Pharmacy Purchasing Outlook

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

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Biosimilar Drug Approvals

Hercessi™ Injection - Biosimilar To Herceptin®

On April 29, Accord BioPharma, Inc. of Durham, North Carolina (the U.S. specialty division of Intas Pharmaceuticals, Ltd. of Gujarat, India) announced the FDA has approved Hercessi™ (trastuzumab-strf, 150mg) Injection for intravenous (IV) use, indicated to treat HER2-overexpressing breast and gastric or gastroesophageal junction adenocarcinoma.

This product is a biosimilar drug, referencing Herceptin® Injection by Genentech, Inc.

Hercessi is indicated for adjuvant treatment of HER2-overexpressing breast cancer, the treatment of HER2-overexpressing metastatic breast cancer, and the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. HER2 cancers in general are particularly aggressive cancer types that respond well to targeted treatment. Hercessi works by binding to and inactivating the HER2 receptor, slowing down cell replication.

Additionally, a 420mg strength version of Hercessi is currently in development with Accord BioPharma, and its FDA decision is expected to be announced by the end of this year, 2024.

Hercessi is the first U.S. FDA-approved biosimilar from Accord BioPharma, who also plans on introducing several additional biosimilars to the U.S. market during the next 5 years. Accord has already submitted

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Evolving The Ambulatory Pharmacy Buyer: Mastering 340B For Cost-Efficiency & Compliance

By Fatimah Muhammad, DrPH, MPH

In the dynamic landscape of healthcare, the role of the ambulatory pharmacy buyer has evolved into a position of critical importance and increasing complexity. As healthcare organizations strive to balance cost optimization with high-quality patient care, a comprehensive understanding of the 340B Drug Pricing Program has become indispensable for pharmacy buyers. This article explores the necessity of restructuring the ambulatory pharmacy buyer role to ensure a thorough grasp of 340B, with the dual objectives of minimizing Wholesale Acquisition Cost (WAC) spending and maintaining strict compliance with program regulations.

Ambulatory pharmacies, serving outpatients across various healthcare settings, face a unique set of challenges in today's healthcare environment. These include rising drug costs, complex reimbursement models, stringent regulatory requirements, and an increased focus on patient outcomes and satisfaction. To effectively address these challenges, the traditional role of the pharmacy buyer must evolve to encompass a broader range of skills and knowledge, particularly concerning the 340B Drug Pricing Program.

The 340B Drug Pricing Program, established in 1992, allows certain healthcare providers, known as covered entities, to purchase outpatient drugs at significantly discounted prices. The program aims to stretch scarce federal resources and expand access to comprehensive healthcare services for vulnerable patient populations. Key aspects of the 340B program that pharmacy buyers must understand include eligibility criteria for covered entities, patient definition and eligibility, drug diversion prohibition, duplicate discount prohibition, manufacturer compliance requirements, and auditing and reporting

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Highlights Inside This Edition

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1. Hertig, J., Jarrell, K., Arora, P., Nwabueze, J., Moureaud, C., Degnan, D. D., & Trujillo, T. (2020). *A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste.* Hosp Pharm. 2021;56(5):584-591

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Join Us For The 28th Annual 2025 NPPA Conference, In Late September!

We hope you can all join us for our 28th Annual 2025 NPPA Conference, over the dates of September 29-October 2, 2025, at the Horseshoe Las Vegas hotel in Nevada. Be sure to plan ahead and mark your calendars!

Opening Reception for Attendees: Monday, September 29

Main Program: Tuesday, Sept. 30 through Thursday, Oct. 2

Attendee Registration is expected to open in February. See the NPPA website (PharmacyPurchasing.com) for updates on our opening.

In addition, an optional **340B University event is also being offered** by the 340B Prime Vendor Program Managed By Apexus on Monday, September 29, the day before our NPPA Conference begins, with no additional fee as sponsored by Apexus.

Horseshoe LV hotel room rates for the "2025 NPPA" Group Room Block are $75 plus tax per weeknight (Sunday through Thursday), with a ***discounted*** $35/night+tax Resort Fee (otherwise $40/night).

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Within This Edition

Editorial

By Amy Empson
NPPA Event & Office Assistant

Heart Attacks

Do you ever find yourself researching things that you know and double checking it because suddenly you realize the importance of it? I found myself rereading some of the past news releases from the American Heart Association (AHA) that we include regularly here in our publication.

The reason being that in the last couple of months alone, I have lost two classmates to heart attacks, and each of them were even more sadly under the age of 55. They each had different family histories of heart disease or related issues, although one had a previous heart attack once before several years ago. They each lived in different states and were a different gender. The one thing they both did have alike were loving families, wonderful lives they were living, and were generally happy again after previously going through some difficult times.

Heart attacks and heart disease do not discriminate. About every 40 seconds, someone in the United States has a heart attack.

After the death of someone I know, I often look closely into what they had and what caused it, finding myself going through as much information as I can find on the subject. What I found about heart attacks and heart disease is so extensive though, it's quite overwhelming. And since I realize many of you either know someone with heart disease or knew someone that has died from it (or may even struggle with heart disease yourselves), I wanted to share as much as I could about it all for you to arm yourself with more information in future. Here follows is a link to the AHA web page with extensive facts and resources about heart attacks: www.heart.org/en/health-topics/heart-attack/about-heart-attacks

Another thing that came to mind again after my friends' recent deaths, was how much cardiopulmonary resuscitation (CPR) came to the forefront in the news last year in January 2023, when Buffalo Bills player Damar Hamlin suffered an almost fatal cardiac event after a hit on the field during a game. When Damar Hamlin's heart stopped and was restarted with CPR and defibrillator on live television, its significance quickly propelled CPR into the news and people's minds.

The dramatic unfolding of Damar Hamlin's cardiac arrest immediately spiked interest in automated external defibrillators (AEDs) and CPR, giving rise to an increase in training and education around the nation. The AHA said views of its hands-only CPR web pages jumped more than 600% in the ensuing days. By April 2023 only a short few months after the incident with Hamlin, 1 million people had watched the AHA video on how to perform hands-only CPR. Hands-only CPR requires pushing hard and fast in the center of the chest at 100 to 120 beats per minute.

Receiving immediate CPR and a shock from a defibrillator following a cardiac arrest is critical. Yet only 40% of people who have a cardiac arrest outside of hospitals receive bystander CPR and only 9% of those survive, according to AHA statistics.

When a lay responder delivers a shock from an AED, an estimated 44% survive, according to 2022 data from the national Cardiac Arrest Registry to Enhance Survival. Yet AEDs are used by bystanders only 5% of the time.

An AED is a portable device that can be used to treat a person whose heart has suddenly stopped working, which is called sudden cardiac arrest. An AED is used specifically to revive someone from sudden cardiac arrest. This usually happens when a problem in the heart's electrical activity causes a dangerously irregular heartbeat. The irregular heartbeat prevents the heart from pumping as it should and causes the heart to stop.

AEDs are available in many public places, such as government buildings, schools, airports, and other community spaces. Small, lightweight AEDs are available without a prescription for use at home.

Today you can even purchase your own AED online. They all include detailed instructions on how and when to use them. Training in the proper use of an AED is recommended,

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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

Acetaminophen/Ibuprofen Tablets (OTC) - Glenmark Pharmaceuticals

On April 29, Glenmark Pharmaceuticals Inc., USA of Mahwah, New Jersey announced they received final FDA approval for over-the-counter (OTC) Acetaminophen/Ibuprofen Tablets 250mg/125mg.

This product compares to OTC Advil® Dual Action with Acetaminophen Tablets 250mg/125mg by Haleon US Holdings, LLC, which had recent annual U.S. sales (ending March 2024) of $84.1 million, according to IQVIA.

It is indicated to relieve minor aches and pains including headache, backache, toothache, menstrual cramps, muscle aches, or arthritis.

Note that the product will be distributed by the Glenmark Therapeutics Inc., USA division of Glenmark Pharmaceuticals.

Allopurinol Tablets Launch - Camber Pharmaceuticals

On April 2, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Allopurinol Tablets 100mg and 300mg, available in 100-count, 500-count, and 1,000-count bottles.

This product compares to Zyloprim® Tablets by Casper Pharma LLC.

It is indicated for the following.

- Management of patients with signs and symptoms of primary or secondary gout.
- Management of patients with conditions requiring therapies which cause elevations of serum and urinary uric acid levels.
- Management of patients with recurrent calcium oxalate calculi whose daily uric acid excretion exceeds specific thresholds.

Aripiprazole Oral Solution Launch - Camber Pharmaceuticals

On April 26, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Aripiprazole Oral Solution 1mg/mL, available in 150mL bottles (NDC # 31722-684-15).

This product compares to Abilify® Oral Solution by Otsuka America Pharmaceutical, Inc.

It is indicated to treat the following: Schizophrenia; acute manic and mixed episodes associated with bipolar I disorder; irritability associated with autistic disorder; and Tourette's disorder.

Fesoterodine Fumarate Extended-Release Tablets Launch - Camber Pharmaceuticals

On April 17, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Fesoterodine Fumarate Extended-Release Tablets in 30-count bottles, as listed below.

- **4mg:** NDC #31722-033-30.
- **8mg:** NDC #31722-034-30.

This product compares to Toviaz® Tablets by Pfizer Inc. It is indicated for the treatment of overactive bladder in adults with symptoms of urge urinary incontinence, urgency, and frequency.

Fluoxetine Tablets - Strides Pharma

On April 9, Strides Pharma Inc. of Chestnut Ridge, New York announced they received final FDA approval for Fluoxetine Tablets in the strengths of 10mg and 20mg.

The product compares to Prozac® Tablets by Eli Lilly & Company. It is an antidepressant medication of the selective serotonin reuptake inhibitor (SSRI) class, indicated for the treatment of major depressive disorder, obsessive-compulsive disorder, bulimia nervosa, and panic disorder (with or without agoraphobia).

Recent annual market size of Fluoxetine Tablets was estimated at $23.9 million, according to IQVIA.

Levonorgestrel/Ethinyl Estradiol Tablets Launch - Camber Pharmaceuticals

On April 4, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Levonorgestrel/Ethinyl Estradiol Tablets 0.1mg/0.02mg, available in boxes of 3-count blister packs of 28 tablets per packet (NDC# 31722-944-32).

This product compares to Alesse® 28 Tablets by Pfizer Inc. It is indicated for the prevention of pregnancy in women who elect to use oral contraceptives.

Loteprednol Etabonate Ophthalmic Suspension - Lupin Pharmaceuticals

On April 25, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval of their Abbreviated New Drug Application (ANDA) for Loteprednol Etabonate Ophthalmic Suspension 0.5%.

This product compares Lotemax® Ophthalmic Suspension by Bausch & Lomb Inc., which had recent annual U.S. sales (ending February 2024) of $59 million, according to IQVIA. It is indicated for temporary relief of signs and symptoms of seasonal allergic conjunctivitis.

Midazolam Injection (C-IV) PFS Launch - Hikma Pharmaceuticals

On May 8, Hikma Pharmaceuticals USA Inc. of Eatontown, New Jersey announced their ***launch*** of Midazolam Injection (C-IV) 2mg/2mL and 10mg/2mL, available in a prefilled syringe (PFS).

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Generic Approvals & News

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This product compares to Versed® Injection by Hoffmann-La Roche, Inc. *(now a discontinued product).*

Note: Midazolam is classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance.

It is indicated for the following, as detailed below.

- Intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia.
- Intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures (such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures) either alone or in combination with other CNS depressants.
- Intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotic premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period of time. Intravenous midazolam can also be used as a component of intravenous (IV) supplementation of nitrous oxide and oxygen (balanced anesthesia).
- Continuous IV infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

Recent annual U.S. sales (ending February 2024) of Midazolam Injection in these strengths were $20 million, according to IQVIA.

Mirabegron Extended-Release Tablets Launch - Lupin Pharmaceuticals

On April 22, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced their ***launch*** of Mirabegron Extended-Release Tablets 25mg; having already received FDA approval in 2022.

This product compares to Myrbetriq® Extended-Release Tablets in this strength by Astellas Pharma Global Development, Inc., which had recent annual U.S. sales (ending February 2024) of $1.02 billion, according to IQVIA.

It is indicated for the treatment of overactive bladder with symptoms of urgency, frequency, and leakage in adults.

Naloxone HCl Nasal Spray (OTC Narcan®) Launch - Amneal Pharmaceuticals

On April 24, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced the ***launch*** of over-the-counter (OTC) Naloxone HCl Nasal Spray 4mg, following approval of their Abbreviated New Drug Application (ANDA) from the FDA.

This product compares to OTC Narcan® Nasal Spray by Emergent Operations Ireland Ltd., which had recent annual U.S. sales (ending February 2024) of $266 million, according to IQVIA.

It is a medication that is widely used to help treat drug overdose from opioids, including heroin, fentanyl, and prescription opioid medications. In addition, there are significant volumes of the product acquired directly by U.S. states and municipalities.

More than two-thirds of all drug overdose fatalities in 2022 involved illicit, synthetic opioids like fentanyl, which is the culprit in more deaths under age 50 than any other cause, including heart disease, cancer, homicide, suicide, and other accidents. According to the U.S. Centers for Disease Control & Prevention (CDC), in about 46% of overdose deaths, another person is present and has the potential to intervene.

Naloxone HCl Nasal Spray is designed to rapidly reverse the effects of a life-threatening opioid emergency by binding to opioid receptors and reversing or blocking the effects of opioids. It can restore normal breathing within two to three minutes in a person whose breath has slowed, or even stopped, as a result of an overdose from opioids such as heroin, fentanyl, and prescription opioid medications.

The opioid epidemic was declared a national public health emergency in 2017 and has continually been renewed by the U.S. Secretary of Health & Human Services. Ending the epidemic is a top strategic priority of the U.S. government and Congress. Since 2000, about one million people in the U.S. have died of drug overdoses, the majority of which were due to opioids. Drivers of this crisis include the misuse of prescription pain medications, and the unwitting use of drugs laced with fentanyl—which is 50 times more potent than heroin and 100 times more potent than morphine. In 2022, roughly twice as many people died in the U.S. from opioid-related overdoses than from motor vehicle crashes.

Amneal's Naloxone HCl Nasal Spray is manufactured in the United States and contains the same active ingredient and dose as OTC Narcan Nasal Spray 4mg. It is easy to carry and can be safely used even if opioids are not present.

Pantoprazole Sodium Delayed-Release Oral Suspension Launch - Camber

On April 9, Camber Pharmaceuticals, Inc. of Piscataway, New Jersey announced their ***launch*** of Pantoprazole Sodium for Delayed-Release Oral Suspension 40mg, available in unit-dose packets in 30-count cartons (NDC #31722-032-32).

→

Discontinued Drugs

Acyclovir Tablets By Apotex Corp.

On April 26, the FDA announced that Apotex Corp. of Weston, Florida has made a business decision to discontinue the manufacture of Acyclovir Tablets, in the following strengths.

- **400mg:** In 100-count bottles (NDC #60505-5306-1) and 1,000-count bottles (NDC #60505-5306-8).
- **800mg:** In 100-count bottles (NDC #60505-5307-1) and 500-count bottles (NDC #60505-5307-5).

This product is an antiviral medication indicated to slow the growth and spread of the herpes virus in the body. Acyclovir will not cure herpes, but it can lessen the symptoms of the infection. It is also used to treat infections caused by herpes viruses, such as genital herpes, cold sores, shingles, and chicken pox.

ArmonAir® Digihaler®

On April 30, the FDA announced that Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey has discontinued the manufacture of ArmonAir® Digihaler® (fluticasone propionate) Inhalation Powder, in the following strengths of single patient metered inhaler cartons.

- **55mcg:** NDC #59310-114-06.
- **113mcg:** NDC #59310-200-06.
- **232mcg:** NDC #59310-311-06.

This product is indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

AirDuo® Digihaler®

On April 30, the FDA announced that Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey has discontinued the manufacture of AirDuo® Digihaler® (fluticasone propionate/salmeterol xinafoate) Inhalation Powder, in the following strengths of single patient metered inhaler cartons.

- **55mcg/14mcg:** NDC #59310-111-06.
- **113mcg/14mcg:** NDC #59310-129-06.
- **232mcg/14mcg:** NDC #59310-136-06.

This product is indicated in adult and pediatric patients aged 12 years and older for the treatment of asthma.

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Generic Approvals & News

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This product compares to Protonix® Delayed-Release Oral Suspension by Pfizer Inc.

It is indicated for the following.

- Short-term treatment of erosive esophagitis associated with gastroesophageal reflux disease (GERD) in adults and pediatric patients five years of age and older.
- Maintenance of healing of erosive esophagitis and reduction in relapse rates of daytime and nighttime heartburn symptoms in adult patients with GERD.
- Long-term treatment of pathological hypersecretory conditions including Zollinger-Ellison syndrome.

First Generic Versions

Doxycycline Capsules (Generic Oracea®) Launch - Lupin Pharmaceuticals

On April 9, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced the ***launch*** of Doxycycline Capsules 40mg, after its recent FDA approval.

This is the first generic version of Oracea® Capsules 40mg by Galderma Laboratories, L.P., which had recent annual U.S. sales (ending February 2024) of $128 million, according to IQVIA. It is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

Valbenazine Capsules - Lupin Pharmaceuticals

On April 8, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval for their Abbreviated New Drug Application (ANDA) for Valbenazine Capsules in the strengths of 40mg and 80mg.

This product compares to Ingrezza® Capsules by Neurocrine Biosciences, Inc., which had recent annual U.S. sales (ending February 2024) of $1.6 billion, according to IQVIA. It is indicated to treat tardive dyskinesia and chorea associated with Huntington's disease, which are both body movement disorders.

Lupin is one of the first approved applicants for a Competitive Generic Therapy Designation (CGT) and is therefore eligible for 180 days of shared CGT exclusivity.

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Discontinued Drugs

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Cinacalcet HCl Tablets By Aurobindo Pharma

On April 29, the FDA announced that Aurobindo Pharma USA, Inc. of East Windsor, New Jersey has discontinued the manufacture of Cinacalcet Hydrochloride (HCl) Tablets in the following strengths.

- **30mg:** In 30-count bottles (NDC #65862-831-30) and 500-count bottles (NDC #65862-831-05).
- **60mg:** In 30-count bottles (NDC #65862-832-30) and 500-count bottles (NDC #65862-832-05).
- **90mg:** In 30-count bottles (NDC #65862-833-30) and 500-count bottles (NDC #65862-833-05).

This product is indicated to treat hyperparathyroidism (overactive functioning of the parathyroid glands) in people who are on long-term dialysis for kidney disease. It is also used to treat hypercalcemia (high levels of calcium in the blood) in people with cancer of the parathyroid gland and in people with overactive parathyroid glands that cannot be treated surgically.

Cisatracurium Besylate Injection By Pfizer

On April 15, the FDA announced that Pfizer Inc. of New York City has discontinued the manufacture of Cisatracurium Besylate Injection, labeled as PREMIERProRx® in 10-count boxes (and formerly distributed by Hospira, Inc.), as follows.

- **200mg/20mL (10mg/mL):** NDC #0409-3670-10.
- **10mg/5mL (2mg/mL):** NDC #0409-5547-10.
- **20mg/10mL (2mg/mL):** NDC #0409-7083-10.

This product is indicated to provide skeletal muscle relaxation in adults during surgical procedures or during mechanical ventilation in the intensive care unit (ICU). It is also used as an adjunct to general anesthesia to facilitate tracheal intubation.

Clobetasol Propionate Cream, Emollient & Gel By Sandoz

On April 3, the FDA announced that Sandoz Inc. of Princeton, New Jersey has discontinued the manufacture of Clobetasol Propionate 0.05% Cream, Emollient, and Gel with the Fougera Pharmaceuticals, Inc. label in the following sizes.

- **Cream:** In 15Gm tubes (NDC #0168-0163-15), 30Gm tubes (NDC #0168-0163-30), 45Gm tubes (NDC #0168-0163-46), and 60Gm tubes (NDC #0168-0163-60).
- **Cream (emollient):** In 30Gm tubes (NDC #0168-0301-30) and 60Gm tubes (NDC #0168-0301-60).
- **Gel:** In 15Gm tubes (NDC #0168-0293-15), 30Gm tubes (NDC #0168-0293-30), and 60Gm tubes (NDC #0168-0293-60).

Clobetasol Propionate Cream is indicated to treat itching, redness, dryness, crusting, scaling, inflammation, and discomfort of various scalp and skin conditions, including plaque psoriasis and eczema.

Clomipramine HCl Capsules 50mg By Amneal Pharmaceuticals

On April 30, the FDA announced that Amneal Pharmaceuticals, LLC of Bridgewater, New Jersey has made a business-related decision to discontinue the manufacture of Clomipramine HCl Capsules 50mg, in 90-count bottles (NDC #69238-1109-9).

This product is indicated for the treatment of obsessions and compulsions in patients with obsessive-compulsive disorder (OCD).

Doxycycline Hyclate Tablets By Apotex Corp.

On April 30, the FDA announced that Apotex Corp. of Weston, Florida has discontinued the manufacture of Doxycycline Hyclate Tablets, in 60-count bottles of 75mg (NDC #60505-4382-6) and 150mg (NDC #60505-4384-6).

This product is an antibiotic indicated to treat several conditions including: rickettsial infections; sexually transmitted infections; respiratory tract infections; specific bacterial infections; ophthalmic infections; anthrax, including inhalational anthrax (post-exposure); alternative treatment for selected infections when penicillin is contraindicated; adjunctive therapy for acute intestinal amebiasis and severe acne; and prophylaxis of malaria.

Discontinued Drugs

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Fesoterodine Fumarate Extended-Release Tablets By ANI Pharmaceuticals

On April 30, the FDA announced that ANI Pharmaceuticals, Inc. of Baudette, Minnesota has discontinued the manufacture of Fesoterodine Fumarate Extended-Release Tablets, in the following strengths.

- **4mg:** In 30-count bottles (NDC #62559-375-30) and 90-count bottles (NDC #62559-375-90).
- **8mg:** In 30-count bottles (NDC #62559-376-30) and 90-count bottles (NDC #62559-376-00).

This product is indicated in adults for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency.

Lacosamide Tablets (C-V) By Amneal Pharmaceuticals

On April 15, the FDA announced that Amneal Pharmaceuticals, LLC of Bridgewater, New Jersey has discontinued the manufacture of Lacosamide Tablets, in the following 60-count bottle strengths.

- **50mg:** NDC #65162-923-06.
- **100mg:** NDC #65162-924-06.
- **150mg:** NDC #65162-925-06.
- **200mg:** NDC #65162-926-06.

This product has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 5 (C-V) controlled drug substance and is indicated to treat partial onset seizures.

ProAir® Digihaler®

On April 30, the FDA announced that Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey has discontinued the manufacture of ProAir® Digihaler® (albuterol sulfate) Inhalation Powder 0.65Gm, in 1-count single patient metered inhaler cartons (NDC #59310-117-20).

This product is indicated in patients 4 years of age and older to treat or prevent bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

Repatha® Pushtronex® Injection System

On April 12, the FDA announced that Amgen, Inc. of Thousand Oaks, California has discontinued the manufacture of Repatha® Pushtronex® (evolocumab) Injection System 420mg/3.5mL, in a 1-count prefilled single-dose cartridge with 1-count on-body infusor cartons (NDC #55513-770-01 and NDC #72511-770-01).

This product is indicated for the following.

- In adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization.
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C.
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH to reduce LDL-C.
- As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Temazepam Capsules (C-IV) By Amneal Pharmaceuticals

On April 30, the FDA announced that Amneal Pharmaceuticals, LLC of Bridgewater, New Jersey has made a business-related decision to discontinue the manufacture of Temazepam Capsules, as detailed below.

- **15mg:** In 100-count bottles (NDC #65162-556-10) and 500-count bottles (NDC #65162-556-50).
- **30mg:** In 100-count bottles (NDC #65162-557-10) and 500-count bottles (NDC #65162-557-50).

This product has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance and is indicated for the short-term treatment of insomnia (generally 7 to 10 days).

Tikosyn® Capsules

On April 23, the FDA announced that Pfizer Inc. of New York City has discontinued their manufacture of Tykosyn® (dofetilide) Capsules supplied in 40-count unit-dose boxes, in the following strengths.

- **125mcg (0.125mg):** NDC #0069-5800-43.
- **250mcg (0.25 mg):** NDC #0069-5810-43.
- **500mcg (0.5mg):** NDC #0069-5820-43.

This product is an antiarrhythmic drug that is indicated to treat an abnormal heartbeat.

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Outstanding Buyer Nominee - Heather Heidrich

What is the nominee's name, job title, facility name, and location? **Heather Heidrich**, CPhT-Adv, Pharmacy Buyer & Supply Coordinator, Banner Wyoming Medical Center, Casper, Wyoming.

As a nominating third party, please provide your own name, title, facility, and relationship to the nominee. **Ronald Maxwell**, PharmD, Director of Pharmacy, Banner Wyoming Medical Center. I am the nominee's direct supervisor.

Second additional nominator: **Adriana Gutierrez**, Backup Buyer, Acute Charge Audit Pharmacy Technician, Banner Wyoming Medical Center. I am the nominee's co-worker.

Third additional nominator: **Bree Gray**, PharmD, RPh, Pharmacy Supervisor & Clinical Coordinator, Director of Post-Graduate Year 1 (PGY1) Pharmacy Residency Program, Banner Wyoming Medical Center. I help oversee the entire pharmacy department.

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

Is the nominee a current NPPA member, and will be current through August 2024? Yes, the nominee is a current NPPA member and will be through August 2024.

What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban.) 249-bed rural community teaching hospital.

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

What is the average dollar amount of pharmacy inventory the nominee controls each year? $1.4 million as of May 2024.

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

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Biosimilar Drug Approvals

Continued from Page 1

a Biologics License Application to the FDA for biosimilar versions of pegfilgrastim, filgrastim, and ustekinumab.

Chrys Kokino, U.S. President of Accord, said: "The approval of Hercessi, our first biosimilar to be approved in the U.S., marks an important milestone for Accord BioPharma in our efforts to improve access for patients. Because breast and gastric cancers are among the most common types of cancer and cancer can have a high-cost burden for patients, there is a need to provide these patients with additional treatment options that may be more affordable, such as biosimilars."

Hercessi was originally developed by Accord's business partner Shanghai Henlius Biotech, Inc. headquartered in Shanghai, China. In 2021, Henlius granted Accord BioPharma the exclusive rights to develop and commercialize Hercessi in the U.S. and Canada.

Selarsdi™ Injection - Biosimilar To Stelara®

On April 16, Alvotech USA Inc. of Arlington, Virginia and Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey jointly announced the FDA has approved Selarsdi™ (ustekinumab-aekn) Injection for Subcutaneous use, indicated for the treatment of moderate to severe plaque psoriasis and for active psoriatic arthritis in adults and pediatric patients 6 years and older.

This product is a biosimilar to Stelara® by Janssen Biotech, Inc., which had 2023 U.S. sales of $7 billion. The availability of a Stelara biosimilar will now create opportunities for cost savings across U.S. healthcare systems and introduce additional treatment options for patients.

Product is expected to be available on or after February 21, 2025, following a patent dispute case between the respective companies.

Plaque psoriasis is the most common form of psoriasis in the U.S., while psoriatic arthritis accounts for approximately 6% of all cases of juvenile arthritis. The main drug ingredient in Selarsdi (ustekinumab) is a human monoclonal antibody (mAb) that selectively targets the p40 protein, a component common to both interleukin (IL)-12 and IL-23 cytokines, which play crucial roles in treating immune-mediated diseases like psoriasis and psoriatic arthritis.

Alvotech developed and produces Selarsdi using Sp2/0 cells and a continuous perfusion process, which are the same type of host cell line and process used in the production of Stelara.

Under the partnership agreement between Teva and Alvotech, Teva is responsible for the exclusive commercialization of Selarsdi in the U.S., with Alvotech handling the product's development and manufacturing.

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Outstanding Buyer, Heidrich

Continued from Page 12

How long has the nominee been a Pharmacy Buyer? 2 years and 8 months as Buyer, 10 years as Backup Buyer.

What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise?

- Purchases and maintains inventory.
- Communicates with vendors and manufacturers.
- Coordinates medication recalls.
- Conducts monthly inventory counts and controlled drug substance audits.
- Audits our sterile compounding records.
- Codes expenses and handles interdepartmental billing.
- Creates the department technician schedule.
- Ensures that we have minimal outdated medications.

Additional comments by co-worker Adriana Gutierrez (at same facility as nominee):

- Expedites backorders and emergency orders to ensure critical shortages are resolved.
- Must be knowledgeable of the hospital pharmacy formulary, current medication usage trends, and purchasing needs of the department.

Additional comments by Coordinator Bree Gray (at same facility as nominee):

- Responsible for maintaining outpatient-infusion drug stock specific for individual patients to ensure our costs are minimized.
- Continually works double-duty shifts when we have sick calls.

What may be unique or challenging about the nominee's facility? We are centrally located in the state of Wyoming and serve as the state's hub for traumas and care. Shipments in the winter are often unreliable due to weather and our remote location.

Additional comments by co-worker Ms. Gutierrez: We also keep a smaller inventory than larger facilities, so being available on the weekends and after hours is essential in case of emergent patient need.

List any accomplishments or projects the nominee instituted that have either saved money for their department/facility, or helped to make their job or the department/facility run more efficiently. Pyxis™ inventory reduction of $50k. Inventory plans for our new East Campus operations. Changes to our 503B products for cost reduction. Managed multiple drug shortages over the last year. Reporting drug shortage information to our facility's Pharmacy & Therapeutics (P&T) committee.

Additional comments by co-worker Ms. Gutierrez: Over two years, Heather helped us change from Omnicell® to Pyxis and helped reconfigure our inventory to fit into smaller spaces. We also got new carousels that had to be manually loaded and assigned locations, which took several days.

Additional comment by Coordinator Ms. Gray: Heather vets different vendors for 503B cost savings initiatives.

How has the nominee's job changed over the years? We went from a single entity facility to managing multiple facilities and clinics.

Additional comments by Coordinator Ms. Gray: Transition from independent hospital to a Banner Health System hospital. We successfully navigated the challenges of changing from independent non-restricted formulary to more restricted health system formulary. Healther implemented change from vendors that independent hospital held to health system vendors, which resulted in significant cost savings to our facility. She was also responsible for the role of charge and audit technician in addition to being the Buyer role during our transition to Banner Health in under a year, until a full-time technician was hired.

What does the nominee like about their job? Heather likes the challenging nature of managing drug inventory and shortages along with the ever-changing nature of the Buyer role.

Additional comments by co-worker Ms. Gutierrez: Heather appreciates the ability to be more independent in her role as a Pharmacy Tech. She enjoys networking and working with multiple facilities and vendors to make sure patients are cared for. She loves the opportunity to grow as a Pharmacy Tech to multiple roles. She also loves the leadership team she has grown to work with along with her fellow co-workers.

Additional comments by Coordinator Ms. Gray: Heather enjoys caring for patients with regards to medication management and enjoys the fast-paced environment and challenges of navigating drug shortages. She likes the independence and responsibility of being a Buyer. She also takes satisfaction in being a part of system teams that troubleshoot the management of drug shortages and coordinates supply sales within our local community.

What does the nominee dislike about their job? Heather has not indicated that she dislikes any part of her job.

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Outstanding Buyer, Heidrich

Continued from Page 13

Additional comment by co-worker Ms. Gutierrez: There are likely a few things Heather does not like about her role as is often the case with any job. The everlasting backorders can surely be challenging.

Additional comment by Coordinator Ms. Gray: It can be stressful when finding a solution to drug shortages that proves more challenging than usual, but ultimately, she enjoys the challenges.

What advice would the nominee have for drug company vendor representatives? Continued communication to help navigate the constant drug supply-chain issues.

Additional comment by co-worker Ms. Gutierrez: To continue reaching out leaving voicemails and emails, even when it seems repetitive because we appreciate the information that they provide us. Know that we will get back to them as soon as possible.

Additional comment by Coordinator Ms. Gray: Understand that health systems work differently than small entities and there are many channels that must be navigated to get results.

What specific challenges does the nominee face on the job? Medication shortages are always a huge challenge. Heather somehow manages to get us through each shortage.

Additional comments by co-worker Ms. Gutierrez: Heather faces constant backorders and ever-changing weather in our area which can lead to delayed order arrivals and mail. The seasons always bring other challenges from rattlesnake bites in the summer to frostbite in the winter. It was also a challenging time when we switched formularies from Wyoming Medical Center (WMC) to Banner Health.

Additional comments by Coordinator Ms. Gray: Drug shortages, formulary allowed medications, navigating appropriate pars depending on the season (winter, summer, flu/RSV season, trauma season, cardiac season, etc.) Seeking the least costly alternatives as effectively as possible. It can be challenging to satisfy physician requests for non-formulary medications and then receiving approval within a reasonable period.

How has the nominee's NPPA membership helped them in their job and/or personally? (Overall, or from information provided in NPPA's official member-publication Pharmacy Purchasing Outlook.) The education and information provided by NPPA in their publication helps her better navigate the drug shortages and the new and changing products coming to the market.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? If not, what prevented them from attending? Yes, I send Heather each year. The NPPA Conference provides education and contacts within the Buyer community and from vendors.

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

Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any of them beyond being a member? Heather holds 4 advanced certifications from the Pharmacy Technician Certification Board (PTCB).

Additional comments by co-worker Ms. Gutierrez: Heather is part of the Decon team at Banner Health, which responds in the event of a chemical spill. She is also part of our facility's P&T committee as well as the Stewardship committee.

List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, volunteer work, etc.

In 2023, Heather received a facility MVP award (Most Valuable Player), for her work in our transition from Omnicell to Pyxis.

Additional comments by co-worker Ms. Gutierrez: Heather volunteers for our pharmacy mission meal that we hold twice a year. She is consistently recognized for her commitment to the pharmacy and her conscious purchasing to make sure that our patients are taken care of. She also received an award in August 2022 for her continued efforts for a smooth transition during our "go live" with Banner Health.

Additional comments by Coordinator Ms. Gray: Heather was recognized by the Banner Health CEO for her outstanding work in making it a smooth transition to Banner Wyoming Medical Center. She volunteers at the local Sleep in Heavenly Peace nonprofit to help build beds for children who need them. She also volunteers to serve dinner at a local homeless shelter and reports drug shortages to the facility P&T committee monthly. Last but not least, Heather peripherally teaches pharmacy technician students, pharmacy students, and pharmacy residents.

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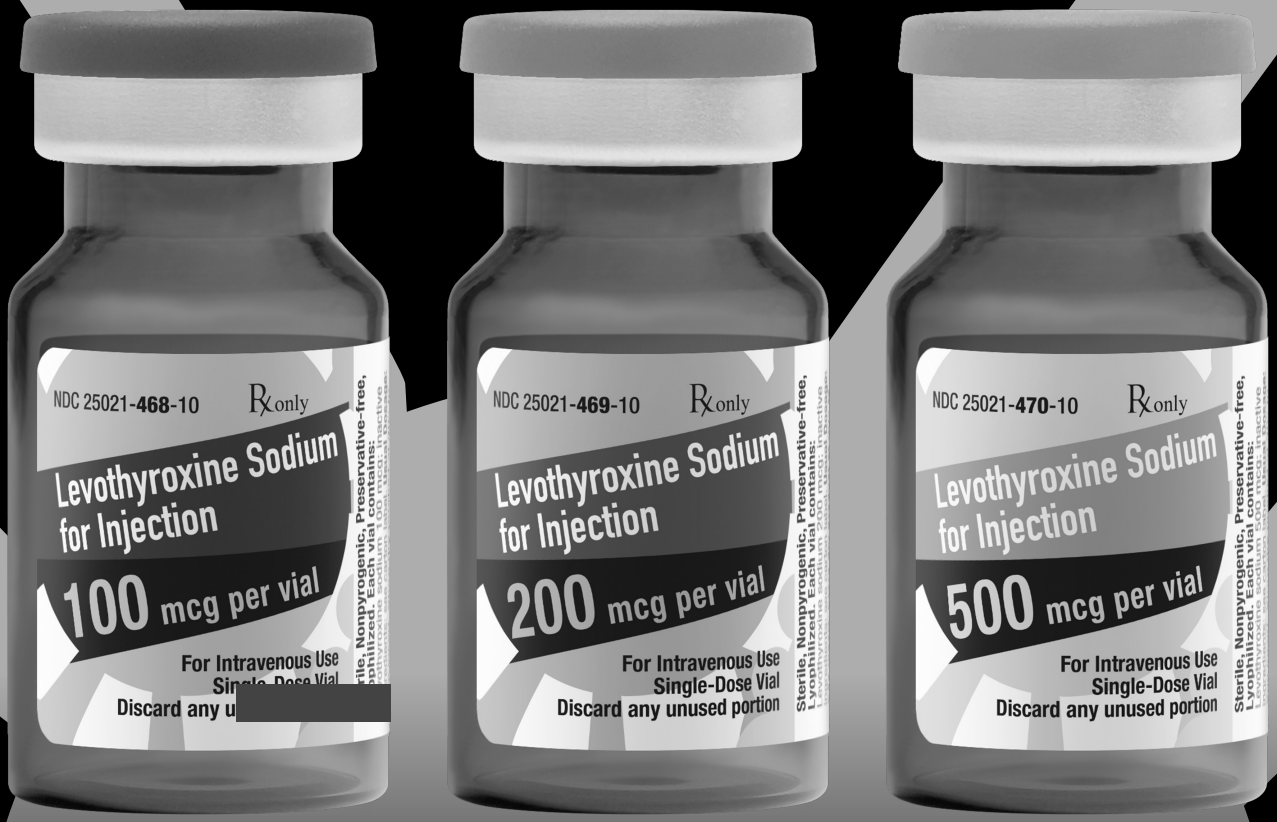

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New Drugs/Indications

Anktiva® As First-In-Class Il-15 Receptor Agonist For BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

On April 22, ImmunityBio, Inc. of Culver City, California announced the FDA approved Anktiva® (nogapendekin alfa inbakicept-pmln) Solution for Intravesical use, plus Bacillus Calmette-Guérin, indicated for the treatment of patients with Bacillus Calmette-Guérin-unresponsive non-muscle invasive bladder cancer with carcinoma in situ, with or without papillary tumors.

Product is ***now available***.

The recommended dose is 400mcg administered intravesically with Bacillus Calmette-Guérin (BCG) once a week for 6 weeks as induction therapy. A second induction course may be administered if complete response (CR) is not achieved at month 3. For maintenance after induction therapy, the recommended dose is 400mcg administered intravesically with BCG once a week for 3 weeks at months 4, 7, 10, 13, and 19 (for a total of 15 doses).

For patients with an ongoing CR at month 25 or later, maintenance instillations with BCG may be administered once a week for 3 weeks at months 25, 31, and 37 for a maximum of 9 additional instillations. Treatment should be discontinued for disease persistence after second induction, disease recurrence or progression, or unacceptable toxicity. The maximum treatment duration is 37 months.

Bladder cancer is the 10th most diagnosed cancer globally, and in the U.S., the American Cancer Society estimates there will be 83,190 new cases and 16,840 deaths from bladder cancer in 2024. At the time of diagnosis, about 80% of cases are non-muscle invasive bladder cancer (NMIBC), wherein the cancer is found only on the inner layer of the bladder wall.

Anktiva plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells (NK and CD8+ killer T cells) that are involved in killing cancer cells.

The standard therapy for NMIBC is intravesical instillation (delivery to the bladder via a catheter) of BCG. BCG is a benign bacterium that induces an immune response in the bladder in proximity to the cancer cells, leading to clearance of the cancer in many patients. In about 30% to 40% of patients, however, BCG will fail, and in about 50% that initially respond, cancer will recur.

Anktiva is a novel cytokine interleukin-15 (IL-15) super agonist complex consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha, which binds with high affinity to IL-15 receptors on NK, CD4, and CD8 T cells. This mimics the natural biological properties of dendritic cells and drives the generation of memory killer T cells that have specifically been trained to recognize the cancer cells, resulting in activation and proliferation of these killing cells with durable complete response. Anktiva has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in vivo.

With the approval of Anktiva in combination with BCG, NMIBC patients who would otherwise face highly invasive surgery with life-long consequences have an important new therapeutic option with a long-term durable CR.

Andrea Maddox-Smith, CEO of the Bladder Cancer Advocacy Network (BCAN) in Bethesda, Maryland, said: "NMIBC has a high rate of recurrence that sometimes results in major surgery to remove the bladder to prevent further disease progression. The addition of Anktiva to BCG gives NMIBC patients and their physicians a much-needed, new option to effectively treat the disease and offers an important non-surgical alternative to a cystectomy."

The FDA granted Anktiva with Breakthrough Therapy designation.

Beqvez™ Injection As One-Time Gene Therapy For Hemophilia B

On April 26, Pfizer Inc. of New York City announced the FDA approved Beqvez™ (fidanacogene elaparvovec-dzkt) Injection, for intravenous (IV) infusion, indicated for the treatment of adults with moderate to severe hemophilia B who currently use factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and do not have neutralizing antibodies to adeno-associated virus serotype Rh74var capsid as detected by an FDA-approved test.

Beqvez is a one-time treatment that is designed to enable people living with hemophilia B to produce factor IX (FIX) themselves rather than the current standard of care, which requires regular intravenous infusions of FIX that are often administered multiple times a week or multiple times a month.

Hemophilia B is a rare genetic bleeding disorder that prevents normal blood clotting because of a deficiency in FIX that causes those with the disease to bleed more frequently and longer than others. The standard of care for hemophilia B treatment is prophylactic infusions of FIX replacement therapy that temporarily replace or supplement low levels of blood-clotting factor. Despite prophylaxis and regular IV infusions, many people living with moderate to severe hemophilia B are at risk of spontaneous bleeding episodes. The current

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New Drugs/Indications

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standard of care also places strain on healthcare systems' budgets and resource utilization. According to the World Federation of Hemophilia, more than 38,000 people worldwide are living with hemophilia B.

Beqvez is an adeno-associated virus (AAV)-based gene therapy designed to introduce in the transduced cells a functional copy of the FIX gene encoding a high-activity FIX variant. For eligible patients living with hemophilia B, the goal of this gene therapy is to enable them to produce FIX themselves via this one-time treatmenrather than having to receive frequent infusions of FIX, as is the current standard of care.

Hemophilia is a rare genetic bleeding disorder that prevents normal blood clotting because of a deficiency in one of several blood clotting factors and is predominately found in males. People with hemophilia are at risk for excessive and recurrent spontaneous and/or post-traumatic bleeding, which can be life-threatening, particularly in those with severe hemophilia. People with severe hemophilia often bleed spontaneously into their muscles or joints, or rarely into other critical closed spaces such as the intracranial space, where bleeding can be fatal.

According to the World Federation of Hemophilia, more than 38,000 people worldwide are living with hemophilia B. People with hemophilia B have a deficiency in clotting FIX, a specific protein in the blood. Hemophilia B is also called congenital FIX deficiency or Christmas disease. The current standard of care requires recurrent IV infusions of either plasma-derived or recombinant FIX to control and prevent bleeding episodes.

In December 2014, Pfizer licensed Beqvez from Spark Therapeutics, Inc. of Philadelphia, Pennsylvania. Under the agreement, Pfizer assumed responsibility for pivotal studies, any regulatory activities, and potential global commercialization of this gene therapy.

Adam Cuker, M.D., M.S., Director of Penn Comprehensive & Hemophilia Thrombosis Program in Philadelphia, said: "Many people with hemophilia B struggle with the commitment and lifestyle disruption of regular FIX infusions, as well as spontaneous bleeding episodes, which can lead to painful joint damage and mobility issues. A one-time treatment with Beqvez has the potential to be transformative for appropriate patients by reducing both the medical and treatment burden over the long term."

Libervant™ Buccal Film (C-IV) - First & Only Oral Formulation For Pediatric Seizure Clusters

On April 29, Aquestive Therapeutics, Inc. of Warren, New Jersey announced the FDA has approved Libervant™ (diazepam) Buccal Oral Film, indicated in pediatric patients between 2 to 5 years of age with epilepsy for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (such as seizure clusters and acute repetitive seizures) that are distinct from a patient's usual seizure pattern.

Note: This product contains diazepam, which is a benzodiazepine classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 4 (C-IV) controlled drug substance.

Libervant is a buccally (inside of the cheek) administered film formulation of diazepam, available in the following strengths: 5mg, 7.5mg, 10mg, 12.5mg, and 15mg.

In 2023, over 55,000 prescriptions were filled for patients between the ages of 2 and 5. This was an increase of 10.8% over the previous year and an average increase of 9.3% over the last 3 years for this patient population. Over 90% of filled prescriptions in 2023 for this patient population were for diazepam rectal gel. Prescription writing for this indication is highly concentrated among pediatric epileptologists and pediatric neurologists.

Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products.

Michael Rogawski, M.D., Ph.D., Distinguished Professor of Neurology & Pharmacology at the University of California in Davis, said: "Libervant provides a new way to deliver diazepam for the treatment of acute repetitive seizure emergencies in children aged 2 to 5. The film is placed onto the buccal mucosa inside the cheek where it adheres firmly and dissolves quickly, delivering a consistent dose of diazepam. Studies show that the film is easy to administer and performs reliably in children as young as 2 years of age. Libervant is packaged in a compact foil pouch that is convenient to carry so that the treatment can be available wherever these children may be."

Ojemda™ For Relapsed BRAF-Altered Pediatric Low-Grade Glioma

On April 23, Day One Biopharmaceuticals, Inc. of Brisbane, California announced the FDA approved Ojemda™ (tovorafenib) for Oral Suspension & Tablets, indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.

Note: Product will be available through specialty pharmacy partners Biologics by

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McKesson of Cary, North Carolina, and Onco360® Oncology Pharmacy of Louisville, Kentucky.

The recommended dose based on body surface area (BSA) is 380mg/m2 orally once weekly (the maximum recommended dosage is 600mg orally once weekly) with or without food, as a tablet or oral suspension, until disease progression or intolerable toxicity.

Ojemda is a Type II RAF kinase inhibitor of mutant BRAF V600, wild-type BRAF, and wild-type CRAF kinases and represents the first FDA approval of a systemic therapy for the treatment of patients with pediatric low-grade glioma with BRAF rearrangements, including fusions.

Pediatric low-grade glioma (pLGG) is the most common brain tumor with an estimated incidence of 1,100 children per year who are eligible for front-line systemic therapy. BRAF is the gene most commonly altered in pLGG, of which there are two primary types of BRAF alterations: a BRAF gene fusion and a BRAF point mutation. In children with BRAF-altered pLGG, approximately 80% have BRAF fusions or rearrangements, while the remaining 20% have a V600 mutation.

Pediatric low-grade gliomas can be chronic and relentless, with patients suffering profound side effects from both the tumor and the treatment, which may include chemotherapy and radiation. These side effects can impact their life over the long term, and may include muscle weakness, loss of vision, and difficulty speaking. This type of tumor has a high risk of progression, and many children with pLGG require long-term treatment. While most children with pLGG survive their cancer, children who do not achieve a complete resection following surgery may face years of increasingly aggressive treatment. Until now, there had been no medicines approved for patients with pLGG driven by BRAF fusions.

Sabine Mueller, M.D., Ph.D., MAS, Pediatric Neuro-Oncologist at University of California at San Francisco Benioff Children's Hospitals, said: "pLGG is a chronic and relentless cancer that can devastate children and their families, often stealing their vision, balance, and speech. The goal of pLGG treatment is to stabilize or shrink the tumor without further disrupting the child's and family's life. Historically, there has been no standard of care for children with pLGG who have relapsed. We are excited to welcome a new targeted treatment option with once-weekly oral dosing designed specifically for these kids and their families."

The FDA granted Ojemda with Priority Review, Breakthrough Therapy, Orphan Drug, and Rare Pediatric Disease designations.

Pemrydi RTU® Injection As RTU Oncology Injectable For NSCLC & Malignant Pleural Mesothelioma - Now Available

On April 16, Amneal Pharmaceuticals, Inc. of Bridgewater, New Jersey announced the ***launch*** of Pemrydi RTU® (pemetrexed disodium) Injection, the first and only ready-to-use (RTU) presentation of pemetrexed for injection, which received FDA approval in June 2023 *(see June-December 2023 PPO)*.

Product is available in 2 vial sizes: 100mg/10mL and 500mg/50mL. It does not require reconstitution, dilution, or refrigeration, which is different than other versions of pemetrexed for injection.

In combination with pembrolizumab and platinum chemotherapy, Pemrydi RTU is indicated for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberration; and for initial treatment when in combination with cisplatin, for patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

Recent annual U.S. sales (ending February 2024) for Pemetrexed were $287 million, according to IQVIA.

Sean McGowan, VP of Biosimilars & Branded Oncology at Amneal, said: "In this first ready-to-use version, we offer hospitals and oncology clinics a new, value-added presentation that should improve pharmacy efficiency by eliminating preparation steps and freeing up refrigerator space with shelf stability for up to 24 months."

Note: Pemrydi RTU has a unique J-Code from the Centers for Medicare & Medicaid Services (CMS) to facilitate payment reimbursement: J9324, Injection, pemetrexed (pemrydi-RTU).

Ryzumvi™ Ophthalmic Solution 0.75% - Now Available

On April 1, Viatris Inc. of Pittsburgh, Pennsylvania announced the ***launch*** of Ryzumvi™ (phentolamine) Ophthalmic Solution 0.75%, after its previous FDA approval in September 2023 *(see June-December 2023 PPO)*.

It is indicated to treat pharmacologically induced mydriasis produced by adrenergic agonists (phenylephrine) or parasympatholytic (tropicamide) agents. Its onset of action generally occurs in 30 minutes.

Ryzumvi is now the only FDA-approved commerically available eye drop indicated to reverse dilation.

An estimated 100 million eye dilations are conducted every year in the U.S. to examine the retina (back-of-the-eye) either for routine check-ups, disease monitoring, or surgical

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New Drugs/Indications

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procedures. The average time of dilation lasts 3 to 8 hours but can last up to 24 hours in some people and prolonged dilation may lead to patients refusing dilation. However, the onset of action of Ryzumvi generally occurs in 30 minutes.

According to the American Academy of Ophthalmology of San Francisco, California and the American Optometric Association of St. Louis, Missouri, clinical practice guidelines recommend dilation as a standard of care. Dilation allows eye care professionals to identify both common and serious eye health issues, including signs of systemic disease.

Comprehensive dilated eye exams play a vital role in detecting potential vision-impairing ophthalmic conditions such as cataracts and potentially blinding diseases like glaucoma, diabetic retinopathy, and age-related macular degeneration. Additionally, comprehensive dilated eye exams can uncover evidence of systemic diseases like diabetes, rheumatoid arthritis, and hypertension.

Jeffrey Nau, Ph.D., President of the Eye Care Division at Viatris, said: "Comprehensive dilated eye exams are vital for early detection of vision-compromising diseases. Our hope is that by addressing patient dilation barriers, we're empowering eye care professionals to broaden exam availability, leading to enhanced eye health outcomes."

Risvan® Injectable Suspension For Schizophrenia

On April 2, Laboratorios Farmacéuticos ROVI, S.A. (referred to as ROVI) of Madrid, Spain announced the U.S. FDA approval of Risvan® (risperidone ISM®) Extended-Release Injectable Suspension for intramuscular use, indicated in adults for the treatment of schizophrenia.

The recommended dose for Risvan is 75mg or 100mg once monthly. It is administered by intramuscular injection in the gluteal or deltoid muscle by a healthcare professional with no more than one dose administered per month.

Risperidone ISM is a prolonged-release injectable antipsychotic developed and patented by ROVI for the treatment of schizophrenia in adults. With the first injection, it provides immediate and sustained plasmatic drug levels. It also doesn't require loading doses or supplementation with oral risperidone.

Schizophrenia is a chronic, serious, and disabling mental disorder that affects around 1% of the world population. Patients are characterized by a mixture of symptoms, both positive (delusional ideas, hallucinations, disorganized language, and behavior) and negative (affective flattening, speech poverty, abulia) in nature. The disease usually starts at an age that is critical for personal development, often forcing patients to leave their educational or work activity and resulting in a great deal of suffering for the patients and their family environment, as well as an important loss for society. It is estimated that between 3% and 5% of total global healthcare expenditure is spent on schizophrenia.

ISM is a technology platform for the release of drugs, patented by ROVI, which is based on the in-situ formation of biodegradable matrices after the administration of a liquid carrier. Its unique characteristics allow therapeutic levels of the medicine to be obtained quickly after its administration, without the need for oral co-administration, additional boosters, or loading injections to achieve and maintain the levels in a predictable and sustained manner, thus having a greater likelihood of meeting the patient's clinical needs.

Juan López-Belmonte Encina, Chairman & CEO of ROVI, said: "We think our medicine will be able to contribute to the clinical management of schizophrenia patients, helping to improve treatment adherence."

Voydeya™ Tablets - Add-On Therapy For Extravascular Hemolysis With Paroxysmal Nocturnal Hemoglobinuria

On April 1, AstraZeneca USA of Wilmington, Delaware and Alexion Pharmaceuticals, Inc. (an AstraZeneca Rare Disease company) of Boston, Massachusetts jointly announced the FDA approval of Voydeya™ (danicopan) Tablets, indicated in adults for the treatment of extravascular hemolysis with paroxysmal nocturnal hemoglobinuria, as add-on therapy to ravulizumab or eculizumab.

The recommended dose is 150mg three times a day orally, with or without food, up to a maximum of 200mg three times a day.

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Voydeya is a first-in-class, oral, Factor D inhibitor developed as an add-on to standard-of-care Ultomiris® (ravulizumab-cwvz) or Soliris® (eculizumab), both by Alexion Pharmaceuticals—to address the needs of the approximately 10% to 20% of patients with paroxysmal nocturnal hemoglobinuria (PNH) who experience clinically significant extravascular hemolysis (EVH) while treated with a C5 inhibitor. Voydeya works to breakdown the red blood cells that takes place outside of blood vessels (extravascular hemolysis) in adults with PNH.

The FDA granted Voydeya with Breakthrough Therapy and Orphan Drug designations.

Bart Scott, M.D., Professor for the Division of Hematology & Oncology at the University of Washington Medical Center and Professor for the Clinical Research Division at Fred Hutchinson Cancer Center both located in Seattle, said: "The approval of Voydeya offers this small subset of PNH patients an add-on therapy designed to address EVH, while maintaining disease control with Ultomiris or Soliris. Terminal complement inhibition with Ultomiris can address the life-threatening complications of PNH, building on the efficacy and safety of Soliris established over nearly 20 years."

Xolremdi™ Capsules - First Drug For Rare Immunodeficiency Disorder

On April 29, X4 Pharmaceuticals, Inc. of Boston, Massachusetts announced the FDA approval of Xolremdi™ (mavorixafor) Capsules, indicated for use in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis).

This is the first treatment for patients with WHIM syndrome, a rare, combined primary immunodeficiency and chronic neutropenic disorder caused by CXCR4 pathway dysfunction.

WHIM syndrome is a rare genetic disease, estimated to occur in about 1 in 5 million live births. Approximately 60 cases have been reported in the medical literature. The syndrome causes the body's immune system to not function properly. While symptoms vary, patients can have serious and/or recurrent infections, including pneumonia, sinusitis, and skin infections; and they are also at risk for life-threatening bacterial and viral infections. WHIM syndrome reduces the number of mature neutrophils and lymphocytes (types of white blood cells important in fighting infection) circulating within the body.

Xolremdi, a selective CXC chemokine receptor 4 (CXCR4) antagonist drug, works to increase the number of circulating mature neutrophils and lymphocytes.

Teresa K. Tarrant, M.D., Associate Professor of Medicine, Rheumatology & Immunology at Duke University School of Medicine in Durham, North Carolina (and a principal investigator in the drug's clinical trial), commented: "Until now, supportive care for people with WHIM syndrome has focused on symptom management and not the underlying cause of disease—the dysfunction of the CXCR4 pathway. I am thrilled that with the approval of Xolremdi, a therapy designed to address dysregulated CXCR4 pathway signaling, we now have a targeted treatment that has demonstrated the ability to elevate absolute neutrophil and lymphocyte counts, increasing WHIM patients' ability to fight infections."

New/Expanded Drug Indications

Abecma® Suspension For Triple-Class Exposed Relapsed Or Refractory Multiple Myeloma - Expanded Indication

On April 5, Bristol Myers Squibb of Princeton, New Jersey and 2seventy bio, Inc. of Cambridge, Massachusetts jointly announced the FDA approved an ***expanded indication*** for Abecma® (idecabtagene vicleucel and ide-cel) Suspension for intravenous (IV) infusion, now also for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

Its newly recommended dose is for a range of 300 to 510 x 106 CAR-positive T cells, and it is administered as a one-time infusion.

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Despite advances in treatment, multiple myeloma remains an incurable disease characterized by periods of remission and relapse. In early lines of treatment, regimens consisting of combinations of immunomodulatory agents (IMiDs), proteasome inhibitors (PIs), and anti-CD38 monoclonal antibodies are often used to help manage the disease. Unfortunately, as many patients go on to relapse and/or become refractory to these classes of therapy, more patients are becoming triple-class exposed earlier in their treatment journey. There are limited options for these patients, and triple-class exposed relapsed and/or refractory multiple myeloma is associated with poor outcomes and a median progression-free survival (PFS) of 3 to 5 months.

Abecma is a CAR-T cell therapy that recognizes and binds to B-cell maturation antigen (BCMA) on the surface of multiple myeloma cells leading to CAR-T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells.

Al-Ola A. Abdallah, M.D., Clinical Director of Hematologic Malignancies & Cellular Therapeutics at the University of Kansas Medical Center and Director of Care for Plasma Cell Disorders & Chair of the U.S. Myeloma Innovations Research Collaborative at the University of Kansas Health System in Westwood, said: "The results in the clinical study are remarkable, especially given the historic outcomes with standard regimens for these patients with relapsed or refractory disease. With this approval, these patients now have an opportunity to be treated at an earlier line of therapy with a potentially transformative therapy that offers significantly improved progression-free survival for this difficult-to-treat disease that has had no established treatment approach."

Abecma is being jointly developed and commercialized in the U.S. by Bristol Myers Squibb and 2seventy bio Inc.

Note: Abecma is only available through a restricted Risk Evaluation & Mitigation Strategy (REMS) program, called the Abecma REMS.

Alecensa® Capsules As First Adjuvant Treatment For ALK-Positive Early-Stage Lung Cancer - New Indication

On April 18, Genentech, Inc. (a member of the Roche Group) of South San Francisco, California announced the FDA approved a ***new indication*** for Alecensa® (alectinib) Capsules, now also for adjuvant treatment following tumor resection for patients with anaplastic lymphoma kinase-positive non-small cell lung cancer (tumors 4cm plus or node positive), as detected by an FDA-approved test.

Alecensa is now the ***first and only*** anaplastic lymphoma kinase (ALK) inhibitor approved for people with ALK-positive early-stage non-small cell lung cancer (NSCLC) who have undergone surgery to remove their tumor.

The recommended dose of Alecensa is 600mg twice daily, taken with food.

According to the American Cancer Society, it is estimated that more than 238,000 Americans will be diagnosed with lung cancer in 2023, and NSCLC accounts for 80% to 85% of all lung cancers. Treating lung cancer early, before it has spread, may help prevent the disease from returning and provide people with the best opportunity for a cure. Approximately 5% of people with NSCLC are ALK-positive. ALK-positive NSCLC is often found in younger people, usually 55 and under. Today, about half of all people with early lung cancer (45% to 76%, depending on disease stage) still experience a cancer recurrence following surgery, despite adjuvant chemotherapy.

Alecensa is a kinase inhibitor currently approved as first- and second-line treatment for ALK-positive metastatic NSCLC. It can now be used to help prevent lung cancer from coming back in patients after their tumor has been removed by surgery (adjuvant), or to treat patients when their lung cancer has spread to other parts of the body (metastatic).

Ken Culver, Director of Research & Clinical Affairs at ALK Positive, Inc. of Atlanta, Georgia, said: "The approval of Alecensa marks a pivotal moment for people newly diagnosed with early-stage ALK-positive lung cancer, who until now, were not able to receive ALK-specific therapy. These patients, who are typically

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diagnosed at a younger age, often face recurrence and have a higher risk of developing brain metastases than those with other types of NSCLC. With this significant advance, it is more important than ever that all people diagnosed with early-stage lung cancer undergo testing for ALK and other recommended biomarkers to receive the treatment most appropriate for them."

The approval for this indication was conducted under the FDA's Project Orbis initiative and Real-Time Oncology Review program.

Enhertu® Injection As First Tumor-Agnostic HER2-Directed Therapy - New Indication

On April 5, Daiichi Sankyo, Inc. of Basking Ridge, New Jersey and AstraZeneca U.S. of Wilmington, Delaware jointly announced the FDA approved a ***new indication*** for Enhertu® (fam-trastuzumab deruxtecan-nxki) Injection for intravenous (IV) use, now also for the treatment of adult patients with unresectable or metastatic HER2 positive solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.

Enhertu is a specifically engineered HER2 directed antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed and commercialized by Daiichi Sankyo and AstraZeneca.

Dave Fredrickson, Executive VP of the Oncology Business Unit at AstraZeneca, said: "As the first antibody drug conjugate to be granted a tumor-agnostic indication, Enhertu is truly delivering on its potential across metastatic HER2-targetable tumors. The approval also elevates the importance of testing for biomarkers, including HER2, across a broad range of tumors to ensure these patients with advanced cancer who have few options know whether a targeted medicine might be right for them."

The approval for this indication was granted with Priority Review and Breakthrough Therapy designations and was conducted under the FDA's Real-Time Oncology Review program.

Note: Taking Enhertu during pregnancy can cause embryo-fetal harm; patients must be advised of these risks and the need for effective contraception.

Fanapt® Tablets For Acute Treatment Of Bipolar I Disorder - New Indication

On April 2, Vanda Pharmaceuticals Inc. of Washington, D.C. announced the FDA approved a ***new indication*** for Fanapt® (iloperidone) Tablets, now also for the acute treatment of adults with manic or mixed episodes associated with bipolar I disorder.

The recommended dose for this indication is 12mg twice daily without regard to meals, with a starting dose of 1mg twice daily.

Bipolar disorder is a serious, highly prevalent psychiatric chronic condition affecting approximately 2.8% of the U.S. adult population, with 83% of them classified as severe. Bipolar disorder is a group of disorders that are characterized by periods of elevated mood alternating with periods of depressed mood.

For the diagnosis of bipolar I, people must have experienced one or more episodes of mania and most would have episodes of both mania and depression. Patients with bipolar I disorder with manic or mixed episodes are a subset of those approximately 10 million Americans with bipolar disorder.

Fanapt is an atypical antipsychotic agent that has been used for the acute treatment of patients with schizophrenia since its FDA approval in 2009.

Stephen Stahl, M.D., Ph.D., Professor of Psychiatry at the University of California in San Diego, said: "Many patients today are still unable to find suitable treatment options for effectively managing bipolar disorder. Tailoring the right treatment for the right patient is critical for effective care, and the approval of Fanapt represents an important milestone. Fanapt possesses a well-studied safety profile, and its approval will provide patients with a new and effective option for treating a highly complex disorder."

Fasenra® Injection For Pediatric Severe Asthma - Expanded Indication

On April 11, AstraZeneca U.S. of Wilmington, Delaware announced the FDA approved an ***expanded indication*** for Fasenra® (benralizumab) Injection for subcutaneous use, now also for add-on maintenance treatment for pediatric patients with severe asthma aged 6 to 11 years old with an eosinophilic phenotype.

The recommended dose is 30mg for patients 6 years and older who weigh 35kg or more. For patients aged 6 to 11 who weigh less than 35kg, a new 10mg dose will be available.

Asthma is the most common chronic childhood disease and can cause serious symptoms such as coughing, wheezing, and difficulty breathing. Children with severe asthma and their families face a significant burden, including impaired school performance, substantially higher healthcare resource use, and a poorer quality of life. Severe asthma is a debilitating type of asthma that can be complicated and challenging to treat.

Fasenra is a monoclonal antibody that binds directly to IL-5 receptor alpha on eosinophils

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and attracts natural killer cells to induce rapid and near-complete depletion of blood and tissue eosinophils in most patients via apoptosis (programmed cell death).

Lynda Mitchell, MA, CAE, Allergy & Asthma Network CEO in Fairfax, Virginia, said: "We welcome additional treatment options for children living with severe asthma, a condition that remains complicated to manage, further helping to address the unmet need in this patient population and reducing the burden of disease for the broader asthma community."

Fasenra was developed by AstraZeneca and is in-licensed from BioWa, Inc., a wholly owned subsidiary of Kyowa Kirin Co., Ltd. of Tokyo, Japan.

The product was originally FDA-approved in 2017, as an add-on maintenance for the treatment of severe eosinophilic asthma (SEA) in patients aged 12 and older.

Ingrezza® For Tardive Dyskinesia & Chorea Associated With Huntington's Disease - New Formulation

On April 30, Neurocrine Biosciences, Inc. of San Diego, California announced the FDA has approved Ingrezza® Sprinkle (valbenazine) Capsules, which is a ***new formulation*** **as oral granules**, indicated for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.

Ingrezza Sprinkle provides an alternative administration option for patients who experience dysphagia or have difficulty swallowing. Like the original formulation of Ingrezza capsules, the granules offer simple dosing that's always one capsule, once daily with no complex titration.

Ingrezza is also the only selective vesicular monoamine transporter 2 (VMAT2) inhibitor that offers 3 effective dosages (40mg, 60mg, and 80mg) that can be adjusted by the healthcare provider based on patient response and tolerability. The Sprinkle formulation offers the same dosage strengths as the original capsules version, and its contents can be easily sprinkled on soft food for oral administration.

Tardive dyskinesia (TD) is estimated to affect approximately 600,000 people in the United States. It is a movement disorder that is characterized by uncontrollable, abnormal, and repetitive movements of the face, torso, and/or other body parts, which may be disruptive and negatively impact patients. The condition is associated with taking certain kinds of mental health medicines (antipsychotics) that help control dopamine receptors in the brain. Taking antipsychotics commonly prescribed to treat mental illnesses such as major depressive disorder, bipolar disorder, schizophrenia, and schizoaffective disorder and other prescription medicines (metoclopramide and prochlorperazine) used to treat gastrointestinal disorders are associated with TD. In patients with TD, these treatments are thought to result in irregular dopamine signaling in a region of the brain that controls movement. The symptoms of TD can be severe and are often persistent and irreversible.

Huntington's disease (HD) is a hereditary, progressive neurodegenerative disorder in which the loss of certain neurons within the brain causes motor, cognitive, and psychiatric symptoms. Symptoms generally appear between the ages of 30 and 50 years old and worsen over a 10- to 25-year period. Most people with HD experience chorea, an abnormal involuntary movement disorder, characterized by irregular and unpredictable movements. Chorea can affect various body parts and interfere with motor coordination, gait, swallowing, and speech. HD is estimated to affect approximately 41,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease.

Taking pills can be difficult for people experiencing chorea associated with HD in addition to those living with TD, as described below.

- In a survey of patients with chorea associated with HD and their caregivers, 62% reported difficulty swallowing because of their involuntary movements.
- In a survey of patients with TD experiencing moderate-to-severe involuntary movement symptoms, 37% reported that their movements impacted their ability to eat and drink.

Ingrezza, developed by Neurocrine Biosciences, selectively inhibits VMAT2 with no appreciable binding affinity for the VMAT1 inhibitor, dopaminergic (including D2), serotonergic, adrenergic, histaminergic, or muscarinic receptors.

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While the specific way Ingrezza works to treat TD and HD chorea is not fully understood, the drug selectively targets VMAT2 to inhibit the release of dopamine, which is a chemical in the brain that helps to control movement. Ingrezza is believed to reduce extra dopamine signaling, which may lead to fewer uncontrollable movements.

This approval was based on chemistry, manufacturing, and controls information and data demonstrating the bioequivalence and tolerability of Ingrezza Sprinkle as compared to Ingrezza Capsules.

Eiry W. Roberts, M.D., Chief Medical Officer of Neurocrine Biosciences, said: "We developed Ingrezza Sprinkle to make administration easier for patients who have difficulty swallowing or prefer not to take a capsule. We are pleased to offer the proven efficacy of Ingrezza in reducing uncontrollable movements in a new formulation."

Lutathera® As First For Pediatric Gastroenteropancreatic Neuroendocrine Tumors - Expanded Indication

On April 23, Novartis Pharmaceuticals Corp. of Hanover, New Jersey, along with their subsidiary Advanced Accelerator Applications USA, Inc. of Millburn, New Jersey, announced the FDA approval of an ***expanded indication*** for Lutathera® (lutetium Lu 177 dotatate) Injection for intravenous (IV) use, now also for the treatment of pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut neuroendocrine tumors.

The recommended dose of Lutathera is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses.

This approval makes Lutathera the ***first therapy*** specifically for the treatment of pediatric patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

Neuroendocrine tumors (NETs) are a type of cancer that originates in neuroendocrine cells throughout the body and are commonly considered slow-growing malignancies. The diagnosis of NETs is often delayed due to the inactive nature of the disease, and approximately 10% to 20% of pediatric patients are diagnosed with metastatic disease. Even though NETs are an orphan disease, their incidence has increased over the past several decades.

Theodore Laetsch, M.D., Pediatric Oncologist & Director of the Developmental Therapeutics Program at the Children's Hospital of Philadelphia in Pennsylvania (and an investigator in the drug's clinical trial), said: "While GEP-NETs in children and adolescents are rare, the impact can be devastating. This approval addresses a critical need for new treatment options for these vulnerable patients. The introduction of radioligand therapy significantly advanced how we treat GEP-NETs, and I'm encouraged that younger patients now have the potential to benefit from this innovation."

The FDA granted Lutathera with Priority Review and Orphan Drug designations for this indication.

Xcopri® Tablets (C-V) For Seizures - Two New Administration Options

On April 11, SK Life Science, Inc. of Paramus, New Jersey announced the FDA approval of two ***new administration options*** for Xcopri® (cenobamate) Tablets, an antiseizure medication for adults with partial-onset (focal) seizures.

Product can now be crushed and mixed with water and either administered by mouth as an oral suspension, or administered via a nasogastric tube.

This product has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 5 (C-V) controlled drug substance.

Product is available in the following tablet strengths: 12.5mg, 25mg, 50mg, 100mg, 150mg, and 200mg. Its recommended initial dosage is 12.5mg once-daily, with titration every 2 weeks to the recommended maintenance dosage of 200mg once-daily. Xcopri can either be used alone or combined with other antiseizure medications.

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Epilepsy is the fourth most common neurological disorder in the United States, affecting approximately 3.4 million people with 150,000 new cases each year. It is characterized by recurrent, unprovoked seizures. The seizures in epilepsy may be related to a brain injury or a family tendency, but often the cause is completely unknown. Having seizures and epilepsy can affect one's safety, relationships, work, driving, and much more. People with epilepsy are at risk for accidents and other health complications including falling, drowning, depression, and sudden unexplained death in epilepsy (SUDEP). Despite the availability of many antiepileptic therapies, almost 40% of people with epilepsy are not able to achieve seizure freedom, meaning they have epilepsy that remains uncontrolled.

Xcopri is an ASM discovered and developed by SK Life Science, a subsidiary of SK Biopharmaceuticals. While the precise mechanism by which it exerts therapeutic effect is unknown, it is believed to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. It is also a positive allosteric modulator of the γ-aminobutyric acid (GABAA) ion channel.

Louis Ferrari, B.S., RPh, MBA, SK Life Science's VP of Medical Affairs, noted: "This approval addresses the needs of patients living with epilepsy who are currently taking, or who may benefit from starting XCOPRI, but are unable to swallow the tablets whole. In some patients, crushing tablets offers an additional option for dosing and administration by nasogastric tube. This label update addresses an unmet need for this patient population and offers administration alternatives to the healthcare providers managing their care."

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Legal News

Cabometyx® Patent Litigation Settled

On May 20, Exelixis, Inc. of Alameda, California announced it has entered into a settlement and license agreement with Cipla Ltd. of Mumbai, India and their U.S. subsidiary Cipla USA, Inc. of Warren, New Jersey.

This settlement resolves two patent litigations brought by Exelixis in response to Cipla's Abbreviated New Drug Application (ANDA) seeking approval to market generic versions of Cabometyx® (cabozantinib) Tablets brand product by Exelixis, prior to the expiration of the applicable patents.

The first case filed on March 16, 2023 relates to Cipla's requested ANDA for a 60mg cabozantinib dosage strength; and the second case filed on May 9, 2024 relates to an amendment for the primary purpose of seeking additional approval for 20mg and 40mg dosage strengths.

Pursuant to the terms of the agreement, Cipla will need to wait until January 1, 2031 to be able to market generic versions of Cabometyx in the United States (if approved by the FDA by then, and being subject to conditions and exceptions common to agreements of this type).

Jubbonti® & Wyost® Biosimilar Patent Litigation Resolved

On April 30, Sandoz Inc. of Princeton, New Jersey (with global headquarters Sandoz Group AG in Basel, Switzerland) announced it has reached an agreement with Amgen, Inc. of Thousand Oaks, California to resolve all patent disputes between the two companies relating to the FDA-approved Sandoz denosumab biosimilars.

Patent infringement proceedings were initially filed by Amgen in the U.S. Federal District Court of New Jersey in May of 2023 pursuant to the Biologics Price Competition & Innovation Act (BPCIA). Resolution of the BPCIA litigation followed months of vigorous defense by Sandoz against claims by Amgen that the company infringed up to 21 patents expiring as late as 2037, protecting reference medicines Prolia® and Xgeva® (denosumab) Injections, both by Amgen.

Under the terms of the agreement, Sandoz may enter the U.S. market with a biosimilar version of Prolia and Xgeva on May 31, 2025 (or earlier under certain circumstances if customary acceleration provisions are triggered).

On March 5, 2024, Sandoz received FDA approval for the first and only denosumab biosimilars: Jubbonti® and Wyost® (denosumab) Injections. These two drugs are interchangeable with and approved by the FDA for all indications of reference medicines Prolia and Xgeva. Thus they have the same dosage form, route of administration, dosing regimen, and presentation as the respective reference medicines.

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Outstanding Buyer Nominee - Michael Gwynn

What is the nominee's name, job title, facility, and location? **Michael Gwynn**, CPhT, Pharmacy Buyer, St. Mark's Hospital (in the MountainStar Health System), Salt Lake City, Utah.

As a nominating third party, please provide your own name, title, facility, and relationship to the nominee. **Scott Mitchell**, Director of Pharmacy, St. Mark's Hospital, Salt Lake City, Utah. I am Michael's supervisor.

Is the nominee certified, licensed, and/or registered, as a Pharmacy Technician in their state? Yes, the nominee is a Certified Tech.

Is the nominee a current NPPA member, and will be current through August 2024? Yes, the nominee is a current NPPA member through August 2024.

What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban, etc.)
330-bed community hospital.

Approximately how many dollars per year of pharmaceutical-related expenditures does the nominee purchase or supervise the purchasing of at the nominee's facility? $8.195 million.

What is the average dollar amount of pharmacy inventory the nominee controls each year? $1.43 million.

What is the nominee's/Pharmacy Department's current Inventory "Turns"? 5.7.

How long has the nominee been a Pharmacy Buyer?
Over 43 years.

What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise? To help ensure that we have all medications/ pharmacy supplies needed for the hospital, acting as our Pyxis™ expert, and managing our controlled substance paperwork.

What may be unique or challenging about the nominee's facility? We are part of the Hospital Corporation of America (HCA) parent company. We work with a local warehouse which provides some of the medications needed. However, there are a large amount of medications that they do not supply and Michael needs to know which suppliers to order from.

List any accomplishments or projects the nominee instituted that have either saved money for their department/facility, or helped to make their job or the department/facility run more efficiently. Michael continually finds a way to get the shortage medications for our patients despite other facilities running out.

How has the nominee's job changed over the years? There have been many changes over the 40-plus years that Michael has been a Buyer. From the early days at the hospital to the highly regulated pharmacy of today, he has always found a way to always adapt and be ahead of the curve. He steps up to help ensure that not only do we have the proper medications, but that we also follow all of the regulatory measures. He is often able to place orders, sometimes in the middle of the night, to fill our stock.

What does the nominee like about their job? Finding a way of providing for patients on an everyday basis.

What does the nominee dislike about their job? Nothing that I know of.

What advice would the nominee have for drug company vendor representatives?
Try to give us a heads-up if they see a product may become short or hard-to-find.

What specific challenges does the nominee face on the job? Shortages as usual. The technicians being able to keep an accurate inventory. Management of controlled substance paperwork for 8 off-site locations in addition to the main hospital.

How has the nominee's NPPA membership helped them in their job and/or personally? (Overall, or from information provided in NPPA's official member-publication Pharmacy Purchasing Outlook.)
His membership to NPPA has created many great relationships over time.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? Yes, Michael's attendance at the past NPPA Conferences he's been to has fostered relationship building.

If the nominee were one of the top-2 placing awardees for this program, would they be able to attend the upcoming NPPA Conference? Yes, he would.

Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any beyond being a member? None that I'm aware of.

List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, volunteer work, etc.
Michael has been recognized as our facility's Employee of the Month many times. The entire pharmacy staff looks up to him.

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First New Formulation In Over 15 Years: Corticosteroid Topical Ophthalmic Suspension Drug For Ocular Surgery Post-Op Pain

On March 4, Formosa Pharmaceuticals, Inc. of Taipai, Taiwan and AimMax Therapeutics of Durham, North Carolina jointly announced they received final FDA approval for a ***new formulation*** of Clobetasol Propionate Ophthalmic Suspension 0.05%, a corticosteroid drug indicated for topical ophthalmic use in the treatment of post-operative inflammation and pain following ocular surgery.

Note: The new product will be distributed by Eyenovia, Inc. of New York City, the commercialization and co-development partner of Formosa and AimMax. It is expected to be available in late September of this year.

The super potent corticosteroid medication is to be used in combination with the Optejet® dispensing technology device, developed by Eyenovia. The Optejet device is approved for use in connection with Eyenovia's own therapeutic product for pediatric progressive myopia as well as out-licensing for additional indications such as this (inflammation and pain following ocular surgery) and also for the short-term relief of dry eye disease. Optejet has been shown in prior studies to deliver a therapeutic dose of medication with 80% less drug volume, thereby minimizing exposure to harmful preservatives and improving tolerability.

This new formulation is the first FDA-approved new ophthalmic clobetasol propionate product and the first new steroid of its type in the ophthalmic market in over 15 years. It also offers patients a convenient and straightforward dosing regimen of taking it twice daily for 14 days, without the need to taper as most other steroids of its kind require.

Dosage and administration: Instill one drop of clobetasol propionate ophthalmic suspension 0.05% into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period. Wash hands well before each use.

A recent survey of 100 ophthalmic surgeons highlighted efficacy and cost as the two most important factors when choosing a treatment for postoperative inflammation and pain. Clobetasol's proven efficacy, allowing for just twice-daily dosing, offers an easier regimen versus other treatments that require up to four doses per day plus titration. Additionally, Clobetasol will be competitively priced to enhance affordability for all patients, regardless of their insurance coverage.

Michael Rowe, Chief Executive Officer of Eyenovia, commented: "Clobetasol propionate has a unique profile that lends itself to exploring for use in dry eye. The drug's efficacy in pain and inflammation relief as well as its low incidence of adverse events could one day be a boon to the millions of dry eye patients who suffer from periodic flare-ups of the disease."

This is also the first product developed using Formosa's proprietary APNT® nanoparticle formulation platform. The APNT platform reduces an active pharmaceutical ingredient's particle size with high uniformity and purity, thereby allowing penetration to relevant compartments in the eye, and ultimately enhancing bioavailability.

The current market for topical ophthalmic steroids and steroid combinations is approximately $1.3 billion, driven by an estimated 7 million ocular surgeries performed annually in the United States.

Francis S. Mah, M.D., Director of the Cornea Service at Scripps Clinic in La Jolla, California and member of the Eyenovia Scientific Advisory Board, commented: "Clobetasol is the first new ophthalmic steroid to be approved in the U.S. in over 15 years, with benefits that may position it as a leading choice for postsurgical care. Clinical studies have shown that 80% of patients experienced rapid, complete relief from postsurgical pain within 4 days of the procedure, and 60% achieved total resolution of inflammation within 15 days after surgery. From a safety perspective, fewer than 1% of patients experienced an increase in eye pressure, a side effect of concern to ocular surgeons and commonly associated with steroids."

Formosa Pharmaceuticals, Inc. is a clinical stage biotechnology company with a primary focus in the areas of ophthalmology and oncology.

Eyenovia, Inc. is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its proprietary Optejet dispensing platform.

AimMax Therapeutics, Inc. engages in the research and development of pharmaceuticals at various stages of development through its discovery or by co-development with strategic partners.

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zydus Pharmaceuticals USA

DOXOrubicin Hydrochloride Liposome Injection

AB-rated to Doxil®

AVAILABLE AS
20 mg/10 mL (2 mg/mL), 50 mg/25 mL (2mg/mL)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch (fda.gov/medwatch) or call 1-800-FDA-1088.

For more product details, please visit www.zydususa.com

WARNING: CARDIOMYOPATHY and INFUSION-RELATED REACTIONS

- **Doxorubicin hydrochloride liposomal infusion can cause myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy was 11% when the cumulative anthracycline dose was between 450 mg/m² to 550 mg/m². Assess left ventricular cardiac function prior to initiation of doxorubicin hydrochloride liposomal infusion and during and after treatment *[see Warnings and Precautions]*.**
- **Serious, life-threatening, and fatal infusion-related reactions can occur with doxorubicin hydrochloride liposomal infusion. Acute infusion-related reactions occurred in 11% of patients with solid tumors. Withhold doxorubicin hydrochloride liposomal infusion for infusion-related reactions and resume at a reduced rate. Discontinue doxorubicin hydrochloride liposomal infusion for serious or life-threatening infusion-related reactions *[see Warnings and Precautions]*.**

Brief Summary of Prescribing Information
These highlights do not include all the information needed to use DOXORUBICIN HYDROCHLORIDE LIPOSOME INJECTION safely and effectively. See full prescribing information for DOXORUBICIN HYDROCHLORIDE LIPOSOME INJECTION.

DOXORUBICIN HYDROCHLORIDE LIPOSOME injection, for intravenous use
Initial U.S. Approval: 1995

INDICATIONS AND USAGE:

Ovarian Cancer: Doxorubicin hydrochloride liposomal infusion is indicated for the treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy. **AIDS-Related Kaposi's Sarcoma:** Doxorubicin hydrochloride liposomal infusion is indicated for the treatment of AIDS-related Kaposi's sarcoma in patients after failure of prior systemic chemotherapy or intolerance to such therapy. **Multiple Myeloma:** Doxorubicin hydrochloride liposomal infusion, in combination with bortezomib, is indicated for the treatment of patients with multiple myeloma who have not previously received bortezomib and have received at least one prior therapy.

CONTRAINDICATIONS: Doxorubicin hydrochloride liposomal infusion is contraindicated in patients who have a history of severe hypersensitivity reactions, including anaphylaxis, to doxorubicin hydrochloride *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS:

Cardiomyopathy: Doxorubicin hydrochloride can cause myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy with doxorubicin hydrochloride is generally proportional to the cumulative exposure. Include prior use of other anthracyclines or anthracenediones in calculations of cumulative dose. The risk of cardiomyopathy may be increased at lower cumulative doses in patients with prior mediastinal irradiation. In a clinical study in 250 patients with advanced cancer who were treated with doxorubicin hydrochloride liposomal infusion, the risk of cardiomyopathy was 11% when the cumulative anthracycline dose was between 450 mg/m² to 550 mg/m². Cardiomyopathy was defined as >20% decrease in resting left ventricular ejection fraction (LVEF) from baseline where LVEF remained in the normal range or a >10% decrease in LVEF from baseline where LVEF was less than the institutional lower limit of normal. Two percent of patients developed signs and symptoms of congestive heart failure without documented evidence of cardiomyopathy. Assess left ventricular cardiac function (e.g. MUGA or echocardiogram) prior to initiation of doxorubicin hydrochloride liposomal infusion, during treatment to detect acute changes, and after treatment to detect delayed cardiomyopathy. Administer doxorubicin hydrochloride liposome injection to patients with a history of cardiovascular disease only when the potential benefit of treatment outweighs the risk. **Infusion-Related Reactions:** Serious, life-threatening, and fatal infusion-related reactions characterized by one or more of the following symptoms can occur with doxorubicin hydrochloride liposomal infusion: flushing, shortness of breath, facial swelling, headache, chills, chest pain, back pain, tightness in the chest and throat, fever, tachycardia, pruritus, rash, cyanosis, syncope, bronchospasm, asthma, apnea, and hypotension. Of 239 patients with ovarian cancer treated with doxorubicin hydrochloride liposomal infusion in Trial 4, 7% of patients experienced acute infusion-related reactions resulting in dose interruption. All occurred during cycle 1 and none during subsequent cycles. Across multiple studies of doxorubicin hydrochloride liposomal infusion monotherapy including this and other studies enrolling 760 patients with various solid tumors, 11% of patients had infusion-related reactions. The majority of infusion-related events occurred during the first infusion. Ensure that medications to treat infusion-related reactions and cardiopulmonary resuscitative equipment are available for immediate use prior to initiation of doxorubicin hydrochloride liposomal infusion. Initiate doxorubicin hydrochloride liposomal infusions at a rate of 1 mg/min and increase rate as tolerated *[see Dosage and Administration]*. Withhold doxorubicin hydrochloride liposomal infusion for Grade 1, 2, or 3 infusion-related reactions and resume at a reduced infusion rate. Discontinue doxorubicin hydrochloride liposomal infusion for serious or life-threatening infusion-related reactions. **Hand-Foot Syndrome (HFS):** In Trial 4, the incidence of HFS was 51% of patients in the doxorubicin hydrochloride liposomal infusion arm and 0.9% of patients in the topotecan arm, including 24% Grade 3 or 4 cases of HFS in doxorubicin hydrochloride liposomal infusion-treated patients and no Grade 3 or 4 cases in topotecan-treated patients. HFS or other skin toxicity required discontinuation of doxorubicin hydrochloride liposomal infusion in 4.2% of patients. HFS was generally observed after 2 or 3 cycles of treatment but may occur earlier. Delay doxorubicin hydrochloride liposome injection for the first episode of Grade 2 or greater HFS *[see Dosage and Administration]*. Discontinue doxorubicin hydrochloride liposomal infusion if HFS is severe and debilitating. **Secondary Oral Neoplasms:** Secondary oral cancers, primarily squamous cell carcinoma, have been reported from post-marketing experience in patients with long-term (more than one year) exposure to doxorubicin hydrochloride liposomal infusion. These malignancies were diagnosed both during treatment with doxorubicin hydrochloride liposome injection and up to 6 years after the last dose. Examine patients at regular intervals for the presence of oral ulceration or with any oral discomfort that may be indicative of secondary oral cancer. The altered pharmacokinetics and preferential tissue distribution of liposomal doxorubicin that contributes to enhanced skin toxicity and mucositis compared to free doxorubicin may play a role in the development of oral secondary malignancies with long-term use. **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, doxorubicin hydrochloride liposomal infusion can cause fetal harm when administered to a pregnant woman; avoid the use of doxorubicin hydrochloride liposomal infusion during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of doxorubicin hydrochloride during the 2nd and 3rd trimesters. At doses approximately 0.12 times the recommended clinical dose, doxorubicin hydrochloride liposomal infusion was embryotoxic and abortifacient in rabbits. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during and for 6 months after treatment with doxorubicin hydrochloride liposomal infusion *[see Use in Specific Populations]*.

ADVERSE REACTIONS:

The following adverse reactions are discussed in more detail in other sections of the labeling.

- Cardiomyopathy *[see Warnings and Precautions]*
- Infusion-Related Reactions *[see Warnings and Precautions]*
- Hand-Foot Syndrome *[see Warnings and Precautions]*
- Secondary Oral Neoplasms *[see Warnings and Precautions]*

Adverse Reactions in Clinical Trials: Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed cannot be

directly compared to rates on other clinical trials and may not reflect the rates observed in clinical practice. The safety data reflect exposure to doxorubicin hydrochloride liposomal infusion in 1310 patients including: 239 patients with ovarian cancer, 753 patients with AIDS-related Kaposi's sarcoma, and 318 patients with multiple myeloma. The most common adverse reactions (>20%) observed with doxorubicin hydrochloride liposomal infusion are asthenia, fatigue, fever, nausea, stomatitis, vomiting, diarrhea, constipation, anorexia, hand-foot syndrome, rash and neutropenia, thrombocytopenia and anemia. The following tables present adverse reactions from clinical trials of single-agent doxorubicin hydrochloride liposomal infusion in ovarian cancer and AIDS-Related Kaposi's sarcoma.

Patients With Ovarian Cancer

The safety data described below are from Trial 4, which included 239 patients with ovarian cancer treated with doxorubicin hydrochloride liposomal infusion 50 mg/m2 once every 4 weeks for a minimum of four courses in a randomized, multicenter, open-label study. In this trial, patients received doxorubicin hydrochloride liposomal infusion for a median number of 3.2 months (range 1 day to 25.8 months). The median age of the patients is 60 years (range 27 to 87), with 91% Caucasian, 6% Black, and 3% Hispanic or Other.
Table 3 presents the hematologic adverse reactions from Trial 4.

Table 3: Hematologic Adverse Reactions in Trial 4

	Doxorubicin Hydrochloride Liposomal Infusion Patients (n=239)	Topotecan Patients (n=235)
Neutropenia		
500 - <1,000/mm^3	8%	14%
<500/mm^3	4.2%	62%
Anemia		
6.5 - <8 g/dL	5%	25%
<6.5 g/dL	0.4%	4.3%
Thrombocytopenia		
10,000 - <50,000/mm^3	1.3%	17%
<10,000/mm^3	0.0%	17%

Table 4 presents the non-hematologic adverse reactions from Trial 4.

Table 4: Non-Hematologic Adverse Reactions in Trial 4

Non-Hematologic Adverse Reaction 10% or Greater	Doxorubicin Hydrochloride Liposomal Infusion (%) Treated (n=239)		Topotecan (%) Treated (n=235)	
	All grades	Grades 3-4	All grades	Grades 3-4
Body as a Whole				
Asthenia	40	7	52	8
Fever	21	0.8	31	6
Mucous Membrane Disorder	14	3.8	3.4	0
Back Pain	12	1.7	10	0.9
Infection	12	2.1	6	0.9
Headache	11	0.8	15	0
Digestive				
Nausea	46	5	63	8
Stomatitis	41	8	15	0.4
Vomiting	33	8	44	10
Diarrhea	21	2.5	35	4.2
Anorexia	20	2.5	22	1.3
Dyspepsia	12	0.8	14	0
Nervous				
Dizziness	4.2	0	10	0
Respiratory				
Pharyngitis	16	0	18	0.4
Dyspnea	15	4.1	23	4.3
Cough increased	10	0	12	0
Skin and Appendages				
Hand-foot syndrome	51	24	0.9	0
Rash	29	4.2	12	0.4
Alopecia	19	N/A	52	N/A

The following additional adverse reactions were observed in patients with ovarian cancer with doses administered every four weeks (Trial 4). Incidence 1% to 10%

Cardiovascular: vasodilation, tachycardia, deep vein thrombosis, hypotension, cardiac arrest.
Digestive: oral moniliasis, mouth ulceration, esophagitis, dysphagia, rectal bleeding, ileus.
Hematologic and Lymphatic: ecchymosis.
Metabolic and Nutritional: dehydration, weight loss, hyperbilirubinemia, hypokalemia, hypercalcemia, hyponatremia.
Nervous: somnolence, dizziness, depression.
Respiratory: rhinitis, pneumonia, sinusitis, epistaxis.
Skin and Appendages: pruritus, skin discoloration, vesiculobullous rash, maculopapular rash, exfoliative dermatitis, herpes zoster, dry skin, herpes simplex, fungal dermatitis, furunculosis, acne.
Special Senses: conjunctivitis, taste perversion, dry eyes.
Urinary: urinary tract infection, hematuria, vaginal moniliasis.

Patients With AIDS-Related Kaposi's Sarcoma

The safety data described is based on the experience reported in 753 patients with AIDS-related Kaposi's sarcoma (KS) enrolled in four open-label, uncontrolled trials of doxorubicin hydrochloride liposomal infusion administered at doses ranging from 10 to 40 mg/m^2 every 2 to 3 weeks. Demographics of the population were: median age 38.7 years (range 24-70); 99% male; 88% Caucasian, 6% Hispanic, 4% Black, and 2% Asian/other/unknown. The majority of patients were treated with 20 mg/m^2 of doxorubicin hydrochloride liposomal infusion every 2 to 3 weeks with a median exposure of 4.2 months (range 1 day to 26.6 months). The median cumulative dose was 120 mg/m^2 (range 3.3 to 798.6 mg/m^2); 3% received cumulative doses of greater than 450 mg/m^2. Disease characteristics were: 61% poor risk for KS tumor burden, 91% poor risk for immune system, and 47% poor risk for systemic illness; 36% were poor risk for all three categories; median CD4 count 21 cells/mm^3 (51% less than 50 cells/mm^3); mean absolute neutrophil count at study entry approximately 3,000 cells/mm^3. Of the 693 patients with concomitant medication information, 59% were on one or more antiretroviral medications [35% zidovudine (AZT), 21% didanosine (ddI), 16% zalcitabine (ddC), and 10% stavudine (D4T)]; 85% received PCP prophylaxis (54% sulfamethoxazole/trimethoprim); 85% received antifungal medications (76% fluconazole); 72% received antivirals (56% acyclovir, 29% ganciclovir, and 16% foscarnet) and 48% patients received colony-stimulating factors (sargramostim/filgrastim) during their course of treatment. Adverse reactions led to discontinuation of treatment in 5% of patients with AIDS-related Kaposi's sarcoma and included myelosuppression, cardiac adverse reactions, infusion-related reactions, toxoplasmosis, HFS, pneumonia, cough/dyspnea, fatigue, optic neuritis, progression of a non-KS tumor, allergy to penicillin, and unspecified reasons. Table 5 and Table 6 summarize adverse reactions reported in patients treated with doxorubicin hydrochloride liposomal infusion for AIDS-related Kaposi's sarcoma in a pooled analysis of the four trials.

Table 5: Hematologic Adverse Reactions Reported in Patients With AIDS-Related Kaposi's Sarcoma

	Patients With Refractory or Intolerant AIDS-Related Kaposi's Sarcoma (n=74*)	Total Patients With AIDS-Related Kaposi's Sarcoma (n=720**)
Neutropenia		
<1,000/mm^3	46%	49%
<500/mm^3	11%	13%
Anemia		
<10 g/dL	58%	55%
<8 g/dL	16%	18%
Thrombocytopenia		
<150,000/mm^3	61%	61%
<25,000/mm^3	1.4%	4.2%

*This includes a subset of subjects who were retrospectively identified as having disease progression on prior systemic combination chemotherapy (at least 2 cycles of a regimen containing at least 2 of 3 treatments: bleomycin, vincristine or vinblastine, or doxorubicin) or as being intolerant to such therapy.
**This includes only subjects with AIDS-KS who had available data from the 4 pooled trials.

Table 6: Non-Hematologic Adverse Reactions Reported in ≥ 5% of Patients With AIDS-Related Kaposi's Sarcoma

Adverse Reactions	Patients With Refractory or Intolerant AIDS-Related Kaposi's Sarcoma (n=77*)	Total Patients With AIDS-Related Kaposi's Sarcoma (n=705**)
Nausea	18%	17%
Asthenia	7%	10%
Fever	8%	9%
Alopecia	9%	9%
Alkaline Phosphatase Increase	1.3%	8%
Vomiting	8%	8%
Diarrhea	5%	8%
Stomatitis	5%	7%
Oral Moniliasis	1.3%	6%

*This includes a subset of subjects who were retrospectively identified as having disease progression on prior systemic combination chemotherapy (at least 2 cycles of a regimen containing at least 2 of 3 treatments: bleomycin, vincristine or vinblastine, or doxorubicin) or as being intolerant to such therapy.
**This includes only subjects with AIDS-KS who had available adverse event data from the 4 pooled trials.
The following additional adverse reactions were observed in 705 patients with AIDS-related Kaposi's sarcoma.
Incidence 1% to 5%
Body as a Whole: headache, back pain, infection, allergic reaction, chills.
Cardiovascular: chest pain, hypotension, tachycardia.
Cutaneous: herpes simplex, rash, itching.
Digestive: mouth ulceration, anorexia, dysphagia.
Metabolic and Nutritional: SGPT increase, weight loss, hyperbilirubinemia.
Other: dyspnea, pneumonia, dizziness, somnolence.
Incidence Less Than 1%
Body As A Whole: sepsis, moniliasis, cryptococcosis.
Cardiovascular: thrombophlebitis, cardiomyopathy, palpitation, bundle branch block, congestive heart failure, heart arrest, thrombosis, ventricular arrhythmia.
Digestive: hepatitis.
Metabolic and Nutritional Disorders: dehydration.
Respiratory: cough increase, pharyngitis.
Skin and Appendages: maculopapular rash, herpes zoster.
Special Senses: taste perversion, conjunctivitis.

Patients With Multiple Myeloma

The safety data described are from 318 patients treated with doxorubicin hydrochloride liposomal infusion (30 mg/m^2) administered on day 4 following bortezomib (1.3 mg/m^2 i.v. bolus on days 1, 4, 8 and 11) every 3 weeks, in a randomized, open-label, multicenter study (Trial 6). In this trial, patients in the doxorubicin hydrochloride liposomal infusion + bortezomib combination group were treated for a median number of 4.5 months (range 21 days to 13.5 months). The population was 28 to 85 years of age (median age 61), 58% male, 90% Caucasian, 6% Black, and 4% Asian and Other. Table 7 lists adverse reactions reported in 10% or more of patients treated with doxorubicin hydrochloride liposomal infusion in combination with bortezomib for multiple myeloma.

Table 7: Frequency of Treatment-Emergent Adverse Reactions Reported in ≥10% Patients Treated for Multiple Myeloma With Doxorubicin Hydrochloride Liposomal Infusion in Combination With Bortezomib

Adverse Reaction	Doxorubicin hydrochloride Liposomal Infusion + bortezomib (n=318)		Bortezomib (n=318)	
	Any (%)	Grades 3-4	Any (%)	Grades 3-4
Blood and lymphatic system disorders				
Neutropenia	36	32	22	16
Thrombocytopenia	33	24	28	17
Anemia	25	9	21	9
General disorders and administration site conditions				
Fatigue	36	7	28	3
Pyrexia	31	1	22	1
Asthenia	22	6	18	1
Gastrointestinal disorders				
Nausea	48	3	40	1
Diarrhea	46	7	39	5
Vomiting	32	4	22	1
Constipation	31	1	31	1
Mucositis/Stomatitis	20	2	5	<1
Abdominal pain	11	1	8	1
Infections and infestations				
Herpes zoster	11	2	9	2
Herpes simplex	10	0	6	1
Investigations				
Weight decreased	12	0	4	0
Metabolism and Nutritional disorders				
Anorexia	19	2	14	<1
Nervous system disorders				
Peripheral Neuropathy[1]	42	7	45	11
Neuralgia	17	3	20	4
Paresthesia/dysesthesia	13	<1	10	0
Respiratory, thoracic and mediastinal disorders				
Cough	18	0	12	0
Skin and subcutaneous tissue disorders				
Rash[2]	22	1	18	1
Hand-foot syndrome	19	6	<1	0

[1] Peripheral neuropathy includes the following adverse reactions: peripheral sensory neuropathy, neuropathy peripheral, polyneuropathy, peripheral motor neuropathy, and neuropathy NOS.
[2] Rash includes the following adverse reactions: rash, rash erythematous, rash macular, rash maculo-papular, rash pruritic, exfoliative rash, and rash generalized.

Postmarketing Experience: The following additional adverse reactions have been identified during post approval use of doxorubicin hydrochloride liposomal infusion. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Musculoskeletal and Connective Tissue Disorders: muscle spasms
Respiratory, Thoracic and Mediastinal Disorders: pulmonary embolism (in some cases fatal)
Hematologic Disorders: Secondary acute myelogenous leukemia
Skin and Subcutaneous Tissue Disorders: erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, lichenoid keratosis
Secondary Oral Neoplasms: [see Warnings and Precautions].

DRUG INTERACTIONS:
No formal drug interaction studies have been conducted with doxorubicin hydrochloride liposomal infusion.

USE IN SPECIFIC POPULATIONS:
Pregnancy:
Risk Summary: Based on findings in animals and its mechanism of action, doxorubicin hydrochloride liposomal infusion can cause fetal harm when administered to a pregnant woman; avoid the use of doxorubicin hydrochloride liposomal infusion during the 1st trimester. In animal reproduction studies, doxorubicin hydrochloride liposomal infusion was embryotoxic in rats and abortifacient in rabbits following intravenous administration during organogenesis at doses approximately 0.12 times the recommended clinical dose *(see Data)*. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of doxorubicin hydrochloride during the 2nd and 3rd trimesters. Advise pregnant women of the potential risk to a fetus. The background risk of major birth defects and miscarriage for the indicated populations are unknown. However, the background risk in the U.S. general population of major birth defects is 2-4% and of miscarriage is 15-20% of clinically recognized pregnancies.
Data:
Animal Data: Doxorubicin hydrochloride liposomal infusion was embryotoxic at doses of 1 mg/kg/day in rats and was embryotoxic and abortifacient at 0.5 mg/kg/day in rabbits (both doses are about 0.12 times the recommended dose of 50 mg/m^2 human dose on a mg/m^2 basis). Embryotoxicity was characterized by increased embryo-fetal deaths and reduced live litter sizes.
Lactation:
Risk Summary: It is not known whether doxorubicin hydrochloride liposomal infusion is present in human milk. Because many drugs, including anthracyclines, are excreted in human milk and because of the potential for serious adverse reactions in breastfed infants from doxorubicin hydrochloride liposomal infusion, discontinue breastfeeding during treatment with doxorubicin hydrochloride liposomal infusion.
Females and Males of Reproductive Potential:
Pregnancy Testing: Verify the pregnancy status of females of reproductive potential prior to initiating doxorubicin hydrochloride liposomal infusion.
Contraception:
Females: Doxorubicin hydrochloride liposomal infusion can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations]*. Advise females of reproductive potential to use effective contraception during and for 6 months after treatment with doxorubicin hydrochloride liposomal infusion.
Males: Doxorubicin hydrochloride liposomal infusion may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Males with female sexual partners of reproductive potential should use effective contraception during and for 6 months after treatment with doxorubicin hydrochloride liposomal infusion *[see Non-clinical Toxicology]*.
Infertility:
Females: In females of reproductive potential, doxorubicin hydrochloride liposomal infusion may cause infertility and result in amenorrhea. Premature menopause can occur with doxorubicin hydrochloride. Recovery of menses and ovulation is related to age at treatment.
Males: Doxorubicin hydrochloride liposomal infusion may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men. This may occur several years after the end of therapy *[see Non-clinical Toxicology]*.
Pediatric Use: The safety and effectiveness of doxorubicin hydrochloride liposomal infusion in pediatric patients have not been established.
Geriatric Use: Clinical studies of doxorubicin hydrochloride liposomal infusion conducted in patients with either epithelial ovarian cancer (Trial 4) or with AIDS-related Kaposi's sarcoma (Trial 5) did not contain sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger subjects. In Trial 6, of 318 patients treated with doxorubicin hydrochloride liposomal infusion in combination with bortezomib for multiple myeloma, 37% were 65 years of age or older and 8% were 75 years of age or older. No overall differences in safety or efficacy were observed between these patients and younger patients.
Hepatic Impairment: The pharmacokinetics of doxorubicin hydrochloride liposomal infusion has not been adequately evaluated in patients with hepatic impairment. Doxorubicin is eliminated in large part by the liver. Reduce doxorubicin hydrochloride liposomal infusion for serum bilirubin of 1.2 mg/dL or higher.

OVERDOSAGE:
Acute overdosage with doxorubicin hydrochloride causes increased risk of severe mucositis, leukopenia, and thrombocytopenia.

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Zydus Lifesciences Ltd.
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Pennington, NJ 08534

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News Briefs

NovaBay Pharmaceuticals & Eyenovia To Co-Promote Ophthalmic Products

On March 13, NovaBay Pharmaceuticals, Inc. of Emeryville, California and Eyenovia, Inc. of New York City jointly announced the signing of a co-promotion agreement to commercialize prescription ophthalmic products to eyecare professionals across the United States.

Under the agreement, NovaBay will market Eyenovia's clobetasol propionate ophthalmic suspension 0.05%, a steroid indicated for the treatment of inflammation and pain following ocular surgery, through its U.S. physician-dispensed channel.

Eyenovia will market NovaBay's prescription Avenova® (pure hypochlorous acid, 0.01%) Antimicrobial Lid & Lash Solution, through its sales representatives strategically located across the United States.

NovaBay Pharmaceuticals develops and sells scientifically created and clinically proven eyecare, skincare, and wound care products.

Eyenovia is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet® platform.

Bora Pharmaceuticals Completes The Acquisition Of Upsher-Smith Laboratories

On April 1, Bora Pharmaceuticals Co., Ltd. of Taipei, Taiwan (the parent company of TWi Pharmaceuticals, Inc. of Minneapolis, Minnesota) and Upsher-Smith Laboratories, Inc. of Maple Grove, Minnesota jointly announced that Upsher-Smith has been successful acquired by Bora Pharmaceuticals, and is now a wholly-owned subsidiary of the Bora Group.

Upsher-Smith, founded in 1919, is respected in the industry and recognized as a reliable partner with superior manufacturing capabilities, a robust distribution network, and established commercial relationships. They currently have 48 generic products with manufacturing facilities in Plymouth and Maple Grove, Minnesota. The two facilities can commercialize and produce a range of dosage forms including oral solids, powders (oral and topical) and liquids.

Through this acquisition, Bora Pharmaceuticals not only gains additional capacity to support its Contract Development & Manufacturing Organization (CDMO) business, but also adds to its capability to serve customers throughout the pharmaceutical value chain, covering the entire U.S. market.

Apotex To Acquire Searchlight Pharma

On April 2, Apotex Inc. of Ontario, Canada (with U.S. headquarters in Weston, Florida) and Searchlight Pharma, Inc. of Montreal, Canada jointly announced they have reached an agreement whereby Apotex will acquire Searchlight to become a division of Apotex and serve as its platform for expansion and growth of branded pharmaceuticals across the United States.

Closing of this transaction is expected in the second quarter of 2024.

Following the acquisition, Searchlight's headquarters will remain based in Montreal and the operations of Apotex will expand within the province of Quebec.

Searchlight is a private, Canadian specialty and innovative branded pharmaceutical company with global reach that executes search, acquisition, commercialization, and focused development of innovative and unique specialty branded healthcare products.

Allan Oberman, President & CEO at Apotex, said: "Searchlight has an experienced and proven track record as one of Canada's fastest-growing companies with deep institutional knowledge across a range of domestic and international markets and a strong specialty and innovative branded product portfolio. This acquisition is a strategic complement to Apotex's market in generic and biosimilar pharmaceuticals, in alignment with our ongoing focus to expand into the high-value, innovative branded pharmaceuticals sector. We look forward to working with Searchlight's talented team as we plan the integration of our companies and a seamless transition for patients, customers and employees."

Mark Nawacki, Searchlight's President and Chief Executive Officer, noted: "For the past decade, Searchlight has successfully pursued its branded pharmaceutical growth strategy by providing dependability and value to Canadian patients and healthcare professionals. Thinking forward to an ambitious future, we know that Apotex is the right partner for Searchlight given our shared purpose of providing access to innovative medicines that improve people's lives. We are confident and excited that joining forces to create a Canadian pharmaceutical champion and global health company will harness a combined passion, scale and talent that will accelerate our plans."

Lilly Acquires New Injectable Facility From Nexus Pharmaceuticals

On April 22, Eli Lilly & Company of Indianapolis, Indiana and Nexus Pharmaceuticals, LLC of Lincolnshire, Illinois jointly announced a definitive agreement whereby Lilly will acquire an FDA-approved manufacturing facility from Nexus.

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News Briefs

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The acquisition of the facility, located in Pleasant Prairie, Wisconsin will further expand Lilly's global parenteral (injectable) product manufacturing network and support increased demand for the company's medicines.

Production at the facility is expected to begin at the end of next year, 2025.

The facility does not provide contract manufacturing services, allowing it to be solely dedicated to Lilly's manufacturing mission to deliver medicines to patients with safety first and quality always.

Edgardo Hernandez, Executive VP & President of Lilly manufacturing, commented: "The acquisition of this state-of-the-art facility underscores our unwavering commitment to growth and innovation, and we look forward to welcoming talented new Nexus colleagues to Lilly from the Pleasant Prairie facility. We are investing boldly to serve our patients, to meet product demand and to build capabilities for our robust pipeline of the future."

Nexus Pharmaceuticals specializes in innovative processes to make difficult-to-manufacture specialty and generic drugs that are easier to use, less labor intensive, and more streamlined in practice. Nexus ensures that its high-quality FDA-approved drugs fulfill a critical unmet medical need and deliver dependable life-saving treatment options when and where they're needed most.

Global Rights To Zokinvy® Capsules Acquired By Sentynl Therapeutics

On May 3, Sentynl Therapeutics, Inc. of Solano Beach, California, wholly-owned by Zydus Lifesciences, Ltd. (the Zydus Group), and Eiger BioPharmaceuticals, Inc. of Palo Alto, California jointly announced that Sentynl has successfully acquired the global rights of Zokinvy® (lonafarnib) Capsules from Eiger.

Zokinvy is the first and only treatment approved by the FDA to target the cause and symptoms of progeria, also known as Hutchinson-Gilford progeria syndrome (HGPS) and processing-deficient progeroid laminopathies (PDPL), in young people 12 months of age and older. Collectively known as progeria, HGPS and PDPL are ultra-rare, fatal, genetic premature aging diseases that accelerate mortality in young patients.

Audrey Gordon, President & Executive Director of The Progeria Research Foundation (PRF) of Peabody, Massachusetts, said: "Without Zokinvy therapy, children with progeria die of the same heart disease that affects millions of normally aging adults, but by an average age of 14.5 years old. Zokinvy gives these beautiful children longer, healthier lives. Since we first launched PRF in 1999, we have achieved tremendous progress in global awareness, breakthrough research, and treatment of progeria. We are thankful for our successful partnership with Eiger and are excited to now join forces with Sentynl in our journey to continue advancing the research and treatment of this syndrome, with the ultimate goal to find the cure."

Sentynl Therapeutics is a U.S. based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases. The company was acquired by the Zydus Group in 2017.

Eiger Biopharmaceuticals is a commercial-stage biopharmaceutical company focused on the development of innovative therapies for rare metabolic diseases.

As previously disclosed by Eiger on April 1, 2024, Eiger and its direct subsidiaries filed voluntary petitions for relief under Chapter 11 in the United States Bankruptcy Court for the Northern District of Texas. On April 17, 2024, following the completion of the auction held as part of the Eiger's court-supervised sale process, Sentynl was designated the winning bidder with a final bid during the auction. Under the terms of the acquisition, Sentynl acquired global rights to Zokinvy and will be responsible for its manufacture and commercialization.

Matt Heck, President & CEO of Sentynl, commented: "It is an honor to add Zokinvy to our portfolio of products that have a tangible impact on the lives of rare disease patients, whose needs are too often unmet or overlooked. We are firmly committed to provide best-in-class global access to Zokinvy and are eager to serve the patients and their families affected by progeria. We are grateful to Eiger and The Progeria Research Foundation for their dedicated effort to develop and secure availability of this life-changing product."

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Jynneos® Vaccine For Monkeypox & Smallpox - Now Available

On April 2, Bavarian Nordic A/S of Copenhagen, Denmark announced that the only FDA-approved monkeypox vaccine: Jynneos® (monkeypox and smallpox live vaccine, non-replicating) Suspension for Injection (subcutaneous) is ***now available*** commercially across the United States.

This marks a significant expansion for access to Jynneos by establishing additional pathways for vaccine procurement, distribution, and reimbursement by both public and private payers. Healthcare providers can now order Jynneos through their preferred wholesaler and distribution partners to make it available for at-risk individuals at local pharmacies and physician offices in addition to public health clinics.

Jynneos is indicated for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox and monkeypox infection. The vaccine was developed in collaboration with the U.S. government originally to ensure supply of a smallpox vaccine for the entire population, including immunocompromised individuals who are not recommended vaccination with traditional replicating smallpox vaccines.

Originally, Jynneos was FDA-approved in September 2019. Then in 2021, the U.S. Centers for Disease Control & Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend Jynneos for pre-exposure vaccination of people at occupational risk for orthopox virus exposures.

During the monkeypox outbreak in 2022, the CDC issued interim guidance enabling pre- and post-exposure use of Jynneos, and an Emergency Use Authorization (EUA) was issued allowing its use in people under 18 years of age.

Then in October 2023, the CDC further updated its guidance for use of Jynneos, and now recommends routine use of the vaccine for at risk individuals 18 years and older.

Monkeypox (mpox) is a rare viral zoonotic disease (by transmission from animals to humans) that is similar to human smallpox. Its causative agent, variola virus, is also a member of the Orthopox virus genus. However, mpox infection is less transmissible human-to-human than smallpox, and also less deadly (case fatality estimates for monkeypox are up to 10%). Orthopox virus infections produce antibody responses that are cross-protective against other viruses within the genus. It is this property of Orthopox viruses that allows Jynneos to be used as a vaccine against both smallpox and mpox.

Until recently, infections of monkeypox in humans had mostly been limited to central and western regions of Africa, where the virus is naturally occurring. However, during the ongoing monkeypox outbreak in Nigeria, increased human-to-human transmission has been observed and the wide geographic spread, predominantly in urban areas, has raised concerns over the disease. The cases of monkeypox observed in the U.K., Israel, and Singapore all originated from Nigeria, demonstrating that the virus is no longer only a domestic challenge. Nigeria is Africa's largest country by both population and economy, including the large oil and gas industry, which employs a significant number of local and foreign employees. It is estimated that more than 5 million people travel to countries affected by monkeypox in Central Africa each year, suggesting a market potential for a monkeypox vaccine for travelers.

While mpox no longer constitutes a current public health emergency, infections are still occurring throughout the U.S., with around 200 cases every month on average and transmission of the virus having been reported across most of the states in 2024 to-date. Since the beginning of the outbreak in 2022, more than 32,000 cases have been reported in the U.S., representing a third of all cases reported globally.

According to estimates from the CDC, about 2 million U.S. individuals are eligible for vaccination against mpox. Recent data shows 60% of this population remains completely unvaccinated, and 15% have only received 1 dose of the vaccine. Real-world data show that protection against mpox disease is superior in vaccinees who received the full schedule of 2 vaccinations as recommended by the CDC, compared to those who are unvaccinated or have only received 1 dose of the vaccine.

Paul Chaplin, President & CEO of Bavarian Nordic, commented: "From the beginning of the monkeypox outbreak in 2022, the prompt availability of an approved vaccine combined with a strong public health response have helped to significantly reduce the impact of this debilitating disease, but unfortunately, mpox has not gone away completely. Building on the trust and reliability as a supplier of vaccines to the U.S. government for more than a decade, we are proud to extend our commitment to improving the nation's public health by making our mpox vaccine widely available to at-risk individuals through the regular channels. We look forward to working with healthcare providers across the nation to increase awareness and availability of the monkeypox vaccine."

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zydus Pharmaceuticals USA

Methylene Blue Injection, USP

AP-rated to ProvayBlue®

AVAILABLE AS
50 mg/10 mL single-dose vial.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch (fda.gov/medwatch) or call 1-800-FDA-1088.

For more product details, please visit www.zydususa.com

WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS AND OPIOIDS

Methylene blue may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs and opioids. Avoid concomitant use of methylene blue with selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), and monoamine oxidase inhibitors (MAOIs) and opioids [see Warnings and Precautions and Drug Interactions].

Brief Summary of Prescribing Information
These highlights do not include all the information needed to use METHYLENE BLUE INJECTION safely and effectively. See full prescribing information for METHYLENE BLUE INJECTION.

METHYLENE BLUE Injection, USP for intravenous use
Initial U.S. Approval: 2016

INDICATIONS AND USAGE: Methylene blue injection is indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials *[see Clinical Studies]. Clinical Studies information is approved for PROVEPHARM SAS's Provayblue® (Methylene blue solution, intravenous). However, due to PROVEPHARM SAS's marketing exclusivity rights, this drug product is not labeled with that information.*

CONTRAINDICATIONS: Methylene blue is contraindicated in the following conditions: Severe hypersensitivity reactions to methylene blue or any other thiazine dye *[see Warnings and Precautions]*. Patients with glucose-6-phosphate dehydrogenase deficiency (G6PD) due to the risk of hemolytic anemia *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS: **Serotonin Syndrome with Concomitant Use of Serotonergic Drugs and Opioids:** The development of serotonin syndrome has been reported with the use of methylene blue class products. Most reports have been associated with concomitant use of serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs). Opioids and dextromethorphan may increase the risk of developing serotonin syndrome. Some of the reported cases were fatal. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, and hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, and incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Avoid concomitant use of methylene blue with serotonergic drugs and opioids. Patients treated with methylene blue should be monitored for the emergence of serotonin syndrome. If symptoms of serotonin syndrome occur, discontinue use of methylene blue, and initiate supportive treatment. Inform patients of the increased risk of serotonin syndrome and advise them to not to take serotonergic drugs within 72 hours after the last dose of methylene blue injection *[see Drug Interactions, Patient Counseling Information]*. **Hypersensitivity:** Anaphylactic reactions to methylene blue class products have been reported. Patients treated with methylene blue should be monitored for anaphylaxis. If anaphylaxis or other severe hypersensitivity reactions (e.g., angioedema, urticaria, bronchospasm) should occur, discontinue use of methylene blue and initiate supportive treatment. Methylene blue is contraindicated in patients who have experienced anaphylaxis or other severe hypersensitivity reactions to a methylene blue class product in the past. **Lack of Effectiveness:** Methemoglobinemia may not resolve or may rebound after response to treatment with methylene blue in patients with methemoglobinemia due to aryl amines such as aniline or sulfa drugs such as dapsone. Monitor response to therapy with methylene blue through resolution of methemoglobinemia. If methemoglobinemia does not respond to 2 doses of methylene blue injection or if methemoglobinemia rebounds after a response, consider additional treatment options *[see Dosage and Administration]*. Patients with glucose-6-phosphate dehydrogenase deficiency may not reduce methylene blue to its active form in vivo. Methylene blue may not be effective in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. **Hemolytic Anemia:** Hemolysis can occur during treatment of methemoglobinemia with methylene blue. Laboratory testing may show Heinz bodies, elevated indirect bilirubin and low haptoglobin, but the Coombs test is negative. The onset of anemia may be delayed 1 or more days after treatment with methylene blue injection. The anemia may require red blood cell transfusions *[see Adverse Reactions]*. Use the lowest effective number of doses of methylene blue injection to treat methemoglobinemia. Discontinue methylene blue and consider alternative treatments of methemoglobinemia if severe hemolysis occurs. Treatment of patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency with methylene blue may result in severe hemolysis and severe anemia. Methylene blue is contraindicated for use in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency *[see Contraindications]*. **Interference with In Vivo Monitoring Devices:** *Inaccurate Pulse Oximeter Readings:* The presence of methylene blue in the blood may result in an underestimation of the oxygen saturation reading by pulse oximetry. If a measure of oxygen saturation is required during or shortly after infusion of methylene blue it is advisable to obtain an arterial blood sample for testing by an alternative method. *Bispectral index monitor:* A fall in the Bispectral Index (BIS) has been reported following administration of methylene blue class products. If methylene blue is administered during surgery, alternative methods for assessing the depth of anesthesia should be employed. **Effects on Ability to Drive and Operate Machinery:** Treatment with methylene blue may cause confusion, dizziness and disturbances in vision *[see Adverse Reactions]*. Advise patients to refrain from driving or engaging in hazardous occupations or activities such as operating heavy or potentially dangerous machinery until such adverse reactions to methylene blue have resolved. **Interference with Laboratory Tests:** Methylene blue is a blue dye which passes freely into the urine and may interfere with the interpretation of any urine test which relies on a blue indicator, such as the dipstick test for leucocyte esterase.

ADVERSE REACTIONS: The following adverse reactions are discussed in greater detail in other sections of the labeling:
- Serotonin Syndrome with Concomitant Use of Serotonergic Drugs and Opioids *[see Warnings and Precautions]*
- Anaphylaxis *[see Warnings and Precautions]*
- Lack of Effectiveness *[see Warnings and Precautions]*
- Hemolytic Anemia *[see Warnings and Precautions]*
- Interference with In-Vivo Monitoring Devices *[see Warnings and Precautions]*
- Effects on Ability to Drive and Operate Machinery *[see Warnings and Precautions]*
- Interference with Laboratory Tests *[see Warnings and Precautions]*

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of methylene blue was determined in 82 healthy adults of median age of 36 years (range, 19-55 years); 54% were male, and 68% were white. Each individual in the safety population received a single dose of methylene blue 2 mg/kg intravenously. There was one serious adverse reaction reported (syncope due to sinus pauses of 3-14 seconds). The most common (≥2%) moderate or severe adverse reactions were pain in the extremity (56%), headache (7%), feeling hot (6%), syncope (4%), back pain (2%), hyperhidrosis (2%) and nausea (2%). Table 1 lists the adverse reactions of any severity that occurred in at least 2% of individuals who received methylene blue.

Table 1
Adverse Reactions Following Infusion of Methylene Blue Injection 2 mg/kg

Adverse Reaction	Any Grade TEAE (n=82)		Moderate-Severe TEAE (n=82)	
Pain in extremity	69	84%	46	56%
Chromaturia	61	74%	0	
Dysgeusia	16	20%	1	1%
Feeling hot	14	17%	5	6%
Dizziness	13	16%	4	5%
Hyperhidrosis	11	13%	2	2%
Nausea	11	13%	2	2%
Skin discoloration	11	13%	0	
Headache	8	10%	6	7%
Musculoskeletal pain	7	9%	0	
Paresthesia oral	7	9%	0	
Paresthesia	7	9%	0	
Infusion site pain	5	6%	1	1%
Feeling cold	5	6%	0	
Pallor	4	5%	0	
Dermatitis contact	4	5%	0	
Syncope	3	4%	3	4%
Influenza like illness	3	4%	1	1%
Pruritus	3	4%	1	1%
Anxiety	3	4%	0	
Decreased appetite	3	4%	0	
Chest discomfort	3	4%	0	
Back pain	2	2%	2	2%
Cold sweat	2	2%	1	1%
Dizziness postural	2	2%	1	1%
Muscle spasms	2	2%	1	1%
Presyncope	2	2%	1	1%
Vomiting	2	2%	1	1%
Arthralgia	2	2%	1	1%
Chills	2	2%	0	
Diarrhea	2	2%	0	
Discomfort	2	2%	0	
Dyspnea	2	2%	0	
Erythema	2	2%	0	
Hypoesthesia oral	2	2%	0	
Infusion site	2	2%	0	
Limb discomfort	2	2%	0	
Oral discomfort	2	2%	0	
Catheter site pain	2	2%	0	
Ecchymosis	2	2%	0	

Other adverse reactions reported to occur following administration of methylene blue class products include the following: *Blood and lymphatic system disorders:* hemolytic anemia, hemolysis, hyperbilirubinemia, methemoglobinemia *Cardiac disorders:* palpitations, tachycardia *Eye disorders:* eye pruritus, ocular hyperemia, vision blurred *Gastrointestinal disorders:* abdominal pain lower, dry mouth, flatulence, glossodynia, tongue eruption *General disorders and administration site conditions:* death, infusion site extravasation, infusion site induration, infusion site pruritus, infusion site swelling, infusion site urticaria, peripheral swelling, thirst *Investigations:* elevated liver enzymes *Musculoskeletal and connective tissue disorders:* myalgia *Renal and urinary disorders:* dysuria *Respiratory, thoracic and mediastinal disorders:* nasal congestion, oropharyngeal pain, rhinorrhea, sneezing *Skin and subcutaneous tissue disorders:* necrotic ulcer, papule, phototoxicity *Vascular disorders:* hypertension *Clinical Studies information is approved for PROVEPHARM SAS's Provayblue® (Methylene blue solution, intravenous). However, due to PROVEPHARM SAS's marketing exclusivity rights, this drug product is not labeled with that information.*

DRUG INTERACTIONS: Clinically significant drug interactions with methylene blue are described below: The concomitant use of methylene blue with other drugs that affect the serotonergic neurotransmitter system has resulted in serotonin syndrome. Although the mechanism is not clearly understood, literature reports suggest methylene blue is a potent reversible inhibitor of monoamine oxidase. Avoid concomitant use of methylene blue with medicinal products that enhance serotonergic transmission including antidepressants like SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin and norepinephrine reuptake inhibitors), MAOIs (monoamine oxidase inhibitors), bupropion, buspirone, clomipramine, mirtazapine, linezolid, opioids, and dextromethorphan because of the potential for serious CNS reactions, including potentially fatal serotonin syndrome. If the intravenous use of methylene blue cannot be avoided in patients treated with serotonergic medicinal products, choose the lowest possible dose and observe the patient closely for CNS effects for up to 4 hours after administration *[see Warning and Precautions and Clinical Pharmacology]*.

USE IN SPECIFIC POPULATIONS: **Pregnancy:** *Risk Summary:* Methylene blue may cause fetal harm when administered to a pregnant woman. Intra-amniotic injection of pregnant women with a methylene blue class product during the second trimester was associated with neonatal intestinal atresia and fetal death. Methylene blue produced adverse developmental outcomes in rats and rabbits when administered orally during organogenesis at doses at least 32 and 16 times, respectively, the clinical dose of 1 mg/kg *[see Data]*. Advise pregnant women of the potential risk to a fetus. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2-4% and 15-20%, respectively. Clinical Considerations: *Fetal/neonatal adverse reactions: Intra*-amniotic injection of a methylene blue class product hours to days prior to birth can result hyperbilirubinemia, hemolytic anemia, skin staining, methemoglobinemia, respiratory distress and photosensitivity in the newborn. Following administration of methylene blue to a pregnant woman at term, observe the newborn for these adverse reactions and institute supportive care. Data: *Animal Data:* Methylene blue was administered orally to pregnant rats at doses of 50 to 350 mg/kg/day, during the period of organogenesis. Maternal and embryofetal toxicities were observed at all doses of methylene blue and were most evident at the 200 and 350 mg/kg/day doses. Maternal toxicity consisted of increased spleen weight. Embryo-fetal toxicities included reduced fetal weight, post-implantation loss, edema, and malformations including enlarged lateral ventricles. The dose of 200 mg/kg (1200 mg/m^2) in rats is approximately 32 times a clinical dose of 1 mg/kg based on body surface area. Methylene blue was administered orally to pregnant rabbits at doses of 50, 100, or 150 mg/kg/day, during the period of organogenesis. Maternal death was observed at the methylene blue dose of 100 mg/kg. Embryofetal toxicities included spontaneous abortion at all dose levels and a malformation (umbilical hernia) at the 100 and 150 mg/kg/day doses. The dose of 50 mg/kg (600 mg/m^2) in rabbits is approximately 16 times a clinical dose of 1 mg/kg based on body surface area. **Lactation:** *Risk Summary:* There is no information regarding the presence of methylene blue in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions including genotoxicity, discontinue breast-feeding during and for up to 8 days after treatment with methylene blue *[see Clinical Pharmacology]*. **Pediatric Use:** The safety and effectiveness of methylene blue have been established in pediatric patients. Use of methylene blue is supported by two retrospective case series that included 2 pediatric patients treated with methylene blue and 12 treated with another methylene blue class product. The case series included pediatric patients in the following age groups: 3 neonates (less than 1 month), 4 infants (1 month up to less than 2 years), 4 children (2 years up to less than 12 years), and 3 adolescents (12 years to less than 17 years). The efficacy outcomes were consistent across pediatric and adult patients in both case series *[see Clinical Studies]*. **Geriatric Use:** The retrospective case series included 3 patients age 65 years and over treated with methylene blue injection (or a bioequivalent formulation) and 5 treated with another methylene blue class product. The efficacy outcomes were consistent across adult and elderly patients in both case series *[see Clinical Studies]*. Methylene blue is known to be substantially excreted by the kidney, so the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, treatment of methemoglobinemia in these patients should use the lowest number of doses needed to achieve a response *[see Dosage and Administration]. Clinical Studies information is approved for PROVEPHARM SAS's Provayblue® (Methylene blue solution, intravenous). However, due to PROVEPHARM SAS's marketing exclusivity rights, this drug product is not labeled with that information.* **Renal Impairment:** Methylene blue concentrations increased in subjects with renal impairment (eGFR 15 to 89 mL/min/1.73m^2) significantly *[see Clinical Pharmacology]*. Adjust methylene blue dosage in patients with moderate or severe renal impairment (eGFR 15 to 59 mL/min/1.73 m^2) *[see Dosage and Administration]*. No dose adjustment is recommended in patients with mild renal impairment (eGFR 60 - 89 mL/min/1.73 m^2). **Hepatic Impairment:** Methylene blue is extensively metabolized in the liver. Monitor patients with any hepatic impairment for toxicities and potential drug interactions for an extended period of time following treatment with methylene blue.

OVERDOSAGE: Hypotension, wheezing and reduced oxygenation have been reported in patients who received methylene blue class products in single doses of 3 mg/kg or more. Administration of large intravenous doses (cumulative dose ≥ 7 mg/kg) of a methylene blue class product caused nausea, vomiting, precordial pain, dyspnea, tachypnea, chest tightness, tachycardia, apprehension, tremor, mydriasis, blue staining of the urine, the skin and mucous membranes, abdominal pain, dizziness, paresthesia, headache, confusion, mild methemoglobinemia (up to 7%) and electrocardiogram changes (T-wave flattening or inversion). These effects lasted 2-12 hours following administration. A severe overdosage (single dose of 20 mg/kg or more) of a methylene blue class product caused severe intravascular hemolysis, hyperbilirubinemia and death. In case of overdose of methylene blue, maintain the patient under observation until signs and symptoms have resolved, monitor for cardiopulmonary, hematologic and neurologic toxicities, and institute supportive measures as necessary.

Call your doctor for medical advice about side effects.
You may report side effects to FDA at 1-800-FDA-1088.

Please address medical inquiries to, MedicalAffairs@zydususa.com or Tel.: 1-877-993-8779.

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Rev.: 3/24

Outstanding Buyer Nominee - Letia Schimming

What is the nominee's name, job title, facility name, and location? **Letia Schimming**, Medical Center Senior Pharmacy Buyer, James Cancer Hospital & Solove Research Institute, The Ohio State University Wexner Medical Center (OSUWMC), Columbus, Ohio.

As a nominating third party, please provide your own name, title, facility, and relationship to the nominee. **Stephen Polley**, PharmD, MPA, MS, BCPS, Associate Director at Cancer Pharmacy Services, James Cancer Hospital & Solove Research Institute, OSUWMC. I am Letia's current supervisor and have also worked with her for about 8 years in various roles.

Is the nominee certified, licensed, and/or registered, as a Pharmacy Technician in their state? No, since the nominee is not a Technician.

Is the nominee a current NPPA member, and will be current through August 2024? Yes, the nominee is a current NPPA member through November 2024.

What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban, etc.) We are an academic medical center with 350 beds for Inpatient and 210 chairs for Infusion.

Approximately how many dollars per year of pharmaceutical-related expenditures does the nominee purchase or supervise the purchasing of at the nominee's facility? $51 million for Inpatient and $404 million for Infusion.

What is the average dollar amount of pharmacy inventory the nominee controls each year? $5 million for Inpatient and $11 million for Infusion.

What is the nominee's/Pharmacy Department's current Inventory "Turns"? 10 for Inpatient and 36 for Infusion.

How long has the nominee been a Pharmacy Buyer? 6 years.

What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise?

- Manage drug shortages, safety stock inventory, and shortage mitigation.
- Work with drug manufacturers and wholesalers.
- Train new staff on purchasing best practices and new technologies.
- Maintain electronic inventory counts.
- Develop workflows for centralized purchasing (i.e., bulk buys).
- Manage purchase orders.
- Fulfill clinic medication requests.
- Troubleshoot purchasing issues for frontline staff.
- Identify spoilage programs.
- Inventory optimization.
- Drug Supply Chain Security Act (DSCSA) compliance, contracting changes, and medication assistance.

What may be unique or challenging about the nominee's facility?

- AMC with cancer-specific focus.
- Primary Cancer Center for central Ohio.
- A large number of ambulatory locations.
- Growth, with multiple construction projects occurring at the same time.
- High dollar and complex inventory management.
- High use of automation and tech, with over 30 Pyxis™ machines.

List any accomplishments or projects the nominee instituted that have either saved money for their department/facility, or helped to make their job or the department/facility run more efficiently. Letia implemented drug shortage and safety stock expansion of the University Hospital central pharmacy in The James Cancer Hospital. She helped to open our largest ambulatory site with 2 pharmacies servicing the Operating Room (OR), extended recovery wing, cancer clinics, and the infusion unit. In 2023, Letia set up our largest ambulatory location, James Outpatient Care. This ambulatory location is 8 floors and includes OR and extended recovery units (overnight), as well as Hematology and GU clinics, Phase 1 infusion unit and a large chemo infusion unit. In addition to her usual inpatient responsibilities, she trained staff, set up the Swisslog BoxPicker®, and set par levels. She also helped our teams become more united and efficient during intense growth, multiple construction projects, and an overwhelming number of drug shortages.

How has the nominee's job changed over the years? Letia recently transitioned from the Inpatient team to the Infusion team as we grew buyer support in infusion.

What does the nominee like about their job? The unexpected and the ability to pivot quickly for success and working with multiple teams in the pharmacy department.

What does the nominee dislike about their job? Drug shortages and the time that is needed to manage them.

What advice would the nominee have for drug company vendor representatives?

Success is both parties gaining something from the relationship. Bottom lines matter, but so does trust and availability.

→

Outstanding Buyer, Schimming

Continued from Page 34

What specific challenges does the nominee face on the job? Handling drug shortages and the rapid pace of change.

How has the nominee's NPPA membership helped them in their job and/or personally? (Overall, or from NPPA's official member-publication Pharmacy Purchasing Outlook.)
The references provided in the publication.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? Yes, Letia attended the 2023 NPPA Conference. She returned with a connection to a community of buyers to lean on and reach out to, colleagues who understand buyer challenges and are willing to share their successes.

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

Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any of them beyond being a member? No other organizations I'm currently aware of.

List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, volunteer work, etc. Letia was a prior nominee for OSUWMC Department of Pharmacy Maddie Harris Award for outstanding technician/support personnel.

Editorial Note: *In addition to the above, Letia's supervisor (**Stephen Polley**, PharmD) also submitted a separate letter of recommendation, as follows.*

"On behalf of the entire James Pharmacy Leadership team, I am honored to submit this nomination letter for Letia Schimming. I have worked with Letia for 8 years and in various roles. She is an asset to our department, and I am fortunate to have her as a member of our team. Letia is always available to help, provide a consult, troubleshoot, or track something down.

Letia is a very deserving candidate for this position. When Letia joined our inpatient buyer team, she quickly focused on building relationships. She bridged the various purchasing teams at our medical center; prior to her, each group mainly worked within their siloes, often duplicating work. Information sharing between teams was minimal. Letia used her strength of building relationships to change this culture. The change in culture has been evident, especially in the last few years, as our teams have become more united through intense growth, multiple construction projects, and an overwhelming number of drug shortages.

Another strength Letia has is being proactive and thinking about the big picture. This skill has been immensely helpful during the significant growth of our medical center. She has been an extremely important consultant in numerous construction projects. Specific to my team, she worked intimately to set up our largest ambulatory location, James Outpatient Care in the summer of 2023. This ambulatory location is 8 floors and includes OR and extended recovery units (overnight), as well as Hematology and GU clinics, and Phase 1 infusion unit and a large chemo infusion unit. The building has 2 pharmacies with one serving as a mini-inpatient pharmacy servicing the OR locations and fills all Pyxis and Pyxis anesthesia machines in the building. As of today, we have 31 Pyxis and Pyxis anesthesia machines in this building.

In addition, this pharmacy uses a Swisslog Boxpicker, a high-density storage device. The second pharmacy services our Cancer Clinics & Infusion. Letia was instrumental in training staff to use the various technoogy and its impact on inventory management. She helped order drug and supplies, set up the boxpicker, and set par levels. She did all of this in addition to her usual inpatient responsibilities.

Recently, we expanded our infusion buyer team, and Letia was the easiest hire I have ever made. She understands the unique challenges of our sites (multiple locations, disease-state focus, busy sites with frontline technicians handling daily purchases). From day one, she focused on establishing positive relationships with our pharmacists and technicians. Our staff feel very supported, and we are quickly noticing the positive impact of her being on our team.

As you can likely see, I could go on and on in my praise for Letia. Thank you for your consideration of her nomination."

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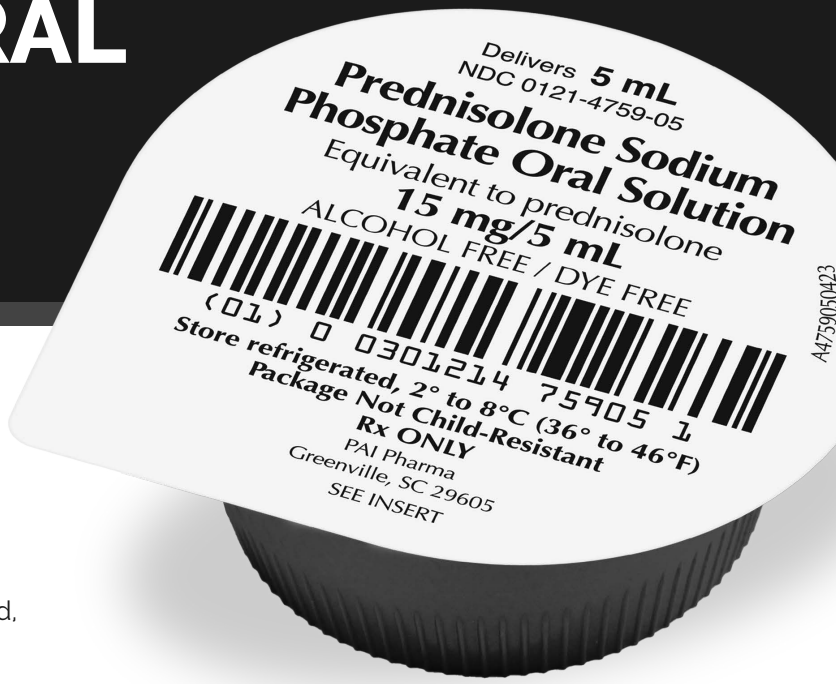
PAI Pharma

PREDNISOLONE SODIUM PHOSPHATE ORAL SOLUTION USP

15 mg/5 mL



PRODUCT OVERVIEW:

- **Alcohol, Dye, Lactose and Gluten-Free**
- **Rx or OTC:** Rx
- **Flavor:** Grape
- **Storage & Handling:** Store unit dose cups refrigerated, 2˚ to 8˚C (36˚ to 46˚F).

NDC	Product Description	Cardinal	Cencora	McKesson	Morris Dickson
00121-4759-50	Prednisolone Sodium Phosphate Oral Soln 15 mg/5 mL cups Rx 50/cs	5910799	10287585	2922441	TBD

Product Description	GTIN Product Barcode	GTIN Case Barcode
Prednisolone Sodium Phosphate Oral Soln 15 mg/5 mL cups Rx 50/cs	(01) 00301214759051	(01) 20301214759505

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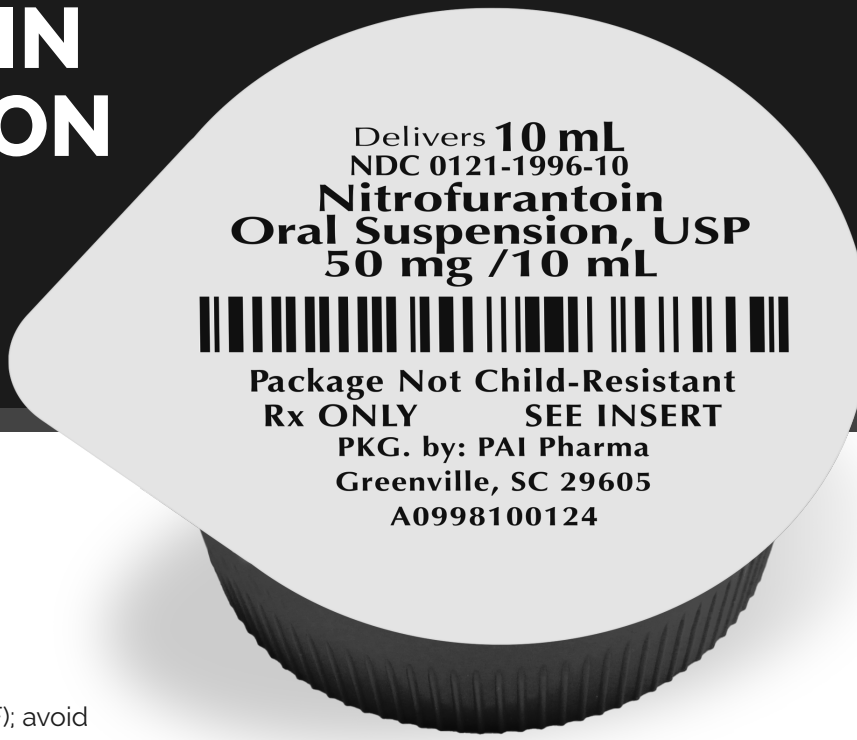

PRODUCT OVERVIEW:

- **Alcohol, Dye, Lactose, & Sugar free**
- **Rx or OTC:** Rx
- **Flavor:** Fruit
- **Storage & Handling:** Store at 20˚ to 25˚C (68˚ to 77˚F); avoid exposure to strong light

NDC	Product Description	Cardinal	Cencora	McKesson	Morris Dickson
00121-1996-00	Nitrofurantoin Oral Solution 50 mg cups OTC 10 mL/10 cs	5934948	10290855	2970846	412965

Product Description	GTIN Product Barcode	GTIN Case Barcode
Nitrofurantoin Oral Solution 50 mg cups OTC 10 mL/10 cs	(01) 00301210998058	(01) 20301210998007

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PAI Pharma is the ***industry leader*** in high-quality, US-made generic unit-dose and liquid medicines.

Heart Health News

Updated Women & Young Children Food Packages For Enhanced Support

On April 9, the American Heart Association (AHA) of Dallas, Texas reported that the U.S. Department of Agriculture (USDA) has announced their final revisions to the Women, Infants & Children food packages.

Nancy Brown, CEO of the AHA, released a statement about the new revisions, as follows.

"More than 6 million infants, young children, pregnant, postpartum, and breastfeeding people rely on Women, Infants & Children (WIC) for healthy and affordable food, nutrition education, breastfeeding support and other services. The AHA greatly values the USDA's commitment to improving nutrition and food security by better aligning the WIC food packages with the current Dietary Guidelines for Americans.

The updated food packages will increase access to fruits, vegetables, whole grains and seafood, all of which provide nutrients to help young children develop and have a healthy future. The packages also will reduce the amount of added sugars by only allowing unflavored milk and setting added sugars limits for yogurt and plant-based milk alternatives. In addition, the revised program will encourage breastfeeding and better support WIC participants' individual breastfeeding goals. We also applaud the increase to the monthly cash-value voucher for fruits and vegetables, a significant change that will provide participants with approximately half of the recommended daily intake for this food group.

We are also pleased the new food packages expand the number of whole grain options WIC participants can select, such as quinoa, wild rice, whole wheat pita and naan. The USDA also took an important step by requiring 75% of cereals be whole grain to help ensure that families are getting the proper nutrition, but we are disappointed that the agency did not adopt a 100% requirement as proposed.

WIC has a proven track record when it comes to promoting the health and development of pregnant, postpartum and breastfeeding people and young children. Participation in the program has been shown to improve pregnancy and birth outcomes, reduce the risk of infant mortality, increase breastfeeding rates, and cut the prevalence of childhood obesity, along with other positive results. WIC also can address disparities in nutrition security and maternal and child health outcomes for families with lower incomes and in communities of color.

The final revisions are a significant step in the administration's efforts to address nutrition security and health equity. The changes will provide new flexibilities that allow participants to choose food and beverages that meet their individual dietary needs, and personal and cultural preferences. The updated food package will build on the program's long history of success in advancing maternal and child health and ensure that all children get a healthy start in life."

Treating Gum Disease After Heart Ablation Reduced Risk Of AFib Recurrence

On April 10, the American Heart Association (AHA) announced the results of new research, which found treating gum disease within the 3-month period after an ablation procedure to correct atrial fibrillation, an irregular heartbeat, may reduce its recurrence—as well as lowering inflammation of the gums.

This study is among the first to investigate the potential impact of gum disease treatment on atrial fibrillation (AFib).

AFib is a condition in which the heart beats irregularly, increasing the risk of stroke by 5-fold. More than 12 million people in the U.S. are expected to have AFib by the year 2030, according to the AHA's 2024 Heart Disease & Stroke Statistics.

Periodontal or gum disease is currently estimated to be the case in some form, at an astounding 50% of American adults ages 30 or older (incidences increasing with age), according to the U.S. Centers for Disease Control & Prevention (CDC).

Shunsuke Miyauchi, M.D., Ph.D., Assistant Professor of Cardiology and Arrhythmia Practice & Research at the Health Service Center at Hiroshima University in Japan (and study author), explained: "Gum disease can be modified by dental intervention. Proper management of gum disease appears to improve the prognosis of AFib, and many people around the world could benefit from it."

Radiofrequency catheter ablation is a common non-surgical procedure utilized to help correct AFib. The radiofrequency energy destroys a small area of heart tissue that is causing the rapid and irregular heartbeats.

Researchers followed 97 patients who had undergone a radiofrequency catheter ablation and also received treatment for gum inflammation, along with an additional 191 ablation patients who did not receive gum disease treatment. The study found that an index measuring the severity of gum inflammation was associated with the return of patients' AFib.

After the ablation procedure, during the average follow-up period of between 8.5 months to 2 years, researchers found the following.

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- AFib recurred among 24% of all participants throughout the follow-up period.
- Patients with severe gum inflammation who had it treated after heart catheter ablation were 61% less likely to have a recurrence of AFib, compared to ablation patients who did not have treatment for severe gum inflammation.
- Patients who had recurrences of AFib had more severe gum disease than those who did not have recurrences.
- Having gum disease, being female, experiencing irregular heartbeat for more than two years, and left atrial volume were predictors for AFib recurrences (left atrial volume often leads to AFib recurrence as it includes thickening and scarring of connective tissues).

Dr. Miyauchi concluded: "While the main findings in the study were consistent with their expectations, we were surprised how useful a quantitative index of gum disease, known as periodontal inflamed surface area or PISA, could be in cardiovascular clinical practice. We are now working on further research to reveal the mechanism underlying the relationship between gum disease and AFib."

While the AHA does not recognize oral health as a risk factor for heart disease, it recognizes that oral health can be an indicator of overall health and well-being. Bacteria from inflamed teeth and gums may travel through the bloodstream to the rest of the body, including the heart and brain. Chronic gum inflammation may be associated with other systemic health conditions, including coronary artery disease, stroke, and Type 2 diabetes.

Adults With Congenital Heart Disease Faced Higher Risk Of Abnormal Heart Rhythms

On April 17, the American Heart Association (AHA) announced results from a 5-year study which revealed that almost 1 in 5 adults with congenital heart disease either had or developed an abnormal heart rhythm or arrhythmia.

The study of more than 11,000 adults living in Israel with congenital heart disease between 2007 and 2011 found that those who developed forms of abnormal heart rhythms had an increased risk for hospitalization and twice the risk of early death, as compared to study participants who did not have an irregular heart rhythm.

Nili Schamroth-Pravda, MBBCh, Cardiologist at the Rabin Medical Center in Petah Tikva, Israel (and lead study author), stated: "Our findings highlight the need for ongoing, lifelong, clinical follow-up for people with congenital heart disease. With the improvement of medical and surgical techniques, the number of patients with congenital heart disease reaching adulthood is increasing, as well as the number of complications associated with these heart conditions. Healthcare systems should be aware of the unfavorable effects of arrhythmias in this increasing population and the consequent increase in both primary care visits and hospitalizations."

The analysis found the following.

- Almost 20% of adults with congenital heart disease had irregular heart rhythms at the study's start or developed them over 5 years.
- Adults with congenital heart disease who developed a fast heart rate originating in the heart's upper chambers—atrial tachyarrhythmia—faced a 65% increased risk of dying earlier compared with those who did not have an irregular heartbeat.
- Those who developed a fast heart rate caused by rapid contracting of the heart's lower chambers (called ventricular tachyarrhythmia) faced a two-fold increase of dying earlier compared with those who did not have an irregular heartbeat.
- Patients who experienced abnormal heart rhythms (atrial arrythmia, ventricular arrythmia, or atrioventricular block—a slowed heartbeat) within the previous 6 months had up to a 33% higher rate of hospitalization compared to those without an abnormal heart rhythm.

The researchers noted that surgical scar tissue in the heart, even years after repairing a congenital heart defect, may increase the risk for abnormal heart rhythms later in life. Most study participants had a single heart defect and all had at least 1 documented congenital heart lesion or a specific congenital heart malformation repair procedure. Within the study, 30% of adults had an atrial septal defect, 26% had aortic valve disease, and 14% had a ventricular septal defect.

The challenge to clinicians is to achieve early detection and early management of arrhythmias that could pose life-threatening health risks. Learning more about the frequency of these different types of arrhythmias and how they progress among adults with congenital heart disease can help improve treatment for these patients and prevent complications and hospitalizations.

Dr. Schamroth-Pravda concluded: "The study suggests that the development of arrythmias is a critical point in the life of adult patients with congenital heart disease and this has a profound impact on the healthcare system providing care for these patients.

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Our study is from large, real-world data and gives insights into a population that is under-studied. Congenital heart disease can be varied with people having simple or complex heart lesions however, they all carry some risk of an abnormal heart rhythm in later life and should be assessed individually and monitored on a regular basis."

At least 18 distinct types of congenital heart defects—some are simple and some are complex—are recognized by the AHA. According to the "2024 Heart Disease & Stroke Statistics: A Report of U.S. & Global Data From the AHA," about 13.3 million people globally were living with congenital heart diseases in 2019. Occurrences increased by 28% between 1990 and 2019, driven largely by increases in the number of adolescents, younger adults, and middle-aged adults living with congenital heart diseases.

Engaging Pharmacists To Improve Atrial Fibrillation Care

On April 23, the American Heart Association (AHA) announced the launch of a new effort to educate and engage pharmacists to help ensure all patients with atrial fibrillation receive the most appropriate care.

Atrial fibrillation (AFib) is the most common type of irregular heartbeat, estimated to affect about 12.1 million U.S. adults by 2030. The abnormal firing of electrical impulses causes part of the heart to quiver, or fibrillate, often leading to complications and up to a five-fold increased risk of stroke.

Pharmacists are an important but underrepresented voice in AFib care. They are not often consulted in the decision-making conversations for AFib patients during the patient care journey. During this next phase of the initiative, the AHA will convene pharmacists in a roundtable event to identify gaps and opportunities related to AFib in this field. The AHA then will share resources and insights nationally across thousands of hospitals and outpatient clinics.

This new effort, being conducted through June 2025, is the latest phase of the Four F's of A Fibrillation Initiative from AHA and supported by the Bristol Myers Squibb-Pfizer Alliance. The Four F's represent AFib patients' health concerns that can impede their guideline-directed anticoagulant therapy, as listed below.

1) Fear of falling.
2) Fear of bleeding.
3) Forgetfulness, or cognitive dysfunction.
4) Frailty.

AFib is often only detectable during physical examination, although some affected people may experience fatigue, rapid and irregular heartbeat, or other discomfort. The use of anticoagulant therapy to reduce stroke risk is supported by science, but many patients remain untreated or undertreated.

Cody Parsons, APh, PharmD, BCCCP, Manager of Clinical Operations for Stanford Health Care's Cardiovascular Health Service Line in California, explained: "Pharmacists are an integral part of the multidisciplinary team to optimize care for individuals with atrial fibrillation. The insight of pharmacists in evaluating the medical complexity and use of multiple medications is essential in facilitating safe and effective anticoagulation and ultimately preventing life-altering medical consequences of AFib."

For more information, visit: https://heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-afib

Depression, Anxiety & Stress Linked To Poor Heart Health

On November 6, 2023, the American Heart Association (AHA) announced study results which found that mental health conditions including depression, anxiety, and stress increase the risks for poor heart health. Additionally from two other studies, researchers measured the extent of how much a person's mental state affects their heart health.

The heart and mind have been found to be strongly connected, with depression, anxiety, and chronic stress all increasing the risk for heart and brain health complications.

Glenn N. Levine, M.D., FAHA, Master Clinician & Professor of Medicine at Baylor College of Medicine and Chief of the Cardiology Section at the Michael E. DeBakey VA Medical Center of Houston, Texas, noted: "There are clear associations between psychological health and cardiovascular disease risk. These studies add to a growing body of data we have on how negative psychological health can increase the risk of heart and brain disease."

Study #1: Mechanism leading to increased risk of cardiac events. The first study examined the mechanism by which the mental state affects heart health. Researchers found that anxiety and depression sped the development of new cardiovascular disease risk factors.

Giovanni Civieri, M.D., Research Fellow at the Cardiovascular Imaging Research Center at Massachusetts General Hospital and Harvard Medical School, both in Boston (and lead study author), said: "While it is known that depression

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and anxiety increase the risk of cardiovascular disease, such as heart attack and stroke, the mechanism underlying this is not completely known. In our study, we identified a mechanism that appears to largely account for the link between these psychological factors and cardiovascular disease."

Dr. Civieri and colleagues studied data from adults enrolled in the Mass General Brigham Biobank with no previous heart events. The time required to develop a new cardiovascular risk factor(s) was measured over 10 years of follow-up.

Researchers found the following.

- 38% of all participants developed a new cardiovascular risk factor, such as high blood pressure, high cholesterol, or Type 2 diabetes during the follow-up.
- Participants previously diagnosed with anxiety or depression developed a new risk factor on average 6 months earlier than those who did not have depression or anxiety.
- Depression and anxiety increased the risk for a major cardiovascular event, such as a heart attack or stroke, by about 35%.
- About 40% of the link between depression and/or anxiety and major heart and stroke events were explained by the accelerated development of cardiovascular disease risk factors.
- People with a higher genetic predisposition to stress developed the first cardiovascular risk factor at a younger age (on average 1.5 years earlier than those without the genetic marker).

Dr. Civoeri explained: "Developing cardiovascular risk factors more than 6 months earlier, over an average of 5 years is a lot. The fact that genetic analysis supported the clinical findings was intriguing and provided further confidence in our results. Although we did not investigate this aspect, it is reasonable to assume that treating depression and anxiety may reduce the accelerated development of cardiovascular risk factors, I also encouraged people with depression or anxiety undergo more frequent screening of their cardiovascular risk factors such as high blood pressure, high cholesterol, and Type 2 diabetes."

Researchers suggest that depression and anxiety might induce brain changes that trigger downstream effects in the body, such as increased inflammation and fat deposition.

Dr. Levine added: "This study illustrates that healthcare professionals should be aware that negative psychological health—things like depression or anxiety—not only affect patient's mental state of being, but also can impact their physical health and the risk for heart disease. So, these are not benign conditions. These are things we want to aggressively refer people to mental health professionals."

The findings emphasize the importance of screening for cardiovascular risk factors among people with depression and anxiety.

Study #1 included the following background details.

- The analysis was conducted using data on 71,262 adults, (average age 49, 45% men) and data were collected from December 2010 to December 2020.
- 16% of the study group were taking medications for depression or anxiety; however, statistical adjustment for such medications did not significantly impact results.
- A genetic marker of stress sensitivity (called a polygenic risk score for neuroticism) was assessed for the subjects who provided their genetic data.

Study #2: Associations of cumulative perceived stress with cardiovascular risk factors and outcomes. In a second, unrelated study, researchers explored the effects of cumulative perceived stress on heart and brain health by examining responses to questionnaires completed by adults in the Dallas Heart Study who did not have existing cardiovascular disease.

Ijeoma Eleazu, M.D., Cardiology Fellow at the University of Texas Southwestern Medical Center in Dallas (and lead study author), stated: "This unique study explored the relationship between our new cumulative stress score and its subcomponents on cardiovascular risk factors as an attempt to understand

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this relationship further. To our knowledge, this is the first study to provide such a multidimensional analysis of the relationships between perceived stress and cardiovascular disease."

Study #2 data was evaluated from 2,685 adults who did not have existing cardiovascular disease and who participated in the Dallas Heart Study phase 2 over years 2007 to 2009, a multiethnic population-based group based in Dallas. The participants' average age was 48 years; 55% were women; 49% were Black adults; and 15% of participants were Hispanic/Latino adults. Participants were followed for an average of 12.4 years, and cardiovascular events and deaths were judged by a panel of cardiovascular specialists.

Over a one-month period, researchers integrated generalized everyday stress, psychosocial stress (stress prompted threats to psychological or social functioning), financial stress, and neighborhood perceived stress into a score termed the "cumulative stress score." This novel score associated strongly and significantly with the development of cardiovascular disease after adjustments were made for known cardiovascular disease risk factors such as high blood pressure, Type 2 diabetes, smoking, and high cholesterol, as well as adjustments for income and education.

Even after adjusting for these risk factors, researchers found that higher cumulative stress was associated with the following.

- 22% increased risk of atherosclerosis, in which plaque builds up in the arteries reducing adequate blood flow.
- 20% increased risk of overall cardiovascular disease including coronary artery disease and heart failure.
- Overall, higher among women, people aged 18 to 45, and individuals with lower income and education levels, as well as among individuals who self-identified as Black or Hispanic adults.

In addition, cumulative stress scores were higher among those who reported racial/ethnic discrimination and lack of health insurance; and higher scores were also associated with high blood pressure, being overweight, being physically inactive, and smoking.

Dr. Eleazu explained: "There are individual-level factors of perceived stress that comprised our psychosocial component of the score, as well as demographic factors that were represented in the financial stress score component, and even environmental factors that were represented in our neighborhood stress score component. These individual factors by themselves appeared to be less strongly correlated with cardiovascular outcomes than the multidimensional cumulative stress score. These findings suggest that we may not be capturing the impact of stress adequately when we only look at one factor or when we assess it broadly and/or subjectively. This is especially important among people in diverse or minoritized populations who may experience various types of and multiple stressors simultaneously."

The analysis also indicates that ongoing stress raised the risk of poor heart and brain health in two significant ways. First by directly influencing physical well-being, as well as increasing poor life-style behaviors such as smoking; and second by being sedentary, which in turn leads to reduced cardiovascular health.

Previous research has shown that chronic stress can lead to elevated levels of stress hormones like cortisol, which, in turn, can affect blood sugar levels, inflammation, and other biological chain reactions that impact the heart.

Dr. Levine concluded: "This novel concept of adding up and assessing someone's cumulative stress is great, because in some aspects of our life we may not experience much stress, but in other aspects of our life, say finances or health, we may have a lot. This study found that it is best to look at a person's overall cumulative stress and not just ask them about one aspect of their livelihood or life that could be affecting stress."

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Outstanding Buyer Nominee - Calethia "Cali" Shockley

What is the nominee's name, job title, facility name, and location? **Calethia "Cali" Shockley**, CPhT, Pharmacy Buyer, Deborah Heart & Lung Center (DHLC) in Browns Mills, New Jersey.

As a nominating third party, please provide your own name, title, facility, and relationship to the nominee. **Deb Sadowski**, RPh, MHA, Director of Pharmacy Services at DHLC. I am Cali's supervisor.

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

Is the nominee a current NPPA member, and will be current through August 2024? Yes, the nominee is a current NPPA member and will be through August 2024.

What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban, etc.) 89-bed; rural area, tertiary-care teaching hospital.

Approximately how many dollars per year of pharmaceutical-related expenditures does the nominee purchase or supervise the purchasing of at the nominee's facility? $4.9 million.

What is the average dollar amount of pharmacy inventory the nominee controls each year? $460,000.

What is the nominee's/Pharmacy Department's current Inventory "Turns"? 10.65.

How long has the nominee been a Pharmacy Buyer? Cali has been a Buyer for 4 years and 8 months.

What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise?

- All aspects of inventory management to help ensure that drug inventory meets the needs of day-to-day operations.
- Medication purchasing/preparation of purchase orders (POs).
- Requesting new products based on need.
- Entering drug products and barcodes into the formulary database.
- Delivering medications in ready-to-use format, including unit dosing as needed.
- Monitoring/communicating drug shortages.
- Contract compliance.
- 503B purchases/inventory.
- Drug Supply Chain Security Act (DSCSA) compliance.
- Annual physical inventory.
- Working as a Tech when needed.
- Attending weekly pharmacy meetings to address pharmacy needs or changes.
- Blocking inventory in our McKesson database which are not compliant with HIXPIX codes for billing.
- Staying current with glove testing requirements to fill in due to a shortage of Satellite tech needs.
- Monthly meetings with vendor reps.
- Working directly with our Specialty Pharmaceutical Distribution (SPD) to keep inventory in stock.

What may be unique or challenging about the nominee's facility? DHLC is an independent, stand-alone teaching hospital. It is a small facility, but delivers at the highest level of care in the state and to highly acute patients as a specialty center. We also do not balance-bill patients, which means our financial challenges can be more significant.

Additional Nominee Comments: Because we only have one Pharmacy Buyer at our hospital, I must always be there. This makes it very challenging in respect to taking time off, because although someone can cover my job to the best of their ability, this often leaves significant clean up when I return. Also, as we are a stand-alone hospital, when drug shortages arise we don't have another sister hospital or channel to call and borrow from.

List any accomplishments or projects the nominee instituted that have either saved money for their department/facility, or helped to make their job or the department/facility run more efficiently. Cali made several brand-to-generic switches when several high-cost drugs went off patent that resulted in over 50% reduction in cost for the previous year's spend, totaling over $400K. She also worked with our IT pharmacist on Level II Healthcare Common Procedure Coding System (HCPCS) code medications to ensure that only correct billable items can be ordered.

Additional Nominee Comments: When drug shortages occur I have been able to channel through them by keeping more stock on hand while balancing the need to do so, versus having too much. To help with shortages, I have recently made agreements with the pharmacy staff at surrounding hospitals so that when the need comes up, we can ask if they can help supply us with the available products in question.

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Outstanding Buyer, Shockley

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How has the nominee's job changed over the years? The role of Pharmacy Buyer has become increasingly more challenging, working with tighter budgets along with fewer resources. This includes the demands on Cali's time to assist in so many capacities in a smaller institution like ours, such as keeping certifications and compounding competencies current. We have also been undergoing expansion at the hospital for the last 18 months. As a result, Cali has been displaced and working out of a makeshift pharmacy area with inventory spread over multiple storage locations, adding to her workload.

What does the nominee like about their job? Cali enjoys the challenge and the opportunity to learn something new each day. She takes on any task asked of her and performs it at a high level.

What does the nominee dislike about their job? The makeshift pharmacy that Cali currently works in during our expansion, hopefully near completion, has been a challenge. Also, she is pulled in many different directions, sometimes to help cover staffing changes, while still performing her own tasks.

Additional Nominee Comments: Although my current office space remains a makeshift one, I have grown accustomed to it and made changes to make it feel more comfortable. I now have a window on one wall to keep the atmosphere bright. As to any dislikes about my job, I honestly don't have anything major in that regard. However, like any other job or setting, you come across many different people and personalities and may not get along with them all. Thus, you must always do your best to be professional and not allow someone to take you away from who you are and the job you're there to do. At the end of the day we are all working towards one primary goal of making sure our patients are getting the best care possible.

What advice would the nominee have for drug company vendor representatives? Be engaged and available, but not "pushy." Answer the questions asked and provide the information requested. Be a partner.

What specific challenges does the nominee face on the job? The salary at our site is less than our competitors due to our mission, but Cali remains because of that mission. With Cali being our only pharmacy buyer, others can only help her on a limited basis with the basic tasks she performs in that capacity. Then add our current space limitations with her duties and time constraints—that becomes a lot of responsibilities and hurdles to manage within 40 hours a week!

Additional Nominee Comments: That is correct. I began my work at this hospital as a technician and within a year's time had the opportunity to take over the Pharmacy Buyer position. This allowed me to learn a new aspect in pharmacy. This position is not only challenging every day, but I learn something new on a regular basis. Although the pay is less than my previous jobs, I love that at DHLC our mission is patient first regardless of payment or cost. This truly excites me to do the best job possible and to make sure drugs are available for all our patients. It is also great to have my supervisor, Deborah Sadowski, available as someone I can go to with challenges I can't resolve on my own. In other jobs I didn't always have the support I needed, but here and with Deborah, I certainly do.

How has the nominee's NPPA membership helped them in their job and/or personally? (Overall, or from information provided in NPPA's official member-publication Pharmacy Purchasing Outlook.) Last year we discovered NPPA and enrolled Cali as a member. She attended the 2023 NPPA Conference and was blown away by the support and networking opportunities in a community of colleagues doing just what she does. She came back with many connections and resources.

Additional Nominee Comments: I brought back information from the exhibiting vendors and related products that I was unaware of before attending NPPA's event. Some products we were able to utilize and switch to, which saved costs and time as related to not having to first compound the medication.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? If not, what prevented them from attending? Cali attended the NPPA Conference in 2023 and felt it was extremely beneficial. It's a great event to network and share ideas. She loved the opportunity to share and learn with others, and I believe she maintains many of those connections. It has been an asset to see how others may do something differently that could be applied or learn about new products, etc. to help our facility and departmental procedures and overall tasks. She especially enjoyed having the opportunity to meet with the vendors that specialize in servicing hospitals and medical centers.

Additional Nominee Comments: I was able to attend NPPA's conference last year for the first time and made new friends to network with, which is very beneficial as a Pharmacy Buyer. We continue to stay in touch across the country, even if just to say hello and ask how each other is doing. I cherish these new friendships and am grateful to have had the opportunity to connect with them at NPPA's event.

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Strength/Dosage & Carton Size

500 mg per vial

NDC Number

10 Digit	39822-0250-1
11 Digit	39822-0250-01

Wholesale Pick Numbers

Cencora	10283374
Cardinal	5870480
McKesson	2853141
Morris Dickson	310375

3 39822 02551 0

Strength/Dosage & Carton Size

1 gram per vial

NDC Number

10 Digit	39822-0255-1
11 Digit	39822-0255-01

Wholesale Pick Numbers

Cencora	10283406
Cardinal	5870464
McKesson	2853133
Morris Dickson	310391

3 39822 02601 2

Strength/Dosage & Carton Size

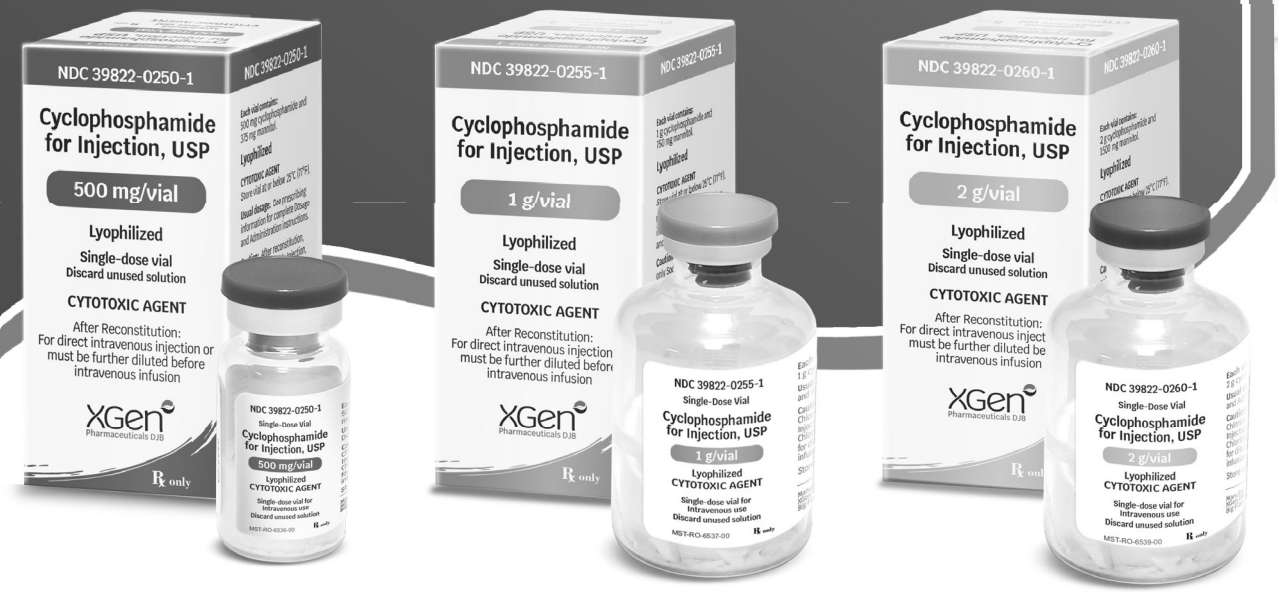
2 grams per vial

NDC Number

10 Digit	39822-0260-1
11 Digit	39822-0260-01

Wholesale Pick Numbers

Cencora	10283362
Cardinal	5870472
McKesson	2853125
Morris Dickson	310417



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New PREVENT™ Heart Disease Risk Calculator From AHA

On November 10, 2023, the American Heart Association (AHA) announced the development of a new risk calculator, which estimates a person's risk for cardiovascular disease over the next 30 years by combining measures of cardiovascular, kidney, and metabolic health for the first time.

The AHA's PREVENT™ (**P**redicting **R**isk of cardiovascular disease **EVENT**s) risk calculator estimates heart attack, stroke, and heart failure risk. The risk calculator helps incorporate cardiovascular-kidney-metabolic or CKM syndrome into cardiovascular disease prevention. CKM syndrome was first defined in an October 2023 Presidential advisory and scientific statement. The syndrome refers to the strong connections among cardiovascular disease, kidney disease, and metabolic disease (Type 2 diabetes and obesity).

According to the AHA's 2023 Statistical Update (www.heart.org/en/about-us/heart-and-stroke-association-statistics), 1 in 3 U.S. adults has 3 or more risk factors that contribute to cardiovascular disease, kidney disease, and/or metabolic disorders. As the underlying conditions of CKM syndrome worsen, the risk of heart attack, stroke, and/or heart failure increases.

Sadiya S. Khan, M.D., M.Sc., FAHA, Magerstadt Professor of Cardiovascular Epidemiology, Associate Professor of Medicine & Preventive Medicine at Northwestern University's Feinberg School of Medicine and Preventive Cardiologist at Northwestern Medicine in Chicago, Illinois, stated: "A new cardiovascular disease risk calculator was needed, particularly one that includes measures of CKM syndrome, which is highly prevalent in the United States. The new PREVENT risk calculator enables clinicians to quantify this risk and may help people receive preventive care or treatment earlier to reduce cardiovascular disease risk."

The PREVENT risk calculator uniquely quantifies risks for cardiovascular disease (CVD) for each biological sex. As more research has been conducted specifically in women, this is an important way to understand their unique differences in CVD presentation and risk factors. PREVENT does not include race in its calculation, acknowledging that race is a social factor and not a biological variable and, therefore, is not a valid factor for predicting CVD risk. There is an option in PREVENT to include social factors if available.

Dr. Khan added: "The last CVD risk calculator, the Pooled Cohort Equation, was released in 2013. However, new treatments are now available for CKM conditions such as obesity, Type 2 diabetes, and kidney disease. Estimating a person's risk for CVD related to these conditions with the new PREVENT risk calculator should prompt conversations between health professionals and patients to increase awareness of CKM health status and CVD risk, and to translate that awareness into actions that improve health and reduce risk. This includes health and lifestyle changes (routine physical activity, eating healthy foods) and possibly medications, if appropriate."

A risk calculator uses health, demographic, and/or socioeconomic information in equations to calculate a risk estimate or score. Equations are developed by scientists based on information in national databases, large research studies, and electronic health records.

The PREVENT equations were developed using data from more than 6 million adults in the U.S. from a variety of racial and ethnic, socioeconomic, and geographic backgrounds. Information from the health records of about half of those people was used to develop the calculator, then it was verified in the other half. Some data were collected from research studies, while other data were drawn from the electronic medical records of people seeking

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

Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any of them beyond being a member? I am unaware of Cali being a member of any professional organizations for Pharmacy Buyers other than NPPA. However, I know Cali was working with one of our drug reps to try organizing some activities/meetings for our area's Buyer-Techs.

List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, doing volunteer work, etc.

Cali recently spoke to students at a local high school regarding a career as a Pharmacy Technician/Buyer. Also as previously mentioned, Cali is working with a drug rep to organize some meetings for the Buyer-Techs in our area.

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PrecisionDose
Unit-Dose Medications

New Name
New Pack Size

Liquid Multivitamin/ Multimineral Supplement

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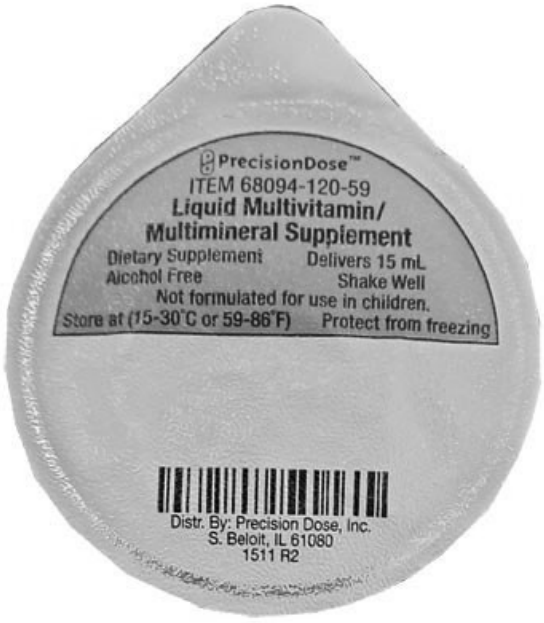

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Heart Disease Risk Calculator

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regular healthcare outside of a research setting. With this broad population, the calculator is more likely to accurately represent and be applicable to the general adult population in the United States.

PREVENT equations use screening tests already in use in primary care to predict risk. Blood pressure measurement; blood tests for cholesterol, blood sugar, and kidney function; and questions about tobacco use and whether people take medications for CVD risk factors are common in health assessments. This information can be entered in the PREVENT risk calculator, along with a person's age and sex, to determine estimated risk.

Key differences in the PREVENT calculator compared to the Pooled Cohort Equations include the following.

PREVENT is for adults as young as age 30 and estimates 10-year and 30-year risk of total cardiovascular disease. The Pooled Cohort Equations were designed to assess 10-year risk of heart attack and/or stroke for people ages 40 to 79. The new calculator can assess CVD risk in people from ages 30 to 79, and it can predict risk for heart attack, stroke, and/or heart failure over the next 10 years and 30 years.

Dr. Khan explained: "Longer-term estimates are important because short-term or 10-year risk in most young adults is still going to be low. We wanted to think more broadly and apply a life-course perspective. Providing information on 30-year risk may reveal earlier opportunities for intervention and prevention efforts in younger people."

PREVENT can also inform a person's CKM syndrome stage when risk is high to help guide further assessments and treatment recommendations. CKM syndrome ranges from Stage 0, or no risk factors and an entirely preventive focus, to Stage 4, the highest-risk stage, when cardiovascular disease is already present.

The PREVENT risk calculator includes measures of kidney function. Kidney function is important in cardiovascular health, and chronic kidney disease increases cardiovascular risks. The calculator includes estimated glomerular filtration rate and allows for the use of urine albumin excretion (which monitors kidney disease) to further individualize risk assessment and help inform personalized treatment options.

The PREVENT risk calculator includes a measure of metabolic health. The PREVENT equations allow the inclusion of hemoglobin A1C, a measure of blood sugar control, if necessary to monitor metabolic health. Abnormal blood sugar is associated with CVD risk in people with and without Type 2 diabetes.

Heart failure risk prediction is included. Heart failure is a serious condition in which the heart is not pumping well enough to keep up with the body's need for oxygen-rich blood. Heart failure is especially important in the context of CKM syndrome. Among people with obesity, Type 2 diabetes, and/or kidney disease, the risk for heart failure can be higher than the risk for heart attack or stroke.

Risk calculations are race-free. While there are clear racial and ethnic disparities in CVD risk factors and in the incidence of CVD among people based on the social construct of race and ethnicity, the statement writing committee concluded that race should not be included in the PREVENT calculator.

This decision is in line with a growing consensus in the scientific and medical community to remove race from algorithms in medical care to reduce the potential for race-specific treatment decisions.

Dr. Khan noted: "The Pooled Cohort Equations were developed with data from only White and Black adults and had separate equations for people of each race. There was not a risk model for individuals from other race and ethnicity groups, so we likely were not accurately estimating risk in many people. Part of the rationale for race-specific equations was that race was considered a proxy or substitute for the lived experience of racism and its potential health effects. However, we were concerned that the inclusion of race as a proxy may still be harmful."

The PREVENT calculator has similar accuracy among varied racial and ethnic groups. Also, the equations include the option to use the Social Deprivation Index, which incorporates measures of adverse social determinants of health such as education, poverty, unemployment, and various factors that are based on a person's environment.

Dr. Khan concluded: "The PREVENT equations are a critical first step toward including CKM health and social factors in risk prediction for CVD. Concerted research efforts are needed to determine the causal and social factors that underlie racial differences in CVD risks and outcomes. As we strive towards more equitable preventive care, we also acknowledge that racism, and not race, operates at multiple levels to increase risk for CVD."

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Outstanding Buyer Nominee - Miah Hayward

What is the nominee's name, job title, facility name, and location? **Miah Hayward**, CPhT, Pharmacy Purchaser, Yellow Belt in Refill-Too-Soon Lean Process, Active Immunization Certified, Point-of-Sale Billing Technician, Oklahoma City Indian Clinic Pharmacy (OKCIC), Oklahoma City, Oklahoma.

As a nominating third party, please provide your own name, title, facility, and relationship to the nominee. **Deborah Faucette**, PharmD, Billing/Contracting Pharmacist Manager Specialist at OKCIC. I am Miah's supervisor.

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

Is the nominee a current NPPA member, and will be current through August 2024? Yes, the nominee is a current NPPA member and will be through August 2024.

What is the number of beds at the nominee's facility, and what type of facility is it? (Teaching vs. community, rural vs. urban, etc.) We're an urban Indian Health Services Clinic I/T/U (Tribal Indian Services urban healthcare organization).

Approximately how many dollars per year of pharmaceutical-related expenditures does the nominee purchase or supervise the purchasing of at the nominee's facility? Approximately $5.94 million.

What is the average dollar amount of pharmacy inventory the nominee controls each year? Approximately $344,100.

What is the nominee's/Pharmacy Department's current Inventory "Turns"? 17.3.

How long has the nominee been a Pharmacy Buyer? Miah has been a Pharmacy Buyer for just over 1 year, by a couple of months.

What are the nominee's primary responsibilities as a Pharmacy Buyer and otherwise?

- Coordinate inventory levels of pharmaceuticals and related supplies.
- Maintain efficient systems for ordering, receiving, managing, and reconciling discrepancies in inventory.
- Identify cost savings and cost containment projects by maintaining a consistent drug cost recovery of more than 536% since April 2023.
- Assist Specialty Pharmacists with formulary management.
- Manage reverse distribution.
- Organize and maintain inventory stock shelves.
- Perform as a secondary Point-of-Sale Billing Technician.
- Participate in quarterly meetings offered by our primary wholesaler about upcoming Drug Supply Chain Security Act (DSCSA) requirements and inventory updates.

What may be unique or challenging about the nominee's facility? The OKCIC Pharmacy has a restrictive formulary, being a 501c(3) facility and Indian Health Services I/T/U service unit. Our pharmacy qualifies for Veterans Affairs (VA) Third-Party Reductions, so purchases are vetted for cost avoidance. Also, there's no automated inventory management system, so we use a manual inventory process.

List any accomplishments or projects the nominee instituted that have either saved money for their department/facility, or helped to make their job or the department/facility run more efficiently. In addition to being a Buyer, Miah is a fully trained Point-of-Sale Billing Technician. She worked payer rejections totaling reimbursements of $273,063.85 and consistently maintained a drug-cost recovery of more than 536% since April 2023, an increase of 122.6% from 2022.

How has the nominee's job changed over the years? Miah's position was new, requested to assist in inventory management and control. She was hired as our Buyer in April 2023, simultaneously mastering Point-of-Sale and learning inventory management. She has streamlined the ordering process and decreased time ordering from 3-4 vendors by 50%. She has been instrumental in reorganizing the stock shelves, implementing shelf dividers to create more inventory space, and relabeling stock shelves. This has led to decreased time of receipt and restocking by 25%.

What does the nominee like about their job? Miah enjoys the organization & planning that are involved with her position. She is very detail oriented so having a job based around that has allowed her to utilize her best qualities to their maximum potential.

What does the nominee dislike about their job? Being detail oriented, Miah's least favorite aspect about her job would have to be drug supply chain unpredictability. There is always a drug going out of stock and she never knows what or when this will occur. Although there is communication from vendors, this uncertainty is frustrating.

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Outstanding Buyer, Hayward

Continued from Page 50

What advice would the nominee have for drug company vendor representatives? Communicate changes that will impact the ordering/delivery process in a timely manner.

What specific challenges does the nominee face on the job? Backorders, shortages, damaged products, and lack of storage due to the significant pharmacy growth in volume and personnel. No automated inventory management system. All drug data, National Drug Codes (NDCs), acquisition costs, par levels and vendors are tracked on a spreadsheet for ease of data manipulation.

How has the nominee's NPPA membership helped them in their job and/or personally? (Overall, or from information provided in NPPA's official member-publication Pharmacy Purchasing Outlook.) Being an NPPA member has assisted Miah in updates with the supply chain and further new developments within pharmacy purchasing and procurement. Being a new position, NPPA membership came at the most opportune time. It has been educational by providing access to the experts in this field & learning from their experiences. Membership has also been instrumental in the success of OKCIC's pharmacy inventory management.

Has the nominee ever attended an NPPA Conference? If so, how did that help in their job after the event? If not, what prevented them from attending? Miah attended her first NPPA Conference in August 2023. She found the networking opportunities have been extremely beneficial with both vendors & other buyers. She also gained a wealth of practical knowledge from other buyers' experiences and lessons learned.

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

Does the nominee belong to any other professional organizations besides NPPA? If so, are they involved with any of them beyond being a member? None at this time.

List any other qualifications the nominee may have for this award, such as being recognized by their facility, having an article published, organizing buyer meetings, public speaking, doing volunteer work, etc.

- Elder Health Fair volunteer.
- Woman's Health Fair Committee member, building a 20-person team of volunteers for the event.
- Organized 666 pharmacy items donated to the OKCIC Bank of America Native Resource & Nutrition Center.
- Coordinated a 21-technician team meeting, compiled ideas for improvement, and implemented suggestions.
- Volunteered to vaccinate employees during the September 2023 Employee Flu Vaccine event.
- Received a People First Core-4 Award and two Core-4 Awards for Quality.

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Stroke-Related News

Young Adults With Migraine & Other Nontraditional Factors May Have Higher Stroke Risk

On March 26, the American Heart Association (AHA) of Dallas, Texas announced the results from a new research study that found adults younger than 35- to 45-years old may have a higher risk of developing a stroke from nontraditional risk factors such as migraines, than from traditional risks like high blood pressure.

Most strokes are caused by traditional stroke risk factors, such as high blood pressure, high cholesterol, Type 2 diabetes, smoking, obesity, low physical activity, alcohol abuse, or coronary heart disease. However, the study data showed an increased incidence of strokes even among young adults without these risk factors.

Michelle Leppert, M.D., M.S., M.B.A., FAHA, Assistant Professor of Neurology at the University of Colorado School of Medicine in Aurora (and lead study author), said: "We wanted to understand which risk factors were the top contributors to stroke risk among young adults."

Researchers collected data from years 2012 to 2019 from the state of Colorado's "all payer claims" database, which mandates the submission of all commercial insurance and Medicare or Medicaid claims. They matched data of more than 2,600 people who had strokes and compared them with over 7,800 people who did not, in order to determine which risk factors may most often lead to strokes.

Among the study's stroke cases selected from adults 18- to 55-years old, 52% were among women and more than 73% were ischemic (clot-caused) strokes, which occur when a vessel supplying blood to the brain is obstructed. Cases were defined as someone admitted to a hospital with a primary diagnosis of ischemic stroke, hemorrhagic (bleeding) stroke, or subarachnoid hemorrhage (bleeding in the space surrounding the brain). Nontraditional stroke risk factors were defined as factors that are rarely the cause of stroke in older adults or unique to young adults and included: migraines, malignancy, HIV, hepatitis, thrombophilia (including history of deep vein thrombosis and pulmonary embolism), autoimmune disease, vasculitis, sickle cell disease, heart valve disease, and renal failure. Hormonal risk factors, such as oral contraceptive use and pregnancy, were considered separately among women. Traditional stroke risk factors were defined as well-established potential causes for stroke routinely considered for adults ages 65 and older and included: high blood pressure, Type 2 diabetes, high cholesterol, sleep apnea, peripheral artery disease, atrial fibrillation, coronary artery disease, alcohol abuse, substance abuse, tobacco use, obesity, and congestive heart failure.

The analysis found that nontraditional stroke risk factors such as migraines, blood clotting disorders, kidney failure, autoimmune diseases, or malignancy were significantly associated with the development of strokes in men and women 18- to 44-years old. The association between stroke and nontraditional stroke risk factors was stronger in adults younger than 35-years old.

Additional results are detailed below.

- Among 18- to 34-year-olds, more strokes were associated with nontraditional risk factors (31% in men and about 43% in women) than traditional risk factors (about 25% in men and more than 33% in women).
- Migraine was the most important nontraditional stroke risk factor among 18- to 34-year-olds, accounting for 20% of strokes in men and nearly 35% in women.
- The contribution of traditional stroke risk factors peaked among adults aged 35 to 44 and were associated with nearly 33% of strokes in men and about 40% in women.
- In the 45 to 55 age group, nontraditional risk factors accounted for more than 19% of strokes in men and nearly 28% in women.
- High blood pressure was the most important traditional stroke risk factor among 45- to 55-year-olds, accounting for 28% of strokes in men and about 27% in women.
- Each additional traditional and nontraditional risk factor was associated with increased risk of stroke in all sex and age groups.

Dr. Leppert concluded: "These findings are significant because most of our attention has been focused on traditional risk factors. We should not ignore nontraditional stroke risk factors and only focus on traditional risk factors; both are important to the development of strokes among young people. In fact, the younger they are at the time of stroke, the more likely their stroke is due to a nontraditional risk factor.

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Stroke-Related News

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We need to better understand the underlying mechanisms of these nontraditional risk factors to develop targeted interventions. There have been many studies demonstrating the association between migraines and strokes, but to our knowledge, this study may be the first to demonstrate just how much stroke risk may be attributable to migraines."

Researchers were surprised to find that non-traditional risk factors were equally important as traditional risk factors in the development of strokes in young men and women. The contribution that migraine headaches had in the development of strokes was also unexpected.

Continuous Exposure To Bright Artificial Light At Night Linked To Higher Stroke Risk

On March 25, the American Heart Association (AHA) announced the results of newly published research, which indicates people continuously exposed to bright, artificial light at night may be at increased risk of developing conditions that affect blood flow to the brain and having a stroke.

Bright, outdoor lights are used at night to enhance the visibility of the environment, improving human safety, and comfort. However, the excessive use of artificial light has resulted in about 80% of the world's population living in light-polluted environments, according to the study's authors.

While previous studies have linked increased exposure to bright, artificial light at night to the development of cardiovascular disease, this is one of the first studies to explore the relationship between exposure to light pollution at night and the potential risk to brain health and stroke.

Jian-Bing Wang, Ph.D., Researcher in the Department of Public Health & Department of Endocrinology at the Children's Hospital of Zhejiang University School of Medicine and the National Clinical Research Center for Children's Health in Hangzhou, China (and study author), said: "Despite significant advances in reducing traditional cardiovascular risk factors such as smoking, obesity, and Type 2 diabetes, it is important to consider environmental factors in our efforts to decrease the global burden of cardiovascular disease."

In a review of 28,302 adults living in China, exposure to residential outdoor nighttime light was assessed by satellite images that mapped light pollution. Cases of stroke were confirmed by hospital medical records and death certificates.

The data analysis (including 6 years of follow-up with participants) revealed the following.

- 1,278 people developed cerebrovascular disease, including 777 ischemic (clot-caused) stroke cases and 133 hemorrhagic (bleeding) stroke cases.
- People with the highest levels of exposure to outdoor light at night had a 43% increased risk of developing cerebrovascular disease compared to those with the lowest levels of exposure.
- People with the highest levels of exposure to particulate matter ($PM_{2.5}$ that is primarily emissions from combustion of gasoline, oil, diesel fuel, or wood) had a 41% increased risk of developing cerebrovascular disease when compared to participants with the lowest levels of $PM_{2.5}$ exposure.
- Participants with highest levels of exposure to PM_{10} (dust and smoke) had a 50% increased risk of developing cerebrovascular disease compared to those with the lowest PM_{10} exposure.
- Participants with the highest exposure to nitrogen oxide (emissions from cars, trucks and buses, power plants, and off-road equipment) had a 31% higher risk of developing cerebrovascular disease compared to those with the lowest exposure.

Of note, an additional analysis that included both outdoor light at night and pollution found that the associations with increased risk of cerebrovascular disease persisted, except for ischemic stroke.

Dr. Wang noted: "Our study suggests that higher levels of exposure to outdoor artificial light at night may be a risk factor for cerebrovascular disease. Therefore, we advise people, especially those living in urban areas, to consider reducing that exposure to protect themselves from its potential harmful impact."

Artificial sources of light include fluorescent, incandescent, and LED light sources. Continuous exposure to these light sources at night can suppress melatonin production, a hormone that promotes sleep. This can disrupt the 24-hour internal clock in people and impair sleep. People with poor sleep, compared to good sleepers, are more likely to experience worse cardiovascular health over time, according to the study. The AHA's Life's Essential 8 includes healthy sleep as 1 of the 8 healthy lifestyle behaviors and health measures that drive optimal cardiovascular health.

Dr. Wang added: "We need to develop more effective policies and prevention strategies to reduce the burden of disease from environmental factors such as light as well as air pollution, particularly for people living in the most densely populated, polluted areas around the world."

Study background and details are as follows.

- The analysis was conducted from 2015 to 2021 and included adults without cardiovascular disease who lived in Ningbo, a major port and industrial city on China's east

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Stroke-Related News

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coast, with a population of more than 8.2 million people according to the 2020 Chinese national census.

- The average age of study participants was 62 years and about 60% were women.
- Participants were enrolled from 2015 to 2018 and followed for up to 6 years for cerebrovascular disease, ischemic stroke, and hemorrhagic stroke.
- People with unavailable addresses or error records, missing covariate data (data not included in the original study that might alter outcomes), extreme levels of exposure to outdoor light at night, previously diagnosed with cerebrovascular disease at enrollment and within 1 year after enrollment were excluded from the analysis.

Nearby Fitness Spaces Linked To Higher Physical Activity Levels After Stroke

On February 1, the American Heart Association (AHA) announced recent study data results which found that stroke survivors were more likely to remain physical activity or even exercise more after their stroke if they lived in neighborhoods with easy access to recreational centers and gyms.

Jeffrey Wing, Ph.D., M.P.H., Assistant Professor of Epidemiology at The Ohio State University in Columbus (and lead study author), said: "We know that stroke survivors need to be physically active as part of their recovery. Our findings suggest that it's important to have a conversation with stroke patients about physical activity resources available in their area so they are able to continue their recovery after hospital discharge. If their neighborhood does not offer fitness resources, neurologists should consider discharging the patient to a rehabilitation facility where they can participate in physical activities."

In this study, researchers examined the potential link between available fitness/exercise centers, pools and gyms, and physical activity among 333 people living in New York City who had a mild stroke. The data was geocoded, assigned to the U.S. census tracts, and merged with data from the National Neighborhood Data Archive (which collects information about the number of physical activity resources at the census tract level). Geocoding is the process of transforming a description of a location (such as an address or a name of a place) to a location on the earth's surface.

Researchers then examined the association between the number of fitness and recreational centers, such as pools, gyms, and skating rinks per square mile, and the self-reported change in physical activity levels (more active, about the same, or less active), one year after stroke.

The analysis found the following.

- About 17% of participants reported being more physically active one year after stroke, and 48% reported having about the same level of physical activity as before the stroke.
- The odds of being more active were 57% higher among participants who lived in areas with more recreational and fitness resources (about 58 fitness resources) compared to people living in neighborhoods with fewer or no fitness resources, after controlling for age, gender, race, ethnicity, education, health insurance, and body mass index.
- Similarly, the odds of reporting the same level of physical activity one year after stroke were 47% higher in participants who lived in areas with more recreational centers and fitness resources compared to those who lived in areas with fewer or no resources available.

Dr. Wing stated: "Previous research has shown that even moderate physical activity is beneficial for stroke recovery and can include walking. However, it's important to recognize the availability or limited availability of exercise resources in a person's immediate neighborhood and to be able to feel safe while participating in exercise activities."

Daniel T. Lackland, Dr.P.H., FAHA, Stroke Council member and Professor of Epidemiology and Director of the Division of Translational Neurosciences & Population Studies in the Department of Neurology at the Medical University of South Carolina in Charleston, noted: "This study is consistent with prior research on the importance of physical activity for optimal health. The new aspect is the focus on stroke survivors. It's important for healthcare professionals to discuss maintaining physical activity with stroke survivors: find out if they know of a safe place to exercise, and if they do not, have that information readily available."

The study included 333 adults hospitalized for mild stroke and enrolled in the Discharge Educational Strategies for Reduction of Vascular Events (DESERVE) study. The study was a randomized clinical trial of 546 stroke survivors, conducted in New York City from years 2012 to 2016. Participants were 52% women with an average age of 65 years. They self-identified as 35% Hispanic adults, 31% Black adults, 28% White adults, and 6% as "other" race.

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Stroke-Related News

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2 Common Types Of Antidepressants Were Safe For Most Stroke Survivors

On February 1, the American Heart Association (AHA) announced results from a research study showing that most stroke survivors were able to safely take two types of common antidepressants.

Among people with ischemic (clot-caused) stroke, those who began taking an antidepressant known as an SSRI (selective serotonin reuptake inhibitor) and/or an SNRI (serotonin and norepinephrine reuptake inhibitor) for the common conditions of post-stroke depression and anxiety, did not have an increased risk of hemorrhagic (bleeds) stroke or other serious bleeding. This included people taking anticoagulation medications.

There was, however, an increased risk of hemorrhagic stroke among stroke patients taking two anti-platelet medications, also called dual anti-platelet therapy (DAPT).

Kent P. Simmonds, D.O., Ph.D., third-year Physical Medicine & Rehabilitation Resident at the University of Texas Southwestern Medical Center in Dallas (and study lead author), stated: "Mental health conditions, such as depression and anxiety, are very common yet treatable conditions that may develop after a stroke. Our results should reassure clinicians that for most stroke survivors, it is safe to prescribe SSRI and/or SNRI antidepressants early after stroke to treat post-stroke depression and anxiety, which may help optimize their patients' recovery. However, caution is needed when considering the risk-benefit profile for stroke patients receiving dual antiplatelet therapy because we did find an increased risk of bleeding among this group."

According to the AHA's Heart Disease & Stroke Statistics 2024 Update, when considered separately from other cardiovascular diseases, stroke ranks fifth among all causes of death, behind diseases of the heart, cancer, COVID-19, and unintentional injuries/accidents. Approximately one-third of stroke survivors develop post-stroke depression. If left untreated, depression may affect quality of life and reduce the chances for optimal poststroke recovery such as returning to their usual daily living activities without assistance.

The most common classes of antidepressants are SSRIs or SNRIs, and they are widely used and effective for treating anxiety and depression. However, they may not be prescribed at all or early enough after a stroke, when the risk of depression or anxiety is particularly high, due to concerns that they may increase the risk of a hemorrhagic stroke or other serious types of bleeding.

Researchers looked at the frequency of serious bleeding among hundreds of thousands of stroke survivors who took different types of SSRI and/or SNRI antidepressants (such as sertraline, fluoxetine, citalopram, or venlalfaxine). Serious bleeding was defined as bleeding in the brain, digestive tract; and shock, which occurs when bleeding prevents blood from reaching the body's tissues.

Researchers also investigated serious bleeding among stroke survivors who took antidepressants combined with different types of blood-thinning medications that are used to prevent future blood clots. These blood-thinning medications may include either anticoagulants or antiplatelet medications. Anticoagulants include medications such as warfarin, apixaban, and rivaroxaban. Antiplatelet medications may be prescribed as either a single medication (commonly aspirin) or two types of antiplatelet medications can be used in dual antiplatelet therapy. DAPT includes aspirin plus another antiplatelet medication called a $P2Y_{12}$ inhibitor (such as clopidogrel, prasugrel, or ticagrelor).

Following are the study findings.

- SSRI and SNRIs were generally safe to start during the important early stages of recovery, as patients taking those medications were not more likely to develop serious bleeding when compared to stroke survivors who did not take an antidepressant. This included ischemic stroke patients who are also taking anti-coagulation therapy.
- An increased risk of serious bleeding occurred when SSRIs or SNRIs were taken in combination with DAPT treatments (aspirin and blood thinners). However, the overall risk remained low as serious bleeding events were rare.
- Among ischemic stroke patients on antidepressant medications, there was a 15% increase in the risk of serious bleeding when taking medications from classes such as mirtazapine, bupropion, and tricyclics compared to SSRI/SNRIs.

Dr. Simmonds noted: "Maximizing rehabilitation early after a stroke is essential because recovery is somewhat time-dependent, and most functional gains occur during the first few months after a stroke. Fortunately, dual antiplatelet therapy is often administered for 14, 30, or 90 days, so, when indicated, clinicians may not need to withhold antidepressant medications for prolonged periods of time. Future research should investigate the risk of bleeding associated with the use of anti-depressant and anxiety medications among patients with hemorrhagic or bleeding stroke."

Crystal Wiley Cené, M.D., M.P.H., FAHA, Professor of Clinical Medicine and Chief Administrative Officer for Health Equity, Diversity & Inclusion at the University of California San Diego Health (and Chair of the Writing Group

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Stroke-Related News

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for the AHA's scientific statement), explained: "According to a 2022 AHA scientific statement, social isolation and loneliness are associated with about a 30% increased risk of heart attack or stroke, or death from either. Depression may lead to social isolation, and social isolation may increase the likelihood of experiencing depression. The current study helps answer safety issues around the use of antidepressants for treatment of mental health issues that may develop after a stroke."

Patients in the study were treated at 70 healthcare centers over a span of 20 years, from 2003 through 2023. They were identified from electronic medical records data of 666,150 ischemic stroke patients from over 70 large U.S. healthcare centers. 35,631 were taking SSRI/SNRI antidepressant medication, 23,241 were taking other antidepressants, however most (607,278) were not taking any antidepressant.

Stroke Alone Or With Neck Artery Tear Almost Doubles Risk Of Heart Attack Within 1 Year

On February 1, the American Heart Association (AHA) announced results from new research, which found heart attack risk almost doubles in the first year after a stroke or when combined with a tear in a neck artery wall, however, a tear without a stroke does not seem to raise heart attack risk.

Aortic dissection is a tear in the wall of the aorta, the large artery that receives blood directly from the heart and is known to increase heart attack risk. Tears in the walls of the carotid or vertebral arteries, which extend out from the aorta and carry blood through the neck to the brain, are called carotid or vertebral artery dissections. These dissections can result in stroke, and stroke is known to be associated with heart attack. It was unclear whether carotid or vertebral artery dissection itself increases heart attack risk prior to this study.

The researchers analyzed health information for more than 800,000 adults (average age of 63 years; 62% women) hospitalized in New York (between 2011 and 2017), or Florida (between 2011 and 2019). The patients with no history of recent major head or neck trauma were separated into four groups based on diagnoses: 1) acute ischemic stroke; 2) cervical artery dissection; 3) both; or 4) a reference group of patients with transient ischemic attack (TIA) known as a "warning stroke," temporary loss of short-term memory (transient global amnesia), or migraine.

Excluded were any participants with a recent history of major head or neck trauma, since those may lead to traumatic carotid dissection, which is different from this study's focus on spontaneous dissection. The analysis controlled for several heart attack risk factors, including age, Type 1 or Type 2 diabetes, heart failure, coronary artery disease, high cholesterol, and high blood pressure. Almost 20,000 of the participants experienced a heart attack within one year of their initial hospitalization, and the risk of heart attack was compared among the diagnostic groups. Among the study group of 823,634 participants, 65.4% were White, 16.2% were Black or African American, and 12.2% were Hispanic or Latino adults.

After adjusting for heart attack risk factors, the study revealed the following.

- Patients who had carotid or vertebral artery dissection without stroke had the same risk of having a heart attack within a year as those in the reference group.
- Patients with stroke, either with or without carotid or vertebral artery dissection, were almost twice as likely to have a heart attack within a year, in comparison to patients in the reference group.

Liqi Shu, M.D., Clinical Fellow in Neurology at the Warren Alpert Medical School of Brown University in Providence, Rhode Island, explained: "Our findings may aid physicians in assessing and managing cardiovascular risk after these events. Before, it was just a guess, but now we know that carotid or vertebral artery dissection not causing a stroke does not raise the risk of a heart attack, and it makes sense that clinicians should focus predominantly on stroke prevention in this subgroup of patients."

While this study is based on hospitalization data only in New York and Florida, it's important to note that these states collectively represent a substantial portion of the U.S. population, accounting for over 10% of the total. These two states also provide a good representation of diverse demographic groups, adding strength to the findings. However, caution should still be exercised when generalizing these results to people living in other geographic areas.

Stroke-Like Symptoms May Be More Traumatic Than An Actual Stroke

On February 1, the American Heart Association (AHA) announced details from a new study, which found that people with so-called "stroke mimics" may be even more likely to develop post-traumatic stress disorder (PTSD) than those with a confirmed stroke.

Stroke mimics are conditions with symptoms that mirror those of stroke, including numbness, weakness, difficulty speaking, vision changes, headache, dizziness, or unsteady gait.

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Melinda Chang, M.S., ANP-BC, Research Nurse at the Center for Behavioral Cardiovascular Health at Columbia University Irving Medical Center in New York City (and lead study author), stated: "Stroke mimics matter. As clinicians, we may be quick to dismiss a patient's less life-threatening diagnosis, such as migraine or vertigo. However, these patients may experience significant psychological distress, which can increase their risk for poorer cardiovascular health. Knowing that being evaluated for stroke in an emergency department can itself be a traumatic experience for many people may help healthcare professionals recognize PTSD symptoms and connect patients quickly to the appropriate resources."

This research was part of the ReACH (Reactions to Acute Care & Hospitalization) Stroke study, which evaluated the impact of PTSD on cardiovascular risk in survivors of stroke and transient ischemic attack. It was funded by the National Heart, Lung & Blood Institute and conducted at Columbia University Irving Medical Center in New York state between June 2016 and March 2022.

Researchers analyzed health data for 1,000 adults (average age of 62 years; 51% female) who received care in a hospital's emergency department for suspected stroke. About 60% were confirmed to have had a stroke, 8% had a transient ischemic attack (TIA, sometimes called a warning stroke), and 27% experienced a stroke mimic. Health information was unclear or missing for the remaining 5% of participants.

During hospitalization, the patients completed the PTSD Checklist for DSM-5, a standard screening tool to identify PTSD symptoms in the past month. Without knowledge of patients' scores, a neurologist reviewed their medical charts to provide a medical diagnosis such as clot-caused stroke or bleeding stroke, TIA, or stroke mimic. The checklist was repeated about one month after discharge to determine if patients had developed probable PTSD.

The most common stroke mimics noted were migraine and other headaches, peripheral or cranial neuropathy (weakness, numbness or pain caused by nerve damage), and peripheral vertigo (dizziness and a spinning sensation caused by factors outside of the brain).

Research findings are detailed below.

- After adjusting for several factors, including age, gender, ethnicity, severity of stroke-like symptoms, previous PTSD, and degree of disability when discharged from the hospital, the risk of PTSD one month after discharge was 3 times as high in people with stroke mimics compared to those with confirmed stroke.
- Specifically, elevated PTSD symptoms were found in 15% of people diagnosed with stroke mimics; in contrast, PTSD symptoms were found in only 6% of those diagnosed with stroke and 5.5% of those with TIA.
- People who had PTSD prior to hospitalization had 10 times the risk of also having elevated PTSD symptoms one month after discharge.

Dr. Chang explained: "Stroke specialists typically view stroke mimics as less serious than a confirmed stroke, so we did not expect patients with stroke mimics to be at higher risk for having PTSD at one-month follow-up. However, the neurologists on our team have noted that patients with stroke mimics can suffer significant distress from their stroke-like conditions, so our findings support these clinical experiences. It is important for people who are evaluated for stroke to know they are not alone if they experience flashbacks, disrupted sleep, or feel on edge after their medical event. They should feel comfortable and empowered to report any concerning symptoms to their healthcare team so they can get the help they need."

According to the researchers, further study is needed to explore the possible contributors to the higher risk of PTSD in people with stroke mimics, including the stroke evaluation or hospitalization itself, a lack of certainty about their diagnosis, or the lack of a standardized treatment for those with their diagnosis.

Amytis Towfighi, M.D., FAHA, Director of Neurological Services for Los Angeles County (LAC) Department of Health Services, Chief of Neurology at LAC+University of Southern California Medical Center and a volunteer expert for the American Stroke Association, noted: "I think most clinicians assume that patients would be relieved to know they did not have a stroke. This study illuminates the psychological impact of a stroke mimic or TIA. There are numerous possible explanations for PTSD experienced

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after a stroke mimic or TIA. One explanation could be that after a stroke, patients receive education about what happened and what to expect and receive more services and support; however, less education is provided after a stroke mimic or TIA. This may lead to fear of the unknown and possible dread of a future event. We should study this phenomenon in more detail to determine how to design effective interventions to support our patients."

Nerve Stimulation Plus Intense Rehab May Improve Arm & Hand Function After Stroke

On February 1, the American Heart Association (AHA) announced results from a new study, which found that combining brain stimulation with intense physical rehabilitation helped stroke survivors recover movement in their arms and hands—plus maintain these improvements for one year.

Teresa J. Kimberley, Ph.D., Professor of Rehabilitation Science & Physical Therapy at Mass General Brigham (MGH) Institute of Health Professions in Boston, Massachusetts (and lead study author), explained: "The recovery of arm and hand function after a stroke often stalls or even declines, leaving many patients with chronic motor deficits that limit their independence and quality of life. New treatments that can boost the benefits of physical rehabilitation are desperately needed."

Vagus nerve stimulation is the first approved neuromodulation device to aid in chronic stroke recovery. It was approved by the FDA in 2021 to treat moderate to severe upper extremity motor function deficits (physical movement and coordination of arms and hands) associated with chronic stroke.

Dr. Kimberley noted: "This is the first time that brain stimulation combined with rehabilitation therapy for stroke is available outside of a clinical trial. It could set the stage for even more advancements in recovery from other impairments beyond the arm. This is a watershed moment for rehabilitation science."

This study represents one-year outcomes of people who had a stroke resulting in moderate to severe upper extremity impairment.

Two groups of participants (108 total people)—a control group and an experimental group—completed 6 weeks of in-clinic, intense rehabilitation paired with active or sham vagus nerve stimulation. All participants were implanted with the nerve stimulation device and then randomized to receive either real nerve stimulation or a sham stimulation that only turned on for a few pulses. The in-clinic therapy was followed by a 3-month home exercise program for both groups. The active vagus nerve stimulation group continued the home exercise program for a year. After the 6-week period of sham stimulation, the control group crossed over and received 6 weeks of active vagus nerve stimulation followed by a year of the home exercise program.

Before and after the stimulation and rehabilitation therapies, motor function was assessed with the Fugl-Meyer Assessment-Upper Extremity, which assesses motor impairment, and the Wolf Motor Function Test, which is a time-based method to evaluate upper extremity motor ability while providing a better understanding of joint-specific and total limb movements.

Final study results represent outcomes for arm and hand function in 74 stroke survivors after 1 year of physical rehabilitation treatment. Data was unavailable for the remaining 34 participants mainly due to the COVID-19 pandemic.

Study findings were as follows.

- At one-year, upper limb function improved by 5.3 points in the Fugl-Meyer Assessment-Upper Extremity and by 0.51 points in the Wolf Motor Function Test when compared to baseline.
- Vagus nerve stimulation therapy improved hand and arm function by 2 to 3 times more than intense rehabilitation alone.

Dr. Kimberley noted: "The pairing of rehabilitation therapy with vagus nerve stimulation likely helps the brain strengthen new neural pathways, like building a bridge to bypass a damaged area. These long-term, pivotal results mirror our long-term results from an earlier pilot study where we found that patients continue to improve or maintain their gains up to 3 years after starting vagus nerve stimulation therapy paired with rehabilitation. As a clinician, it is surprising to see someone with chronic stroke–one that in many ways is a progressive disease, continue to improve and not show a decline. Often after a stroke, people don't seek additional treatment, thinking that their current impairments are permanent. This is not true! Paired vagus nerve stimulation opens a new avenue and new hope for these patients. I'm also excited about future research that will investigate vagus nerve stimulation paired with rehabilitation for other conditions, such as gait and speech impairments after stroke."

Study details and background were as follows.

- The vagus nerve stimulation device in this study included a pacemaker connected to a lead that wraps around the vagus nerve in the neck region. There's one vagus nerve on each side of the body; each one runs from the lower part of the brain through the neck to the chest and stomach.
- The trial participants were between the ages of 22 to 80 and had a stroke 9 months to 10 years prior to study enrollment.

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- Study participants in the experimental group were 64% male and 36% female; 79% White, 17% African American, 2% Asian, Indian or other, and 1% did not have any race reported. The control group was 65% male and 35% female; 78% White, 16% African American, 7% Asian, Indian or other, and 1% did not have any race reported.
- The study took 5 years to complete: 2017 to 2019 for enrollment, and the study ended in 2021.
- The study was triple-blinded, meaning neither the participants, the researchers testing participants, nor the healthcare professionals treating participants knew which intervention group participants were in.

Joel Stein, M.D., FAHA, Simon Baruch Professor & Chair of the Department of Rehabilitation & Regenerative Medicine at Columbia University's Vagelos College of Physicians & Surgeons, Professor & Chair of the Department of Rehabilitation Medicine at Weill Cornell Medicine, and Psychiatrist-In-Chief at New York-Presbyterian Hospital, all in New York City, remarked: "These are encouraging findings. These results demonstrate the durability of the effects of vagus nerve stimulation, an important finding that supports the use of this modality to enhance recovery post-stroke. There is some evidence for lasting improvement with continued use outside of a formal exercise program, which is intriguing, although further research is needed to confirm this finding and clarify who is likely to experience ongoing improvements."

Where You Live May Be Associated With More Successful Stroke Recovery

On February 1, the American Heart Association (AHA) announced results of a recent study that revealed stroke survivors living in areas with poor economic conditions were twice as likely to have a poor recovery compared to survivors living in areas with better conditions.

Leah Kleinberg, B.A., Postgraduate Clinical Research Associate in the Falcone Lab in the Department of Neurology at Yale School of Medicine in New Haven, Connecticut, said: "This research was inspired by the people I work with daily. Although stroke patients from differing socioeconomic backgrounds often have similar functional status at discharge, outcomes can vary dramatically a year later. As a clinical research associate, I get to interact with them far beyond the completion of their urgent treatment, which sparked my interest in exploring the long-term outcomes for these patients."

Researchers used data from Yale's Longitudinal Study of Acute Brain Injury & Area Deprivation Index (ADI) rates for the 2020 U.S. Census blocks, to compare outcomes among stroke survivors by various socioeconomic disadvantage factors. The ADI evaluates a neighborhood on levels of income, education, employment, and housing quality and is specific to each zip code. It was developed by the U.S. Health Resources & Services Administration to inform healthcare delivery and policy for disadvantaged areas.

The study followed 2,164 stroke survivors admitted to the Yale Health System between 2018 and 2021, collecting outcome data at 3 months, 6 months, and then yearly after hospital discharge. The average age was 69 and 48% were women, 7.5% were Black adults, and 7.7% were Hispanic adults. Stroke outcomes were determined by trained assessors using the modified Rankin Scale, which measures disability severity after stroke on a scale of 0 to 6, from no disability (able to carry out all daily living tasks and duties without assistance) to severe disability (bedridden, incontinent, requiring constant nursing care, and attention).

Study data found a significant correlation between functional outcomes after a stroke and the socioeconomic factors noted by census blocks. This analysis revealed the following.

- Among 2,164 people with ischemic (clot-caused) stroke, the one-year unadjusted risk of poor outcomes was 35%, 40%, and 46% for patients residing in neighborhoods with low, intermediate, and high deprivation, respectively.
- After considering the inability of the ADI to specifically measure each level of deprivation, researchers determined that those living in intermediate and high deprivation areas had 44% and 107% greater risk, respectively, of unfavorable outcomes, compared to patients living in neighborhoods with low deprivation levels.
- The patients in the poor outcomes category were unable to look after their own affairs without assistance and required some help in daily activities. In the good outcomes category, patients could live independently, though some might have had residual symptoms or disability.

Ms. Kleinberg added: "The magnitude of this impact is what was most surprising. We did not expect a large disparity in outcomes, yet we found patients in the most economically disadvantaged areas were twice as likely to have unfavorable outcomes compared to patients in areas with less unemployment, better housing quality, and higher income and education levels. We hope this study will help promote awareness of how social determinants of health are as important as clinical variables and health

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information when trying to identify patients who are high risk for poor long-term outcomes."

When considered separately from other cardiovascular diseases, stroke ranks fifth among all causes of death, behind diseases of the heart, cancer, COVID-19, and unintentional injuries/accidents. The AHA also recognizes that considering the role of social determinants of health is essential in improving the cardiovascular health of all Americans.

New Clot-Busting Medication Simplified Stroke Treatment In Specialized Ambulance

On February 1, the AHA announced recent study results involving real-world experiences showing that compared with the standard clot-busting medication alteplase, the newer clot-buster tenecteplase may offer a safe, effective, and simpler way to treat ischemic (clot-caused) stroke in mobile stroke units.

Both tenecteplase and alteplase are clot-busting medications. However, tenecteplase is given in a single injection into the bloodstream, while alteplase requires an hour-long infusion after an initial injection. Alteplase is currently the only FDA-approved clot-buster for treating ischemic stroke. Tenecteplase is FDA-approved for the treatment of clots blocking coronary arteries and is used off-label to treat ischemic stroke.

J. Tyler Haller, Pharm.D., Clinical Pharmacy Specialist in Neurocritical Care at St. Joseph's Hospital & Medical Center in Phoenix, Arizona (and lead author of the study), explained: "One of the most important parts of treating stroke patients is getting them the medication they need as quickly and as safely as possible. We know from another recent, large randominzed study that tenecteplase is superior for stroke treatment when given on an ambulance with imaging capability–however, these findings had not been confirmed outside of a trial. Our study looked at real-world implementation of tenecteplase, and we found that we were able to administer it without delay and provide our stroke patients with safe care as quickly as possible on our mobile stroke unit."

The Barrow Neurological Institute in Phoenix has the only mobile stroke treatment unit in Arizona, a specially equipped and staffed mobile emergency room. It's deployed when fire department dispatchers determine that a 911 call indicates a possible stroke patient. The mobile stroke unit is staffed by stroke-certified personnel and includes a CT scanner, portable lab, and clot-dissolving medications to help quickly diagnose and treat stroke.

Study researchers analyzed the electronic medical records of people who received clot-busting medication in the mobile stroke unit between February 2021 and April 2023. It looked at the medical records of people who received treatment both before and after the mobile stroke unit switched from alteplase to tenecteplase in May 2022. During the study period, 40 participants received alteplase, and 32 participants received tenecteplase. Their median age was 66 years old; and their median score on the National Institute of Health Stroke Scale was a 9, indicating a moderately severe stroke.

The study findings were as follows.

- There was no significant difference in the time span between a patient's entry to the mobile stroke unit and the administration of either clot-busting medication.
- There was no difference in time from entry to imaging results; dispatch of the unit to the administration of medications; or the clinician's decision about treatment to the time medications were administered.
- For safety, the researchers compared how often patients developed bleeding in the brain within 24 hours of receiving a clot-busting medication: No patient receiving either medication developed this complication.

Tiffany O. Sheehan, Ph.D., R.N., FAHA, Manager of the Stroke Center Development at Barrow Neurological Institute at St. Joseph's Hospital and Medical Center in Phoenix (and senior study author), said: "While there was no significant difference in time to administration across the two medications, healthcare staff feedback confirmed that calculation and administration of tenecteplase was easier to administer than with alteplase. Administering a single infusion of tenecteplase is more straightforward and allows healthcare staff extra time to stabilize patients since they do not have to monitor an hour-long infusion of alteplase. This makes the transfer of patients as they are taken to a hospital less complicated."

Dr. Haller added: "Apart from being less expensive, our results confirm tenecteplase is safe and as effective as alteplase. We will continue to collect safety and outcome data on our practice; however, we anticipate that other mobile stroke units across the country will begin to utilize tenecteplase if they are not already."

According to the AHA's Heart Disease & Stroke Statistics 2024 Update (www.heart.org/en/about-us/heart-and-stroke-association-statistics), stroke accounted for approximately 1 of every 21 deaths in the United States as of year 2021.

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AI Technology Innovations For Healthcare

AI Technology Improved Detection Of Heart Disease During & After Pregnancy

On November 13, 2023, the American Heart Association (AHA) of Dallas, Texas announced results of new research that found electrocardiogram (EKG) based screening using an artificial intelligence (AI)-enabled digital stethoscope may detect peripartum cardiomyopathy, a disease of the heart muscle in pregnant and recently pregnant women, at double the rate of standard obstetric care including clinical EKGs. The stethoscope records EKG's and heart sounds and then uses an AI algorithm to predict the likelihood of having a weakened heart muscle.

Heart disease is the No. 1 killer of new mothers in the U.S., according to the AHA. A 2023 joint statement from the AHA, the Association of Black Cardiologists, and American College of Cardiology called pregnancy "nature's first cardiac stress test" for a woman, providing a window to future cardiovascular health.

Peripartum cardiomyopathy is a type of heart failure that can affect women late in pregnancy or after pregnancy. The disease weakens the heart, resulting in a decrease in the amount of blood that is pumped from the heart to other parts of the body. It is typically diagnosed towards the end of pregnancy or in the months following and may be difficult for health professionals to detect because many of the symptoms are similar to those seen with normal pregnancy, such as shortness of breath and swelling in the feet and legs.

The rate of peripartum cardiomyopathy is somewhat low in the U.S., affecting 1 in every 1,000 to 4,000 pregnancies. It is more prevalent in Nigeria, which has the highest reported incidence of peripartum cardiomyopathy worldwide, with it impacting as many as 1 in 96 pregnancies.

In a study of almost 1,200 Nigerian women who were pregnant or had recently had a baby, peripartum cardiomyopathy was detected twice as often among study participants when EKG testing was performed with a digital stethoscope using an AI algorithm, compared to clinical EKG in addition to routine obstetric care.

Demilade A. Adedinsewo, M.D., M.P.H., Assistant Professor of Medicine in the Department of Cardiovascular Medicine at Mayo Clinic in Jacksonville, Florida (and lead study author), said: "We demonstrated for the first time in an obstetric population that AI-guided screening using a digital stethoscope improved the diagnosis of this potentially life-threatening and treatable condition. This research can change current clinical practice from one that is reactive and symptom-driven to a more proactive approach of identifying pregnancy-related cardiac dysfunction using a simple, low-cost and effective screening tool. Earlier diagnosis would facilitate prompt and appropriate management of cardiomyopathy and reduce associated disease and death."

The AI screening included a digital stethoscope to record electrical activity of the heart and record heart sounds. The women in the AI intervention group also had a study-prescribed echocardiogram upon enrollment in the study to validate the effectiveness of the AI algorithm in this group. The AI-enabled stethoscope used an algorithm that was originally developed with 12-lead EKG data and modified for use with a single-lead EKG recorded with a digital stethoscope, making it capable of predicting the likelihood of left ventricular dysfunction. Participants in the control group had traditional EKG testing without use of the AI-assisted digital stethoscope and their results were evaluated by health professionals.

An echocardiogram was used to measure left ventricular ejection fraction, which gauges the heart's pumping ability. A normal ejection fraction level for the heart is between 55% and 70%. In this study, a left ventricular ejection fraction of less than 50% was the criteria used for a cardiomyopathy diagnosis.

Between August 2022 and September 2023, the study enrolled 1,195 Nigerian women between the ages of 18 and 49 who were pregnant or had delivered a baby within the previous 12 months (and who had completed necessary baseline tests). About 73% were pregnant at the beginning of the study; and 39% were in their third trimester.

- Pregnancy-related cardiomyopathy was detected in 4% of pregnant and postpartum women in the group screened with the AI-enabled digital stethoscope.
- The cardiomyopathy detection rate was 1.8% in the control group, suggesting that half of the cases of cardiomyopathy are likely undetected with usual care.

Dr. Adedinsewo said: "While we expected AI-guided screening to improve the diagnosis of cardiomyopathy, we did not anticipate the frequency of cardiomyopathy diagnosis would be doubled. Additional large trials enrolling a diverse group of women in other geographic locations are needed to evaluate the impact of AI-guided screening on cardiomyopathy diagnosis as well as its impact on adverse maternal outcomes."

AI-App Detected Worsening Heart Failure From Changes In Patients' Voices

On November 13, 2023, the AHA announced results from a new study, which found that using a smartphone app with AI technology to detect increasing fluid in the lungs, a sign of worsening heart failure, by recognizing changes in the voice of the app user, was able to predict more than 75%

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of hospitalizations about 3 weeks before a heart failure event. Such advanced warning may help guide earlier treatment needs that may reduce the need for hospitalization.

William T. Abraham, M.D., FAHA, Professor of Medicine, Physiology & Cell Biology and College of Medicine Distinguished Professor in the Division of Cardiovascular Medicine at The Ohio State University Wexner Medical Center in Columbus (and lead study author), said: "Speech analysis is novel technology that may be a useful tool in remote monitoring of heart failure patients, providing early warning of worsening heart failure that frequently results in hospitalization. This technology has the potential to improve patient outcomes, keeping patients well and out of the hospital, through the implementation of proactive, outpatient care in response to voice changes."

Heart failure occurs when the heart muscle cannot pump enough blood to meet the body's needs for blood and oxygen. This can result in fatigue, fluid retention, shortness of breath, and sometimes excessive coughing.

This study evaluated the effectiveness of the artificial intelligence-driven mobile app to predict worsening heart failure in advance of any need for hospitalization and/or intravenous treatment among people diagnosed with heart failure. The mobile phone app was designed to detect changes in speech measures in patients over time. The voice changes could indicate early increases of lung fluid, which is a sign of progressing heart failure.

The study was conducted from March 2018 through April 2023 and enrolled 416 adults living in Israel diagnosed with heart failure. Study participants recorded five sentences in their native language of Hebrew, Russian, Arabic, or English, into the phone app daily. In a training phase of the study, distinct speech measures from 263 participants were used to develop the AI algorithm. Then, the algorithm was used in the remaining 153 participants to validate the tool's effectiveness.

The technology used in this study was Cordio HearO™ from CORDIO Medical of Yehuda, Israel, a remote monitoring system comprised of a smartphone-based mobile speech application. 75% of the participants were men whose average age was 68 years. The 263 patients in the training phase made recordings on 83% of days between April 2018 through November 2021 and were followed for up to 44 months. The test group of 153 patients made recordings on 81% of days between February 2020 through April 2023 and were followed for up to 31 months. The distinct speech measures included pitch, volume, dynamics, and other characteristics.

The study's analysis found the following.

- In the training phase of the study, the app accurately predicted 76% of worsening heart failure (44 of the 58 heart failure events) on average 24 days before hospitalization or the need for IV fluids occurred. The app generated an average of 3 unnecessary alerts per patient, per year.
- In the validation phase, the app was 71% accurate (10 of 14) in detecting heart failure events about 3 weeks in advance. There were about 3 unexplained alerts per patient per year in this group as well.

Researchers conclude that the technology detects future worsening heart failure episodes accurately, with a low unnecessary notification rate. This high rate of accuracy and early notification of worsening heart failure validate the AI tool as a potentially effective way to reduce hospitalization and improve patient outcomes.

AI May Speed Heart Attack Diagnosis & Treatment

On November 13, 2023, the AHA announced results of a new scientific study, which found that technology incorporating AI and electrocardiogram testing reduced the time to diagnose people having a heart attack and transfer them to the cardiac catheterization laboratory for treatment by almost 10 minutes.

The study evaluated patients who had ST-elevation myocardial infarctions (STEMIs), a type of heart attack in which there is a complete blockage of a coronary artery. The study investigated if using AI with electrocardiogram (EKG) testing could help health professionals diagnose STEMIs and get patients to the cardiac catheterization lab faster for procedures to open blockages, such as coronary angioplasty or stenting.

EKG testing is a non-invasive diagnostic tool that shows the heart's electrical activity. It can also reveal if the cardiac episode is a STEMI.

Damage can occur quickly during a heart attack due to inadequate oxygen levels reaching the heart muscle; thus getting treatment faster can lead to better patient outcomes. During a heart attack, the heart is deprived of oxygen because blood flow to the heart is reduced due to a blockage in a coronary artery. Timely diagnosis and treatment are critical to restore blood flow, reduce injury to the heart and increase the chance of recovery after an attack.

Chin-Sheng Lin, M.D., Ph.D., Professor, Director of the Medical Technology Education Center & Vice Dean at the School of Medicine at the National Defense Medical Center and Director of Medical Education, Physician Educator & Cardiologist at Tri-Service General Hospital in

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Taipei, Taiwan (and lead study author), said: "Modern AI may now be as good as expert cardiologists in diagnosing serious heart attacks. Hospitals can use AI tools more to help front-line doctors, especially those with less experience. This could lead to faster treatment and less mistakes when it comes to treating patients who are experiencing heart attacks."

The study was conducted at the largest military hospital in Taiwan, Tri-Service General Hospital, between May 2022 and April 2023. It included 43,176 patients seen either in the emergency department or as inpatients, treated by 20 cardiologists. On average, the patients were 60 years old, and about half of them were male.

The patients were almost equally divided into two groups: an intervention group, which included the AI-enabled EKG testing; and a control group, which received standard care with a health professional interpreting EKG results to determine if cardiac catheterization was needed. All patients who were diagnosed with STEMI had procedures in the cardiac catheterization lab to determine the size and location of the blockage. The trial findings included the following.

- AI-enabled EKGs accurately diagnosed STEMIs patients with positive predictive value of 88% and negative predictive value of 99.9%.
- AI technology helped to reduce the treatment waiting time for patients with STEMI from about 52 minutes to 43 minutes.
- AI-enabled EKGs confirmed STEMI among seven hospitalized patients, while standard care confirmed STEMI in only one hospitalized patient.

Dr. Lin concluded: "The difference in diagnosing STEMI in the emergency room wasn't as great between the two groups, however, the improved accuracy for diagnosis in hospitalized patients was astonishing. This tells us that there's a lot we can do to improve how we diagnose STEMI in hospitalized patients. Due to the recent AI revolution, the accuracy of clinical decision support systems has improved significantly, and doctors are becoming more trusting of this technology. In the future, we might see more of these tech tools being used in new ways, like in ambulances or on wearable devices, which could change how we care for patients with STEMI."

AI May Accurately Detect Heart Valve Disease & Predict Cardiovascular Risk

On November 6, 2023, the AHA announced that according to research in two new studies, advances in AI have enabled the development and application of AI tools that may be effective at detecting heart valvular disease as well as predicting the risk of cardiovascular disease (CVD) events.

Dan Roden, M.D., FAHA, Professor of Medicine, Pharmacology & Biomedical Informatics and Sr. VP for Personalized Medicine at Vanderbilt University Medical Center in Nashville, Tennessee, said: "Computational methods (AI) to develop novel predictors of health and disease are becoming increasingly sophisticated. Both of these studies take a measurement that is easy to understand and easy to acquire and ask what that measurement predicts in the wider world."

Study #1: Real World Evaluation of an AI-Enabled Digital Stethoscope to Detect Undiagnosed Valvular Heart Disease

A study conducted at three different primary care clinics in the U.S. from June 2021 through May 2023 compared the ability of either a physician or nurse practitioner conducting a physical exam using a standard stethoscope to detect potential heart valve disease, versus the ability of an AI program doing an exam using sound data recorded on a digital stethoscope to do the same.

The healthcare professionals who performed their standard exam on the patients were not aware of the AI results or the echocardiogram results, making it a blind study.

None of the participants had a prior diagnosis of heart valve disease or a history of a heart murmur. They included 369 adults all ages 50 and older, with 61% women. 70% identified as White, 18% were Hispanic or Latino, 9% were Black, 2% identified as Asian, and 1% identified as other.

All participants also received an echocardiogram at a follow-up appointment 1 to 2 weeks later to determine if heart valve disease was present, though the results were not shared with the clinician or the patient. The following was found.

- The AI digital stethoscope method detected 94.1% of cases of valvular heart disease compared to the standard stethoscope used by primary care professionals, which detected only 41.2% of cases.
- The AI method identified 22 with previously undiagnosed moderate-or-greater heart valve disease, and the professionals using the standard stethoscopes identified 8 previously undiagnosed people with heart valve disease.

Moshe Rancier, M.D., Senior Medical Director of Mass General Brigham Community Physicians in Lawrence, Massachusetts (and lead author), explained: "The implications of undiagnosed or

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late diagnosis of valvular heart disease are dire and pose a significant cost to our healthcare system. This study demonstrates that healthcare professionals can screen patients for valvular heart disease more effectively and quickly using a digital stethoscope paired with high-performing AI that could detect cardiac murmurs associated with significant valvular heart disease."

While the AI method had greater sensitivity to sounds detected with the digital stethoscope, medical professionals using a standard stethoscope were able to be more specific in their diagnosis, 95.5% versus 84.5% for the AI method, which may reduce the potential for false positives and/or additional tests or screenings for valvular heart disease. However, this study only evaluated the accuracy of the digital stethoscope in comparison to a traditional stethoscope.

Dr. Roden noted: "We saw here that the AI-based stethoscope did extraordinarily well, it predicted nearly 90% of the valve disease diagnoses that were ultimately there. I see that as an emerging technology—using an AI-enabled stethoscope and perhaps combining it with other imaging modalities, like an AI-enabled echocardiogram built into your stethoscope. Use of these new tools to detect the presence of valvular disease as well as the extent of valvular disease and the extent of other kinds of heart disease will likely help to transform cardiovascular disease care."

Study #2: Deep Learning-Based Retinal Imaging to Predict Cardiovascular Disease Events in Prediabetic & Diabetic Patients: A Study Using the UK Biobank

Using data from the UK Biobank, a second study by another research group evaluated the effectiveness of using pictures of the retina at the back of the eye that were analyzed by a deep-learning algorithm tool to predict the risk of CVD events, defined as heart attack, ischemic stroke, transient ischemic attack, or death due to heart attack or stroke.

Deep learning is a method of artificial intelligence that trains computers to analyze multiple layers of data and gives computers the ability to "learn" by evolving their model independent of human intervention based on new information presented to it, a process challenged by the requirement of both large amounts of computing power and data. Previous research had successfully developed a deep learning algorithm to predict CVD events by analysis of retinal images and coronary artery calcium scores.

The UK Biobank is a large biomedical database and research resource with health records of 500,000 adults, enrolled from 2006 until 2010, who receive care through the United Kingdom's National Health Service. Its data was accessed by study researchers in March 2023, who analyzed health records through June 2023. Participants were an average 59 years and 45.5% were female and predominantly identified as White. Of the 1,101 adults with prediabetes or Type 2 diabetes, 550 people were in the low-risk group, 276 were in the moderate-risk group, and 275 were in the high-risk group.

Researchers used the deep-learning algorithm to categorize retinal images of 1,101 people with prediabetes or Type 2 diabetes into low-risk, moderate-risk, and high-risk groups for likelihood of cardiovascular disease. They then measured the number of CVD events among participants over a median period of 11 years. The following analysis was found.

- 8.2% of participants in the low-risk group, 15.2% of participants in the moderate-risk group, and 18.5% of participants in the high-risk group had experienced CVD events by the end of the study period of 11 years.
- After accounting for demographic and other potential CVD risk factors, such as age, gender, high blood pressure medication use, cholesterol medication uses, and smoking history, people in the moderate-risk group were 57% more likely to experience a cardiovascular event compared to people in the low-risk group; and people with high-risk scores were 88% more likely to experience a cardiovascular event compared to those in the low-risk group.

Chan Joo Lee, M.D., Ph.D., Associate Professor at Yonsei University in Seoul, Korea (and lead study author), said: "These results show the potential of using AI analysis of retinal imaging as an early detection tool for heart disease in high-risk groups such as people who have prediabetes and Type 2 diabetes. This could lead to early interventions and better management of these patient groups, ultimately reducing the incidence of heart disease-related complications."

At the end of the study period, 138 (12.5%) of the participants had experienced cardiovascular events. 45 were from the low-risk group, 42 were from the moderate-risk group, and 51 were from the high-risk group.

Dr. Roden added: "Another question is if the retinal scan do a better job of predicting coronary artery disease than the pooled risk equations, or a polygenic risk score for coronary artery disease, or coronary calcium measurements? Those are all questions that need to be answered because as we develop more tools to predict events like coronary artery disease, we want to make sure that we use the right ones and the right combinations, rather than complicating care with alternate tools that have not been validated."

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To thank our NPPA members for spreading the word about our Annual NPPA Conference to the vendors that call on them, we instituted a Sponsor Referral Award incentive program for our members, so that if you successfully refer a vendor to exhibit at our conference, you'll be rewarded for your effort.

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Exhibiting & Sponsoring Vendors, 2024 NPPA

Continued from Page 74

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Editorial

Continued from Page 4

however even someone without training can use the device well and easily enough to reset the heartbeat of a person who has had a sudden cardiac arrest. Using an AED could possibly save a life.

Once Hamlin recovered, he began working with the AHA to teach people about CPR and AEDs. The NFL also worked with the AHA to provide CPR and AED training at the Super Bowl and the April draft. More than half of all NFL teams provided training for their staff or local communities, resulting in roughly 18,000 people getting hands-only CPR training and roughly 500 becoming CPR-trained.

Damar Hamlin's cardiac arrest even spurred state and federal legislation. New York now requires all camps and youth sports organizations to develop AED plans and to have at least one AED-trained staff member on hand. Ohio has renewed its efforts to require AEDs in schools, and similar efforts are underway in Virginia. The federal Access to AEDs Act creates grants for elementary and secondary schools to purchase, maintain, and provide training for AEDs.

When something bad happens, people react. I am working on getting more familiar with this myself, as well as other common emergency situations, so that I have at least some basic knowledge in advance. The military taught me the basics of first aid and CPR training, but I didn't keep up with my CPR certification in more recent years, whereas I previously used to renew it on an annual basis.

The recent death of two of my classmates has now spurred the desire in me to find a CPR class to get re-certified again, and maybe look into aspects of other emergency-related training that may be helpful in the future. Perhaps this information will also spur you into looking into these types of potentially life-saving training and knowledge as well.

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Mastering 340B For Cost-Efficiency

Continued from Page 1

obligations. A comprehensive understanding of these elements is crucial for optimizing program benefits while ensuring compliance.

To meet the demands of the current healthcare landscape, organizations should consider restructuring the ambulatory pharmacy buyer role in several ways. First, implementing a robust training program focused on 340B fundamentals is essential. This should include in-depth study of program requirements and regulations, case studies on common compliance challenges, and regular updates on policy changes and interpretations. Fostering closer collaboration between pharmacy buyers and 340B program managers through regular cross-functional meetings, shared performance metrics, and joint strategies for program optimization can greatly enhance overall effectiveness.

Equipping pharmacy buyers with advanced data analysis capabilities is another crucial aspect of role restructuring. This enables buyers to identify opportunities for cost savings within the 340B program, monitor compliance indicators in real-time, and generate insightful reports for leadership and auditors. Developing a more strategic approach to inventory management that considers 340B eligibility of drugs and patients, optimizes inventory mix to maximize 340B savings, and implements sophisticated inventory tracking systems is also vital.

In our ever-evolving healthcare climate, enhancing the buyer's role in managing relationships with drug wholesalers and manufacturers is critical. This includes negotiating contracts that align with 340B program goals, ensuring timely resolution of pricing discrepancies, and collaborating on strategies to minimize WAC purchases.

By restructuring the pharmacy buyer role to include a deep understanding of 340B, organizations can significantly reduce their WAC spending. Strategies for this include accurate identification of 340B-eligible prescriptions, timely enrollment of new eligible sites and providers, optimization of replenishment models, strategic use of contract pharmacies, and careful management of virtual inventory.

As the 340B program faces increased scrutiny, compliance remains paramount. A restructured pharmacy buyer role should incorporate regular self-audits and mock HRSA audits, continuous monitoring of prescriber and patient eligibility, meticulous record-keeping and documentation practices, and proactive identification and resolution of potential compliance issues.

Restructuring the ambulatory pharmacy buyer role to encompass a comprehensive understanding of the 340B Drug Pricing Program is essential for modern healthcare organizations. By enhancing the buyer's knowledge and skills in this area, organizations can optimize their 340B program participation, minimize WAC costs, and maintain rigorous compliance standards. This evolution of the pharmacy buyer role not only contributes to the financial health of the organization but also supports the broader mission of providing accessible, high-quality healthcare to vulnerable populations.

As the healthcare landscape continues to evolve, the role of the ambulatory pharmacy buyer will undoubtedly continue to change. By investing in the development of this critical position now, healthcare organizations can position themselves for success in an increasingly complex and challenging environment. The restructured role of the ambulatory pharmacy buyer, with its enhanced focus on 340B program expertise, stands as a crucial element in the ongoing effort to improve healthcare delivery while managing costs effectively.

Editorial Note: ***Fatimah Muhammad,*** *DrPH, MPH, FHFMA, CRCR, CSBI, CSPR, is the Director of 340B Pharmaceutical Services & Drug Replacement at Saint Peter's University Hospital in New Brunswick, New Jersey. She is an NPPA member and has been a speaker at the Annual NPPA Conferences, including in 2024 wtih her lecture on "Enhancing Cybersecurity Strategies for Pharmacy".*

We highly encourage other NPPA members to contribute articles of your own—even if it's a brief one or two paragraphs. NPPA can assist with edits for spelling, style, and grammar as necessary, it's content we're looking for. You can write about a project you may have instituted in your pharmacy department; something you learned at one of our NPPA Conferences or elsewhere that helps your daily routine or the pharmacy run more efficiently; or perhaps a a general experience from attending a past NPPA Conference, such as in terms of meeting with and connecting with other Buyers across the country.

NPPA rewards you for such article contributions as well, with our Member Incentives Program (see details on our website, at www.pharmacypurchasing.com/member-incentive-programs).

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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* edition). This provides you with your Member-Only page's login information, which has FDA shortage alerts, recalls, and more.

Also know we pay for published articles! See our NPPA website's "Member Incentives Program" page for details.

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Carla Carroll, Pharmacy Buyer, CHI St. Joseph Health Regional Hospital, Bryan, TX

Lorraine Olguin, Pharmacy Technician & Assistant Buyer, Mercy Hospital Downtown, Bakersfield, CA

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Randi Vargas, Director of Enterprise Pharmacy Procurement, Centura Health Physician Group, Centennial, CO

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Lucia Tafoya-Ponce, Pharmacy Buyer, St. Mary Medical Center, Long Beach, CA

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Teaka Singh, Pharmacy Buyer & 340B Coordinator, Jersey City Medical Center, Jersey City, NJ

Tiana Rain Crouch, Pharmacy Buyer, Adventist Health Ukiah Valley Hospital, Ukiah, CA

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Bob Braverman, President, Medi-Dose, Inc./ EPS, Inc., Ivyland, PA

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NPPA Member Resources Online

NPPA Members: here below please find all of the information about the resources you can utilize 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": 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.

Facebook *"Pharmacy Buyers"* group: one of our NPPA members and Annual Conference attendees **Cassidy Russell,** took it upon herself to setup a Facebook *"Pharmacy Buyers"* group page at the end of 2019, which has been very popular from the start and continues to grow. Buyers there post various questions to each other or provide general information and support. To join the group, search on "Pharmacy Buyers" in your Facebook account, or visit: www.facebook.com/groups/334035183936954

NPPA hopes these resources help you to be an even better Pharmacy Buyer!

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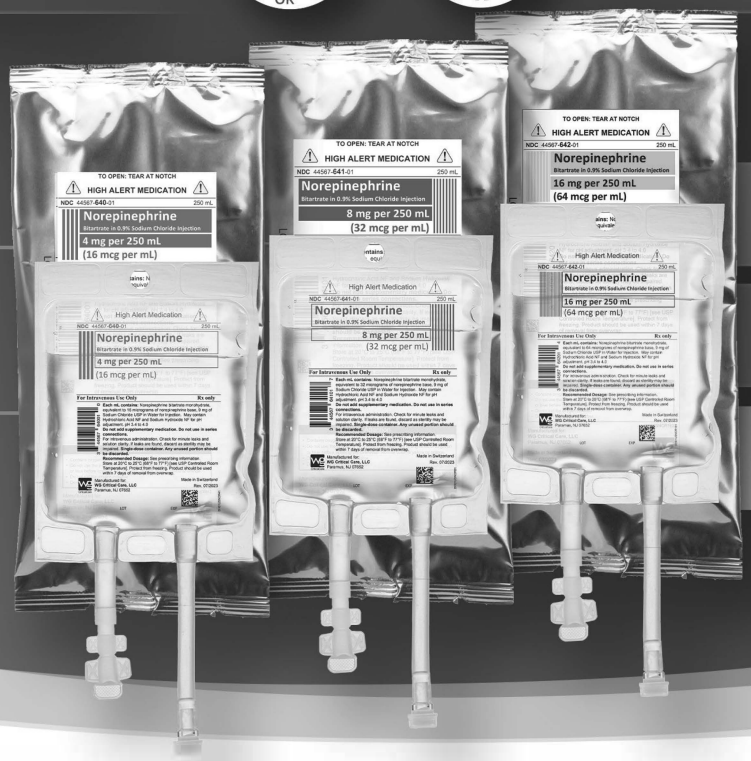

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