not limited by the severity or region of a stroke. These patients may have the chance to more fully recover from stroke and go back to their previous lives and activity levels."

Several outcomes were compared to evaluate the safety of adding endovascular therapy to medical treatment, with researchers key findings as below.

- Within 48 hours, scans revealed that more of the patients who received endovascular therapy had experienced some bleeding within the brain (with or without symptoms), 58% vs. 31%, respectively.

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- However, the number of patients who experienced other adverse outcomes was similar in the two treatment groups. The adverse events included brain bleeding within 48 hours that caused a worsening of neurological status (4 points or greater worsening on the NIH Stroke Scale); the need for surgery to relieve pressure on the brain in the first week; death within 90 days; or the recurrence of ischemic stroke within 90 days.

Dr. Morimoto stated: "The finding of more intracranial bleeding in the patients who received endovascular therapy is very important. However, there were hemorrhages with symptoms and some that caused no symptoms. The hemorrhages with no symptoms were detected on imaging conducted for this study in the endovascular treatment group, not in the standard practice group. Symptomatic intracranial hemorrhage still occurred more commonly among patients in the endovascular group, however, it was not a statistically significant difference from the standard care group."

The results of this study may not be generalizable to the U.S. or western countries because the study was conducted in Japan, where there is less use of intravenous thrombolysis than in the U.S. and other western countries, and where more strokes are imaged with magnetic resonance imaging (MRI) than CT (perhaps leading to different estimates of how many brain regions are affected by the stroke). Due to these differences in treatment protocols, this study's results may over or underestimate the effectiveness of endovascular therapy.

The researchers are currently performing sub-analyses to help identify factors that might signal which patients are more likely to have a greater return of function after the treatment. Dr. Morimoto concluded: "In addition, tools, devices or rehabilitation methods that could potentially improve the likelihood for similar patients to recover with less disability should be investigated."

Magnets In Newer Portable Electronic Devices Can Interfere With Implanted Defibrillators

On March 1, the American Heart Association (AHA) of Dallas, Texas announced that according to new research, magnet technology is increasingly being used in portable electronic devices, such as the Apple AirPods Pro charging case, the Apple Pencil 2nd Generation, and the Microsoft Surface Pen. However, if the devices are carried in pockets near the chest, and the individual has an implanted cardiac device (ICD), the magnets may interfere with the ICD's ability to help regulate the heart.

Corentin Féry, M.Sc., Research Engineer at the Institute for Medical Engineering & Medical Informatics at the University of Applied Sciences & Arts Northwestern Switzerland in Muttenz, Switzerland (and lead study author), said: "If you carry a portable electronic device close to your chest and have a history of tachycardia (rapid heartbeat) with an ICD, strong magnets in these devices could disable your cardioverter defibrillator. Heart patients should be aware of these risks, and their doctor should tell them to be careful with these electronic devices with magnets."

Devices and machinery with magnets exhibit a vector field or area of magnetic influence that can inhibit pulse generators for implanted ICD's and pacemakers. In ICD's, magnets can activate a switch prohibiting the ICD from delivering life-saving shocks. Newer portable electronic devices equipped with strong magnets can disrupt the ICD operation. Earlier research on the iPhone 12 Pro Max demonstrated that its magnetic field is strong enough to interfere with the normal operation of an implanted pacemaker or ICD when held within an inch.

In this study, researchers tested the magnetic field output of the wireless charging case of the Apple AirPods Pro, the Microsoft Surface Pen, and the Apple Pencil 2nd Generation. Their magnetic field strength was measured and compared to the iPhone 12 Pro Max. Using a magnetic mapper with 64 magnetic sensors, researchers measured the magnetic field strength of these products at various distances. The portable electronic devices were also placed closer and closer to five defibrillators from two representative manufacturers until a therapy deactivation occurred. These distances then constitute the minimal safety distance at which an interaction has actually taken place.

The maximum distance for a possible interaction between the portable electronic devices and the implantable cardiac devices are as follows:

- Around 2cm (0.78 inches) away for all of the Apple products;
- 2.9cm (1.14 inches) away for the Microsoft Surface Pen.

While the tests results showed the maximum distance for a possible ICD interaction, researchers said for safety the minimal distance is between 0.8cm (0.31 inches) for the iPhone 12 Pro Max and the Apple Pencil 2nd Generation, and 1.8cm (0.71 inches) for the Microsoft Surface Pen and the opened charging case of the Apple AirPods Pro.

Sven Knecht, D.Sc., Research Engineer at the Cardiovascular Research Institute Basel at University Hospital Basel at the University of Basel in Switzerland (and study co-author), said: "The public needs to be aware of the potential risks of portable electronic devices in addition to the iPhone 12 Pro Max that may affect anyone with

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an ICD. What is most concerning is that magnets are being used in more and more portable electronic devices, and with so many magnets around us, the risk to cardiac patients is even greater."

In the future, the researchers plan to focus on testing e-cigarettes, other pencils for tablets and other portable electronic devices for their potential magnetic interaction with cardiac devices.

The AHA recommends keeping cell phones at least 6 inches away from ICDs or pacemakers by using it on the ear opposite from the implantation and to avoid keeping the cell phone in a front chest pocket.

N.A. Mark A. Estes, M.D., Professor of Medicine & Director of the Clinical Cardiac Electrophysiology Fellowship Program at the Heart & Vascular Institute of the University of Pittsburgh School of Medicine in Pennsylvania, and an AHA volunteer, said: "The American Heart Association and the manufacturers of pacemakers and implantable cardioverter defibrillators have long recommended that magnets be kept away from these implanted devices. A recent *Journal* of the AHA study reported that the magnetic field induced in the receiver coil of the iPhone 12 Pro Max can result in clinically identifiable magnet interference in pacemakers and ICDs. The current study extends observations on magnetic field interactions with even more devices containing magnets. Patients with cardiac electronic implantable devices should be instructed to keep all electronic devices that can generate a magnetic field several inches from their pacemakers or ICDs."

Resistance Exercise May Be Superior To Aerobic Exercise For Getting Better Sleep

On March 3, the American Heart Association (AHA) of Dallas, Texas announced results of a new research study, which found that resistance exercise may be superior to aerobic exercise as a way to get better sleep, and sleep is important for cardiovascular health.

Angelique Brellenthin, Ph.D., Assistant Professor of Kinesiology at Iowa State University in Ames, Iowa (and study author), said: "It is increasingly recognized that getting enough sleep, particularly high-quality sleep, is important for health including cardiovascular health. Unfortunately, more than a third of Americans don't get enough sleep on a regular basis. Aerobic activity is often recommended to improve sleep, yet very little is known about the effects of resistance exercise versus aerobic exercise on sleep. The U.S. Department of Health & Human Services' (HHS) 2018 Physical Activity Guidelines Advisory Committee Scientific Report identified the need for more research into resistance exercise and sleep outcomes. Our study is one of the largest and longest exercise trials in a general adult population to directly compare the effects of different types of exercise on multiple sleep parameters."

Previous research has confirmed that not getting enough sleep (the recommended amount for adults is 7 to 8 hours a day) or getting poor quality sleep increases risks for high blood pressure, elevated cholesterol, and atherosclerosis, which happens when fatty deposits build up in arteries. Not getting enough sleep is linked to weight gain, diabetes, and inflammation, all of which can worsen cardiovascular disease. Sleeping too much or too little also has been shown to increase the risk of stroke, heart attack, and death.

For this study, researchers enrolled 386 adults who met the criteria for overweight or obesity, which was a body mass index from 25 to 40 kg/m². Participants were inactive and had elevated blood pressure measuring from 120 to 139 mm Hg systolic (top number), and 80 to 89 mm Hg diastolic (bottom number).

Participants were randomly assigned to a no-exercise group (for comparison) or 1 of 3 exercise groups (aerobic only, resistance only, or combined aerobic and resistance) for 12 months. Everyone in the exercise groups participated in supervised 60-minute sessions, three times a week, with the combination exercise group doing 30 minutes of aerobic and 30 minutes of resistance exercise.

The various workouts included the following.

- Aerobic exercise participants could choose among treadmills, upright or recumbent bikes or ellipticals for their aerobic modality during each session. Researchers monitored their heart rates to keep them continuously in the prescribed heart rate range for a moderate-to-vigorous intensity exercise.
- The resistance exercise group completed their sets and repetitions (reps) on 12 resistance machines to work all the major muscle groups in a session. The machines included leg press, chest press, lat pulldown, leg curl, leg extension, biceps curl, triceps pushdown, shoulder press, abdominal crunch, lower back extension, torso rotation, and hip abduction. Participants performed 3 sets of 8 to 16 reps at 50% to 80% of their 1-rep maximum.
- The combination group did 30 minutes of aerobic exercise at a moderate-to-vigorous intensity, and then 2 sets of 8 to 16 reps of resistance exercise on 9 machines, instead of 12.

Study participants completed a variety of assessments at the start and at 12 months including the self-reported Pittsburgh Sleep Quality Index (PSQI), which measures sleep quality. Researchers also measured sleep duration; sleep efficiency (how much time one is actually asleep divided by the total amount of time the individual

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is in bed); sleep latency (how much time it takes to fall asleep after getting into bed); and sleep disturbances (how frequently sleep is disturbed by things like being too hot or too cold, snoring or coughing, having to use the bathroom, or having pain). Lower scores on the PSQI indicate better quality sleep, ranging from 0 for the best sleep to 21 as the worst possible sleep. Scores greater than 5 are considered "poor quality sleep."

The study's key findings were as follows.

- More than one third (35%) of study participants had poor quality sleep at the beginning of the study.
- Among the 42% of participants who were not getting at least 7 hours of sleep at the study's start, sleep duration increased by an average of 40 minutes in 12 months for the resistance exercise group, compared to an increase of about 23 minutes in the aerobic exercise group, about 17 minutes in the combined exercise group and about 15 minutes in the control group.
- Sleep efficiency increased in the resistance exercise and combined exercise groups, but not in the aerobic exercise or no exercise group.
- Sleep latency decreased slightly, by 3 minutes, in the group assigned to resistance exercise only, with no notable change in latency in the other participant groups.
- Sleep quality and sleep disturbances improved some in all groups including the group that did not exercise.

Based on these findings, interventions focused on resistance exercises may be a new way to promote better sleep and improve cardiovascular health.

Dr. Brellenthin said: "While both aerobic and resistance exercise are important for overall health, our results suggest that resistance exercises may be superior when it comes to getting better sleep at night. Resistance exercise significantly improved sleep duration and sleep efficiency, which are critical indicators of sleep quality that reflects how well a person falls asleep and stays asleep throughout the night. Therefore, if your sleep has gotten noticeably worse over the past two stressful years, consider incorporating two or more resistance exercise training sessions into your regular exercise routine to improve your general muscle and bone health, as well as your sleep."

$20 Million For Research Focused On Health Equity In Maternal & Infant CVD Health

On March 4, the American Heart Association (AHA) of Dallas, Texas announced that in order to address the growing concern of poor heart health, especially among women of color that puts both mothers-to-be and their infants at risk, they have released a new $20 million scientific research initiative created to fund the *"Health Equity Research Network (HERN) on Disparities in Maternal-Infant Health Outcomes"*.

Heart disease currently causes more than 1 in 4 pregnancy-related deaths (26.5%) in the United States. The initiative seeks to better understand the link between pregnancy complications and cardiovascular health among women and their babies. The AHA will select several teams of researchers to undertake special projects focused on significantly advancing the understanding of the factors underlying the disproportionate impact of maternal complications and deaths among Black women, Native American women and those living in rural areas.

According to the U.S. Centers for Disease & Prevention (CDC), the U.S. has the highest maternal mortality rate among industrialized countries, and is the only industrialized country in which rates are worsening. Conditions related to the heart and vascular system are the leading causes of U.S. pregnancy-related deaths. Pregnancy-related death rates for non-Hispanic Black and American Indian/Alaska Native women are more than two to three times that of white women and Hispanic women. These disparities persist independent of socioeconomic variables.

Michelle A. Albert, M.D., M.P.H., FAHA, Volunteer President-Elect of the AHA, Professor of Medicine, Director of the Center for the Study of Adversity & Cardiovascular Disease, and Associate Dean of Admissions at the University of California in San Francisco, said: "Structural racism in the healthcare system impacts how women of color, especially non-Hispanic Black women, are treated across the spectrum of pre-conception, pregnancy and postpartum care. Chronic stress and associated experiences including racism are linked to cardiovascular disease. Social determinants of health contribute to approximately 80% of cardiovascular risk. In order to inform urgently needed solutions for the maternal health crisis, research is needed that takes into account the unique social determinants and stressors, as well as clinical risk factors such as fibroids and care processes that result in the disproportionate maternal health outcomes by race and ethnicity."

Racial and ethnic maternal health disparities also translate into disparities in infant mortality with Black babies having an infant mortality rate of 10.8 deaths per 1,000 live births compared with 8.2 for American Indian/Alaska Native babies and 4.6 deaths for white babies, according to the CDC. Dr. Albert also noted that geographic disparities

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Heart Health News

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also exist among women living in rural communities who experience higher mortality rates than women living in urban communities.

The Health Equity Research Network on Disparities in Maternal-Infant Health Outcomes is part of the multi-pronged approach of the AHA's unprecedented pledge to aggressively address social determinants of health while working to improve health equity for all communities. This is the second health equity research network funded by the Association. The Health Equity Research Network on Hypertension was launched in July 2021 with research projects focusing on hypertension prevention in underserved populations which historically have the highest prevalence of this mostly preventable, but potentially deadly condition.

People With Serious Mental Illness May Have Increased Heart Disease Risk At Younger Ages

On March 9, the American Heart Association (AHA) of Dallas, Texas announced results of a new research study conducted with nearly 600,000 adults in the United States, which found that those diagnosed with bipolar disorder, schizophrenia, or schizoaffective disorder may have a higher risk of cardiovascular disease at younger ages, when compared to adults not diagnosed with one of those serious mental illnesses.

The researchers believe that this is the first study to examine estimated lifetime (30-year) cardiovascular risk in a large sample of adult outpatients diagnosed with bipolar disorder, schizophrenia, or schizoaffective disorder (the 3 serious mental illnesses specific to this study). Many previous studies of cardiovascular risk for people with serious mental illness have included only people who were hospitalized, and they tend to have more severe mental illness and frailer health than outpatients. In contrast, this study, included a large sample of non-hospitalized U.S. adults.

Rebecca C. Rossom, M.D., M.S., Senior Research Investigator in Behavioral Health at the Center for Chronic Care Innovation at HealthPartners Institute in Minneapolis, Minnesota (and lead study author), said: "Previous research has indicated that people diagnosed with a serious mental illness die 10 to 20 years earlier than the general population, and their leading cause of death is heart disease. Our study focused on the contribution of cardiovascular risk factors, such as blood pressure, cholesterol, blood sugar, body mass index, and

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News Briefs

Amneal Acquires Saol Therapeutics' Baclofen Franchise

On January 5, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey and Saol Therapeutics of Roswell, Georgia jointly announced a definitive agreement under which Amneal will acquire Saol's Baclofen franchise, including Lioresal® (baclofen) Intrathecal Injection and Lyvispah™ (baclofen) Oral Granules, as well as a pipeline product still under development.

Lioresal is delivered through an implantable intrathecal pump that is indicated for use in the management of severe spasticity of cerebral or spinal origin for the institutional market. It has approximately $25 million in annual net revenue. Lyvispah is a baclofen oral granules (5mg, 10mg, and 20mg) specialty product recently approved by the FDA indicated for the treatment of spasticity. Together, Amneal expects these two products to generate between $40 and $50 million in combined annual net revenues by 2025.

Baclofen is a skeletal muscle relaxant used to treat muscle spasms caused by spinal cord injury, multiple sclerosis, and other conditions. It was first approved by the FDA in 1977.

Hikma Acquires Injectable Assets From Teligent

On February 3, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced they have completed their acquisition to acquire the Canadian assets of Teligent Inc. of Buena, New Jersey.

The acquisition marks Hikma's expansion into Canada, and includes a portfolio of 25 sterile injectable products, 3 in-licensed ophthalmic products, and a pipeline of 7 additional products, 4 of which are already approved by Health Canada.

PAI Acquires Teligent Sterile Injectable & Topical Products

On February 3, Pharmaceutical Associates, Inc. (PAI) of Greenville, South Carolina announced they have acquired all of the generic and branded U.S. marketing authorizations from Teligent Inc. of Buena, New Jersey.

The acquisition marks PAI's expansion into sterile injectable and topical products and includes a portfolio of over 60 generic and branded applications, including almost 50 approved applications and a pipeline of over 15 additional filed products. PAI intends to commercialize certain products from the portfolio where favorable U.S. market opportunities exist now and in the future.

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Educational Program - 2022 NPPA Conference
August 9-11 - Bally's Las Vegas

CE Units Available: between 10-12 ACPE-accredited CE units for pharmacy recertification expected to be available, including 1 hour/unit of "Law" CE, for Pharmacy Tech/Buyers (with at least half or more also for Pharmacists).

Timeslots for Educational Sessions are currently still TBD.

Drug Diversion Prevention: A Pharmacy Buyer's Perspective
Angela Westdorp, CPhT, RPT, Inventory Control Specialist, Sarasota Memorial Hospital, North Venice, Florida
Ken LeBoutillier, PharmD, CPh, Pharmacy Administrative Manager, Sarasota Memorial Hospital, and Diversion Program Co-Chair, Sarasota Memorial Healthcare System, Sarasota, Florida
Jodi Emmett, BSN, RN-BC, Medication Diversion Specialist, Sarasota Memorial Hospital, Sarasota, Florida

Pharmacy Buyer Workload, Training & Growth Options - "Where To From Here?"
Sarah Davis, CPhT, B.S., M.A., Apexus Certified 340B Expert, Lead Product Advisor in Pharmacy Analytics, Vizient, Inc., Irving, Texas

Pharmacy Automated Dispensing Cabinets: Configuration, Maintenance & Optimization
Cassi Prosper, CPhT, Pharmacy Buyer & Technician Consultant, and Director/Instructor of Pharmacy Technician Program (for several cities in California)

Medication Storage In Pharmacy: Does It Really Matter?
Cynthia E. Gunn, BS, CPhT, Pharmacy Inventory & Automation Specialist-Continental Division, HealthTrust Purchasing Group (HCA), Denver, Colorado

503B Outsourcing Companies Explained
Pam Shea, CPhT, Retired Pharmacy Buyer, Carlsbad, California (previously the Buyer at Scripps Green Hospital, La Jolla, California)

Drug Supply Chain Quality & Security Act (DSCSA) Information & Updates
Teri Levitt, MS, CPhT, 340B Apexus Certified Expert, Senior Product Advisor, Vizient Inc., Irving, Texas
- ♦ ***Qualifies for Pharmacy "Law" CE requirement***

Pharmacy Inventory: A Team Sport
Angela Nash, CPhT, Pharmacy Buyer, St. Luke's Health-The Vintage Hospital, Houston, Texas

Advantages Of Offsite Hospital Pharmacy Procurement Centers
Bryan Neary, MPA, Assistant Director of Pharmaceutical Supply Chain, University of Rochester Medical Center (URMC), Rochester, New York

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News Briefs

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In October 2021, Teligent filed for voluntary protection under Chapter 11 of the U.S. Bankruptcy Code. As part of this process, Teligent initiated a sale of its core assets, following which PAI has agreed to acquire Teligent's U.S. filings.

UCB To Acquire Zogenix

On January 19, UCB, S.A. of Brussels, Belgium (with U.S. headquarters in Atlanta, Georgia) and Zogenix, Inc. of Emeryville, California announced that the companies have entered into a definitive agreement under which UCB will acquire Zogenix.

The Board of Directors of both companies have unanimously approved the transaction, the closing of which remains subject to the tender of shares representing at least a majority of the total number of Zogenix's outstanding shares, receipt of required antitrust clearances, and other customary conditions.

The transaction will broaden and build upon UCB's continued commitment to, addressing unmet needs of people living with specific or rare forms of epilepsy, in particular, by adding Fintepla® (fenfluramine) Oral Solution (C-IV) to the existing product line. Fintepla has been FDA-approved for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

Zogenix is also pursuing indications for the use of Fintepla in the treatment of seizures associated with additional rare epilepsies, Lennox-Gastaut syndrome (LGS), and CDKL5 Deficiency Disorder (CDD). The FDA recently accepted for filing Zogenix's supplemental New Drug Application (sNDA), granting Priority Review, for LGS. Beginning in childhood, Dravet syndrome and LGS syndrome are 2 of the most devastating and lifelong forms of epilepsy.

Upon the successful completion of the tender offer, UCB's acquisition subsidiary will be merged into Zogenix. The transaction is expected to close by the end of the second quarter of 2022.

In the United States, Fintepla is available only through a restricted distribution program called the Fintepla REMS program.

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Educational Program, 2022 NPPA Conference

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Cost Savings Strategies In Pharmacy
Vicki Sykes, Senior Pharmacy Sourcing Manager/Analyst, Amber Specialty Pharmacy, Omaha, Nebraska

Hospital Pharmacy Inspections & Preparations – "They Could Come at Any Time!"
Kelly Boudreaux, CPhT, Pharmacy Technician Supervisor, Children's Hospital Colorado, Colorado Springs, Colorado

Cyber Attack Awareness For Hospital Pharmacies
Amber Johnston, PharmD, Pharmacy Manager of Central Operations, Nebraska Medicine Medical Center, Omaha, Nebraska
Angela Loftus, CPhT, Senior Purchasing Analyst, Nebraska Medicine Medical Center, Omaha, Nebraska

Managing The Complexity & Rate Of Change In Pharmacy Inventory
Fatimah Muhammad, MPH, 340B Pharmaceutical Services Program Manager, Saint Peter's University Hospital, New Brunswick, New Jersey

Secondary Purchases In Pharmacy & 340B
Elizabeth Faust, MHA, 340B ACE, 340B Education & Compliance Support Specialist, Prime Vendor Program Managed By Apexus, Irving, Texas

Thanks To Renewing NPPA Members

Full Pharmacy Members

Ellka Acevedo, Pharmacy Buyer, Dignity Health Arizona General Hospital, Laveen, AZ

Lupe Gonzales, Pharmacy Buyer, Banner Del E. Webb Medical Center, Sun City West, AZ

Ana Martinez, Pharmacy Buyer, Emanate Health Inter-Community Hospital, Covina, CA

Nick Iinuma, Pharmacy Buyer & Inventory Control Coordinator, Adventist Health White Memorial Hospital, Los Angeles, CA

Donna Falknor, Pharmacy Buyer, Community Hospital of the Monterey Peninsula, Monterey, CA

Lyle Matthews, Inspector, California State Board of Pharmacy, Redlands, CA

Kelsey Kaku, PharmD, Pharmacist, Santa Clara Valley Medical Center, San Jose, CA

Erin Miller, Pharmacy Buyer, Adventist Health Sonora, Sonora, CA

Mindy Pequeno, 340B Compliance Analyst, Adventist Health Saint Helena Hospital, St. Helena, CA

Diane Bednarz, Pharmacy Buyer, Middlesex Hospital, Middletown, CT

Gannon Milne, Corporate Pharmacy Purchasing Analyst, Comprehensive Pharmacy Services (CPS), Atlanta, GA

Brandon Luke, Pharmacy Purchasing Agent, MercyOne Waterloo Medical Center, Waterloo, IA

Rakesh Jain, Pharmacy Purchaser, Shirley Ryan AbilityLab, Chicago, IL

Pamela Marsey, Pharmacy Buyer, OSF Heart of Mary Medical Center, Urbana, IL

Margaretrose Hlinsky, Pharmacy Buyer, Franciscan Health Hammond Hospital, Hammond, IN

Charles (Sandy) Loring, Pharmacy Buyer, Emerson Hospital, Concord, MA

Cindy Neall, Pharmacy Purchasing Manager, UM-Baltimore Washington Medical Center, Glen Burnie, MD

Lisa Herbert, Pharmacy Buyer, Northern Light Eastern Maine Medical Center, Bangor, ME

Marina Rybarz, Commodities Specialist, Henry Ford Macomb Hospital, Clinton Township, MI

Jane VanDierenDonck, Contract Specialist/Pharmacy Purchasing, Henry Ford Wyandotte Hospital, Wyandotte, MI

Ryan Olds, Senior Pharmacy Business Analyst, Mercy Health Systems, Chesterfield, MO

David Huntsman, Pharmaceutical Buyer, Mosaic Medical Center, Saint Joseph, MO

Nancy Fugett, Pharmacy Buyer, Delta Regional Medical Center, Greenville, MS

Diane Plymale, Pharmacy Coordinator, Scotland Memorial Hospital, Laurinburg, NC

Amber Johnston, Pharmacy Manager of Central Operations, Nebraska Medicine, Omaha, NE

Lisa Black, Sr. Pharmacy Buyer, Saint Peter's University Hospital, New Brunswick, NJ

Bryan McCormick, 340B Program Manager, RWJ Barnabas Health, West Orange, NJ

Danielle O'Malley, Pharmacy Buyer/Tech Supervisor, St. Rose Dominican-San Martin, Las Vegas, NV

George Raptou, Pharmacy Buyer, Saint Francis Hospital, Tulsa, OK

Marisa King, Pharmacy Buyer, Asante Rogue Regional Medical Center, Medford, OR

Kristal Frey, Network Pharmacy Business Manager, St. Luke's University Hospital, Bethlehem, PA

Rachel Batchler, 340B Coordinator, The Regional Medical Center, Orangeburg, SC

Sandra Greene, Pharmacy Purchasing Specialist/Buyer, The Regional Medical Center, Orangeburg, SC

Susan Nygaard, Pharmacy Inventory Coordinator, Sanford USD Medical Center, Sioux Falls, SD

Irma Romo Flores, Pharmacy Purchasing Agent, Moore County Hospital District, Dumas, TX

Christine Muzquiz, System Pharmacy Purchasing Coordinator, Texas Health Arlington Memorial Hospital, Fort Worth, TX

Kimberly Broers, Pharmacy Warehouse Operations Lead, Providence Infusion & Pharmacy, Spokane Valley, WA

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Executive (GPO) Members

Rhandel Coloma, Division Pharmacy Analyst, HCA Far West Division, Henderson, NV

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Welcome, New NPPA Members!

Thanks and welcome to all listed below, for your new NPPA memberships! We encourage you to send feedback and contribute articles for this, your member-publication. Send such articles and feedback as either a Word document or within the email memo itself, to: Board@PharmacyPurchasing.com

Be sure to read the next page's "NPPA Website Resources" (which is a regular column in each *PPO*). This provides you with your Member-Only page's login information, which has FDA shortage alerts, recalls, and more.

Also know that we pay for published articles! See our website's "Member Incentives Program" page for details.

Full Pharmacy Members

Alex Gale, Pharmacy Buyer/Biller, Bristol Bay Area Health Corporation, Dillingham, AK

Carlo Riparip, Pharmacy Technician, Bartlett Regional Hospital, Juneau, AK

Krischelle Batac, Pharmacy Technician, Bartlett Regional Hospital, Juneau, AK

Renewing NPPA Members

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Corporate (Vendor) Members

Dana Ryan, Inside Sales Specialist, American Health Packaging, San Diego, CA

Jose Trespalacios, Vice President, Reliance Wholesale, Inc., Miami, FL

Rich Greene, Executive Director of Sales, ProvePharm Inc., Palm Springs, FL

Bryan McGurn, Director of Marketing, International Medical Industries, Inc., Pompano Beach, FL

Warren Swanson, President, Hospak Unit Dose Products, Huntley, IL

Mariam S. Darsot, President, Nexus Pharmaceuticals, Inc., Lincolnshire, IL

Arun Menon, Chief Commercial Operations, Somerset Pharma, LLC, Somerset, NJ

Christina Dalton, Hospital Marketing & Key Account Manager, Azurity Pharmaceuticals, Knoxville, TN

Randy McKitrick, President, Lone Star Pharmaceuticals, Inc., Argyle, TX

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Kevin Moon, Pharmacy Technician Buyer, Adventist Health White Memorial Hospital, Los Angeles, CA

Rudy Villegas, Pharmacy Buyer, Queen of the Valley Hospital, Napa, CA

Loretta De Herrera, Purchasing Agent, San Luis Valley Regional Medical Center, Alamosa, CO

Jordan LeBron, Pharmacy Buyer, BayCare Integrated Service Center, Temple Terrace, FL

Nikki Shearer, Pharmacy Inventory Supervisor, Franciscan Health Hospital, Indianapolis, IN

Nicole Morearty, Pharmacy Buyer, Henry Ford Hospital, Detroit, MI

Erin Curtice, Pharmacy Buyer, Spectrum Health, Hesperia, MI

Ruth Backfisch, Pharmacy Buyer, Southeast Missouri Hospital, Cape Girardeau, MO

Dawna Thompson, 340B Analyst, Providence St. Patrick Hospital, Missoula, MT

Ric Miles, Executive Director, Buddies of New Jersey, Inc., Hackensack, NJ

Fatimah Muhammand, 340B Pharmaceutical Services Manager, Saint Peter's University Hospital, New Brunswick, NJ

Michael Castillo, Sr. Director of Pharmacy, Mariposa Community Health Center, Nogales, NM

Mike Leslie, Pharmacy Purchaser, Central City Concern, Portland, OR

Amanda Cummings, Director of Pharmacy, Mid-Columbia Medical Center, The Dalles, OR

Sarah Isaacson, Pharmacy Buyer, Mid-Columbia Medical Center, The Dalles, OR

Melanie Roberts, Chief Compliance & Ethics Officer, Parkland Heath & Hospital System, Celina, TX

Mary Holmes, VP of Compliance, Parkland Heath & Hospital System, Dallas, TX

April Hairston, Pharmacy Buyer, Sovah Health Danville Hospital, Danville, VA

Alisha Lamphear, Pharmacy Buyer/Lead Tech, Island Hospital, Anacortes, WA

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Heart Health News

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smoking status, to compare overall heart disease risk for people with and without serious mental illness."

This analysis evaluated health data for nearly 600,000 people, ages 18 to 75 years, who visited a primary care clinic in Minnesota and Wisconsin between January 2016 and September 2018. Nearly 2% (approximately 11,000 adults), had a diagnosis of serious mental illness. Of these, 70% were diagnosed with bipolar disorder, 18% with schizoaffective disorder, and 12% with schizophrenia. On average, people with serious mental illness were more likely to be younger; female; self-identify as Black race, Native American, Alaskan race or of multiple races; and be insured by Medicaid or Medicare, compared to their counterparts not diagnosed with one of those three serious mental illnesses.

Prediction models providing a standardized metric were used to assess cardiovascular risk factors and predict the likelihood of a heart attack, stroke, or cardiovascular death. To assess 10-year risk, the atherosclerotic cardiovascular risk scoring tool (as developed by AHA and the American College of Cardiology) was used for adults ages 40 to 75 years old. The Framingham Risk Score was used to estimate 30-year cardiovascular risk among adults ages 18 to 59 years old.

Researchers found the following key study results.

- Adults in the study with one of the serious mental illnesses reviewed had an estimated 10-year cardiovascular risk level of 9.5%, compared to 8% for adults without a mental condition.
- The estimated 30-year risk of cardiovascular disease was significantly higher among those individuals with 1 of the 3 serious mental illnesses (25%, compared to 11% of people without a serious mental illness).
- The increased risk of heart disease was evident even in young adults (ages 18 to 34) with a serious mental illness.
- Within the subtypes of each of the 3 serious mental illnesses in this study, in analyses adjusted for age, sex, race, ethnicity, and insurance coverage, people with bipolar disorder had the highest 10-year cardiovascular risk compared to those with schizophrenia or schizoaffective disorder; while people with schizoaffective disorder had the highest 30-year cardiovascular risk when compared to the other 2 groups.
- Smoking and body mass index (BMI) accounted for much of the risk factors contributing to cardiovascular disease in those with a serious mental illness. Those with a serious mental illness were 3 times more likely to be current smokers (36%), compared to peers without serious mental illness (12%); and 50% of those with a serious mental illness met the criteria for obesity compared to 36% of people without a serious mental illness.
- People with a serious mental illness had double the rate of diagnosed diabetes (Type 1 or Type 2) than people without serious mental illness (14% vs. 7%).
- 15% of adults with a serious mental illness had high blood pressure vs. 13% of those without a serious mental illness.

Dr. Rossum added: "Even at younger ages, people with serious mental illness had a higher risk of heart disease than their peers, which highlights the importance of addressing cardiovascular risk factors for these individuals as early as possible. Interventions to address heart disease risk for these individuals are maximally beneficial when initiated at younger ages. We encourage healthcare systems and clinicians to use the 30-year cardiovascular risk estimates for young adults with serious mental illness, as these may be used starting at age 18, before it it too late to start addressing heart disease risk in people with serious mental illness that would normally not be done until age 40 or over."

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Thanks To New NPPA Members

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Executive (GPO) Members

Jackie Stokes, Manager of Pharmacy Solutions, Vizient, Inc., Athens, GA

Mariah Jordan, Division Pharmacy Analyst, HCA/Health Trust, Las Vegas, NV

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Corporate (Vendor) Members

Karyn Bundrant, Director of Marketing, Athenex, Schaumburg, IL

Grace Shen, President, TWI Pharmaceuticals USA, Inc., Paramus, NJ

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NPPA Website Resources

NPPA Members: here below is all of the information about the resources you can find on the NPPA website, www.PharmacyPurchasing.com

"Member Only Resources" page of the NPPA website: to access this page, the password is: ***"npparesources"*** (all 1 word, case-sensitive). Also, know this page's login is one of the benefits of your paid membership, so please do not share this information with those who are not current NPPA members. On this page, you will find the following sections and information.

"Breaking News, Recalls & Alerts" section: for any important alerts and recalls that we feel are relevant for our members to know about as soon as possible. To alert you of new posts there before having to login, first check our site's Home page under "What's New," where you'll find "Breaking Recalls & Other News," with a date next to it, to show the last time something important was added there you may want to read more about.

"Shortages & Discontinuations" section, which includes:

a) A link to sign up to receive the FDA's "Daily Drug Shortages Bulletin." This way, you can keep up with shortages as soon as possible, and be able to quickly share that information with the rest of your staff when applicable, so they're also aware of what medications are currently short.

b) A live feed from the FDA website, with current product recalls and alerts from their MedWatch Safety Report.

c) A live feed from the American Society of Health System Pharmacists (ASHP) website, that lists the latest reported "Current" & "Resolved" Drug Shortages.

d) A live feed from the ASHP website, that lists the latest reported "Discontinued Drugs."

"Other Industry Resources & Links" section: which includes links to the following: Various websites for additional drug shortage references; Latest flu & vaccine information from the CDC; Information on Emergency & Pandemic Preparedness; Recycling information for healthcare facilities; Educational information; Networking Tools, such as for inexpensive business cards to bring to the NPPA Conference; Career Opportunity websites for your profession.

Pharmacy Buyers Forum on the NPPA Website: please note that we have now ***removed*** access to our old Pharmacy Buyers Forum web page, which was an online "chat" forum established in order to allow for networking with your fellow Pharmacy Buyers across the country. It was removed after determining that over the space of the past year or more, it was just not being used as often as it used to be, and especially so more recently. However, see the below.

Facebook *"Pharmacy Buyers"* group: one of our NPPA members and Annual Conference attendees **Cassidy Russell,** setup a new Facebook *"Pharmacy Buyers"* group page in the winter of 2019, which has approximately 200 Buyers in the Facebook group and is growing steadily. You should have more luck with responses to your various questions and networking attempts there now, once you request to join the group and get approved. To join, go to your Facebook account and search on "Pharmacy Buyers", or go directly to the page, here: www.facebook.com/groups/334035183936954

NPPA sincerely hopes these resources help you to be a better Pharmacy Buyer!

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E-Blast & NPPA Website Banner Advertising - 2022

Vendor E-Blasts & RxBuyer E-News Advertising

***RxBuyer eNews*:** distributed 4 times a year to approximately 1,800, as an advertorial type section with photos, company logos, text, and hyperlinks allowed (within NPPA's existing eNews).

Vendor E-Blasts: your company's devoted content taking over the whole E-Blast, with photos, company logos, text, and hyperlinks allowed.

Additional Details & Submitting Order Requests: see information and respective Order Forms, on the Advertising page of the NPPA website, at: www.pharmacypurchasing.com/eblast-advertising

Website Banner Advertising

Banner Ads on the NPPA website with hyperlinks (various sizes & page placements available).

For Rates, Discounts, Sizes/Placement Availability & Order Forms: see our website's Advertising page, at: www.pharmacypurchasing.com/website-banner-ads

For Questions or to send Order Forms for the above Advertising options,
Send email to: Advertising@PharmacyPurchasing.com

Advertising In PPO (Regular & Digital Version) - 2022

NPPA's member-publication, *Pharmacy Purchasing Outlook (PPO)*

Black & White Ads only, unless doing Color Inserts or in our Digital *PPO* E-Version (see options below)

Premium Positions (full page, right facing)	**Gross Rate**
Outside Back Cover	$675.00
Inside Front Cover	$650.00
Inside Back Cover	$625.00
Center Spread (2 pages)	$600.00 (x 2)
Editorial-Adjacent	$575.00

Note: Premium Ad Positions are reserved & paid in advance, please inquire first.

Standard Positions (full page, right facing)	**Gross Rate**
All Other Inside Pages	$550.00

Color Insert Positions	**Gross Rate**	**Color Front Cover Ads**	**Gross Rate**
Color Insert (loose in envelope)	$1.100.00	Cover Sheet, 1/2 Page	$1,750.00
Color Insert (glued in *PPO*)	$1,450.00	Cover Sheet, Full Page	$2,200.00

Discounts Available & Submitting Order Requests: see details in the *PPO* Ad Rates & Specs Sheet Order Form, found on the Advertising page of the NPPA website, at: www.pharmacypurchasing.com/ppo-advertising

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NPPA's Digital E-Version of *Pharmacy Purchasing Outlook (PPO)*

Premium Position Options & Gross Rate

Editorial Adjacent-Color (+URL): **$750** Editorial Adjacent-B&W (+URL): **$450**
Inside Front Cover-Color (+URL): **$725** Inside Front Cover-B&W (+URL): **$425**
Inside Back Cover-Color (+URL): **$675** Inside Back Cover-B&W (+URL): **$375**
Outside Back Cover-Color (+URL): **$675** Outside Back Cover-B&W (+URL): **$375**
Center Spread-Color (+URL): **$1,250** (2 pages @ $625 ea.)
Center Spread-B&W (+URL): **$650** (2 pages @ $325 ea.)

Standard Inside Ad Positions, Gross Rate ***(right facing, unless a spread)***

Standard Inside Positions (Color+URL): **$625** Standard Inside Positions (B&W+URL): **$325**

URL Links: hyperlinks to your web address of choice will be provided on each Ad Page itself; as well as a "jump to page" link in our Table of Contents on Page 3 of each Digital *PPO* edition where your company's Ad Pages are listed (to go directly to your Ad Pages within the publication, via a link on the page numbers).

Discounts Available & Submitting Order Requests: see details in the *PPO* Ad Rates & Specs Sheet Order Form, found on the Advertising page of the NPPA website, at: www.pharmacypurchasing.com/advertising-digital-ppo

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For Questions or to send completed Order Forms for any of the above Advertising options,
Send email to: Advertising@PharmacyPurchasing.com

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* VistaPharm ACTODOSE™ Quality and Supply Reliability

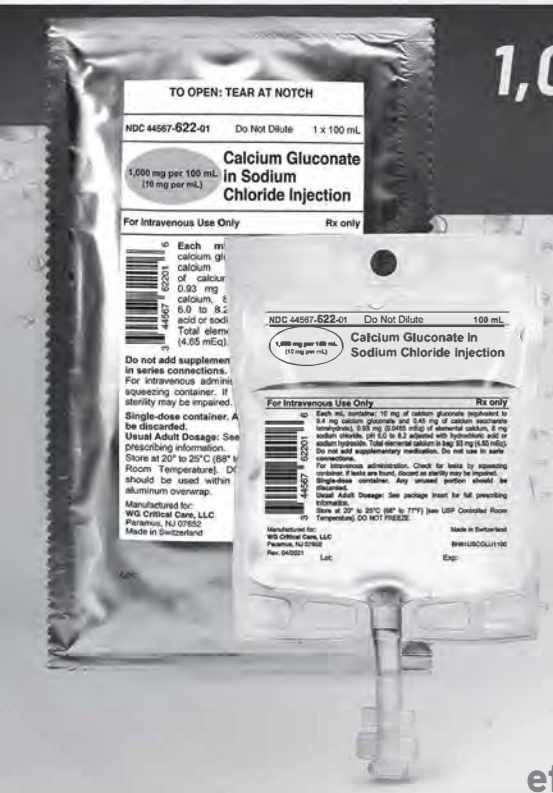
VistaPharm NDC	Strength	Size	Amerisource Bergen	Cardinal	McKesson	Morris & Dickson
66689-106-99	0.12%	15mLx100cups	10264072	5763180	2385532	147462
66689-106-50	0.12%	15mLx50cups	10264111	5763172	2385524	147454

For more information, call VistaPharm at 877-437-8567;
visit www.vistapharm.com or email: info@vistapharm.com

VER22-003

Now Available! Another Choice

Calcium Gluconate
in Sodium Chloride Injection



1,000 mg per 100 mL (10 mg per mL)

FDA APPROVED READY TO USE BAG

- **SHELF STABLE** at controlled room temperature storage[1]
- **FITS IN AUTOMATED DISPENSING CABINETS**
- **60 DAYS STABILITY OUTSIDE OF THE OVERWRAP**

ALSO AVAILABLE

2,000 mg per 100 mL (20 mg per mL)

1,000 mg per 50 mL (20 mg per mL)

Enhanced patient safety, efficient workflow & convenience

CONVENIENT ORDERING THROUGH YOUR WHOLESALER!

NDC # 44567	Bar Code	Total Amount	Fill Volume	Container Type	Concentration	Pack Size	Shelf Life	WHOLESALER ITEM NUMBERS			
								Amerisource Bergen	Cardinal	McKesson	Morris & Dickson
622 - 24		1,000 mg	100 mL	100 mL Premix Bag	10 mg/mL	24	24 months	10260989	5740469	2349777	106666
620 - 24		1,000 mg	50 mL	100 mL Premix Bag	20 mg/mL	24	36 months	10209105	5503305	3672185	511089
621 - 24		2,000 mg	100 mL	100 mL Premix Bag	20 mg/mL	24	36 months	10225251	5547013	3959640	718312

Indications and Usage

Calcium Gluconate in Sodium Chloride Injection is a form of calcium indicated for pediatric and adult patients for the treatment of acute symptomatic hypocalcemia. Limitations of Use: The safety of Calcium Gluconate in Sodium Chloride Injection for long term use has not been established.

Important Safety Information

Contraindicated in hypercalcemia and in neonates receiving ceftriaxone. Warnings and Precautions: cardiac arrhythmias may occur with concomitant cardiac glycoside use; use caution when administering with ceftriaxone as a precipitate may form in the IV line; tissue necrosis and calcinosis may occur with or without extravasation; hypotension, bradycardia and cardiac arrhythmias may occur with rapid administration; contains aluminum which may cause toxicity. The most common adverse events are local soft tissue inflammation and necrosis; calcinosis cutis and calcification related to extravasation; vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmia, syncope and cardiac arrest.

Please see full Presribing Information, inluding Warnings, Precautions, and Important Safety Information for this product at the WGCC website.

References: 1. On file WG Critical Care, LLC. To request data on file, please contact Customer Service at 1-888-493-0861 or CustomerService@wgccrx.com

wgccrx.com

WG CriticalCare
A PHARMASPHERE COMPANY