Pharmacy Purchasing Outlook

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

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Rx-To-OTC Switch Of 3 Existing Drug Brands, Approved By FDA

On February 14, the FDA approved the 3 following drugs for nonprescription, or over-the-counter (OTC) use, through a process called a prescription (Rx)-to-OTC switch. All 3 products will be marketed in the U.S. as nonprescription OTC drugs, and will ***no longer be available as prescription*** drugs.

The approved drugs are as follows.

1) **Pataday® Once Daily Relief Ophthalmic Solution/Drops** (olopatadine HCl, 0.2%) for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair or dander; by Alcon Laboratories of Fort Worth, Texas. Product will be available on March 2.
2) **Pataday® Twice Daily Relief Ophthalmic Solution/Drops** (olopatadine HCl, 0.1%) for the temporary relief of itchy and red eyes due to pollen, ragweed, grass, animal hair or dander; by Alcon Laboratories of Fort Worth, Texas. Product will be available on March 2.
3) **Voltaren® Arthritis Pain Topical Gel** (diclofenac sodium, 1%) for the temporary relief of pain in the hand, wrist, elbow, foot, ankle, or knee in adults (18 years and older); by GlaxoSmithKline (GSK) of Philadelphia, Pennsylvania. Product is anticipated to be available sometime in the spring of this year.

Karen Mahoney, M.D., Acting Deputy Director of the Office of Nonprescription Drugs in the FDA's Center for Drug Evaluation & Research, said: "As a result of the Rx-to-OTC switch process, many products sold OTC today use ingredients or dosage strengths that were available only by prescription 30 years ago. Approval of a wider range of nonprescription drugs has the potential to improve public health by increasing the types of

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Digital Version Of *PPO* Now Offered As Additional Benefit For Members

Dear NPPA Members: as many of you should know by now from getting our e-communications for the official announcement of this already, we just wanted to reiterate the exciting news of moving more into the 21st Century with a new benefit of your membership at no additional cost—our fully digital e-version of our member-publication here, *Pharmacy Purchasing Outlook (PPO)!*

The new digital editions will be sent in one of our e-newsletter communnications shortly after each printed publication is mailed out; with the link to download the newest edition's digital version on a ***private*** page of our NPPA website, only for current members.

These new official full versions include searchable content (by drug name or keyword, etc.), bookmark capability, and links to all of the web addresses listed throughout the publication's content that show in bright blue color; and eventually also clickable Ad Pages (with hyperlinks to advertiser websites).

Although we included those clickable Ad Pages in our first digital version as an initial test, we are now holding off on continuing with those until we hear from our vendor-advertisers, since we will be charging them additional advertising fees for the clickable feature as well as for the

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Highlights Inside This Edition

Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection

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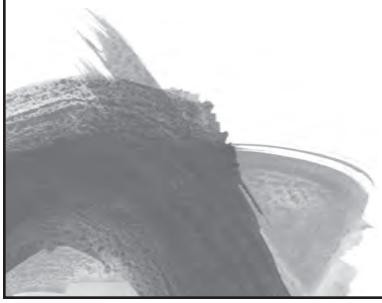

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Join Us For August 2020 24th NPPA Conference!

Be sure to mark your calendars for our 24th Annual NPPA Conference, returning to Bally's Las Vegas, August 11-13, 2020.

Dates: Tuesday, August 11 through Thursday, August 13

Optional Pre-Conference 340B University, Monday, August 10

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

Also note that Apexus will be returning again to host an optional 340B University event, on Monday, August 10, which is the day before our NPPA Conference begins. Registration usually opens in April or May (check our website for updates).

Bally's hotel room rates for our 2020 NPPA Group Room Block are being held at $89/night+tax, which has not increased for the past 2 years (plus mandatory Resort Fee of $35/night+tax).

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NPPA Membership Rates: $125, 1-year; $216, 2-years (comes with 10 editions/year of *Pharmacy Purchasing Outlook*, the member-publication of NPPA). Associate Memberships ($69/year) are available when a Full Member exists at same facility/address (sharing the publication of the Full Member). Issues are distributed via First Class U.S. Mail, by the end of the first week of the month after the publication issue month. See details on our website.

Within This Edition

SUBJECT

Editorial

By Lyle Matthews, Pharm.D.
NPPA Member & Moderator

A Look at the NPPA's Mission

In several issues of *Pharmacy Purchasing Outlook (PPO)* from year 2017, **Dale Kroll,** the Founder and President of the National Pharmacy Purchasing Association (NPPA), presented a brief history of how NPPA started and had grown during its first two decades, offered some ideas about his vision for where it was headed, and described his dream for the future.

Dale's mission, for as long as I have known him, has always remained steadfast: to provide an avenue to promote the profession of the institutional pharmacy buyer. In this issue of *PPO*, I want to take a closer look at Dale's vision, through my eyes.

The official published Mission of the NPPA is printed below this Editorial. In short, the ideals Dale established are as follows: "Promote the Profession, Provide Specific & Enhanced Educational Opportunities, Provide a Unified Voice, and affirm Pharmacy Purchasing as a unique and important specialty, as well as an important aspect of Total Patient Care." It is a very simple model, a straightforward mission, and nothing short of brilliant. More importantly, the organization Dale founded in 1997, along with its current dedicated staff, continue to deliver on the specific mission that Dale established over 20 years ago. It is this laser focus that continues to allow NPPA to provide the platform and services for Pharmacy Buyers across the country. The services provided by NPPA are designed directly around the 5 pillars of their Mission: to promote, educate, provide a unified voice, and affirm the importance of the profession and its vital impact on patient care.

The first line of NPPA's Mission: Promote the Profession of Pharmacy Purchasing, I believe is listed first for a reason. It is, and has always been, Dale's primary goal for NPPA. As I have had the privilege to hold countless discussions with Dale over the years, his passion for where he believes the profession can go is infectious. You cannot help but walk away from those discussions with a clear understanding of Dale's vision.

The second pillar of the Mission: to Educate, the NPPA staff continue to shine. For those of you who have been fortunate to attend their Annual Conference, you are well aware of the educational opportunities available during those several days. However, the NPPA even has educational opportunities all year. *Pharmacy Purchasing Outlook (PPO)*, NPPA's main publication, is packed with industry information, announcements, discontinuations, FDA approvals of new generic and brand drugs, and more. I am personally aware of the countless hours the NPPA staff put into researching the information to put into *PPO*, for our convenience as members and readers. Between the Annual Conference and *PPO*, Dale's goal of providing education is stronger than ever.

The third pillar: to Provide a Unified Voice, the NPPA staff work tirelessly to gather information from the Pharmacy Buyers across the country to discover and assess current needs, and tackle them. There is a session held every year at the Annual NPPA Conference, in which the attendees have an opportunity to speak to the entire NPPA staff to offer feedback on ideas, suggestions, wishes, for both the conference as well as all things related to membership. In addition, know that NPPA has a Pharmacy Buyers Forum on their website, which offers an opportunity to network with other Buyers across the country, in order to discuss current drug shortages and potential solutions, and post other general questions about pharmacy and their jobs.

The fourth and fifth pillars: to Affirm the Importance of the Pharmacy Purchasing Professional and its Effect on Total Patient Care, probably have the most positive long-term impact, and is the direct result of the success of the first 3 pillars. The growth of the Annual NPPA Conference is one example. Many of the Vendor-Exhibitors there have relayed that NPPA's event is their favorite pharmacy

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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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Editorial

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conference to display at, because they get to connect directly with the Buyers who are on the front line, dealing with the day-to-day issues that are most important to them. The relationships and partnerships that have developed between the NPPA staff, Pharmacy Buyers, and the Vendors who serve them, is truly remarkable. It serves to have an extraordinary impact in affirming the importance of your profession.

The dedication of the small NPPA staff to continue the work Dale started and the results they have achieved and continue to, is staggering. The Mission of the NPPA today is stronger than ever; and the opportunities to Promote the Profession, Educate, Provide a Unified Voice, and Affirm the Importance of the Pharmacy Buyer are stronger than ever.

Note from NPPA: Lyle is a long-time and enthusiastic supporter of NPPA and all Pharmacy Buyers, and we believe, was one of the best Pharmacy Directors around while he was working in that position.

In addition, of late we've come to consider Lyle as an NPPA staffer although not officially, since he's been the Moderator of our Annual NPPA Conference over the past few years (as well as speaking several times). Lyle has graciously agreed to contribute with writing some of our publication's Editorials this year, for a new fresh perspective.

We sincerely hope this might also inspire some of our other NPPA members reading this, to write something to contribute as an article for our publication, to share your experiences with your fellow colleagues—and we pay for all such contributions!

See our NPPA website's "Member Incentives" page or call/email our office for details.

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Generic Approvals & News

Azithromycin Tablets - Alembic Pharmaceuticals

On January 28 to 29, Alembic Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they received final FDA approval for its Abbreviated New Drug Application (ANDA) for Azithromycin Tablets 250mg, 500mg, and 600mg.

This product compares to Zithromax® Tablets by Pfizer, Inc. (in the same strengths), which had recent annual U.S. sales (ending September 2019) of $131 million, according to IQVIA™.

It is a macrolide antibacterial drug indicated for mild to moderate infections caused by designated, susceptible bacteria in acute bacterial exacerbations of chronic bronchitis in adults; acute bacterial sinusitis in adults; uncomplicated skin and skin structure infections in adults; urethritis and cervicitis in adults; genital ulcer disease in men; community-acquired pneumonia in adults and pharyngitis/tonsillitis in adults.

Betamethasone Dipropionate Ointment - Lupin

On December 20, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received FDA approval for Betamethasone Dipropionate Ointment 0.05% (augmented).

This product compares to Diprolene® Ointment 0.05% by Merck Sharp & Dohme Corp., which had recent annual U.S. sales (ending September 2019) of $22 million, according to IQVIA. It is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 13 years of age and older.

Bosentan Tablets - Alembic Pharmaceuticals

On January 24, Alembic Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they received final FDA approval of its Abbreviated New Drug Application (ANDA) for Bosentan Tablets 62.5mg and 125mg.

This product compares to Tracleer® Tablets by Actelion Pharmaceuticals Ltd, which had recent annual U.S. sales (ending September 2019) of $68 million, according to IQVIA. It is indicated for the treatment of pulmonary arterial hypertension.

Clobetasol Propionate Cream - Alembic/Aleor

On January 29, Alembic Pharmaceuticals Ltd. of Gujurat, India (with U.S. incorporated headquarters in Bridgewater, New Jersey) announced that its joint venture company Aleor Dermaceuticals Ltd. (also of Gujurat, India) received final FDA approval for its Abbreviated New Drug Application (ANDA) of Clobetasol Propionate Cream 0.05% (distributed in the U.S. by Alembic).

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Generic Approvals & News

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This product compares to Temovate® Cream 0.05% by Fougera Pharmaceuticals Inc., which had recent annual U.S. sales (ending September 2019) of $57 million, according to IQVIA.

It is a super-high potency corticosteroid formulation indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Clonidine HCl ER Tablets Launch - Upsher-Smith Labs

On January 28, Upsher-Smith Laboratories, LLC of Maple Grove, Minnesota announced their ***launch*** of Clonidine HCl ER (extended-release) Tablets 0.1mg; available in 60-count bottles (NDC #0832-0777-60).

This product is AB1-rated to Kapvay® ER Tablets by Concordia Pharmaceuticals Inc. It is indicated to treat Attention Deficit Hyperactivity Disorder (ADHD), both as monotherapy and as adjunctive therapy to stimulant medications.

Clonidine HCl ER tablets had recent annual U.S. sales (ending November 2019) of $30 million, according to IQVIA.

Cyclosporine Liquid-Gel Capsules Launch - Apotex

On January 2, Apotex Corp. of Weston, Florida announced their ***launch*** of Cyclosporine Liquid-Gel Capsules, available in 30-count unit dose blister packs as follows:

- **25mg** (NDC #60505-4630-03);
- **50mg** (NDC #60505-4631-03);
- **100mg** (NDC #60505-4632-03).

This product is AB1-rated to Neoral® Capsules by Novartis Pharmaceuticals Corp. It is also indicated for the following:

1) Prevention of organ rejection in kidney, liver, and heart allogeneic transplants;
2) Treatment of severe active, rheumatoid arthritis where the disease has not adequately responded to methotrexate;
3) Treatment of non-immunocompromised patients with severe recalcitrant, plaque psoriasis who have failed to respond to at least one (1) systemic therapy (such as PUVA, retinoids, or methotrexate) or in patients for whom other systemic therapies are contraindicated or cannot be tolerated.

Deferasirox Tablets For Oral Suspension - Glenmark Pharmaceuticals

On January 7, Glenmark Pharmaceuticals, Inc. USA of Mahwah, New Jersey announced they received final FDA approval for Deferasirox Tablets for Oral Suspension 125mg, 250mg, and 500mg.

This product compares to Exjade® Tablets for Oral Suspension by Novartis Pharmaceuticals Corporation, which had recent annual U.S. sales (ending November 2019) of $106.4 million, according to IQVIA. It is indicated to treat iron overload caused by blood transfusions in adults and children at least 2 years old; and chronic iron overload syndrome that is caused by a genetic blood disorder (called non-transfusion dependent thalassemia) in adults and children who are at least 10 years old.

Fluvoxamine Maleate Tabs Launch - Upsher-Smith Laboratories

On January 10, Upsher-Smith Laboratories, LLC of Maple Grove, Minnesota announced the ***launch*** of Fluvoxamine Maleate Tablets; available in 100-count bottles as follows:

- **25mg** (NDC #0832-1670-11);
- **50mg** (NDC #0832-1671-11);
- **100mg** (NDC #0832-1672-11).

This product compares to Luvox® Tablets by ANI Pharmaceuticals, Inc. It is indicated for the treatment of obsessions and compulsions in patients with Obsessive Compulsive Disorder (OCD).

Recent annual U.S. sales (ending September 2019) were $28 million, according to IQVIA.

Glucagon Emergency Kit Launch - Fresenius Kabi

On February 5, Fresenius Kabi USA, LLC of Lake Zurich, Illinois announced the ***launch*** of their Glucagon Emergency Kit, an FDA-approved and cost-effective alternative to treat severe hypoglycemic episodes in people with diabetes.

The kit includes Glucagon for Injection 1mg and a prefilled glass syringe with 1mL of Sterile Water for Injection.

Glucagon for Injection is an antihypoglycemic agent, indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes.

Generic Approvals & News

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The Glucagon Emergency Kit is designed to be convenient and easy to use. Patients can carry it with them, so it is available should they experience severe hypoglycemia. The bright orange case makes it easy for a patient or caregiver to find it and act quickly. To help make the Glucagon Emergency Kit more affordable, there is a co-pay assistance program for patients who qualify. Fresenius Kabi is also making injection training kits available to healthcare providers to help educate patients.

John Ducker, President & CEO of Fresenius Kabi USA, commented: "For people with diabetes, a severe hypoglycemic episode can occur anywhere and at any time. Our new Glucagon Emergency Kit allows clinicians flexibility and choice for treating patients experiencing severe hypoglycemia, plus it is cost-effective."

Haloperidol Tablets Launch - Upsher-Smith Laboratories

On January 13, Upsher-Smith Laboratories, LLC of Maple Grove announced their ***launch*** of Haloperidol Tablets; available in 100-count bottles as follows:

- **0.5mg** (NDC #0832-1510-11);
- **1mg** (NDC #0832-1520-11);
- **2 mg** (NDC #0832-1530-11);
- **5mg** (NDC #0832-1540-11);
- **10mg** (NDC #0832-1550-11);
- **20mg** (NDC #0832-1560-11).

This product compares to Haldol® Tablets by Johnson & Johnson Corp. *(now discontinued).* It is indicated to treat schizophrenia and to control motor and speech tics in people with Tourette's syndrome.

Recent annual U.S. sales (ending August 2019) were $41 million, according to IQVIA.

Leflunomide Tablets - Lupin Pharmaceuticals

On February 5, Lupin Pharmaceuticals, Inc. of Baltimore, Maryland announced they received final FDA approval to market Leflunomide Tablets 10mg and 20mg.

This product compares to Arava® Tablets by Sanofi-Aventis, which had recent annual U.S. sales (ending December 2019) of $44 million, according to IQVIA. It is indicated for the treatment of adults with active Rheumatoid Arthritis (RA).

Lidocaine Topical Solution 4% Launch - Lannett Company

On January 6, Lannett Company, Inc. of Philadelphia, Pennsylvania announced their ***launch*** of Lidocaine Topical Solution 4%.

This product compares to Laryng-O-Jet® Kit by International Medication Systems, Ltd. (an Amphastar Pharmaceuticals Company). It is indicated for the production of topical anesthesia of the mucous membranes of the respiratory tract.

Recent annual U.S. sales were $17 million, according to IQVIA, although actual generic market values are expected to be lower.

Tim Crew, CEO of Lannett, commented: "Lidocaine Topical Solution 4% is a product we acquired in May 2018 from a subsidiary of Endo International."

Loratadine Soft-Gel Capsules (OTC) - Strides Pharma

On January 16, Strides Pharma Inc. of East Brunswick, New Jersey announced they received final FDA approval for Loratadine Soft-Gel Capsules 10mg over-the-counter (OTC).

This product compares to Claritin® Liqui-Gels® Capsules 10mg OTC by Bayer HealthCare LLC. It is an antihistamine that treats symptoms such as itching, runny nose, watery eyes, and sneezing from "hay fever" and other allergies.

Recent annual U.S. sales of Loratadine Soft-Gel Capsules 10mg OTC were $50 million, according to IQVIA.

Paliperidone ER Tablets Launch - ANI Pharmaceuticals

On January 14, ANI Pharmaceuticals, Inc. of Baudette, Minnesota announced the ***launch*** of Paliperidone ER (extended-release) Tablets 1.5mg, 3mg, 6mg, and 9mg (after its previous FDA-approval in June 2019).

This product is AB-rated to Invega® ER Tablets by Janssen Pharmaceuticals, Inc., which had recent annual U.S. sales of $342 million, according to IQVIA. It is an atypical antipsychotic agent indicated for the treatment of schizophrenia, the treatment of schizoaffective disorder as monotherapy, and as an adjunct to mood stabilizers and/or antidepressants.

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Generic Approvals

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Arthur S. Przybyl, ANI's President & CEO, commented: "This product comes from the portfolio of commercial and pipeline drugs that we recently acquired. Paliperidone ER was developed by Inventia Healthcare Ltd., as part of a 2-drug development, manufacturing, and commercialization partnership with ANI."

Potassium Citrate ER Tablets - ANI Pharmaceuticals

On January 14, ANI Pharmaceuticals, Inc. of Baudette, Minnesota announced they received final FDA approval for Potassium Citrate ER (extended-release) Tablets 10mEq and 15mEq. Product is expected to launch sometime in the first quarter of this year.

This product compares to Urocit®-K ER Tablets by Mission Pharmacal Company, which had recent annual U.S. sales of $75 million, according to IQVIA. It is indicated for the management of the following: renal tubular acidosis with calcium stones; hypocitraturic calcium oxalate nephrolithiasis of any etiology; and uric acid lithiasis with or without calcium stones.

Sodium Nitroprusside Injection Launch - Dr. Reddy's

On December 30, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey announced their ***launch*** of Sodium Nitroprusside Injection 50mg/2mL (25mg/mL) in single-dose vials.

This product compares to Nitropress® Injection by Hospira (now owned by Pfizer, Inc.). Recent annual U.S. sales (ending October 2019) for both the brand and its generic equivalents were $8 million, according to IQVIA. It is indicated for lowering of blood pressure immediately in adults and children with high blood pressure. It is also used to reduce bleeding during surgery and to treat acute heart failure.

Sucralfate Oral Suspension (AG of Carafate®) Launch - Par Pharmaceutical

On January 27, Par Pharmaceutical of Chestnut Ridge, New York (an Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania company), announced their ***launch*** of Sucralfate Oral Suspension 1Gm/10mL.

This product is an Authorized Generic (AG) of Carafate® Oral Suspension by Allergan, Inc., which had recent annual U.S. sales (ending November 2019) of $285 million, according to IQVIA. It is indicated to treat gastrointestinal ulcers.

Par partnered with Allergan for the AG of this product.

Travoprost Ophthalmic Solution 0.004% - Alembic

On December 24, Alembic Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they have received final FDA approval for its Abbreviated New Drug Application (ANDA) for Travoprost Ophthalmic Solution 0.004%.

This product compares to Travatan Z® Ophthalmic Solution 0.004% by Alcon Pharmaceuticals. It is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

Trientine HCl Capsules Launch - Dr. Reddy's Laboratories

On February 7, Dr. Reddy's Laboratories, Inc. of Princeton, New Jersey announced their ***launch*** of Trientine HCl Capsules 250mg; available in 100-count bottles.

This product compares to Syprine® Capsules by Bausch Health Companies, Inc. (formerly Valeant Pharmaceuticals), which had recent annual U.S. sales (December 2019) of $94.2 million, according to IQVIA. It is a chelating compound for removal of excess copper from the body, indicated for the treatment of patients with Wilson's disease who are intolerant of penicillamine.

Trientine HCl Capsules can be stored at room temperature (68°F to 77°F), throughout its shelf life of 24 months.

Venlafaxine ER Tablets Launch - Lannett Company

On January 6, Lannett Company, Inc. of Philadelphia, Pennsylvania announced the ***launch*** of Venlafaxine ER (extended-release) Tablets 150mg and 225mg.

This product is indicated for the treatment of major depressive disorder, anxiety, and panic disorder.

Recent annual U.S. sales (ending November 2019) of Venlafaxine ER Tablets in these strengths were $150 million, according to IQVIA, although actual generic market values are expected to be lower.

Vilazodone HCl Tablets - Alembic

On January 13, Alembic Pharmaceuticals, Inc. of Bridgewater, New Jersey announced they received final FDA approval for its Abbreviated New Drug

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	ABC 8-digit #	Cardinal Health #	McKesson Item #	Morris & Dickson #	Product Description	Cup Delivery	Cup Strength	Pack Size	NDC
	10211921	5517206	3795689	584466	Fluoxetine Oral Solution, USP	5mL	20mg/5mL	40ct	60687-0244-77
	10188404	5465380	3917226	363275	Fluoxetine Oral Solution, USP	5mL	20mg/5mL	50ct	60687-0244-67
NEW	10228115	5552237	3968229	752410	Hydrocodone Bitartrate & APAP Oral Solution CII	15mL	7.25mg/325mg/15mL	50ct	60687-0417-71
	10211783	5517214	3901766	584557	Levetiracetam Oral Solution, USP	5mL	500mg/5mL	40ct	60687-0249-77
	10183100	5430343	3775822	238550	Levetiracetam Oral Solution, USP	5mL	500mg/5mL	50ct	60687-0249-67
	10210354	5512413	3777034	568063	Ondansetron Oral Solution, USP	5mL	4mg/5mL	30ct	60687-0252-86
	10219153	5528518	3949997	603993	Oxycodone HCl Oral Solution CII, USP	5mL	5mg/5mL	40ct	60687-0406-77
	10219154	5528526	3950037	604306	Oxycodone HCl Oral Solution CII, USP	5mL	5mg/5mL	50ct	60687-0406-67
NEW	10209414		3751294	560649	Phenobarbital Elixir CIV, USP*	5mL	20mg/5mL	50ct	60687-0448-67
	10231522	5508114	2549509	822841	Phenytoin Oral Suspension, USP	4mL	100mg/4mL	50ct	60687-0275-66
	10211558	5515705	3935129	575878	Potassium Chloride Oral Solution, USP 10%	15mL	20mEq/15mL	30ct	60687-0341-58
	10212031	5520416	3909884	584904	Potassium Chloride Oral Solution, USP 10%	15mL	20mEq/15mL	40ct	60687-0341-64
	10191061	5486220	3263035	321570	Potassium Chloride Oral Solution, USP 10%	15mL	20mEq/15mL	50ct	60687-0341-71
	10211557	5515713	3935137	575894	Potassium Chloride Oral Solution, USP 10%	15mL	20mEq/15mL	80ct	60687-0341-07
	10212749	5521521	3937786	591016	Potassium Chloride Oral Solution, USP 10%	30mL	40mEq/30mL	40ct	60687-0341-14
	10191066	5487574	3266467	465344	Potassium Chloride Oral Solution, USP 10%	30mL	40mEq/30mL	50ct	60687-0341-72
	10182920	5427497	3772373	231159	Theophylline Oral Solution, USP	45mL	80mg/15mL	50ct	60687-0258-71
NEW	10231260		2080927	793638	Valproic Acid Oral Solution, USP	10mL	500mg/10mL	100ct	60687-0262-56

*Product contains 10% alcohol.

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T10504

Generic Approvals & News

Continued from Page 10

Application (ANDA) of Vilazodone HCl Tablets 10mg, 20mg, and 40mg.

This product compares to Viibryd® Tablets 10mg, 20mg, and 40mg by Allergan, which had recent annual U.S. sales (ending September 2019) of $469 million, according to IQVIA. It is indicated for the treatment of major depressive disorder.

Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification and hence is eligible for 180 days of shared exclusivity.

The launch of this product will be made according to the settlement agreement with Allergan.

Zinc Sulfate Injection Launch - American Regent

On January 28, American Regent, Inc. of Shirley, New York announced their ***launch*** of previously FDA-approved Zinc Sulfate Injection in a ***new concentration,*** available as follows.

- 30mg/10mL (3mg/mL) in 10mL Pharmacy Bulk Package Vial (NDC #0517-6103-25), a new concentration.
- 25mg/5mL (5mg/mL) in 5mL Pharmacy Bulk Package Vial (NDC #0517-8005-25).

Zinc Sulfate is a trace element indicated in adult and pediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Harsher Singh, VP of Chief Commercial & Strategic Officer at American Regent, noted: "We are pleased to offer the first FDA approved Zinc Sulfate Injection, which was developed to align with the American Society for Parenteral & Enteral Nutrition (ASPEN) recommendations for trace element supplementation. The 3mg/mL product represents a new concentration of Zinc Sulfate Injection."

Note: Zinc Sulfate Injection is supplied as a pharmacy bulk package for admixing use only; it is not for direct intravenous (IV) infusion.

Generic News

Strides To Acquire 18 ANDA's From Pharmaceutics

On February 7, Strides Pharma Science Ltd. of Bangalore, India (with U.S. headquarters as Strides Pharma, Inc. in East Brunswick, New Jersey) announced it has entered into a definitive asset transfer and licensing agreement with Pharmaceutics International, Inc. (Pii) of Hunt Valley, Maryland to acquire 18 Abbreviated New Drug Applications (ANDA's) for the U.S. market.

ANDA's are generic products that the FDA has either already approved or are considering for possible approval.

Of the 18 products successfully developed by Pii with their Pharmaceutics Know How™, 11 are currently FDA-approved while the remaining 7 products are submitted and are under different stages of FDA review.

Out of the 11 approved ANDA's, Strides is currently commercializing two ANDA's with product supply from Pii, while the remaining approved ANDA's will be transferred to Strides' global manufacturing facilities and commercialized over the next 18 to 24 months.

In addition, Strides will also have exclusive marketing rights for Levothyroxine Sodium Tablets, a narrow-niche micro-dose product that is indicated as replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism with a market opportunity of $2.5 billion.

Pii has developed the products for submission as ANDA's and has completed the bioequivalence studies for four (4) reference listed drugs: Synthroid® (by AbbVie, Inc.); Unithroid® (by Amneal Pharmaceuticals LLC); Levoxyl® (by Pfizer, Inc.); and Thyro-Tabs® (by Lloyd, Inc.); which covers the entire addressable market opportunity.

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Discontinued Drugs

Anastrozole 1mg Tablets By Apotex

On January 21, the FDA announced that Apotex Corp. of Weston, Florida will discontinue the manufacture of Anastrozole 1mg Tablets (NDC #60505-2985-3).

This product is indicated to treat breast cancer in post-menopausal women.

Argatroban Injection By Novartis

On January 15, the FDA announced that Novartis Pharmaceuticals Corporation of East Hanover, New Jersey has made a business decision to permanently discontinue the manufacture of Argatroban Injection 250mg/2.5mL (100mg/mL) single-dose vial (NDC #0078-0930-61).

This product is indicated to treat and prevent blood clots in adults who have thrombocytopenia (low levels of platelets in the blood) caused by using heparin.

Bethanechol Chloride Tablets By Teva

On January 13, the FDA announced that Teva Pharmaceuticals, USA of Parsippany-Troy Hills, New Jersey will discontinue the manufacture of Bethanechol Chloride Tablets, in the following strengths.

- **5mg:** (NDC #51285-697-02).
- **10mg:** (NDC #51285-690-02).

This product is indicated to treat urinary retention (difficulty urinating), which may occur postoperative, postpartum, and in other situations.

Diltiazem HCl Injection By Akorn/Premier ProRx™

On February 7, the FDA announced that Akorn Pharmaceuticals, Inc. of Lake Forest, Illinois has made a business-related decision to discontinue the manufacture of Diltiazem HCl Injection containing the Premier ProRx™ private-label brand, in the following strengths.

- **5mg/mL, 25mL, 1 vial:** NDC #17478-0817-25.
- **5mg/mL, 25mL, 10 vials:** NDC #17478-0817-26.
- **25mg/5mL, 10mL, 10 vials:** NDC #17478-0817-10.

This product is indicated for the treatment of hypertension (high blood pressure), angina (chest pain), and certain heart rhythm disorders.

Dutasteride 0.5mg Capsules By Apotex

On January 7, the FDA announced that Apotex Corp. of Weston, Florida will discontinue the manufacture of Dutasteride 0.5mg Capsules (NDC #60505-3877-9 and NDC #60505-3877-3).

This product is indicated to treat benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

Gatifloxacin 0.5% Ophthalmic Solution By Mylan

On January 27 the FDA announced that Mylan Pharmaceuticals, Inc. of Canonsburg, Pennsylvania will discontinue their manufacture of Gatifloxacin Ophthalmic 0.5% (5mg/ml) Solution (NDC #0378-5431-35).

This product is indicated to treat bacterial conjunctivitis (pinkeye; infection of the membrane that covers the outside of the eyeballs and the inside of the eyelids) in adults and children 1 year of age and older.

Gemcitabine HCl Injection By Apotex

On January 8, the FDA announced that Apotex Corp. of Weston, Florida has made a business decision to discontinue the manufacture of Gemcitabine HCl Injection in single dose vials, in the following strengths.

- **200mg/5.26mL (38mg/mL):** NDC #60505-6113-6.
- **1Gm/26.3mL (38mg/mL):** NDC #60505-6114-0.
- **2Gm/52.6mL (38mg/mL):** NDC #60505-6115-2.

This product is indicated for the treatment of cancers of the pancreas, lung, ovary, and breast.

Gemcitabine HCl Injection By Teva

On January 7 and 16, the FDA announced that Teva Pharmaceuticals USA, Inc. of North Wales, Pennsylvania will discontinue the manufacture of Gemcitabine HCl Single Dose Vial Injection, in the following strengths.

- **200mg:** NDC #45963-612-57 (discontinued on January 7, 2020).
- **200mg/5.26mL (38mg/mL):** NDC #45963-623-57 (actively selling until January 16, 2020, with the remaining inventory estimated to last through March 2020).
- **1Gm:** NDC #45963-619-59 (although the company's remaining inventory is estimated to last through April 2020).

Continued on Page 14

Discontinued Drugs

Continued from Page 13

- **1Gm/26.3mL (38mg/mL):** NDC #45963-624-58 (actively selling until January 16, 2020, with the remaining inventory estimated to last through July 2020).
- **2Gm:** NDC #45963-620-60 (was discontinued on January 7, 2020).
- **2Gm/52.6mL (38mg/mL):** NDC #45963-636-60 (actively selling until 01/16/2020, with the remaining inventory estimated to last through March 2020).

This product is indicated to treat cancers of the pancreas, lung, ovary, and breast.

Levocetirizine Dihydrochloride Tablets By Apotex

On January 21, the FDA announced that Apotex Corp. of Weston, Florida will discontinue the manufacture of Levocetirizine Dihydrochloride 5mg Tablets (NDC #60505-3713-9 and NDC #60505-3713-5).

This product is an antihistamine indicated to relieve allergy symptoms such as watery eyes, runny nose, itching eyes/nose, sneezing, itching, and hives.

Methscopolamine Bromide Tablets By Par

On January 27, the FDA announced that Par Pharmaceuticals, Inc. of Woodcliff Lake, New Jersey has made a business decision to permanently discontinue Methscopolamine Bromide Tablets, in the following strengths.

- **2.5mg:** NDC #64376-603-01 (in a 100-count bottle).
- **5mg:** NDC #64376-604-61 (in a 6-count bottle).

This product is indicated to reduce stomach acid secretion to help control peptic ulcers.

Nevirapine ER Tablets By Sandoz

On January 24, the FDA announced that Sandoz Inc. of Princeton, New Jersey (a Novartis division) will discontinue the manufacture of Nevirapine ER (extended-release) 400mg Tablets (NDC #0781-5893-31 and NDC #0781-5893-05).

This product is indicated to treat HIV infection for use in adults and in children 6 years of age and older.

Pramipexole Dihydrochloride ER Tablets By Endo

On January 27, the FDA announced that Endo Pharmaceuticals, Inc. of Malvern, Pennsylvania will discontinue the manufacture of Pramipexole Dihydrochloride ER (extended release) 4.5mg Tablets (NDC #10370-255-11).

This product is indicated symptoms of Parkinson's disease (stiffness, tremors, muscle spasms, and poor muscle control) and restless legs syndrome (RLS).

Sodium Lactate Injection By Hospira

On January 9, the FDA announced that Hospira, Inc. of Lake Forest, Illinois will discontinue the manufacture of Sodium Lactate Injection 50mEq/10mL (5mEq/1mL), in a single dose plastic flip-top vial (NDC #00409-6664-02).

This product is indicated for use in adults and pediatric patients as a source of electrolytes, calories, and water for hydration.

Temodar® Capsules

On January 23, the FDA announced that Merck Sharp & Dohme Corp. of Kenilworth, New Jersey will discontinue the manufacture of Temodar® (temozolomide) Capsules (and in Child-Resistant Sachets), as follows.

- **5mg Capsules:** NDC #0781-2691-75; NDC #0781-2691-44. Authorized Generic (AG) is now distributed by Sandoz Inc. of Princeton, New Jersey. All AG presentations were discontinued as of December 31, 2019.
- **5mg Child-Resistant Sachets:** NDC #0085-3004-03; NDC #0085-3004-04. To be discontinued in or near March 2020.
- **20mg Child-Resistant Sachets:** NDC #0085-1519-03. To be discontinued on or near June 2020.
- **20mg Capsules:** NDC #0781-2692-75; NDC #0781-2692-44. Authorized Generic (AG) now distributed by Sandoz. All AG presentations were discontinued as of December 31, 2019.
- **100mg Capsules:** NDC #0781-2693-75; NDC #0781-2693-44. AG now distributed by Sandoz. All AG presentations were discontinued as of December 31, 2019.
- **140mg Capsules:** NDC #0781-2694-75; NDC #0781-2694-44. AG now distributed by Sandoz. All AG presentations were discontinued as of December 31, 2019.
- **140mg Child-Resistant Sachets:** NDC #0085-1425-03. To be discontinued on or near August 2020.

Continued on Page 16

Stability, Competency & Innovation

Piperacillin and Tazobactam

for Injection, USP

Brand Reference: **ZOSYN®**

- ✓ Not made with natural rubber latex
- ✓ Preservative Free

® ZOSYN is a registered trademark of Pfizer.

Product Description	Strength	Format	Pack Size	Therapeutic Class	NDC	GTIN
Piperacillin and Tazobactam for Injection, USP	2.25 g	Vial	10	Anti-infective	61990-0110-2	00361990011026
Piperacillin and Tazobactam for Injection, USP	3.375 g	Vial	10	Anti-infective	61990-0120-2	00361990012023
Piperacillin and Tazobactam for Injection, USP	4.5 g	Vial	10	Anti-infective	61990-0130-2	00361990013020
Piperacillin and Tazobactam for Injection, USP	13.5 g	Vial	1	Anti-infective	61990-0140-1	00361990014010
Piperacillin and Tazobactam for Injection, USP	40.5 g	Vial	1	Anti-infective	61990-0150-1	00361990015017

Product Description	Strength	AmerisourceBergen Item Code	Cardinal Item Code	McKesson Item Code
Piperacillin and Tazobactam for Injection, USP	2.25 g	10228571	5549126	3975570
Piperacillin and Tazobactam for Injection, USP	3.375 g	10228586	5549134	3975588
Piperacillin and Tazobactam for Injection, USP	4.5 g	10228587	5549142	3975596
Piperacillin and Tazobactam for Injection, USP	13.5 g	10228215	5549159	3975562
Piperacillin and Tazobactam for Injection, USP	40.5 g	10228248	5549167	3975604

For more information about this product, please visit **apollopharmainc.com**

Tel: 561-469-9058
Fax: 561-727-8943
4400 PGA Blvd., Suite 102
Palm Beach Gardens, FL, 33410
email: info@apollopharmainc.com

Apollo PHARMACEUTICALS USA INC.

v20191031

Rx-To-OTC Switch Of 3 Drugs

Continued from Page 1

drugs consumers can access and use that would otherwise only be available by prescription. This includes providing the millions of people that suffer with joint pain from arthritis daily OTC access to another non-opioid treatment option."

The process of changing the status of a drug from prescription to nonprescription is called an Rx-to-OTC switch. It is usually initiated by the manufacturer of the prescription drug. For a drug to switch to nonprescription status, the data provided must demonstrate that the drug is safe and effective for use in self-medication as directed in proposed labeling. The manufacturer must show that consumers can understand how to use the drug safely and effectively without the supervision of a healthcare professional.

Pataday Twice Daily Relief was first approved as a prescription drug by the FDA in 1996 under the name Patanol®, indicated for the treatment of the signs and symptoms of allergic conjunctivitis (ocular redness and itching due to allergies). Pataday Once Daily Relief was first approved as a prescription drug by the FDA in 2004 under the name Pataday, and was indicated for the treatment of ocular itching associated with allergic conjunctivitis. Ocular itching caused by allergens is a common ailment in the U.S., affecting approximately 66 million people.

Michael Cooper, O.D., Optometrist with Solinsky Eye Care in Hartford, Connecticut, stated: "While eye allergies impact millions of Americans, only a small percentage of those use over-the-counter allergy eye drops likely due to a lack of awareness of effective options that treat the problem at the source. For years, olopatadine has been my 'go-to' eye drop for patients struggling with itchy allergy eyes and I'm thrilled they will now be able to get the same relief over the counter whenever they need it. My hope is that more allergy sufferers will discover the benefits of Pataday and add it to their medicine cabinet this spring allergy season and beyond."

Voltaren Arthritis Pain is a nonsteroidal anti-inflammatory drug (NSAID) and works by reducing substances in the body that cause pain and inflammation. This product, previously referred to as Voltaren Gel 1%, was first approved by the FDA in 2007 as a prescription drug, indicated for the relief of osteoarthritis of the joints that is responsive to topical treatment (in particular, the joints of the hands, knees and feet).

Osteoarthritis (OA) is the most common type of arthritis, which increases with age, affects approximately 30 million people in the U.S., and can generally be self-diagnosed. Voltaren offers consumers who suffer from OA an alternative option to oral analgesics. It targets pain directly at the site and the amount of diclofenac sodium that is systemically absorbed from Voltaren Arthritis Pain is on average 6% of the systemic exposure from an oral form of diclofenac sodium.

Dr. Roy Altman, Professor of Medicine in Rheumatology at the University of California in Los Angeles, said: "Osteoarthritis treatment guidelines from several international and U.S. medical societies endorse the early use of topical NSAID's for treating arthritis pain of the knee and hand. In contrast to prior guidelines, the recommendations are inclusive of all age groups, not just the elderly."

The Osteoarthritis Research Society International recently updated and expanded their guidelines for non-surgical management of osteoarthritis by developing patient-focused treatment recommendations. These updated guidelines strongly recommend topical NSAID's for individuals with knee osteoarthritis; and topical NSAID's were recommended more strongly than all oral analgesics, due to favorable balance of consistent efficacy and minor transient side effects.

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Discontinued Drugs

Continued from Page 14

- **180mg Capsules:** NDC #0781-2695-75 and NDC #0781-2695-44. AG now distributed by Sandoz. All AG presentations were discontinued as of December 31, 2019.
- **250mg Capsules:** NDC #0781-2696-75. AG now distributed by Sandoz. All AG presentations were discontinued as of December 31, 2019.

This product, used together with radiation therapy, is indicated to treat certain types of brain tumor in adults.

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New Drugs/Indications

Absorica LD™ Capsules For Severe Recalcitrant Nodular Acne - Launch

On February 4, Sun Pharmaceutical Industries, Inc. of Princeton, New Jersey announced the ***launch*** of Absorica LD™ (isotretinoin) Capsules after its recent FDA approval in November 2019; indicated for the management of severe recalcitrant nodular acne in patients 12 years of age and older.

Product was approved and is now available in the following strengths: 8mg, 16mg, 20mg, 24mg, 28mg, and 32mg.

Absorica LD is the only isotretinoin formulation to feature Sun Pharma's micronization technology, which utilizes micronized particles to optimize absorption at a 20% lower dose.

Note: Absorica LD is ***not*** substitutable with Absorica® (also by Sun) because of their different bioavailabilities and recommended dosages. Absorica LD delivers twice the level of absorption of Absorica in a fasted state, with a comparable safety profile. Absorica LD provides maximal isotretinoin absorption with a 20% lower dose, and is not substitutable with any other currently available isotretinoin.

Nicholas Squittieri, M.D., Chief Medical Officer of North America for Sun Pharma, noted: "Severe recalcitrant nodular acne is characterized by nodules, which are hard, solid, painful lumps in the skin, and primarily affects teens and young adults. Ineffective acne treatment can cause lifelong physical scars as well as psychosocial issues such as feelings of isolation. Absorica LD makes visibly clearer skin possible within just 5 months, removes the uncertainty surrounding timing of dosing, and makes absorption more predictable. The availability of a low-dose, highly bioavailable oral isotretinoin option should be welcome news for those suffering from this very severe form of acne."

Note: because of significant adverse reactions associated with their use, Absorica and Absorica LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. Both drugs can cause severe life-threatening birth defects and are contraindicated in pregnancy. Because of this risk, the products are available only through a restricted under a Risk Evaluation & Mitigation Strategy (REMS) program, called the iPledge REMS.

Ajovy® Injection (Autoinjector) - New Administration Route

On January 28, Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey announced the FDA has approved an autoinjector device as a ***new route of administration*** for Ajovy® (fremanezumab-vfrm) Injection (subcutaneous), as a 225mg/ 1.5mL solution in a single-dose prefilled autoinjector.

Product is expected to be available in the coming months.

Ajovy is a calcitonin gene-related peptide antagonist drug, indicated for the preventive treatment of migraine in adults. It should be administered in the abdomen, thigh, or upper arm, subcutaneously (under the skin).

There are 2 subcutaneous dosing options of Ajovy, as follows:

1) 225mg monthly;
2) 675mg every 3 months (to be administered as 3 consecutive injections of 225mg each).

Brendan O'Grady, Executive VP of Teva's North America Operations, said: "The approval of the Ajovy autoinjector is another important step forward for the migraine community. It is the only FDA-approved anti-CGRP drug that offers the flexibility of quarterly (675mg) or monthly (225mg) dosing options, and we are pleased that patients and their healthcare providers will be able to decide if an autoinjector is the right administration option for their needs."

Amzeeq™ Topical Foam For Acne - Now Available

On January 9, Foamix Pharmaceuticals of Bridgewater, New Jersey announced the ***launch*** of Amzeeq™ (minocycline) Topical Foam 4%, indicated for the once-daily treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older.

Amzeeq was recently FDA-approved, approximately 3 months before this announcement date *(see October 2019 PPO)*. It is the first topical minocycline to be approved for any condition. This once-daily therapy will be available in retail, community, and specialty pharmacies nationwide.

Minocycline, a broad-spectrum antibiotic known for its efficacy in treating moderate to severe acne, has not previously been available as a topical treatment due to its instability in traditional topical formulations. With the development of Amzeeq, Foamix has leveraged

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New Drugs/Indications

Continued from Page 17

its proprietary Molecule Stabilizing Technology (MST™) platform to conveniently and effectively deliver minocycline in a foam-based vehicle that maintains the stability of the active ingredient while delivering it directly on the skin.

David Domzalski, CEO of Foamix, commented: "Moderate to severe acne is a challenging and burdensome condition of many sufferers. Amzeeq is now positioned to become an important tool in managing this condition. We recognize that providers and acne sufferers have been seeking alternatives in acne treatment, and I'm very proud of the program we've designed to provide broad awareness and availability of Amzeeq for physicians and patients."

Ayvakit™ For Unresectable Or Metastatic PDGFRA Exon 18 Mutant Gastrointestinal Stromal Tumors

On January 9, Blueprint Medicines Corporation of Cambridge, Massachusetts announced the FDA has approved Ayvakit™ (avapritinib) Tablets, indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. It is the first precision therapy approved to treat this genomically defined population of patients.

Product will be available in mid-January. The recommended dosage is 300mg orally once daily on an empty stomach, at least 1 hour before and 2 hours after a meal.

Gastrointestinal stromal tumors (GIST) are a rare, genomically driven sarcoma of the gastrointestinal (GI) tract. Approximately 6% of patients with newly diagnosed GIST have PDGFRA exon 18 mutations. The most common PDGFRA exon 18 mutation is the D842V mutation, which is resistant to all other approved therapies. GIST is a sarcoma (tumor) of bone or connective tissue in the GI tract. They arise from cells in the wall of the GI tract and occur most often in the stomach or small intestine. Most patients are diagnosed between the ages of 50 to 80, and diagnosis is typically triggered by GI bleeding, incidental findings during surgery or imaging, and in rare cases, tumor rupture or GI obstruction.

In unresectable or metastatic GIST, clinical benefits from existing treatments can vary by mutation type. Mutational testing is critical to tailor therapy to the underlying disease driver and is recommended in expert guidelines. Currently, there are no approved therapies for patients with KIT-driven GIST whose disease progresses beyond imatinib, sunitinib, and regorafenib.

Michael Heinrich, M.D., Professor of Medicine at Oregon Health & Science University in Portland (and an investigator in the product's trial study), said: "This approval of Ayvakit brings forward a new standard of care for patients with PDGFRA exon 18 mutant GIST, a genomically defined population that previously had very limited treatment options. For the first time, we can offer these patients a highly effective treatment that targets the underlying genetic cause of their disease. Building on our growing understanding of the molecular basis of GIST, this milestone ushers in a new era of precision medicine in this disease. The FDA approval represents a call to action to conduct mutational testing in all patients with GIST before initiating kinase inhibitor therapy, as recommended by clinical guidelines, so appropriate patients may realize the benefits of this promising new medicine."

Note: healthcare professionals should advise pregnant women that Ayvakit may cause harm to a developing fetus or newborn baby, so effective contraception should be used during treatment and for 6 weeks after the final dose.

The FDA granted this application Breakthrough Therapy, Fast Track, and Orphan Drug designation.

Richard Pazdur, M.D., Director of the FDA's Oncology Center of Excellence & Acting Director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation & Research, said: "GIST harboring a PDGFRA exon 18 mutation do not respond to standard therapies for GIST. However, this approval provides patients with the first drug specifically approved for GIST harboring this mutation. Clinical trials showed a high response rate with almost 85% of patients experiencing tumor shrinkage with this targeted drug."

Caldolor® For Injection Now In Ready-To-Use Formulation

On January 7, Cumberland Pharmaceuticals Inc. of Nashville, Tennessee announced their ***launch*** of Caldolor® (ibuprofen) for Injection 800mg/200mL, which comes in a ready-to-use (RTU) bag that may be administered without dilution

Continued on Page 20

pai Pharmaceutical Associates, Inc.

STILL AVAILABLE

Ranitidine Syrup

15 mg/mL

(Ranitidine Oral Solution, USP)

PAI's Ranitidine Syrup product was tested by the FDA and found to be below the FDA's established 0.32 ppm daily limit for NDMA content.

- *AA Rated*
- *Alcohol Free / Dye Free*
- *Alternative to Solid Dosage Forms*

Ranitidine Syrup Oral Solution, USP						
CASE NDC 00121-	Description	Case Pack	ABC	Cardinal	McKesson	Morris & Dickson
0727-16	15 mg/mL	12	10043277	4017992	1805050	450775
4727-10	150 mg/10 mL	40	10043676	4018016	1804434	978072

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New Drugs/Indications

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for pain relief; after its 2019 FDA approval of the product's new delivery method.

The new formulation of Caldolor comes in a pre-mixed bag containing 800mg of ibuprofen in a 200mL patented low sodium formulation for injection that is ready-to-use (RTU); providing healthcare professionals a formulation that is easy to administer, helping manage the treatment of patient pain and fever, while reducing opioid consumption. It is the first and only FDA-approved pre-mixed bag of ibuprofen.

In addition, Caldolor is also still available as an 800mg/8mL single-dose vial (100mg/mL) for dilution, as well as the RTU bag (4mg/mL).

Caldolor is indicated in adults and pediatric patients 6 months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever.

A non-steroidal anti-inflammatory drug (NSAID), Caldolor may be used as the sole method of treatment for mild-moderate pain or as part of a multi-modal treatment for severe pain. Thus, it is positioned to play an important role in combatting the nation's opioid crisis.

Even short-term opioid use after surgery can lead to long-term addiction. Prompt and appropriate pain management is vital to mitigating opioid use. Published data for Caldolor supports administration just prior to surgery and throughout the postoperative period. As a result, patients experience significantly less pain upon awakening, then remain in significantly less pain, while also reducing their opioid consumption.

A.J. Kazimi, CEO of Cumberland Pharmaceuticals, noted: "We have been encouraged by the significant number of physicians who have incorporated Caldolor into their pain management regimens as a way to combat the negative effects of opioid use. The new RTU presentation of Caldolor offers hospitals and other medical facilities a proven product that is now easier to administer, and thus, has the potential to further reduce opioid use."

Caldolor can be a key component in cost effective Enhanced Recovery After Surgery (ERAS) multimodal treatment protocols. Clinical studies of Caldolor demonstrate the following:

- Up to a 58% reduction in opioid use compared to placebo group;
- Up to a 43% reduction in visual analog scale (VAS) scores (a validated, subjective measure for acute and chronic pain), at rest compared to opioids alone;
- Patients reporting significantly less pain shortly after waking;
- Patients remain in significantly less pain during recovery;
- Potential to improve quality of recovery and reduce postsurgical fatigue;
- Significant pain and fever reduction in children ages 6 months and older.

Note: Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAID's, patients with a history of asthma or other allergic-type reactions after taking aspirin or other NSAID's.

Dificid® Oral Suspension & Tablets For *C. Difficile* In Children 6 Months & Older - New Formulation & Indication

On January 27, Merck & Co., Inc. of Kenilworth, New Jersey announced the FDA has approved a ***new oral suspension formulation and indication*** for Dificid® (fidaxomicin) Oral Suspension & Dificid Tablets, now also for the treatment of *Clostridioides* (formerly *Clostridium*) *difficile*-associated diarrhea (CDAD) in children aged 6 months and older.

The recommended dose for pediatric patients weighing at least 12.5kg and able to swallow tablets is one 200mg tablet administered orally twice daily for 10 days. If unable to swallow tablets, pediatric patients may be dosed with Dificid Oral Suspension orally twice daily for 10 days, based on weight.

New Drugs/Indications

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Dificid is a macrolide antibacterial medicine indicated in adults and pediatric patients aged 6 months and older for treatment of CDAD. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dificid and other antibacterial drugs, Dificid should be used only to treat infections that are proven or strongly suspected to be caused by *Clostridioides difficile*.

Clostridioides (formerly *Clostridium*) *difficile*, also known as *C. difficile* or *C. diff*, is one of the most common causes of healthcare-associated infections in U.S. hospitals. Recent estimates suggest *C. difficile* causes almost 500,000 infections annually in the United States and is associated with approximately 29,000 deaths within 30 days of initial diagnosis. According to the U.S. Centers for Disease Control & Prevention (CDC) report on: "Antibiotic Resistance Threats in the United States-2019," *C. diff* is categorized as an urgent threat and is stated as a public health threat that requires crucial and aggressive action.

Dr. Larry K. Kociolek, Associate Medical Director of Infection Prevention & Control at Ann & Robert H. Lurie Children's Hospital in Chicago, Illinois, stated: "*C. difficile* is an important cause of healthcare and community associated diarrheal illness in children, and sustained cure is difficult to achieve in some patients. The fidaxomicin pediatric trial was the first randomized controlled trial of *C. diff* infection treatment in children. I am very excited to have a new *C. diff* infection treatment option for my pediatric patients."

Enhertu® For HER2 Positive Unresectable Or Metastatic Breast Cancer - Now Available

On January 6, AstraZeneca of Wilmington, Delaware and Daiichi Sankyo, Inc. of Basking Ridge, New Jersey jointly announced the ***availability*** (after its recent FDA approval in late December), of Enhertu® (fam-trastuzumab deruxtecan-nxki), indicated for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received 2 or more prior anti-HER2-based regimens in the metastatic setting.

Shanu Modi, M.D., Breast Medical Oncologist for Memorial Sloan Kettering Cancer Center, commented: "Once patients with HER2 positive metastatic breast cancer progress following at least two HER2 targeted regimens in the metastatic setting, there are limited treatment options. Enhertu has the potential to become a new standard of care."

Enhertu is a human epidermal growth factor receptor 2 (HER2)-directed antibody and topoisomerase inhibitor conjugate, meaning that the drug targets the changes in HER2 that help the cancer grow, divide and spread, and is linked to a topoisomerise inhibitor, a chemical compound that is toxic to cancer cells.

HER2-positive breast cancer is a type of breast cancer that tests positive for a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of cancer cells. Approximately 1 of every 5 breast cancers have a gene mutation in the cancer cells that makes an excess of the HER2 protein. HER2-positive breast cancers are an aggressive type of breast cancer.

José Baselga, M.D., Ph.D., Executive VP of Oncology R&D for AstraZeneca, stated: "Enhertu has shown impressive results in women with HER2 positive metastatic breast cancer, with the majority of women benefiting from treatment and the median duration of response exceeding 14 months. With this first approval, we are proud to bring Enhertu to patients with high unmet need and we look forward to further exploring its potential in additional settings."

Note: Enhertu is approved with a Boxed Warning for interstitial lung disease/pneumonitis and embryo-fetal toxicity and harm. Advise patients of the need for effective contraception as well as the risk of interstitial lung disease/pneumonitis and to immediately report symptoms (cough, dyspnea, fever, and other new or worsening respiratory symptoms).

Fiasp® Injection For Children With Diabetes - Expanded Indication

On January 6, Novo Nordisk, Inc. of Plainsboro, New Jersey announced the FDA has approved an ***expanded indication*** for Fiasp® (insulin aspart) Injection 100units/mL, now also for use as a new mealtime insulin option for children with diabetes mellitus.

Fiasp is the first and only fast-acting mealtime insulin injection that does not have a pre-meal dosing recommendation. It is administered at the beginning of a meal or within 20 minutes after starting a meal.

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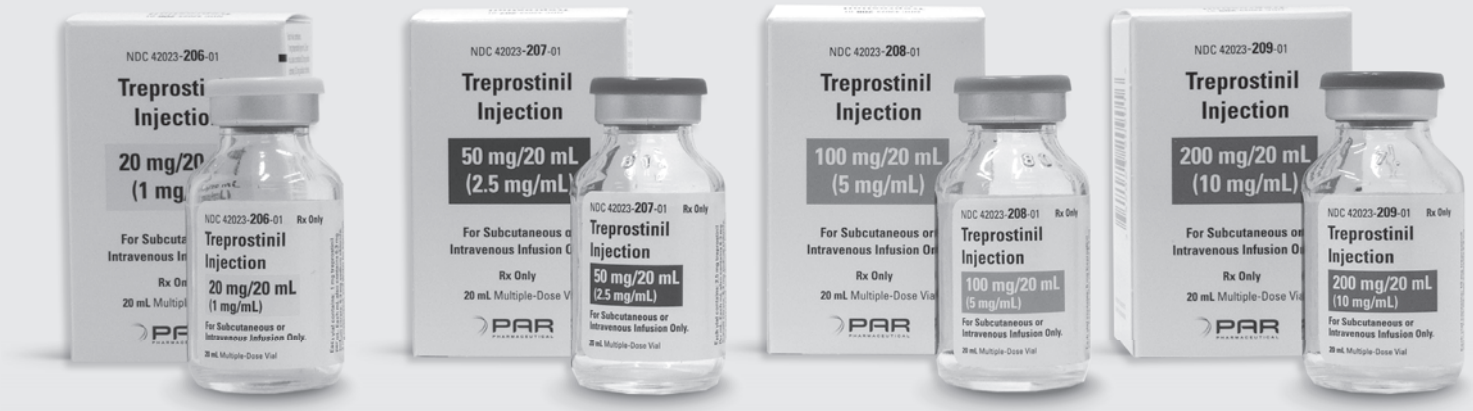

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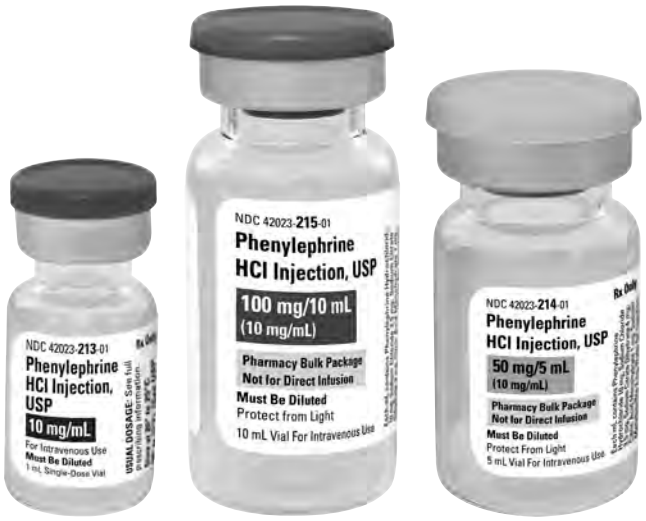

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New Drugs/Indications

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Product is now available for use in children and adults in 3 different dosing option, as follows: 1) multiple daily injections (MDI); 2) continuous subcutaneous insulin infusion pumps; and 3) intravenous infusion under supervision by a healthcare professional.

Diabetes is one of the most common chronic conditions diagnosed in childhood, with nearly 18,000 new cases of type 1 diabetes each year. Managing diabetes can be challenging for parents and caregivers given it is hard to know exactly how much or how quickly their children will eat, making mealtime insulin dosing difficult. Conventional rapid-acting insulins must be administered ahead of meals, which requires some guesswork to dose properly, and children living with diabetes may not achieve adequate blood sugar control.

Todd Hobbs, Vice President & U.S. Chief Medical Officer of Novo Nordisk, explained: "As a parent of a son living with type 1 diabetes, I know first-hand how tough it can be to address the inevitable blood sugar spikes around mealtimes. Children can be unpredictable and having the option of a fast-acting insulin that doesn't require pre-meal dosing like Fiasp is a welcome development for the diabetes community."

Keytruda® For Certain Patients With High-Risk, Non-Muscle Invasive Bladder Cancer - New Indication

On January 8, Merck & Co., Inc. of Kenilworth, New Jersey announced the FDA has approved a ***new indication*** for Keytruda® (pembrolizumab) Injection, now also as monotherapy for the treatment of patients with Bacillus Calmette-Guerin (BCG) unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

The recommended pembrolizumab dose is 200mg every 3 weeks.

Keytruda is an anti-PD-1 therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Keytruda is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

Arjun V. Balar, M.D., Associate Professor of Medicine & Director of Genitourinary Medical Oncology at NYU Langone Health's Perlmutter Cancer Center in New York City, explained: "High-risk, non-muscle invasive bladder cancer is a serious disease, characterized by frequent recurrences and progression. Historically, patients with high-risk, non-muscle invasive bladder cancer with CIS whose cancer is unresponsive to BCG treatment had limited non-surgical treatment options. As a physician who specializes in the management of bladder cancer, it is encouraging to now have a new treatment option for these patients."

Lynparza® For gBRCAm Metastatic Pancreatic Adenocarcinoma - New Indication (& Companion Diagnostic Test)

On December 30, AstraZeneca Pharmaceuticals LP of Wilmington, Delaware and Merck & Co., Inc. of Kenilworth, New Jersey jointly announced the FDA has approved a ***new indication*** for Lynparza® (olaparib), now also for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

In addition, the FDA also approved a companion diagnostic: the BRACAnalysis CDx test by Myriad Genetic Laboratories, Inc., for the selection of patients with pancreatic cancer for treatment with Lynparza based upon the identification of deleterious or suspected deleterious germline mutations in BRCA1 or BRCA2 genes.

New Drugs/Indications

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The recommended dose is 300mg taken orally twice daily with or without food.

In the United States this year, it is expected that over 55,000 people will be diagnosed with pancreatic cancer and approximately 45,750 people or more will die of the disease. Early diagnosis is difficult, as often there are no symptoms. There are 2 types of pancreatic cancer. Exocrine tumors, of which the most common type is pancreatic ductal adenocarcinoma (PDAC), start in the exocrine cells, where enzymes help to digest food. Neuroendocrine tumors start in neuroendocrine cells, which produce hormones such as insulin, that control different functions of the body.

Lynparza is a first-in-class PARP inhibitor that leads to the trapping of PARP bound to DNA single-strand breaks, stalling of replication forks, their collapse and the generation of DNA double-strand breaks and cancer cell death. BRCA1 and BRCA2 (breast cancer susceptibility genes 1/2) are human genes that produce proteins responsible for repairing damaged DNA and play an important role in maintaining the genetic stability of cells. When either of these genes is mutated, or altered, such that its protein product either is not made or does not function correctly, DNA damage may not be repaired properly, and cells become unstable. As a result, cells are more likely to develop additional genetic alterations that can lead to cancer.

Hedy L. Kindler, Professor of Medicine at University of Chicago Medicine in Illinois (and Co-Principal Investigator of the product's study trial), commented: "This approval of olaparib based on the product's study results gives clinicians an important 1st-line maintenance treatment option which nearly doubled the progression-free survival benefit in patients with germline BRCA-mutated metastatic pancreatic cancer."

In July 2017, AstraZeneca and Merck & Co., Inc. announced a strategic oncology collaboration to co-develop and co-commercialize Lynparza as well as potential new medicine selumetinib (an MEK inhibitor), for multiple cancer types. Working together, the companies will develop Lynparza and selumetinib in combination with other potential new medicines and as monotherapies.

Monoferric® Injection For Iron Deficiency Anemia

On January 29, PRNewswire.com reported that Pharmacosmos Therapeutics Inc. of Morristown, New Jersey announced the FDA has approved Monoferric® (ferric derisomaltose) Injection 100mg/mL, an intravenous iron indicated for the treatment of iron deficiency anemia in adult patients who have an intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-hemodialysis dependent chronic kidney disease.

Ferric derisomaltose is an iron carbohydrate complex with a matrix structure composed of interchanging layers of ferric hydroxide and the carbohydrate derisomaltose. Derisomaltose consists of linear, hydrogenated isomaltooligosaccharides with an average molecular weight of 1,000 daltons and a narrow molecular weight distribution that is almost devoid of mono and disaccharides. Ferric derisomaltose is also known as iron isomaltoside 1,000.

Monoferric was first approved in Europe in 2009, as Monofer® (iron isomaltoside 1,000 injection) and is currently marketed in more than 30 countries worldwide, including in the EU, Canada, and Australia. Pharmacosmos has been established to commercialize Monoferric in the rapidly growing U.S. intravenous iron market.

Michael Auerbach, M.D., F.A.C.P., Clinical Professor of Medicine at Georgetown University School of Medicine in Washington D.C., explained: "Iron deficiency anemia remains a serious health issue both in the United States and globally. I am very happy that Monoferric, which is supported by a robust clinical trial program, is now approved in the U.S. for administration of a total dose infusion in a single visit, making it the first intravenous iron formulation in the United States to receive such an approval."

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New Drugs/Indications

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Mycamine® Injection For Invasive Candidiasis In Pediatric Patients Less Than 4 Months Of Age - Expanded Indication

On January 8, Astellas Pharma U.S. Inc. of Northbrook, Illinois announced the FDA has approved an ***expanded indication*** for Mycamine® (micafungin) Injection, now for the treatment of candidemia, acute disseminated candidiasis, candida peritonitis, and abscesses without meningo-encephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.

The approved dose for Mycamine in neonates and young infants less than 4 months is 4mg/kg once daily.

Mycamine is now the first antifungal drug approved in the United States specifically for the treatment of invasive candidiasis for this patient population. Candidiasis in newborns is associated with 20% mortality and significant morbidity and mortality in infants.

Invasive candidiasis is a fungal infection caused by a yeast called Candida. Candidemia is a bloodstream infection with Candida and is the most common form of invasive candidiasis. Invasive candidiasis infections are often associated with high rates of morbidity and mortality, as well as increases in cost and length of hospital stay.

The U.S. Centers for Disease Control & Prevention (CDC) estimate that approximately 25,000 new cases of candidemia occur nationwide each year; and it occurs in 9 of every 100,000 persons per year.

Laura Kovanda, Ph.D., Senior Director & Global Development Project Leader of Infectious Diseases & Oncology for Astellas, noted: "Although rare, invasive candidiasis in newborns constitutes a unique pathogenesis unlike that demonstrated in older children and adults as marked by a higher incidence of organ involvement, especially in the central nervous system. We're pleased with this decision and the potential benefits Mycamine may offer to young infants and their families impacted by invasive candidiasis."

Mycamine can be used concomitantly with a variety of other drugs, including the HIV protease inhibitor ritonavir and transplant medications cyclosporine and tacrolimus.

Numbrino® (C-II) Nasal Solution 4% - For Local Anesthesia

On January 13, Lannett Company, Inc. of Philadelphia, Pennsylvania announced that the FDA has approved the New Drug Application (NDA) for Numbrino® (cocaine HCl) Nasal Solution 4% (40mg/mL), an ester local anesthetic drug indicated for the introduction of local anesthesia of the mucous membranes for diagnostic procedures and surgeries on or through the nasal cavities of adults.

Product is expected to be available shortly after this announcement date. It has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 2 (C-II) controlled drug substance.

Ozempic® For Cardiovascular Risk Reduction In Adults With Type 2 Diabetes & Known Heart Disease - New Indication

On January 16, Novo Nordisk, Inc. of Plainsboro, New Jersey announced the FDA has approved a ***new indication*** for Ozempic® (semaglutide) Injection 0.5mg or 1mg, now also to reduce the risk of major adverse cardiovascular events (MACE) such as heart attack, stroke, or death in adults with type 2 diabetes and known heart disease.

Cardiovascular disease (CVD) is the main cause of death and disability among people with type 2 diabetes. Adults with type 2 diabetes are 2 to 4 times more likely to develop CVD than adults without diabetes.

Ozempic Injection 0.5mg or 1mg is a once-weekly gluca-gon-like peptide-1 (GLP-1) receptor

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0283-0914-60	10160106	5170071	3509528	Spray Kit 2 oz. spray can and 100 individually sealed disposable extension tubes
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New Drugs/Indications

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agonist drug, indicated along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes mellitus; and to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes mellitus with known heart disease.

Ozempic was originally FDA-approved in December 2017.

Todd Hobbs, VP & U.S. Chief Medical Officer of Novo Nordisk, commented: "There is a well-established link between cardiovascular disease and type 2 diabetes. It's one of our biggest concerns with type 2 diabetes because even when patients reach their blood sugar targets, the risk of a major adverse CV event remains. This milestone establishes Ozempic as an option for patients to help address 2 critical aspects of managing type 2 diabetes, blood sugar control, and cardiovascular risk reduction, in those with known heart disease."

Note: Ozempic is not a substitute for insulin, nor is it for use in people with type 1 diabetes or diabetic ketoacidosis.

Palforzia™ - First Treatment For Peanut Allergy

On January 31, Aimmune Therapeutics, Inc. of Brisbane, California announced the FDA has approved Palforzia™ Peanut *(Arachis hypogaea)* Allergen Powder-dnfp, which is the first approved treatment for patients with peanut allergies. It is an oral immunotherapy drug, indicated for the mitigation of allergic reactions (including anaphylaxis) that may occur with accidental exposure to peanut, approved for use in patients with a confirmed diagnosis of peanut allergy.

Palforzia is a powder that is manufactured from peanuts and packaged in pull-apart color-coded capsules for dose escalation and up-dosing, and in a sachet for maintenance treatment. The powder is emptied from the capsules or sachet and mixed with a small amount of semisolid food (such as applesauce, yogurt, or pudding), that the patient then consumes.

Peter Marks, M.D., Ph.D., Director of the FDA's Center for Biologics Evaluation & Research, said: "Peanut allergy affects approximately 1 million children in the U.S. and only 1 out of 5 of these children will outgrow their allergy. Because there is no cure, allergic individuals must strictly avoid exposure to prevent severe and potentially life-threatening reactions. Even with strict avoidance, inadvertent exposures can and do occur. When used in conjunction with peanut avoidance, Palforzia provides an FDA-approved treatment option to help reduce the risk of these allergic reactions in children with peanut allergy."

Treatment with Palforzia consists of 3 phases: initial dose escalation (administered to patients aged 4 through 17 years); up-dosing; and maintenance (up-dosing and maintenance may be continued in patients 4 years of age and older). The initial dose escalation phase is given on a single day. The up-dosing phase consists of 11 increasing dose levels and occurs over several months. Initial dose escalation and the first dose of each up-dosing level, are administered under supervision of a healthcare professional in a healthcare setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. While anaphylaxis can occur at any time during Palforzia therapy, patients are at highest risk during and after the initial dose escalation and the first dose of each up-dosing level. During up-dosing, if the patient tolerates the first dose of an increased dose level, the patient may continue that dose level daily at home. After a patient completes all up-dosing levels, they may begin the daily maintenance dose. Patients who experience certain allergic reactions due to Palforzia may need to discontinue treatment or have their dosing schedule modified.

Palforzia is to be used in conjunction with a peanut-avoidant diet, and is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Peanut allergy is one of the most common food allergies in the world, affecting more than 1.6 million children and teens in the United States alone, and can be a chronic and life-long condition. Reactions to peanut can range from mild to potentially life-threatening, with 1 in 5 peanut-allergic patients visiting emergency rooms each year due to accidental exposures. Physical symptoms can develop within seconds of exposure and may include skin reactions, digestive discomfort, or more dangerous reactions, such as constriction of the throat and airways, and loss of adequate blood flow to vital organs of the body. Antihistamines and epinephrine can be used to treat allergic reactions, but severe reactions can be fatal even with appropriate and prompt treatment. Aimmune Therapeutics company was founded directly in response to a united call to action by leading stakeholders in food allergies.

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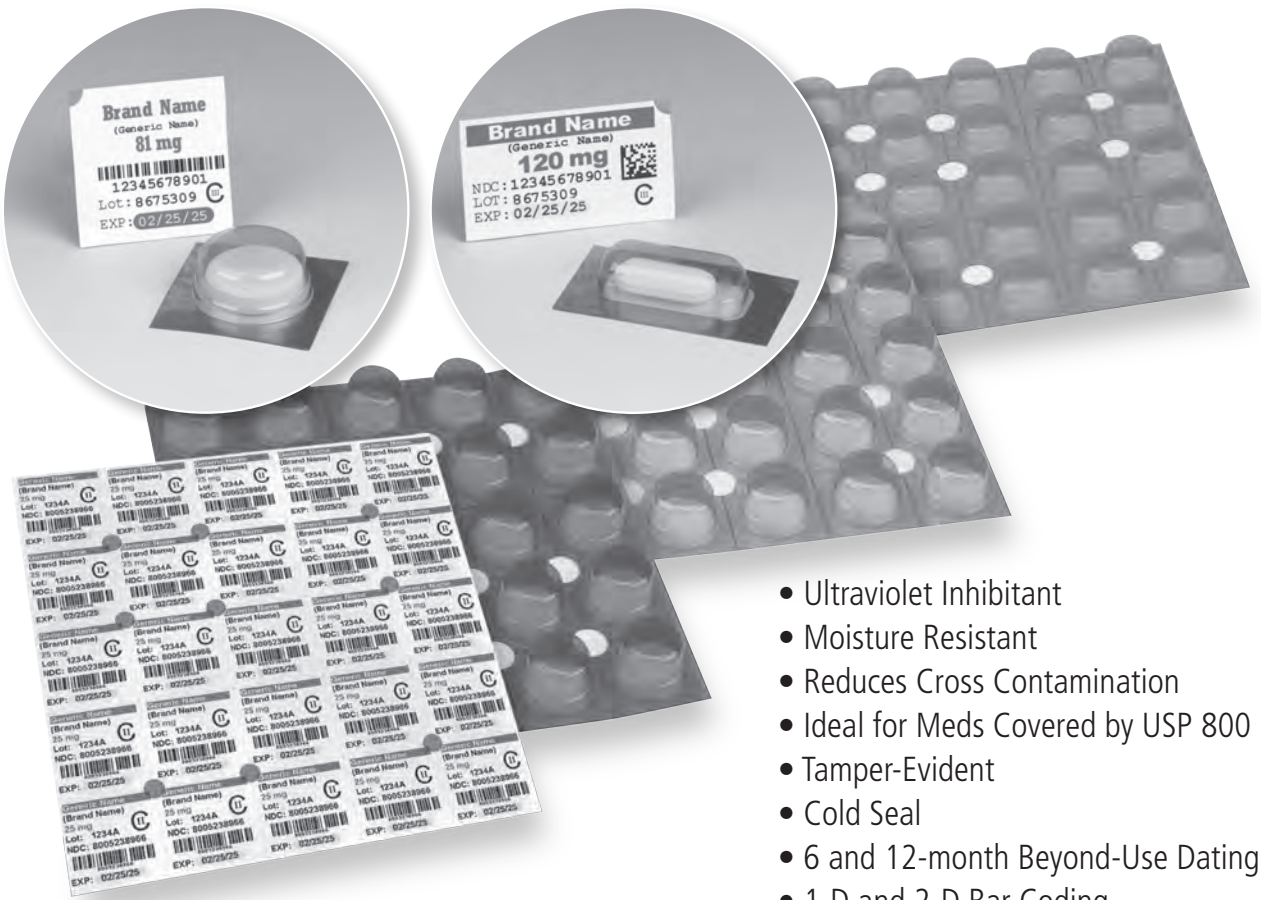

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New Drugs/Indications

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Palforzia is a complex biologic drug used with a structured dosing approach that builds on a century of oral immunotherapy (OIT) research. With OIT, the specific allergenic proteins are ingested initially in very small quantities, followed by incrementally increasing amounts, resulting in the ability to mitigate allergic reactions to the allergen over time. Palforzia is a rigorously developed, pharmaceutical-grade OIT for peanut allergy with a well-defined allergen profile to assure that every dose, whether 0.5mg (equivalent to 1/600th of a peanut) or 300mg, has been prepared and analyzed for consistency.

Note: Palforzia is available only through a Risk Evaluation & Mitigation Strategy (REMS) Program. Requirements of the REMS include the following: pharmacies and distributors must be certified with the REMS Program, and only dispense Palforzia to certified healthcare settings or to patients who are enrolled in it; the initial dose escalation and first dose of each up-dosing level must be administered in a certified healthcare setting; epinephrine must always be immediately available to patients; and the prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment.

Lisa Gable, CEO of Food Allergy Research & Education (FARE), said: "Peanut allergy carries an overwhelming psychosocial burden that impacts patients and their families daily; peanuts are everywhere, and the threat of a severe reaction related to an accidental peanut exposure dominates families' daily lives. The risk of accidental exposure is real, and we, as a community, have long awaited an option beyond avoiding peanuts alone. As one of the organizations that originally highlighted the need for an FDA-approved oral treatment approach to food allergy back in 2011, we are thrilled with this FDA approval of Palforzia as it fills a long-standing need in the treatment of peanut allergy."

Pancreaze® DR Capsules With A 36-Month Shelf Life - New Formulation

On February 5, Vivus, Inc. of Campbell, California announced that the FDA has approved the supplemental New Drug Application (sNDA) for a ***new formulation*** of Pancreaze® (pancrelipase) DR (delayed-release) Capsules, that now extends the shelf life to 36 months across all Pancreaze dosages.

Pancreaze is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. It is used to treat people who cannot digest food normally because their pancreas does not make enough enzymes, due to cystic fibrosis or other conditions. It may help the body use fats, proteins, and sugars from food, and is safe and effective in children when taken as prescribed.

Originally approved in 2010, Pancreaze is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. The pancreatic enzymes in Pancreaze act like digestive enzymes physiologically secreted by the pancreas.

John Amos, CEO of Vivus, stated: "The approval of this sNDA is an important milestone for Vivus and for the patients with exocrine pancreatic insufficiency that we seek to treat. It highlights our ability to derive additional value from our marketed products and allows patients to store Pancreaze for longer periods of time, which may help to reduce their out-of-pocket expenses. We also expect that the 36-month shelf life will limit the amount of returned product, and over time, will lower our overall supply chain costs."

Pemfexy™ For Injection - Ready-To-Dilute Formulation For Locally Advanced Or Metastatic Nonsquamous Non-Small Cell Lung Cancer

On February 17, Eagle Pharmaceuticals, Inc. of Woodcliff Lake, New Jersey announced that it has received final FDA approval for Pemfexy™ (pemetrexed) for Injection in a new ready-to-dilute formulation, indicated for the following.

→

New Drugs/Indications

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- Locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin;
- Locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, as maintenance treatment;
- Locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy as a single agent;
- Malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin.

Pemfexy is a branded alternative to Alimta® Injection by Eli Lilly & Company. Pemfexy's final FDA approval follows Eagle's recent settlement agreement with Eli Lilly & Company, in mid-December 2019. This agreement provides for a release of all claims by the parties and allows for an initial entry of Pemfexy into the market on February 1, 2022, and a subsequent uncapped entry on April 1, 2022.

Scott Tarriff, CEO of Eagle, said: "We are pleased to receive final approval from FDA and look forward to making Pemfexy available to the patients who can benefit. Our initial market exclusivity for Pemfexy represents a significant opportunity for Eagle and builds on the successes of our expanding presence in the oncology space."

Reyvow™ (C-V) Tablets - A New Class Of Acute Treatment For Migraine, Now Available

On January 31, Eli Lilly & Company of Indianapolis, Indiana announced the ***launch*** of Reyvow™ (lasmiditan) Tablets 50mg and 100mg, an oral medication indicated for the acute treatment of migraine with or without aura in adults.

Product is available in 50mg, 100mg, and 200mg doses for patients, which offers dosing flexibility for physicians and other prescribers.

It has been classified by the U.S. Drug Enforcement Administration (DEA) as a Schedule 5 (C-V) controlled drug substance; being a non-opioid/non-narcotic, with low abuse potential and no evidence of physical dependence.

Reyvow works differently than other acute treatments for migraine. It is a new class of acute treatment for migraine, being the first and only FDA-approved ditan, (a 5-HT1F receptor agonist drug) that is believed to act both centrally and peripherally.

Migraine is a severely disabling neurologic disease characterized by recurrent episodes of moderate to severe headache accompanied by other symptoms including nausea, sensitivity to light, and sensitivity to sound. More than 30 million American adults have migraine, with 3 times more women than men affected by migraine. Migraine is often incapacitating, leading to high personal, societal and economic burden. According to the Medical Expenditures Panel Survey, total annual healthcare costs associated with migraine are estimated to be as high as $56 billion in the United States, yet it remains under-recognized and under-treated.

Dr. Cori Millen, Medical Director of Summit Headache & Neurologic Institute, commented: "As a healthcare professional, I am thrilled that Reyvow is now available. In only 2 hours and with a single dose, Reyvow has demonstrated the chance for patients to achieve rapid and complete elimination of migraine pain and their most bothersome symptom of sensitivity to light, sensitivity to sound, or nausea. Recent guidance that was issued by both the FDA and the American Headache Society raised the clinical bar by recommending migraine clinical trial efficacy demonstrates pain freedom and freedom from most bothersome symptoms, rather than just pain relief. Reyvow is the first FDA-approved acute medicine for migraine to meet this new standard."

A migraine attack is often incapacitating and excruciating. In the International Burden of Migraine Study, a web-based survey of 9,715 adults with migraine, 79% of patients reported experiencing severe pain during a migraine attack. Triptans are recommended as an acute therapy for migraine for appropriate patients by the American Headache Society. However, when speaking to patients with migraine, 79% said they would be willing to try another acute treatment.

Michael Cobas Meyer, M.D., VP of Global Medical Affairs for Lilly BioMedicines, commented: "People with migraine experience attacks that can be severely burdensome, intensely painful and debilitating. With a single dose, Reyvow offers the chance for quick and complete elimination of moderate to severe migraine pain in just 2 hours.

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New Drugs/Indications

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When asking people with migraine, they prioritize fast and complete elimination of pain from acute treatments. We feel fortunate we can now provide patients with a treatment option that helps achieve that outcome."

Note: Reyvow may cause significant driving impairment. Advise patients not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery, for at least 8 hours after each dose of Reyvow.

Tazverik™ For Epithelioid Sarcoma

On January 23, Epizyme, Inc. of Cambridge, Massachusetts announced the FDA has approved Tazverik™ (tazemetostat) Tablets, indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection (surgically removal).

Product is expected to be available within 2 weeks of this announcement date.

The recommended dosage of Tazverik is 800mg taken orally twice daily with or without food.

Richard Pazdur, M.D., Director of the FDA's Oncology Center of Excellence & Acting Director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation & Research, said: "Epithelioid sarcoma accounts for less than 1% of all soft tissue sarcomas. Until now, there were no treatment options specifically for patients with epithelioid sarcoma. The approval of Tazverik provides a treatment option that specifically targets this disease. When we brought Tazverik's application to the Oncologic Drugs Advisory Committee in December, the committee voted unanimously that the benefits of the drug outweighed the risks."

Epithelioid sarcoma (ES) is a rare and slow-growing subtype of soft tissue sarcoma, that often occurs in young adults. Most cases begin as a small and firm painless growth or lump in the soft tissue under the skin of an extremity (finger, hand, forearm, lower leg, foot), though it can start in other areas of the body. Surgical removal is considered the main treatment when the cancer is localized to one area of the body. Chemotherapy or radiation may also be given. However, there is a high likelihood for local and regional spread of the disease even with treatment and approximately 50% of patients have metastatic disease at the time of diagnosis. Metastatic disease is considered life-threatening to the patient. Tazverik blocks activity of the EZH2 methyltransferase, which may help keep the cancer cells from growing.

Gary K. Schwartz, M.D., Chief of Hematology & Oncology at Columbia University & New York-Presbyterian Hospital, Deputy Director of the Herbert Irving Comprehensive Cancer Center, and Professor of Oncology at Columbia University Vagelos College of Physicians & Surgeons (all based in New York City), stated: "Despite industry advancements, there are limited therapeutic options for treating patients with epithelioid sarcoma who struggle with high rates of recurrence and toxicities associated with currently used therapies. The Tazverik data from the drug's Phase 2 trial study supports its potential to provide clinically meaningful and durable responses, and tolerability for ES patients. This approval of Tazverik represents an important advancement in the treatment of patients with ES."

Note: Tazverik must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks; because it may cause harm to a developing fetus or newborn baby.

The FDA granted Tazverik with Accelerated Approval and an Orphan Drug designation.

Tepezza™ For Thyroid Eye Disease

On January 21, Horizon Therapeutics of Lake Forest, Illinois (with parent company in Dublin, Ireland) announced the FDA has approved Tepezza™ (teprotumumab-trbw) Injection, the first and only FDA-approved medicine indicated for the treatment of thyroid eye disease.

Product is expected to be available in the U.S. shortly after this announcement date.

Tepezza is administered to patients once every 3 weeks for a total of 8 infusions.

Raymond Douglas, M.D., Ph.D., Director of the Orbital & Thyroid Eye Disease Program at Cedars-Sinai Medical Center in Los Angeles, California (and co-principal investigator of the drug's clinical trial), stated: "The FDA approval of Tepezza is momentous for the thyroid eye disease community, and has the potential

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New Drugs/Indications

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to change its treatment paradigm, providing new hope for people who are living with this horrible, vision-threatening disease. This news brings forward a medicine for patients that targets the underlying biology of the disease and has been shown to significantly improve eye bulging and double vision, which are the most debilitating aspects of the disease."

Thyroid eye disease (TED) is a serious, progressive, and vision-threatening rare autoimmune disease that is associated with proptosis (eye bulging), diplopia (double vision), blurred vision, pain, inflammation, and facial disfigurement. This disease impacts a relatively small number of Americans, with more women than men affected. Although this condition impacts relatively few individuals, thyroid eye disease can be incapacitating. For example, the troubling ocular symptoms can lead to the progressive inability of people with thyroid eye disease to perform important daily activities, such as driving or working.

The FDA granted Tepezza with Priority Review, and Orphan Drug, Fast Track, and Breakthrough Therapy designations.

Wiley Chambers, M.D., Deputy Director of the Division of Transplant & Ophthalmology Products in the FDA's Center for Drug Evaluation & Research, said: "This new approval marks an important milestone for the treatment of thyroid eye disease. Currently, there are very limited treatment options for this potentially debilitating disease. Tepezza has the potential to alter the course of the disease, potentially sparing patients from needing multiple invasive surgeries by providing an alternative, non-surgical treatment option. Additionally, thyroid eye disease is a rare disease that impacts a small percentage of the population, and for a variety of reasons, treatments for rare diseases are often unavailable. This approval represents important progress in the approval of effective treatments for rare diseases, such as thyroid eye disease."

Trijardy™ XR - Only Triple-Combination Tablet For Type 2 Diabetes

On January 27, Boehringer Ingelheim Pharmaceuticals, Inc. of Ridgefield, Connecticut and Eli Lilly & Company of Indianapolis, Indiana jointly announced the FDA has approved the once daily Trijardy™ XR (empagliflozin/linagliptin/metformin HCl, extended-release) Tablets, indicated to lower blood sugar in adults with type 2 diabetes, along with diet and exercise.

Trijardy XR will be available in the following 4 different dosage strengths:

1) 5mg empagliflozin/2.5mg linagliptin/1,000mg metformin HCl ER;
2) 10mg empagliflozin/5mg linagliptin/1,000 mg metformin HCl ER;
3) 12.5mg empagliflozin/2.5mg linagliptin/1,000mg metformin HCl ER;
4) 25mg empagliflozin/5mg linagliptin/1,000mg metformin HCl ER.

Cardiorenal metabolic conditions are a group of interconnected disorders affecting the heart, kidneys and endocrine system. In aggregate, these conditions are the leading cause of deaths worldwide, accounting for up to 20 million deaths annually. Conditions within this group include coronary artery disease, heart failure, chronic kidney disease and type 2 diabetes, among many others.

Emerging science on the link between the cardiorenal and metabolic systems supports taking a multidisciplinary approach toward diagnostic, preventive and therapeutic strategies for people living with these conditions. We remain committed to developing treatments with broad cardiorenal metabolic effects, which may help improve outcomes for people with serious chronic conditions such as these.

Ralph DeFronzo, M.D., Professor & Division Chief of Diabetes at the University of Texas Health in San Antonio, explained: "Many adults living with type 2 diabetes who are already on a treatment plan including multiple medications still struggle to keep their blood sugar under control, and may require additional agents to reach their A1C targets. Adding new medicines to an individual's plan can be challenging for some, which is why new treatment options that can help improve blood sugar without the burden of an increased pill count are important. In addition, type 2 diabetes is a complex disease that often requires the use of multiple antidiabetic medications to improve glycemic control. Having 3 different diabetes medications in a single tablet is an important advance in diabetes treatment."

New Drugs/Indications

Continued from Page 34

Trijardy XR provides three (3) type 2 diabetes medicines in one (1) pill, including Jardiance® (empagliflozin), Tradjenta® (linagliptin), and metformin HCl extended-release. Jardiance and Trijardy XR are also from Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly & Company. Both Jardiance and Tradjenta are once-daily tablets used along with diet and exercise to lower blood sugar in adults with type 2 diabetes; and Jardiance is also approved to reduce the risk of cardiovascular death in adults with type 2 diabetes who have known cardiovascular disease.

Ubrelvy™ - For Acute Treatment Of Migraine With Or Without Aura

On December 23, Allergan USA Inc. of Parsippany, New Jersey announced the FDA approved a New Drug Application (NDA) for Ubrelvy™ (ubrogepant) Tablets 50mg and 100mg, indicated for the acute treatment of migraine with or without aura in adults.

This product is non-narcotic (nor scheduled), and does not have potential for addiction. It has been approved with two (2) dosage strengths: 50mg and 100mg, so that healthcare providers can provide a personalized treatment approach for appropriate patients. The recommended dose is 50mg; however if needed, a second 50mg dose may be taken at least 2 hours after the initial dose (with a maximum dose in a 24-hour period of 200mg).

Billy Dunn, M.D., Acting Director of the Office of Neuroscience in the FDA's Center for Drug Evaluation & Research, said: "Migraine is an often disabling condition that affects an estimated 37 million people in the United States. Ubrelvy represents an important new option for the acute treatment of migraine in adults, as it is the first drug in its class approved for this indication. The FDA is pleased to approve a novel treatment for patients suffering from migraine and will continue to work with stakeholders to promote the development of new safe and effective migraine therapies."

Ubrelvy is the first and only orally-administered drug in the class of calcitonin gene-related peptide (CGRP) receptor antagonist that is indicated for the treatment of acute migraine attacks once they start. It works without constricting blood vessels, which some older treatments are known to do. The new way it functions is by blocking CGRP, a protein released during a migraine attack, from binding to its receptors.

Migraine is a neurological disease with episodic attacks defined by symptoms such as headache pain, sensitivity to light and sound, and nausea. It is highly prevalent, affecting approximately 37 million Americans and more than 10% of people worldwide. Migraine is associated with significant disability leading to high personal, family, occupational, societal, and economic burden; being the third most common disease and second leading cause of disability worldwide. There has long been a need for new treatments for migraine with improved benefit-risk profiles as compared to current standard of care.

In clinical trials supporting the FDA's approval, Ubrelvy provided quick and lasting pain relief for the majority of migraine patients, for up to 24 hours. It also met co-primary endpoints of freedom from pain and freedom from the most bothersome symptoms (nausea, hypersensitivity to light, or hypersensitivity to sound), a recent, more stringent standard of efficacy the FDA set in 2018.

Kristin Molacek, Ubrelvy clinical trial patient, commented: "As someone living with migraine for 14 years, my life seems to be on pause when I experience a migraine attack. During the clinical trial, my experience with Ubrelvy was positive. It relieved the migraine symptoms that bothered me the most without any serious side effects. We have needed this type of on-demand oral relief for a very long time, and I look forward to having the ability to better manage my migraine attacks."

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Outstanding Buyer Nomination - Jennifer Clifton

Nominee: **Jennifer Clifton,** Pharmacy Procurement Analyst, St. Cloud Hospital-CentraCare System, St. Cloud, Minnesota.

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

Are you a current NPPA member, and will be an active member through August 2020? Yes.

What is your facility's bed size, and what type of facility is it? 489-bed, non-profit Community Hospital.

Approximately how many dollars of pharmaceutical related expenditures do you purchase or supervise the purchasing of, at your facility per year? $19.1 million.

What is the dollar amount of the average inventory that you control throughout the year? $6.2 million.

Provide the current Inventory "Turns" you/your Pharmacy Department currently have: 12.

How long have you been a Pharmacy Buyer? 1 year.

What are the main responsibilities you have in your position (as Buyer and if otherwise in addition)? Purchasing of medications for the St. Cloud Hospital, 13 kidney dialysis sites, as well as 2 Wound Care Centers all around Minnesota state. Participating as a compliant 340b and Disproportionate Share Hospital. Helping my assistants with their day to day receiving of inventory. Filling in technician duties when needed. I also manage all drug shortages, which includes making changes to our Electronic Medical Records (EMR) database and Automated Dispensing System (ADS) machines. I also manage the supply of consigned inventory of factor products to 5 critical access hospitals. Facilitate outdate checking and management on recalled products.

What is unique about your facility? We are a Disproportionate Share Hospital (DSH), operating with 13 to 15 child sites and multiple critical access hospitals. Our nonprofit includes 6 hospitals, 7 senior care facilities, 18 clinics, 4 pharmacies, and numerous inpatient and outpatient specialty care services.

List any accomplishments or projects that you may have instituted, which has either saved your department/facility money, or helped to make your job or the department run more efficiently. Since I've become the new pharmacy buyer here, our secondary wholesaler purchases have decreased by almost 50%. We have had 30% less emergency shipments from our wholesaler, thus saving the department $3,600 a year. I also successfully completed an evaluation of our entire inventory, optimizing PAR/reorder levels, with a projected cost avoidance of $114,315. In the last couple of months, we successfully transitioned our kidney dialysis unit sites to "Bill to Ship" to Cardinal deliveries.

How has your job changed over the years? Just a few years ago, we were not a DSH hospital. Since that has changed, the pharmacy buyer role has drastically changed and evolved into so much more. This position takes a lot of critical thinking and analysis to make sure we follow all of the rules. In addition, our kidney dialysis sites have grown tremendously over the last 4 years.

What do you like about your job? I enjoy the people I work with, which makes coming to work each day delightful. I like the challenges it presents on a day-to-day basis. In fact, since starting this position, I have yet to dread coming to work for a single day. I've made a very positive impact in our pharmacy's drug budget, and I'm very proud of that. I feel like I'm really making a difference in our patient's lives, by making sure the facility has what we need to take care of them all.

What are your dislikes about your job? I've realized that sometimes there are outcomes you cannot change, such as those to do with drug shortages. The best we can do is to plan ahead, without being a part of the problem. I dislike having to purchase mass quantities in anticipation of a possible shortage, but I also hate paying premium prices when medications are short. I want what is best for our patients, but sometimes drug shortages make that very difficult.

What would be your advice to vendors? Communication. For instance, I especially appreciate any information on upcoming or current drug shortages. If you can take time to send a quick message about a possible shortage on your products beforehand, us buyers would greatly

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News Briefs

Nucynta® Franchise Of Products Sold To Collegium

On February 13, Assertio Therapeutics, Inc. of Lake Forest, Illinois and Collegium Pharmaceutical, Inc. of Stoughton, Massachusetts jointly announced the closing of its previously disclosed definitive agreement, to which Collegium has acquired the Nucynta® franchise of products from Assertio.

Arthur Higgins, President & CEO of Assertio, said: "With this sale closing and accelerated repayment of our senior debt obligations, it allows us the ability to invest in our core business, which will help us build and grow for the future."

Nucynta is a strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short-term (acute) pain in adults when other pain treatments, such as non-opioid pain medicines, do not treat the pain well enough or patients cannot tolerate them.

BioMotiv & Bristol-Myers Squibb Launch New Company: Anteros Pharmaceuticals

On February 4, BioMotiv LLC of Radnor, Pennsylvania (associated with The Harrington Project of Cleveland, Ohio for discovery and development) and Bristol-Myers Squibb Company of New York, jointly announced the launch of Anteros Pharmaceuticals, a new biotechnology company focused on developing a new class of drugs for the treatment of fibrotic and other inflammatory diseases.

The intellectual property behind Anteros was first developed by Yale University, in-licensed by Bristol-Myers Squibb, and subsequently assigned to Anteros. This is the first company that BioMotiv and Bristol-Myers Squibb have launched since executing their Strategic Partnership Agreement, as previously announced in September 2019.

Under the terms of the partnership, Bristol-Myers Squibb will contribute the IP, data, and reagents for a series of small molecules against an undisclosed mechanism; and BioMotiv through the formation of Anteros Pharmaceuticals and working in close partnership with Yale, will be solely responsible for research and development. Once Anteros nominates a preclinical candidate, Bristol-Myers Squibb has the option to acquire the company from BioMotiv under pre-agreed terms.

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Outstanding Buyer, J. Clifton

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appreciate that! It might even make the shortage less impactful for our department and the facility's patients.

What kind of specific challenges do you have? Our hospital has struggled with Pharmacy Technician staffing for quite some time. One of the challenges I face is filling in for techs and completing my own work to the best of my abilities at the same time. My favorite challenge is the quarterly Inventory. We manually count every item 4 times a year and enter the numbers into spreadsheets. These spreadsheets need to be updated with new formulary products and new prices all of the time, which is an ongoing challenge.

How has your membership to NPPA/subscription to PPO helped? Every month, I page through the NDC updates and find new generics or alternatives that we haven't discovered yet. My excitement about a new generic is like a kid on Christmas morning.

Has your ever attended an NPPA Conference? If so, how did that help in your job after the event? If not, what is stopping you from attending? Yes, I actually attended my first NPPA Conference last year. I thought many of the speakers brought great topics and strategies to consider using in our own pharmacy. I really enjoyed the speakers who presented on new drug information, even though it doesn't pertain directly to my pharmacy purchasing duties (being more of a clinical decision).

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

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

List any other qualifications you may have for this award (such as being honored by your facility; having an article published; organizing buyer meetings; doing public speaking; volunteer work). New to this role, nothing yet.

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Myxredlin

INSULIN INFUSION

THE FIRST AND ONLY READY-TO-USE **INSULIN** INFUSION

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

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

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

IMPORTANT RISK INFORMATION

Indication

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

Contraindications

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

Warnings and Precautions

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

Dosage and Administration

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

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

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

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

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

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

Myxredlin (insulin human in sodium chloride injection), for intravenous use.
Initial U.S. Approval: 1991

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

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

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

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

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

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

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

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

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

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

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

Please visit www.baxterpi.com for Full Prescribing Information

Baxter Healthcare Corporation Deerfield, IL 60015 USA

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

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Satish Jindal, Ph.D., BioMotiv's CEO, said: "Anteros Pharmaceuticals is the first of several companies that BioMotiv and Bristol-Myers Squibb intend to form under the Strategic Partnership Agreement. Anteros will focus on refining a new class of drug candidates for inflammatory diseases, where currently there are no real answers to multiple diseases that afflict millions of patients. Our broader mission is to translate novel discoveries into breakthrough therapies for patients in need, forming companies such as Anteros to achieve this goal."

Alexion Completes Acquisition Of Achillion Pharmaceuticals

On January 28, Alexion Pharmaceuticals, Inc. of Boston, Massachusetts announced it has completed its acquisition of Achillion Pharmaceuticals, Inc.; which will add 2 clinical-stage oral small molecule Factor D inhibitors to Alexion's pipeline and provides the foundation and expertise for a broader oral Factor D inhibition development platform with the potential to treat numerous additional complement-mediated diseases.

Alexion will continue development of Achillion's oral Factor D inhibitor portfolio, which includes 2 clinical-stage medicines-in-development: danicopan (ACH-4471), and ACH-5228, as well as multiple other compounds in preclinical development. Phase 3 development is being initiated for danicopan as an add-on therapy for paroxysmal nocturnal hemoglobinuria (PNH) patients with extravascular hemolysis (EVH). Danicopan is also in Phase 2 development for C3G, and ACH-5228 is in Phase 2 development for PNH.

Factor D is an essential serine protease and critical control point in the alternative pathway (AP) of the complement system, a part of the innate immune system.

Paroxysmal nocturnal hemoglobinuria (PNH) is a chronic, progressive, debilitating, and life-threatening ultra-rare blood disorder characterized by the destruction of red blood cells (hemolysis), that is mediated by uncontrolled activation of the complement system, a component of the body's immune system. Patients with PNH may experience a wide range of signs and symptoms, such as fatigue, difficulty swallowing, shortness of breath, abdominal pain, erectile dysfunction, dark-colored urine, and anemia. However the most devastating consequence of chronic hemolysis is thrombosis, which can occur in blood vessels throughout the body, damaging vital organs and causing premature death. PNH is primarily a disease of intravascular hemolysis (IVH), where the red blood cell destruction occurs within the blood vessels.

C3G is an ultra-rare kidney disease for which there is no currently approved treatment. The disease is characterized by the deposition of C3 protein fragments in the filtering units (glomeruli) of the kidney, caused by overactivation of the complement alternative pathway (AP). Over time, the chronic deposition of C3 fragments results in permanent kidney damage and kidney failure. Today, C3G patients are treated with steroids and broad-acting immunosuppressants to slow the progression of kidney damage. Oral Factor D inhibitors have demonstrated proof-of-mechanism to interrupt the overactivation of the AP and reduce C3 fragment deposition, providing a potential treatment approach for targeting the underlying cause of C3G.

Abbvie & Allergan To Divest Brazikumab & Zenpep®

On January 27, Allergan, Inc. of Madison, New Jersey and AbbVie, Inc. of North Chicago, Illinois jointly announced that Allergan has entered into definitive agreements to divest the following two (2) drugs: brazikumab (IL-23 inhibitor), and Zenpep® (pancrelipase).

These agreements are in conjunction with the ongoing regulatory approval process for AbbVie's recent acquisition of Allergan.

AstraZeneca of Wilmington, Delaware will acquire brazikumab, an investigational IL-23 inhibitor in Phase 2b/3 development for Crohn's Disease and in Phase 2 development for ulcerative colitis, including global development and commercial rights.

Nestlé Health Science of Bridgewater Township, New Jersey will acquire and take full operational ownership of Zenpep upon closing the transaction, with customary transition support from Allergan. Zenpep is a treatment that is currently available in the United States and is indicated for exocrine pancreatic insufficiency due to cystic fibrosis and other conditions. As part of the same transaction, Nestlé will also be acquiring Viokace™, which is another pancreatic enzyme preparation.

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accord
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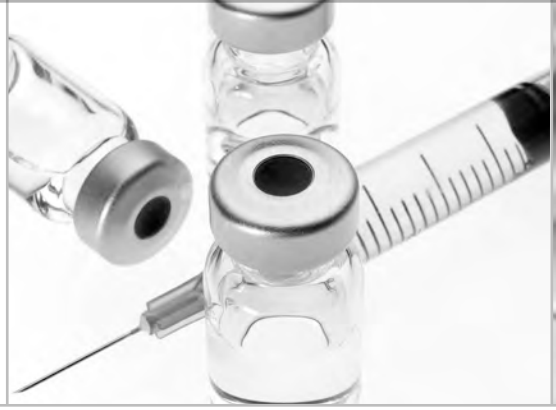

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Product	Brand
Daptomycin Injection	Daptomycin For Injection

NDC #	Description	Strength	Package
16729-434-05	Daptomycin Injection	350mg/Vial	Pack of 1 Vial

NDC #	Description	Strength	Package
16729-434-45	Daptomycin Injection	350mg/Vial	Pack of 10 Vials

For questions regarding this product from
Accord Healthcare, Inc., please call 1.866.941.7875 or visit www.accordhealthcare.us.

News Briefs

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The closings of the divestitures of brazikumab and Zenpep are contingent upon receipt of U.S. Federal Trade Commission approval, closing of AbbVie's pending acquisition of Allergan, and the satisfaction of other customary closing conditions.

Sanofi Completes Acquisition Of Synthorx, Inc.

On January 23, Sanofi U.S. of Bridgewater, New Jersey announced the successful completion of its acquisition of Synthorx, Inc.

Following its acceptance of the tendered shares, Sanofi completed its acquisition of Synthorx through the merger with and into Synthorx; with Synthorx continuing as the surviving corporation and becoming an indirect, wholly owned subsidiary of Sanofi.

Paul Hudson, CEO of Sanofi, stated: "The acquisition of Synthorx perfectly aligns with our Research & Development strategy, enhancing our position in the area of oncology and immunology. We gain access to both great scientists and science with THOR-707, an engineered not-alpha IL-2 for the treatment of solid tumors which induces strong immunological responses in vivo, additional intriguing pre-clinical assets, and a powerful platform that complements our ongoing oncology and immunology research."

Astellas Completes Acquisition of Audentes Therapeutics

On January 15, Astellas Pharma US, Inc. of Northbrook, Illinois announced it has successfully completed the previously announced acquisition of Audentes Therapeutics, Inc. of San Francisco, California.

Within Astellas, Audentes will operate as a wholly-owned subsidiary, and will serve as the Center of Excellence for the newly created Genetic Regulation Primary Focus, providing leadership for adeno-associated virus (AAV) pipeline advancement through commercialization, manufacturing expansion, and next-generation research initiatives.

Natalie C. Holles, Newly Appointed President & CEO of Audentes, said: "This marks the start of an exciting new chapter for Audentes. By joining the Astellas group of companies, we are confident we can achieve our mandate to expand the breadth and scope of our work to new geographies and patient populations. Now backed by the substantial resources and global footprint of Astellas, we remain focused on achieving our goal of submitting a Biologics License Application (BLA) for AT132 for the treatment of X-linked Myotubular Myopathy to the FDA later this year, advancing the new combined pipeline, and building a world-class genetic medicines company."

Eli Lilly To Acquire Dermira

On January 10, Eli Lilly & Company of Indianapolis, Indiana and Dermira, Inc. of Menlo Park, California, jointly announced a definitive agreement for Lilly to acquire Dermira, a biopharmaceutical company dedicated to developing new therapies for chronic skin conditions.

The acquisition will expand Lilly's immunology pipeline with the addition of lebrikizumab, which is a novel, investigational, monoclonal antibody designed to bind IL-13 with high affinity that is being evaluated in a Phase 3 clinical development program for the treatment of moderate-to-severe atopic dermatitis in adolescent and adult patients, ages 12 years and older (and in December 2019, it was granted Fast Track review designation by the FDA).

The acquisition of Dermira will also expand Lilly's portfolio of marketed dermatology medicines with the addition of Qbrexza® (glycopyrronium) cloth, a medicated cloth approved by the FDA for the topical treatment of primary axillary hyperhidrosis (uncontrolled excessive underarm sweating).

Patrik Jonsson, Senior VP & President of Lilly Bio-Medicines, stated: "People suffering from moderate-to-severe atopic dermatitis have significant unmet treatment needs, and we are excited about the potential that lebrikizumab has to help these patients. This acquisition provides an opportunity to add a promising Phase 3 immunology compound for atopic dermatitis, while also adding an approved dermatology treatment for primary axillary hyperhidrosis."

The transaction is not subject to any financing condition and is expected to close by the end of the first quarter of 2020, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Dermira's common stock.

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New Technician Certification Requirements & Updated Exam From PTCB

On January 14, the Pharmacy Technician Certification Board® (PTCB®) announced they have implemented new eligibility requirements and an updated Pharmacy Technician Certification Exam® (PTCE®) for its Certified Pharmacy Technician (CPhT) Program.

The 2020 changes are based on data generated by PTCB's most recent pharmacy Job Task Analysis, reflecting input from more than 40,000 technicians across practice settings, and guidance from the pharmacy community, including employers, educators, and organizations.

William Schimmel, PTCB Executive Director & CEO, said: "PTCB is focused solely on advancing medication safety, and we rely on data and input from pharmacy professionals to guide the direction of our program updates. With the 2020 changes, PTCB reaffirms our commitment to ensuring that PTCB's CPhT Program advances patient care. Pharmacists can trust that technicians who earn PTCB credentials have demonstrated current knowledge that is critical to performing their jobs safely in today's pharmacy workplace."

The 2020 modifications now in effect require aspiring CPhT's to either complete a PTCB-Recognized Education/Training Program or have equivalent work experience before they take the PTCE. More than 1,400 PTCB-recognized programs are now available, including all pharmacy technician programs accredited by the American Society of Health-System Pharmacists/Accreditation Council for Pharmacy Education (ASHP/ACPE) or by the Accrediting Bureau of Health Education Schools (ABHES), as well as non-accredited programs that comply with PTCB's curriculum requirements.

Nicole Barriera, CPhT, Pharmacy Technician Department Chair & Program Director at Pikes Peak Community College in Colorado Springs, Colorado, stated: "PTCB's new requirement for completion of recognized education and training strengthens patient care and advances medication safety in pharmacy. It ensures that PTCB CPhTs are held to a consistent and rigorous professional standard. The role of the technician is critical to safe pharmacy practice. The 2020 requirements will help ensure competency and accuracy in skills and tasks that directly affect patients."

The alternate work experience eligibility pathway is available to experienced technicians who are not in a position to enroll in education/training. They must complete at least 500 work hours and fulfill certain knowledge requirements before applying for certification.

The content of the updated PTCE reflects data on roles and responsibilities collected from the Job Task Analysis. Instead of the previous exam's 9 knowledge domains, the new PTCE categorizes knowledge into 4 domains: medications, federal requirements, patient safety and quality assurance, and order entry and processing.

The new requirements and modifications to the PTCE are part of a suite of PTCB initiatives that also include new credential programs for CPhT's in advanced roles. Schimmel added: "PTCB's CPhT Certification is fundamental across practice settings and is also the foundation for those who choose to advance their careers. In 2019, PTCB introduced Assessment-Based Certificate Programs in Technician Product Verification (TPV) and Medication History, and this year plans to launch 3 more, Hazardous Drug Management, Controlled Substances Diversion Prevention, and Billing & Reimbursement, for a total of 5 Certificate Programs."

Active CPhT's who complete at least 4 certificates, including TPV and/or Medication History, or 3 certificates and PTCB's Compounded Sterile Preparation Technician® (CSPT®) Certification, and have 3 years of work experience, will be eligible to earn an Advanced CPhT Certification (CPhT-Adv) in the future.

Schimmel concluded: "Building a career ladder for pharmacy technicians is part of advancing safety and patient care. Recognizing CPhT's for their advanced responsibilities rewards their dedication to patient care and reinforces efficiency and safe medication practices."

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Legal News

Alimta® - Patent Lawsuit Resolved

On January 1, Eli Lilly & Company of Indianapolis, Indiana announced that the U.S. District Court for the Southern District of Indiana ruled in favor of Lilly that the Alimta® (pemetrexed) for Injection vitamin regimen patent would be infringed by a competitor that had stated its intent to market alternative salt forms of pemetrexed prior to the patent's expiration in May 2022.

The ruling came in the case of Eli Lilly & Company v. Apotex Corp. of Weston, Florida.

Last August (2019), the U.S. Court of Appeals for the Federal Circuit Court ruled in favor of Lilly in appeals by Dr. Reddy's Laboratories, Inc. and Hospira, Inc., affirming the June 2018 District Court's decisions finding infringement of Lilly's patent under the doctrine of equivalents.

This ruling means Apotex will be prevented from launching its alternative salt form of pemetrexed until the patent expires. Lilly expects Apotex to appeal.

In October 2017, the Patent Trial & Appeal Board of the U.S. Patent & Trademark Office ruled in the company's favor regarding patentability of the vitamin regimen for Alimta.

In March 2014, the U.S. District Court for Southern Indiana upheld the validity of the vitamin regimen patent. In August 2015, the same court ruled in Lilly's favor regarding infringement of the vitamin regimen patent. The U.S. Court of Appeals for the Federal Circuit confirmed these rulings in a unanimous decision in January 2017, finding the patent is valid and would be infringed by the generic challengers' proposed products.

Fanapt® Court Ruling

On January 13, Vanda Pharmaceuticals Inc. of Washington, D.C. announced that the U.S. Supreme Court has denied the petition for an appellate court to review a case that was previously filed by West-Ward Pharmaceuticals of Eatontown, New Jersey (a subsidiary of Hikma Pharmaceuticals), relating to the patent for Fanapt® (iloperidone) Tablets by Vanda.

This order by the U.S. Supreme Court ensures that the patent will remain exclusive at least through November 2, 2027, absent further challenges from other parties.

By denying the petition for a writ of certiorari, the Supreme Court leaves undisturbed the U.S. Court of Appeals for the Federal Circuit decision that West-Ward's Abbreviated New Drug Application (ANDA) for iloperidone infringed the patent, and that West-Ward had not proven it invalid.

Linzess® Patent Litigation Settlements

On January 6, Ironwood Pharmaceuticals, Inc. of Boston, Massachusetts and Allergan plc of Dublin, Ireland (with U.S. headquarters in Madison, New Jersey) jointly announced that the companies have reached an agreement with Sandoz Inc. of Princeton, New Jersey (a Novartis division) resolving patent litigation brought in response to Sandoz's Abbreviated New Drug Application (ANDA) seeking approval to market generic versions of Linzess® (linaclotide) Capsules by Ironwood, prior to the expiration of the drug's applicable patents.

Linaclotide is marketed by Ironwood and Allergan in the U.S. as Linzess, and is indicated for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC).

Pursuant to the terms of the settlement, Ironwood and Allergan will grant Sandoz a license to market its 145mcg and 290mcg generic version of Linzess in the U.S. beginning February 5, 2030 (subject to FDA approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. As a result of the settlement, the ongoing Hatch-Waxman litigation between the companies and Sandoz regarding Linzess patents pending in the U.S. District Court of Delaware will be dismissed.

As required by law, the companies will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

Patent infringement litigation brought by the companies against Teva Pharmaceuticals USA, Inc. of Parsippany, New Jersey and affiliates, which submitted ANDA's to the FDA seeking approval to market generic versions of Linzess remain pending in the U.S. District Court of Delaware. However, the trial that was scheduled to begin on January 7, 2020 has been postponed to enable the parties to continue settlement negotiations.

In addition, on January 22, Ironwood and Allergan announced that they have reached an agreement with Teva Pharmaceuticals USA, Inc. of Parsippany-Troy Hills, New Jersey, resolving patent litigation brought in response to Teva's) seeking approval to market generic versions of 145mcg and 290mcg Linzess (linaclotide)

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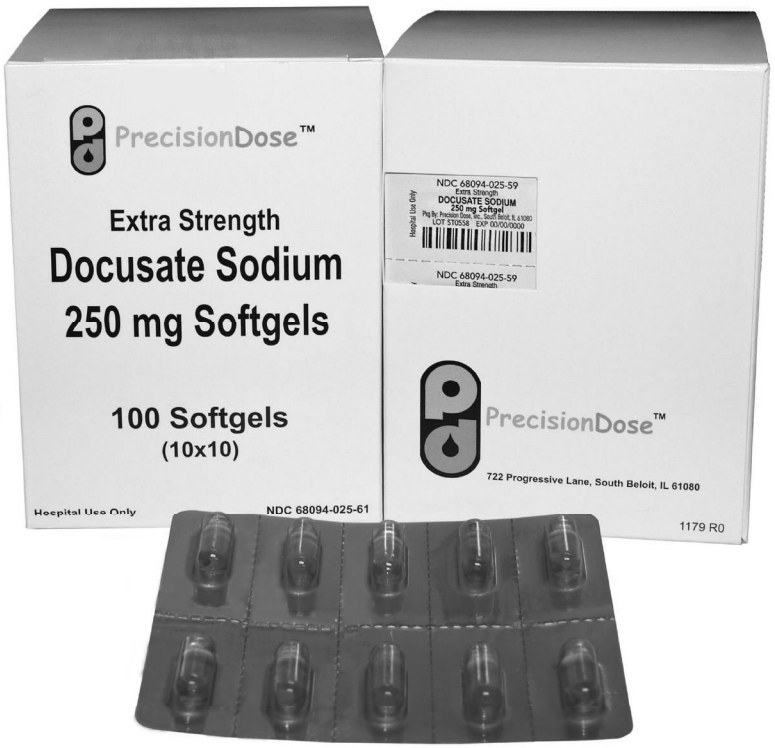

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Capsules by Ironwood, prior to the expiration of the companies' applicable patents.

This settlement does not grant any license to Teva with regard to its 72mcg generic version of Linzess.

Pursuant to the terms of the settlement, Ironwood and Allergan will grant Teva a license to market its 145mcg and 290mcg generic version of Linzess in the U.S. beginning March 31, 2029 (subject to FDA approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur.

As a result of the settlement, the ongoing Hatch-Waxman litigation between the companies and Teva regarding Linzess patents that were still pending in the U.S. District Court of Delaware, was dismissed.

As required by law, the companies will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

Previously, upon the parties' request, the District of Delaware dismissed without prejudice the pending patent infringement litigations relating only to Teva's 72mcg generic version of Linzess. Ironwood and Allergan had asserted patents against Teva's 72mcg ANDA, the last of which expires in 2026, subject to possible pediatric extension. Prior to this dismissal, Teva stipulated to infringement of certain claims of those patents. Ironwood and Allergan are also pursuing additional patent applications covering formulations related to the Linzess 72mcg dosage strength.

Loestrin® 24 Fe & Minastrin™ 24 Fe Litigation Resolved

On January 6, Allergan USA, Inc. of Madison, New Jersey announced that its Warner Chilcott and Watson subsidiaries have reached resolutions with all plaintiffs. This includes a class of direct purchasers, individual direct purchasers that previously opted out of the direct purchaser class, and a class of indirect purchasers, for the following 2 products.

- Loestrin® 24 Fe Tablets (norethindrone acetate/ethinyl estradiol and ferrous fumarate);
- Minastrin™ 24 Fe Tablets (norethindrone acetate/ethinyl estradiol and ferrous fumarate) by Warner Chilcott, concluding the previously disclosed antitrust litigation in the U.S. District Court of Rhode Island.

The settlements make no admission of wrongdoing on the part of the company and resolve the litigation that was scheduled to go to trial on January 6, 2020.

Warner Chilcott and Watson will pay approximately $300 million under the settlement agreements. The settlements are subject to court approval of the agreements with the direct and indirect purchaser classes.

Coronavirus News

First Travel-Related Case Of 2019 Novel Coronavirus In U.S.

On January 21, the U.S. Centers for Disease Control & Prevention (CDC) announced they have confirmed the first case of 2019 Novel (new) Coronavirus (or "2019-nCoV") in the United States in the state of Washington *(and since this announcement date, several additional cases in the U.S. were confirmed, in California, Arizona, and Illinois).*

The first confirmed patient returned from Wuhan, China shortly before this announcement date, where an outbreak of pneumonia caused by this novel coronavirus has been ongoing since December 2019. While originally thought to be spreading from animal-to-person, there are growing indications that limited person-to-person spread is happening. However, it is still unclear how easily this virus is spreading between people.

The patient from Washington with confirmed coronavirus infection returned to the United States from Wuhan on January 15, 2020. They sought care at a medical facility in the state of Washington, where they were treated for the illness. Based on the patient's travel history and symptoms, healthcare professionals suspected this new coronavirus. A clinical specimen was collected and sent to the CDC overnight, where laboratory testing then confirmed the diagnosis, via the CDC's Real-Time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) test.

The CDC has been proactively preparing for the introduction of coronavirus in the U.S. for weeks, including the following.

- First alerting clinicians on January 8 to be on the look-out for patients with respiratory symptoms and a history of travel to Wuhan, China.
- Developing guidance for clinicians for testing and management of coronavirus, as well as guidance for home care of its patients.

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Coronavirus News

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- Developing a diagnostic test to detect this virus in clinical specimens, accelerating the time it takes to detect infection. Currently, testing for this virus must take place at the CDC, but in the coming days and weeks, the CDC will share these tests with domestic and international partners.
- On January 17, the CDC began implementing public health entry screening at San Francisco (SFO), New York (JFK), and Los Angeles (LAX) airports. Next the CDC will add entry health screening at 2 more airports: Atlanta (ATL) and Chicago (ORD).
- The CDC has activated its Emergency Operations Center to better provide ongoing support to the coronavirus response.

The CDC is working closely with the state of Washington and local partners. A CDC team has been deployed to support the ongoing investigation in the state of Washington, including potentially tracing close contacts to determine if anyone else has become ill.

Coronaviruses are a large family of viruses, some causing respiratory illness in people and others circulating among animals including camels, cats, and bats. Rarely, animal coronaviruses can evolve and infect people and then spread between people, such as has been seen with Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). When person-to-person spread has occurred with SARS and MERS, it is thought to happen via respiratory droplets with close contacts, similar to how influenza and other respiratory pathogens spread. Symptoms associated with this virus have included fever, cough, and trouble breathing.

The situation with regard to coronavirus is still unclear. This is a rapidly evolving situation and the CDC will continue to update the public as circumstances warrant.

- For updates on the outbreak, visit: www.cdc.gov/coronavirus/novel-coronavirus-2019.html and www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html
- For healthcare professional guidelines, visit: www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html

Public Health Screening To Begin At 3 U.S. Airports For Coronavirus

On January 21, the U.S. Centers for Disease Control & Prevention (CDC) announced that together with the U.S. Department of Homeland Security's Customs & Border Protection (CBP), they will implement enhanced health screenings in 3 U.S. airports that receive most of the travelers from Wuhan, China: San Francisco (SFO), New York (JFK), and Los Angeles (LAX) airports; to help detect sick travelers coming from Wuhan, China into the United States, on either direct or connecting flights, in response to the outbreak in China caused by the coronavirus, with exported cases to Thailand and Japan.

Entry screening is part of a layered approach used with other public health measures already in place to detect arriving travelers who are sick (such as detection and reporting of ill travelers by airlines during travel and referral of ill travelers arriving at a U.S. port of entry by CBP), to slow and reduce the spread of any disease into the United States.

The CDC is deploying about 100 additional staff to the 3 airports (SFO, JFK, and LAX) to supplement existing staff at the CDC quarantine stations located at those airports.

The CDC is actively monitoring this situation for pertinent information about the source of outbreak, and risk for further spread through person-to-person or animal-to-person transmission. The CDC may adjust screening procedures and other response activities as this outbreak investigation continues and more is learned about the newly emerging virus. Entry screening alone is not a guarantee against the possible importation of this new virus but is an important public health tool during periods of uncertainty and part of a multilayered government response strategy. As new information emerges, the CDC will reassess entry screening measures and could scale activities up or down accordingly.

CDC Advises Travelers To Avoid All Nonessential Travel To China

On January 27, the U.S. Centers for Disease Control & Prevention (CDC) issued an updated travel guidance for China, recommending that travelers avoid all nonessential travel to all of the country (in a Level 3 Travel Health Notice).

This warning is in response to an ongoing outbreak of respiratory illness caused by the 2019 coronavirus that is spreading between people in many parts of that country.

Chinese health officials have reported thousands of coronavirus cases in China,

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as well as severe illness including deaths. Sustained person-to-person community spread with this virus is reportedly occurring in China.

As of this announcement date, a number of travel-associated cases of coronavirus infection also have been identified in other locations, including the United States. In other parts of Asia, some limited person-to-person spread has been detected among close contacts of travelers returning from Wuhan, China, the epicenter of the outbreak, however, community spread with this virus has not been reported in locations outside China.

Anti-Coronavirus Foundation Created To Fund Vaccine Research

On January 27, the Anti-Coronavirus Foundation of Geneva, Switzerland announced that it will raise funds for the further financing of a vaccine against coronavirus.

The outbreak of a new coronavirus in China has killed at least 17 people and infected more than 400 (as of this announcement date), and the Foundation feels there might be a risk of the virus spreading to several other countries. The Foundation fears the new virus may resemble or even out-pass damage brought on by the severe acute respiratory syndrome (SARS) virus, which affected thousands of people around the world and killed nearly 800 during the 2003 outbreak.

There is currently very little known about the virus with the way it spreads, its incubation period (which is believed to be about 2 weeks), and who is most at risk. For now, the coronavirus is the pathogen behind a mysterious illness that had affected 59 people in Wuhan, a city of 11 million in central China.

The Foundation intends to finance the first company or group of individuals to develop a working vaccine, available for mass production and use. The first task set by the creators of the foundation is to create a $30 million reward pool to be given to a person or institution which creates a vaccine for the coronavirus. They feel it is important that all resources are mobilized to start financing of the laboratory work and clinical studies in as many medical and scientific institutions around the globe as possible to deliver the solution of the problem to be able to help the affected.

The Foundation's funding platform will allow anyone to send funds to finance future research. Initially, developers are considering cryptocurrency donations, but a Coinstelegram report referring to the official website of the project, suggests support for fiat donations will appear in the near future.

On the official website of the Anti-Coronavirus Foundation, the founders have also turned to pharmacological corporations with a message, urging them to make every effort to solve the problem. The published message also urges prominent entrepreneurs, philanthropists, and humanitarian organizations to help mobilize support for the affected.

For more information about the Anti-coronavirus Foundation, visit: https://vaccine.run

GSK & Coalition For Epidemic Preparedness To Develop Vaccine

On February 3, the Coalition for Epidemic Preparedness Innovations (CEPI) of Oslo, Norway and GlaxoSmithKline (GSK) of London, England (with U.S. headquarters in Philadelphia, Pennsylvania), jointly announced a new collaboration aimed at helping the global effort to develop a vaccine for the 2019 coronavirus.

In this new move, GSK will make its established pandemic vaccine adjuvant platform technology available to enhance the development of an effective vaccine against coronavirus. GSK develops innovative vaccines using different adjuvant systems. An adjuvant is added to some vaccines to enhance the immune response, thereby creating a stronger and longer lasting immunity against infections than the vaccine alone. The use of an adjuvant is of particular importance in a pandemic situation since it can reduce the amount of antigen required per dose, allowing more vaccine doses to be produced and made available to more people.

Thomas Breuer, Chief Medical Officer, of GSK Vaccines, commented: "GSK believes that we can help to contribute to the fight against coronavirus with one of our advanced vaccine adjuvant systems. Our adjuvant technology has previously been used successfully in the pandemic flu setting. It enables using only small quantities of the vaccine antigen which allows the production of more doses of the vaccine, a crucial advantage in a pandemic."

This announcement complements 4 prior CEPI programs relating to coronavirus vaccine development previously announced by

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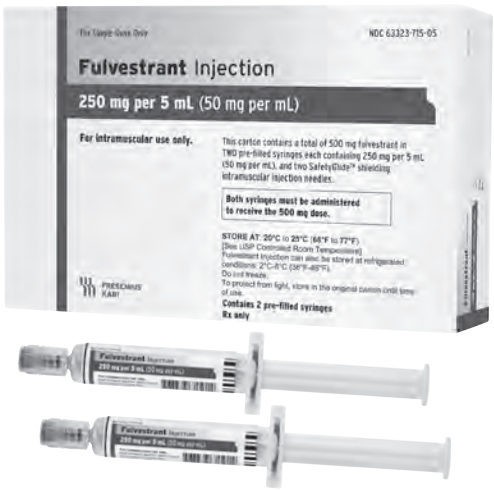

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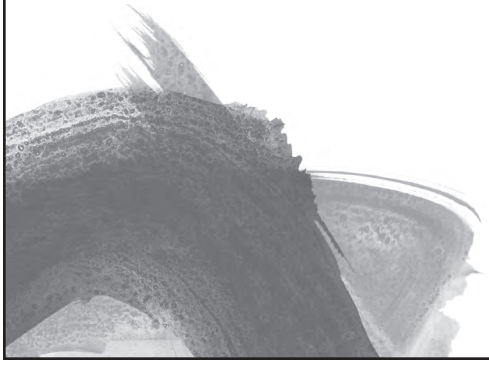

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CEPI, in partnership with: CureVac; Inovio Pharmaceuticals; The University of Queensland in Australia; Moderna, Inc.; and the U.S. National Institute of Allergy & Infectious Diseases. These partnerships seek to improve the scientific understanding of the novel coronavirus, and to develop vaccines against it. These programs will leverage rapid response platforms already supported by CEPI with the aim of advancing coronavirus vaccine candidates into clinical testing as quickly as possible. In addition, CEPI launched a new call for proposals to rapidly develop and manufacture already proven vaccine technology that can be used against the new coronavirus.

Both CEPI and GSK are committed to principles of equitable access and will work together in this collaboration to ensure that this principle governs the development, use and access of any coronavirus vaccine developed through the collaboration.

First Diagnostic Test For 2019 Coronavirus Authorized By FDA (& Now Available)

On February 5, the FDA issued an emergency use authorization (EUA) for a diagnostic test from the U.S. Centers for Disease Control & Prevention (CDC), to test for the coronavirus, called the "2019-nCoV Real-Time RT-PCR Diagnostic Panel." To date, this test has been limited to use at CDC laboratories, however this new emergency authorization now allows the use of the test at any CDC-qualified lab across the country, and is ***available immediately.***

Stephen M. Hahn, M.D., Commissioner of the FDA, stated: "Since this outbreak first emerged, we've been working closely with our partners across the U.S government and around the globe to expedite the development and availability of critical medical products to help end this outbreak as quickly as possible. This continues to be an evolving situation and the ability to distribute this diagnostic test to qualified labs is a critical step forward in protecting the public health. Our collaboration with the CDC has been vital to rapidly developing and facilitating access to this diagnostic test. The FDA remains deeply committed to utilizing our regulatory tools and leveraging our technical and scientific expertise to advance the availability of critical medical products to respond to this outbreak in the most expeditious, safe and effective manner possible."

Under this EUA, the use of the Diagnostic Panel is authorized for patients who meet the CDC criteria for 2019 coronavirus testing. It is limited to qualified laboratories designated by the CDC and in the U.S., those certified to perform high complexity tests.

The diagnostic is a reverse transcriptase polymerase chain reaction (PCR) test that provides presumptive detection of coronavirus from respiratory secretions, such as nasal or oral swabs. A positive test result indicates likely infection with coronavirus and infected patients should work with their healthcare provider to manage their symptoms and determine how to best protect the people around them. Negative results do not preclude coronavirus infection and should not be used as the sole basis for treatment or other patient management decisions (they must be combined with clinical observations, patient history, and epidemiological information).

The FDA can issue an EUA to permit the use, based on scientific data, of certain medical products that may be effective in diagnosing, treating, or preventing such disease or condition when there is a determination made by the U.S. Department of Health & Human Services (HHS) that there is a public health emergency or a significant potential for one. On January 31, HHS Secretary **Alex Azar** declared a public health emergency recognizing the potential threat that coronavirus poses and reiterating the government's dedication to leveraging all available resources to help prevent, mitigate, and respond to this threat. Since there are no commercially available diagnostic tests cleared or approved by the FDA for the detection of coronavirus, it was determined that an EUA is crucial to ensure timely access to diagnostics.

On January 27, the FDA outlined its approach to expediting the development and availability of critical medical products to prevent, diagnose, and treat coronavirus using all applicable regulatory authorities to respond to this outbreak. The agency remains committed to working with developers, international partners, and the U.S. government to help support this public health response. Several coronavirus diagnostic developers have already requested and received the EUA template for this outbreak.

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Regeneron Pharmaceuticals Expands Collaboration With HHS To Develop Antibody Treatments For Coronavirus

On February 4, Regeneron Pharmaceuticals, Inc. of Tarrytown, New York and the U.S. Department of Health & Human Services (HHS) jointly announced an expanded agreement, for Regeneron to develop new treatments combating the novel coronavirus, which was recently declared a global public health emergency by the World Health Organization (WHO).

Regeneron has a number of active collaborations with HHS's Biomedical Advanced Research & Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness & Response (ASPR), including a collaboration to advance Regeneron's investigational Ebola treatment REGN-EB3, which demonstrated positive clinical data in 2019.

The HHS and Regeneron Other Transaction Agreement (OTA), originally established in 2017, is focused on discovery, research, development, and manufacturing of a portfolio of antibodies targeting up to 10 pathogens that pose significant risk to public health, now including the influenza (flu) virus and coronavirus. This effort utilizes Regeneron's proprietary VelociSuite® technologies, including the VelocImmune® platform, which uses a unique genetically-engineered mouse with a humanized immune system that can be challenged with all or parts of a virus of interest, to facilitate swift identification, preclinical validation, and development of promising antibody candidates. Regeneron's rapid response VelociSuite technologies are particularly well-suited for use in quickly-developing outbreak situations, as was done for Ebola.

Sanofi Joins Forces With HHS To Advance A Novel Coronavirus Vaccine

On February 18, Sanofi Pasteur, Inc. of Swiftwater, Pennsylvania (the vaccine division of Sanofi Aventis U.S., LLC) announced they will collaborate with the Biomedical Advanced Research & Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness & Response (ASPR) at the U.S. Department of Health & Human Services (HHS) and leverage previous development work for a severe acute respiratory syndrome vaccine which may unlock a fast path forward for developing a coronavirus disease 2019 (COVID-19) vaccine.

The COVID-19 belongs to a family of coronaviruses that can cause respiratory disease. In late 2002, the severe acute respiratory syndrome (SARS) coronavirus emerged and then largely disappeared by 2004. Sanofi plans to further investigate an advanced pre-clinical SARS vaccine candidate that could protect against COVID-19.

David Loew, Global Head of Vaccines at Sanofi, said: "Addressing a global health threat such as this newest coronavirus is going to take a collaborative effort, which is why we are working with BARDA to quickly advance a potential vaccine candidate. While we are lending our expertise where possible, we believe the collaboration with BARDA may provide the most meaningful results in protecting the public from this latest outbreak."

Sanofi will use its recombinant DNA platform to produce a 2019 novel coronavirus vaccine candidate. The recombinant technology produces an exact genetic match to proteins found on the surface of the virus. The DNA sequence encoding this antigen will be combined into the DNA of the baculovirus expression platform, the basis of Sanofi's licensed recombinant influenza product, and used to rapidly produce large quantities of the coronavirus antigen which will be formulated to stimulate the immune system to protect against the virus.

In December 2019, Sanofi also entered into an agreement with BARDA to establish state of the art facilities in the U.S. for the sustainable production of an adjuvanted recombinant vaccine for use in the event of an influenza (flu) pandemic and based on the same technology platform that will be used for the COVID-19 program.

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Top 10 List Of Medication Errors & Hazards

On January 16, the Institute for Safe Medication Practices (ISMP) of Horsham, Pennsylvania announced their release of the "Top 10 Most Persistent Medication Errors & Safety Issues" that had been previously covered in the ISMP newsletters in 2019 last year.

The list focuses on safety problems that are frequently reported, caused serious harm to patients, and could be avoided or minimized with system and practice changes attainable by all healthcare providers.

ISMP believes that these issues merit attention and priority if action has not already been taken to mitigate risk, and the article provides specific prevention recommendations. They hope the following hazards and errors become an essential part of healthcare's strategic medication safety improvement plans.

1) **Selecting the wrong medication after entering the first few letters of the drug name.** Entering just the first few letter characters of a drug name or combination of the first few letters and product strength can allow the presentation of similar-looking drug names on technology screens, leading to selection errors. This is a problem that has increased in frequency with the upswing in technology use. In fact, wrong selection errors may now rival or exceed those made with handwritten orders.

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Janssen Joins Forces With BARDA To Protect Against Threat Of A Global COVID-19 Pandemic

On February 11, Janssen Pharmaceutical Companies of Raritan, New Jersey (a Johnson & Johnson company) announced they will further expedite its investigational coronavirus vaccine program through an expanded collaboration with the Biomedical Advanced Research & Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness & Response (ASPR) at the U.S. Department of Health & Human Services (HHS).

The collaborative partnership with BARDA builds on Johnson & Johnson's multipronged response to the new coronavirus disease (COVID-19) outbreak. In addition to Janssen's efforts to develop a vaccine candidate, the company is working closely with global partners to screen its library of antiviral molecules to accelerate the discovery of potential COVID-19 treatments and provide relief for people in China and around the world.

Paul Stoffels, M.D., Vice Chairman of the Executive Committee & Chief Scientific Officer at Johnson & Johnson, explained: "Developing an effective vaccine will be critical if we are to protect people against the novel coronavirus and combat future outbreaks. This partnership will ensure that vital research is made possible at rapid speed and underscores the importance of public-private partnerships to tackle the worldwide novel coronavirus epidemic. We are also in discussions with other partners, that if we have a vaccine candidate with potential, we aim to make it accessible to China and other parts of the world."

Through this agreement, created under an existing U.S. Government's Other Transaction Authority, Janssen and BARDA will both contribute to the research and development costs and mobilize resources to rapidly advance the initial stages of Janssen's COVID-19 vaccine development program. BARDA will provide funding to support accelerated development of a vaccine candidate into Phase 1 clinical studies, with options for additional funding to progress a promising candidate. In parallel, Janssen will work to upscale the production and manufacturing capacities required to meet public health needs.

The vaccine program will leverage Janssen's AdVac® and PER.C6® technologies that provide the ability to rapidly upscale production of the optimal vaccine candidate. These are the same technologies that were used in the development and manufacturing of Janssen's investigational Ebola vaccine, which is currently deployed in the Democratic Republic of the Congo and Rwanda. They were also used to construct the company's vaccine candidates for the Zika respiratory syncytial virus (RSV), and HIV (human immunodeficiency virus).

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10232235	5586151	3479839	826214

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[1] Gudeman J, Jozwiakowski M, Chollet J, Randell M. Potential risks of pharmacy compounding. Drugs R D. 2013;13(1):1–8. doi:10.1007/s40268-013-0005-9.

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Leucadia™

Top 10 List Of Drug Errors & Hazards

Continued from Page 52

2) **Daily instead of weekly oral methotrexate for non-oncologic conditions.** An ISMP QuarterWatch® report analysis of methotrexate administration errors over 18 months between 2018 and 2019 found that approximately half were made by older patients who became confused about frequency, and half by healthcare providers who inadvertently prescribed, labeled, and/or dispensed methotrexate daily when weekly was intended.
3) **Errors and hazards due to look-alike labeling of manufacturers' products.** Highly stylized graphics and prominent corporate names and logos that may overshadow essential information, along with similar label and cap colors, can make different products look alike and lead to mix-ups.
4) **Misheard drug orders or recommendations during verbal or telephone communication.** Even in an era of electronic health records, certain situations still require verbal or telephone orders for medications, such as prescribing a drug during an emergency or sterile procedure, or oral communication of consultant drug therapy recommendations. Those oral communications can be misunderstood and result in errors if not verified.
5) **Unsafe "overrides" with automated dispensing cabinets (ADC's).** The ISMP continues to receive reports of unsafe practices associated with ADC's that have jeopardized patients. Now that ADC use is widespread, healthcare organizations should review safe use and identify vulnerabilities; the ISMP's ADC guidelines outline standard best practices and processes.
6) **Unsafe practices associated with IV push medications.** In 2019, the ISMP conducted a gap analysis of safe adult IV push medication administration and identified areas in need of substantial improvement. Healthcare organizations are strongly encouraged to follow the ISMP's safe practice guidelines for adult IV push medications.
7) **Wrong route (intraspinal injection) errors with tranexamic acid.** Multiple cases have recently been reported, and this error has a mortality rate of 50%. Tranexamic acid can be mixed up with bupivacaine or ropivacaine, since all 3 are available in vials with blue caps and are often stored upright near each other with only the caps (not labels) visible.
8) **Unsafe labeling of prefilled syringes and infusions by 503B compounders.** ISMP has received an increasing number of error reports related to this issue. The FDA does not hold outsourcing facilities to the same labeling standards as for commercial manufacturers, which increases the chance for variations that can lead to confusion.
9) **Unsafe use of syringes for vinca alkaloids.** Because vinca alkaloids continue to be erroneously administered by the intrathecal route, in 2019 the ISMP called upon the FDA to remove administration by syringe from the prescribing information, in favor of minibag administration only. Despite strong advocacy to always dilute vinca alkaloids in minibags, approximately 15% to 20% of U.S. hospitals still use syringes, mainly for pediatric patients.
10) **1,000-fold overdoses with zinc.** Critical dose warnings are not available for IV zinc and other trace elements used as parenteral nutrition additives, making errors more likely, particularly involving pediatric patients. Even 1,000-fold overdoses can happen.

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CDC Invests In Innovation To Combat Antibiotic Resistance

On January 23, the U.S. Centers for Disease Control & Prevention (CDC) announced that they in 2019, they invested more than $14 million in academic and healthcare innovators and other researchers, in order to combat antibiotic resistance (AR), according to the agency's latest interactive AR Investment Map.

The investments total more than $125 million toward innovation, plus millions more to public health departments, since 2016. The interactive map shows the CDC's commitment to discover, test, and scale up strategies that protect people from antibiotic-resistant germs, which infect someone in the United States every 11 seconds and kills someone every 15 minutes.

Through its AR Solutions Initiative, the CDC invests and collaborates with innovators to find solutions that protect people by studying antibiotic resistance in healthcare, food, the environment (e.g., water and soil), and communities. This includes the following.

- Collaborating with medical academic investigators to protect patients from antibiotic-resistant germs in healthcare settings. This includes research on improving cleaning methods in intensive care units, assessing stewardship programs that improve antibiotic use, and obtaining stronger surveillance data that can drive action.
- Identifying public health approaches that protect people, their microbiomes, and the effectiveness of antibiotics. These projects focus on, for example, how to restore a microbiome (the community of naturally-occurring germs in and on our bodies) that has been wiped out by antibiotics, and a test that can predict how an antibiotic might impact a specific person's microbiome.
- Addressing knowledge gaps around how antibiotic resistance in agriculture and the environment may impact human health. This includes investigating how water systems near healthcare and agriculture settings may impact people.

We cannot rely on new antibiotics alone, since antibiotic resistance will continue to emerge and spread. The CDC remains committed to helping the world innovate and uncover stronger prevention solutions that will protect people from the global threat of antibiotic resistance.

See the AR Investment Map and each of the Fiscal Year 2019 innovation projects along with other CDC work to combat antibiotic resistance on the following CDC web page: www.cdc.gov/ARinvestments

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Innovative News

CapMedic® - Wireless Technology To Help Use Inhalers Correctly

On January 27, Cognita Labs™, LLC of Santa Ana, California announced the FDA clearance for CapMedic®, the world's first interactive digital inhaler sensor indicated for asthma, Chronic Obstructive Pulmonary Disease (COPD), and other pulmonary conditions.

CapMedic is the fusion of digital technology with traditional Metered Dose Inhalers (MDI's) that guides patients with engaging live audio-visual cues to help them use inhalers correctly and regularly, crucial for effective therapy and avoiding flare-ups. It is also the only FDA-cleared wireless technology that empowers users to track the progression of their lung health through an in-built spirometer. With its artificial intelligence (AI)-powered sensor technology, provides precisely timed step-by-step interactive cues to break down complex steps such as correct coordination and deep inhalation and easy-to-forget steps like shaking the inhaler and upright positioning.

Rajoshi Biswas, Ph.D., Chief Scientific Officer & Co-Founder at Cognita Labs, said: "Decades of studies have shown that almost 90% of patients are unable to use MDIs correctly; a result of their complex, multi-step usage requirements. The Cognita team has conducted drug deposition studies showing a tenfold improvement in the delivery of medication from just 4-5% to 45% when inhalers are used correctly. Getting an effective daily dose means patients are more likely to avoid costly, life-threatening hospitalizations. Our goal with CapMedic is to make inhalers fun and easy to use while allowing patients to build good inhaler use habits and better manage their respiratory conditions."

CapMedic is dual-purpose, so it also assists with disease management through its spirometer, measuring lung parameters

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Innovative News

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Forced Expiratory Volume in 1 second (FEV1) and Peak Expiratory Flow (PEF).

The medication and lung function data can be transferred to the CapMedic smartphone app, empowering patients to actively engage in managing their condition and enabling Remote Patient Monitoring (RPM) for providers.

Dr. Chris Landon, Pediatric Pulmonologist at the Pediatric Diagnostic Center in Ventura, California (also the leader in charge of piloting the new device), said: "We've never really known if our patients are getting the medication they need at home because many of them struggle to use inhalers correctly. Patients travel hundreds of miles for consultation or go off to school. CapMedic brings us the data we didn't have before. We have seen our little patients, and our big ones, loving the sounds and lights of CapMedic while improving their technique. Parents synchronize lung function and medication data with their smartphone app, which gives us a snapshot of their compliance remotely."

The consumer-friendly device can be attached to the following inhalers: Ventolin® (albuterol sulfate); Proair® (albuterol sulfate); Symbicort® (budesonide; formoterol fumarate dihydrate); Advair® (fluticasone propionate; salmeterol xinafoate); Flovent® (fluticasone propionate); Dulera® (formoterol fumarate; mometasone furoate); Proventil® (albuterol sulfate); Asmanex® (mometasone furoate); Xopenex® (levalbuterol HCl); Alvesco® (ciclesonide); and Atrovent® (ipratropium bromide).

14-Day Ambulatory Monitor Patch

On January 23, Bardy Diagnostics, Inc. (BardyDx) of Seattle, Washington announced the commercial launch of the 14-day version of the Carnation Ambulatory Monitor (CAM™), the industry's only P-wave centric™ ambulatory cardiac patch monitor and arrhythmia detection device, following its recent clearance by the FDA in September 2019.

The CAM Patch is a non-invasive, P-wave centric™ ambulatory cardiac monitor and arrhythmia detection device that is designed to improve patient compliance for adults and children through its lifestyle-enabling form factor. Designed to be worn comfortably and discreetly for up to 14 days, the female-friendly, hourglass-shaped CAM Patch is placed on the center of the chest, directly over the heart for optimum ECG signal collection. The proprietary technology of the CAM Patch provides optimal detection and clear recording of the often difficult-to-detect P-wave, the signal of the ECG waveform that is essential for accurate arrhythmia diagnosis.

Clinical studies found that the BardyDx CAM Patch identified 40% more arrhythmias and resulted in better, more informed clinical decision-making in 41% of patients over the other currently marketed leading cardiac patch. It was also found to have 4 times increase in arrhythmia detection compared to a traditional Holter monitor, including arrhythmias missed or incorrectly identified.

The growing market recognition of the innovative P-wave centric CAM Patch includes recently being selected as the winner of the "Remote Monitoring in Arrhythmias Digital Health Pitch Session" at the European Society of Cardiology Congress 2019; as well as being the finalist of the University of California in San Francisco (UCSF) Digital Health Award for "Best Cardiovascular Digital Diagnostic." In addition, BardyDx was also named the winner of the 2019 MedTech Breakthrough Award for "Best New Diagnostic Technology;" and the winner of the 2019 Frost & Sullivan Award for "Technology Innovation in Remote Cardiac Monitoring."

Gust H. Bardy, M.D., Founder & CEO of BardyDx, said: "The 14-day CAM is the culmination of years of development focused on uncovering the full complexity and meaning of a patient's cardiac rhythm. We are proud to develop and introduce the most advanced and accurate cardiac monitoring technologies that enable new opportunities to reimagine and redefine patient care."

BardyDx is a provider of ambulatory cardiac monitoring technologies, custom data solutions, and digital health and remote patient monitoring, with a focus on providing the most diagnostically-accurate and patient-friendly cardiac monitors to the industry.

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11 DIGIT NDC			Cardinal	5557707	
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PharMEDium Permanently Ceases All Operations

As of January 30, AmerisourceBergen Corporation of Chesterbrook, Pennsylvania and PharMEDium Services, LLC of Lake Forest, Illinois (an AmerisourceBergen company) jointly announced the ***permanent closing*** of PharMEDium, a company that provides outsourced compounded sterile drug preparations to hospitals.

The company has ceased all compounding operations and will close entirely over the coming months, and it is not able to fulfill any outstanding orders that may have been placed, nor accept any additional new orders.

AmerisourceBergen made this difficult decision following a comprehensive strategic and financial review of the business, due to significant issues with the compounding business being plagued by both regulatory and operational obstacles over the past 2 years.

AmerisourceBergen said it would encourage the approximately 1,000 employees affected by the closure to apply for other positions within the company.

A company spokesperson said: "PharMEDium has been on a journey to reach full and continuous compliance with 503B outsourced sterile compounding regulations. While we have made tremendous progress, the challenges associated with regulatory, financial, and commercial operations have become too great. Unfortunately, closing the business was the only viable path forward. We deeply appreciate your business and support over more than 25 years in operation. Should you have any immediate questions, our customer service team is available to support you."

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Heart Health News

Heart Disease & Stroke Deaths Continue To Decline, But Trend Has Slowed Significantly In Recent Years

On January 29, the American Heart Association (AHA) announced results of new research, which show that heart disease and stroke deaths continue to decline, but that trend has slowed significantly in recent years. Further discouraging is that more people are living in poor health, beginning at a younger age, as a direct result of risk factors that contribute to these leading causes of death worldwide.

To build on its mission to be a force for a world of longer, healthier lives, AHA has published a presidential advisory outlining new national and global "Impact Goals for 2030," to help all people live healthier for more years of their life.

- **Across the United States:** Together, we will equitably increase healthy life expectancy from 66 to at least 68 years, by the year 2030.
- **Around the World:** Together with global and local collaborators, we will equitably increase worldwide healthy life expectancy from 64 to at least 67 years, by 2030.

Goal progress will be tracked by the Health-Adjusted Life Expectancy (HALE) metric, commonly referred to as Healthy Life Expectancy, which anticipates the number of years that a person can expect to live in good health. It is a comprehensive single metric that provides an estimate of overall health across a person's lifetime and captures both physical and mental health conditions. That is especially relevant to the broader focus on overall health and well-being emphasized in the new goals.

Over the past decade, key factors that support ideal cardiovascular health have seen some positive movement across the United States. Reports show adults are getting more active and overall, people are eating healthier, smoking cigarettes less, and better controlling their cholesterol. However, that good news is offset by major setbacks in other critical areas, especially among youth, which is a trend that puts upcoming generations at even higher risk for facing major health issues at younger ages.

The following is according to the AHA's Heart & Stroke Statistics 2020 Update.

- Obesity rates are on the rise in U.S. children and adults. Nearly 40% of adults and 18.5% of youth are now considered as obese.

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Heart Health News

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- Physical activity rates are abysmally low among youth. Less than a third of U.S. students take part in a daily physical education class and only 26% meet the national recommendations of an hour a day of moderate to vigorous physical activity.
- Rates for uncontrolled high blood sugar are leading more people toward diabetic and pre-diabetic conditions. Diabetes prevalence in the U.S. increased 129.7% for males and 120.9% for females between 1990 and 2017.
- While cigarette smoking in the U.S. is down among adults and at all-time lows for teens, the growing youth vaping epidemic is making daily headlines and the global use of tobacco continues to climb. In 2015, there were more than 933 million smokers, globally.
- The trends are even more devastating among certain races, ethnicities, genders, and geographic locations. At least 80% of the world's smokers, most of whom are male, live in low and middle-income countries.

John Warner, M.D., Fellow of AHA, Past President of AHA (2017-2018), and Executive VP for Health System Affairs at the University of Texas Southwestern Medical Center in Dallas, Texas (and lead author of the presidential advisory), stated: "We believe every person should enjoy health and well-being no matter their age, gender, race, or even the zip code in which they live. And, we know disparities exist even to that level; from one block of a city to another. To improve individual health, we must make the environments where we live, work, learn, and play equitably supportive of healthy behaviors. We also need to help people better understand the impact their communities have in driving choices for health and well-being."

In a Harris Poll recently conducted for the AHA, most of the respondents (93%) agreed that living a long, healthy life is important to them and believe everyone deserves the longest, healthiest life possible (92%). However, there appears to be a disconnect between their desires and their understanding of how those intentions connect back to their behaviors, as less than half of the respondents (49%) strongly agreed that their behavior influences their health and well-being; and only a third (34%) strongly agreed that their environment influences or supports their health choices.

Robert A. Harrington, M.D., Fellow & President of AHA, Arthur L. Bloomfield Professor of Medicine and Chairman of the Department of Medicine at Stanford University in California, explained: "We need to make healthy choices the easy ones, make healthcare accessible and affordable, and we need to get better at stopping preventable diseases before they start. Sometimes parents are more worried about whether they can feed their children anything, much less whether it's healthy or not. If you're living with high blood pressure, you shouldn't have to worry about choosing between whether to pay rent or buy your medicine. We want everyone of all ages and backgrounds to be healthy and experience every simple joy, make every heartfelt memory, celebrate every special occasion they need and want to do. This is so much more than just wanting people to live to a ripe old age, we want them to live healthier, longer. And we're dedicating ourselves to doing just that over the next decade."

The advisory also states that what will drive the success of the goals is working collaboratively with many diverse groups from local neighborhoods to global governments. Additional improvements will still need to come through increased efforts for primary and secondary prevention, public health policies that impact populations, the establishment of effective, comprehensible and affordable healthcare systems, and finally, modifications to individual lifestyle behaviors.

While the basic metric of healthy life expectancy is well established, tracking progress and understanding trends to meet the 2030 goals will also require improvements in capturing the way health information is reported and analyzed. An accompanying publication to the 2030 goals is an AHA policy statement, outlining major recommendations for enhancing cardiovascular health and disease surveillance worldwide.

Only 1 In 4 Medicare Patients Participate In Cardiac Rehab

On January 14, the American Heart Association (AHA) announced results of new research, which show that too few people covered by Medicare participated in outpatient cardiac rehabilitation after a heart attack or acute heart event or surgery; principally women, the elderly, and non-white patients.

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Heart Health News

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Every year, an estimated 1.3 million U.S. adults with heart disease may qualify for cardiac rehabilitation (not including those with qualifying heart failure). Outpatient cardiac rehab has been shown to improve health outcomes among patients who have heart failure, have suffered heart attacks, or have undergone a cardiac procedure such as coronary artery bypass surgery. This observational study measured participation rates and identified the populations and regions most at risk for suboptimal cardiac rehabilitation.

In the review of more than 366,000 patients covered by Medicare (Part B provides coverage for the program) who were eligible for outpatient cardiac rehab in 2016, researchers found the following.

- Only about 25% (approximately 90,000) participated in a cardiac rehab program.
- Among those who did participate in cardiac rehab, only 24% began the program within 21 days of the acute cardiac event or surgery.
- Only about 27% of those in cardiac rehab completed the full course of the recommended 36 or more sessions, which have been shown to improve health outcomes.
- Participation in outpatient cardiac rehab decreased with increasing age, with only about 10% of patients age 85 and older participating, versus about 32% of those age 65 to 74.
- Participation was lower among women than men, about 19% versus about 29%, respectively.
- Over half of the cardiac rehab eligible patients had less than 5 co-morbid conditions.
- Non-Hispanic whites had the highest participation rate at about 26%, versus 16% for Asians, 14% for non-Hispanic blacks, and 13% for Hispanics.
- Participation also varied by region, with cardiac rehab being lowest in the Southeastern United States and the Appalachian region.
- Patients who had a procedure such as coronary bypass surgery were more likely to participate in cardiac rehab than those who had a heart attack with no procedure performed.

Researchers noted that patients face systematic, logistical, and cultural barriers to attending and completing an outpatient cardiac rehab program. At the system level, there are no universally accepted, automated, electronic referral processes for cardiac rehab services. On a personal level, patients may not complete rehabilitation due to the costs and/or the time needed to participate in the program versus returning to work and other personal commitments.

In 2019, the AHA issued a new Scientific Statement, a collaboration with the American Association for Cardiovascular & Pulmonary Rehabilitation and the American College of Cardiology (ACC), detailing the need for and benefits of home-based cardiac rehabilitation programs to improve patient access and health outcomes.

Matthew D. Ritchey, P.T., D.P.T., O.C.S., M.P.H., Researcher at the U.S. Centers for Disease Control & Prevention (CDC) Division for Heart Disease & Stroke Prevention (and lead study author), explained: "Improving awareness of the value of cardiac rehabilitation, increasing referral of eligible patients, and reducing system and patient barriers to participation are all critical steps in improving the referral, enrollment, and participation rates, which, in turn, can improve patient outcomes. For example, the Agency for Healthcare Research & Quality, recently launched the TAKEheart initiative to implement automatic referral processes with care coordination to increase cardiac rehabilitation referrals, enrollment, and retention across hundreds of hospitals. Each of these programs are important building blocks for continued improvement for patients. It is also important to improve the capacity within existing cardiac rehabilitation programs and to address shortages in available programs, especially in rural areas. One strategy for addressing these shortages could be to increase the use of home-based or tele-cardiac rehabilitation, which have been shown to achieve similar health outcomes as compared to center-based rehab care."

Continued on Page 62

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Product Description	Strength	AmerisourceBergen Item Code	Cardinal Item Code	McKesson Item Code
Tranexamic Acid Injection, USP	100 mg/mL	10230101	5568068	3986874

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Government Agency News

FDA Requests Withdrawal Of Weight-Loss Drugs Belviq® & Belviq XR® Due To Cancer Risk

On February 13, the FDA announced that they and Eisai Inc. of Woodcliff Lake, New Jersey, the manufacturer of Belviq® (lorcaserin) Tablets and Belviq XR® (lorcaserin extended-release) Tablets, have voluntarily withdrawn the weight-loss drug from the U.S. market, due to results from a safety clinical trial that showed an increased occurrence of cancer in patients taking the drug.

When the FDA approved lorcaserin in 2012, they required Eisai to conduct a clinical trial to evaluate the risk of cardiovascular problems. The trial found a range of cancer types reported, with several different types of cancers occurring more frequently in the lorcaserin group, including pancreatic, colorectal, and lung.

In January 2020, the FDA announced they were reviewing the drug's clinical trial data and alerted the public about a possible risk of cancer associated with lorcaserin based on preliminary analysis of the data.

Health professionals should stop prescribing and dispensing lorcaserin to patients. Patients should be informed of the increased occurrence of cancer seen in the clinical trial, asked to stop taking the medicine, and alternative weight-loss medicines or strategies should also be discussed.

Belviq was originally FDA approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in obese adult patients (as classified with an initial body mass index-BMI of 30kg/m² or greater.

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Heart Health News

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New CPR & First Aid In Youth Sports Kit Aims To Teach Lifesaving Skills

On January 10, the American Heart Association (AHA) unveiled its new lifesaving "CPR & First Aid in Youth Sports™ Training Kit," since sudden cardiac arrest is the leading cause of death in athletes during exercise and usually results from underlying cardiac conditions that are triggered by the demands of vigorous exercise.

AHA along with U.S. Lacrosse of Sparks, Maryland, the national governing body of team sport lacrosse for men and women, share a desire for safety and preparedness for all youth sports participants.

The new Training Kit is designed specifically for youth sports coaches and parents to teach the lifesaving skill of CPR, how to use an automated external defibrillator (AED), and how to help during sports-related emergencies. It is completely self-facilitated, with no additional training required for a facilitator.

Raina Merchant, M.D., M.S., Assistant Professor in the Department of Emergency Medicine at the University of Pennsylvania in Philadelphia and Chair of the Emergency Cardiovascular Care Committee at the AHA, said: "Sudden cardiac death during sports is a tragic event that has a significant impact not only on the victim, but also the broader community. Coaches and athletic trainers play a pivotal role in the prevention, management, and aftermath of sudden cardiac arrest in young athletes. Preparing coaches and athletic trainers for an emergency is important for improving the likelihood of survival in the event of cardiac arrest. CPR is an important skill everyone should know and could double or triple a person's chance of survival."

From July 2017 to June 2018, there were a total of 85 catastrophic cardiac-related injuries or illnesses among high school and college organized sports participants due to or during sport-related activities. Current rates of sudden cardiac death appear to be at least 4 to 5 times higher than previously estimated, with men, African Americans, and specifically male basketball players being at greatest risk.

Bruce Griffin, Ph.D., Director of the Center for Sport Science at U.S. Lacrosse in Sparks, Maryland, stated: "Often in youth sports there are no athletic trainers, EMS, or other first responders on-site, so if a cardiac arrest occurs during practice or a game, it is important that coaches, parents, and athletes are prepared to act."

To get the Kit, visit: https://cpr.heart.org/en/cpr-courses-and-kits/cpr-first-aid-in-youth-sports-training-kit

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Government Agency News

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The FDA is not recommending special screening for patients who have taken lorcaserin. However as with any individual patient, regardless of prior lorcaserin treatment, standard screening recommendations for cancer should be implemented.

Patients should stop taking lorcaserin and talk to their health professionals about alternative weight-loss medicines and weight management programs. It is best to dispose of unused lorcaserin using a drug take-back location, but if you can't get to one, you can dispose of it in your household trash as follows.

- Mix the pills with an unappealing substance such as dirt, cat litter, or used coffee grounds (do not crush them);
- Place the mixture in a container such as a sealed plastic bag;
- Throw away the container in your trash at home;
- Remove or delete all personal information on the prescription label of empty medicine bottles or packaging, then throw away or recycle them.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information & Adverse Event Reporting Program online, at: www.accessdata.fda.gov/scripts/medwatch/index.cfm

FDA Office Of Pharmaceutical Quality Issues Annual Report For 2019

On February 10, the Office of Pharmaceutical Quality (OPQ) within the FDA's Center for Drug Evaluation & Research announced they have published their 2019 annual report, describing accomplishments in 2019 and over the office's 5-year life.

The OPQ's accomplishments included efforts in drug assessment, inspection, surveillance, policy, and research. These accomplishments have helped support patient and consumer access to needed medicines.

The OPQ has a unique role at the FDA, with activities that impact all human drug user fee programs: new drugs, generics, and biologics, including biosimilars. The OPQ has the same expectations for quality for all classes of drugs whether made in the U.S. or abroad.

A quality product of any kind consistently meets the expectations of the user; drugs are no different. Patients expect safe and effective drugs with every dose they take. All drugs marketed in the U.S. must meet quality standards that ensure every dose is safe and effective, and free of contamination and defects. Quality is what gives patients and consumers, confidence in their next dose of medicine.

To read the full report, visit: www.fda.gov/media/135046/download

FDA Withdraws Bacitracin For Injection From Market

On January 31, the FDA requested that all current manufacturers of bacitracin for injection, voluntarily withdraw their product from the market.

Bacitracin for injection is currently FDA-approved to treat infants with pneumonia and empyema (a collection of pus in the space between the membranes lining the lungs) caused by *staphylococci*, a type of bacteria, shown to be susceptible to the drug. However, healthcare professionals no longer use bacitracin for injection to treat this condition because other effective FDA approved treatments are available that do not have the same serious risks, including nephrotoxicity (harm to the kidneys), anaphylactic reactions, and the need for repeated intramuscular injections.

In April 2019, the Antimicrobial Drugs Advisory Committee met and discussed the safety and effectiveness of bacitracin for injection. The advisory committee voted almost unanimously, with one abstention, that the risks outweigh the benefits for the drug's only approved indication.

Based on the FDA's review of currently available data, they believe that the potential problems associated with bacitracin for injection are sufficiently serious to remove the drug from the market.

Note: this requested voluntary withdrawal does not impact any of the approved topical or ophthalmic drugs that contain bacitracin.

CDC Maps America's High Levels Of Inactivity

On January 16, the U.S. Centers for Disease Control & Prevention (CDC) announced the release of new state maps showing adult physical inactivity prevalence, indicating that all states and territories had more than 15% of adults

Continued on Page 66

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GANCICLOVIR Injection 500 mg per 10 mL	
25021-185-11	single pack
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Please see the Brief Summary of Prescribing Information for GANCICLOVIR Injection.

For ordering information, visit www.**SagentPharma**.com.

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GANCICLOVIR Injection

Brief Summary of Prescribing Information

INDICATIONS AND USAGE

Ganciclovir Injection is indicated for the treatment of cytomegalovirus (CMV) retinitis in immunocompromised adult patients, including patients with acquired immunodeficiency syndrome (AIDS) and for the prevention of CMV disease in adult transplant recipients at risk for CMV disease.

IMPORTANT SAFETY INFORMATION

WARNING: HEMATOLOGIC TOXICITY, IMPAIRMENT OF FERTILITY, FETAL TOXICITY, MUTAGENESIS AND CARCINOGENESIS

Hematologic Toxicity: Granulocytopenia, anemia, thrombocytopenia, and pancytopenia have been reported in patients treated with Ganciclovir Injection.

Impairment of Fertility: Based on animal data, Ganciclovir may cause temporary or permanent inhibition of spermatogenesis in males and suppression of fertility in females.

Fetal Toxicity: Based on animal data, Ganciclovir Injection has the potential to cause birth defects in humans.

Mutagenesis and Carcinogenesis: Based on animal data, Ganciclovir Injection has the potential to cause cancers in humans.

CONTRAINDICATIONS

Ganciclovir Injection is contraindicated in patients who have shown hypersensitivity to ganciclovir or valganciclovir.

WARNINGS AND PRECAUTIONS

- Granulocytopenia (neutropenia), anemia, thrombocytopenia and pancytopenia have occurred in patients treated with Ganciclovir Injection, with wide variation in frequency and severity in different patient populations. Ganciclovir is not recommended if the absolute neutrophil count is <500 cells/µL, hemoglobin is <8 g/dL, or the platelet count is <25,000 cells/µL. Use with caution in patients with pre-existing cytopenias and in patients receiving myelosuppressive drugs or irradiation. A complete blood count with differential and platelet count should be performed in all patients receiving Ganciclovir due to the above mentioned hematological toxicities.
- Ganciclovir Injection should be used with caution in patients with impaired renal function because reduced renal clearance will increase the half-life and plasma/serum concentrations of ganciclovir. If renal function is impaired, dosage adjustments are recommended. Monitoring renal function during therapy is essential, particularly for elderly and patients taking nephrotoxic medication.
- Ganciclovir Injection at the recommended human dose may cause temporary or permanent inhibition of spermatogenesis in males, and may cause suppression of fertility in females. Advise patients that fertility may be impaired.
- Ganciclovir Injection may cause fetal toxicity when administered to pregnant women. Women of childbearing potential should use effective contraception during treatment and for at least 30 days following treatment. Men should practice barrier contraception during and for at least 90 days following treatment.
- Advise nursing mothers that breastfeeding is not recommended during treatment with Ganciclovir Injection because of the potential for fetal toxicity, mutagenesis and carcinogenesis.
- Ganciclovir is mutagenic and carcinogenic as indicated by animal data, so Ganciclovir Injection should be considered a potential carcinogen in humans.

ADVERSE REACTIONS

The following serious adverse reactions are discussed in detail in **Warnings and Precautions**: hematologic toxicity, renal impairment, impairment of fertility, fetal toxicity, and mutagenesis and carcinogenesis.

OVERDOSAGE

The following adverse reactions after Ganciclovir Injection overdose, some with fatal outcomes, have been reported: myelosuppression, bone marrow failure, hepatitis and liver function disorder, worsening of hematuria in a patient with pre-existing renal impairment, acute renal failure, elevated creatinine, abdominal pain, diarrhea, vomiting, and seizures. Dialysis may be useful in reducing serum concentrations. Maintain adequate hydration. The use of hematopoietic growth factors should be considered in patients with cytopenias

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

Please see full prescribing information for GANCICLOVIR Injection.

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Government Agency News

Continued from Page 63

who were physically inactive, and this estimate ranged from 17.3% to 47.7%.

Inactivity contributes to 1 in 10 premature deaths in the United States. Inadequate levels of physical activity are associated with $117 billion in annual healthcare costs.

Physical inactivity for adults is defined as not participating in any leisure-time physical activities over the last month; activities such as running, walking for exercise, or gardening.

The new maps are based on combined 2015 to 2018 data from the Behavioral Risk Factor Surveillance System (BRFSS), an on-going state-based telephone interview survey conducted by the CDC and state health departments. This is the first time that the CDC has created state maps of physical inactivity by race and ethnicity.

State and territory-level estimates of physical inactivity range from 17.3% of people in Colorado to 47.7% in Puerto Rico. In 7 states and 2 territories (Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Oklahoma, Tennessee, Puerto Rico, and Guam), 30% or more of adults were physically inactive. By region, the South had the highest prevalence of physical inactivity (28%), followed by the Northeast (25.6%), Midwest (25%), and the West (20.5%).

Ruth Petersen, M.D., Director of the CDC's Division of Nutrition, Physical Activity & Obesity, said: "Too many adults are inactive, and they may not know how much it affects their health. Being physically active helps you sleep better, feel better, and reduce your risk of obesity, heart disease, type 2 diabetes, and some cancers."

The Demographics Of Physical Inactivity: The maps point to notable differences in physical inactivity levels by race and ethnicity. Overall, Hispanics had the highest prevalence of self-reported physical inactivity (31.7%), followed by non-Hispanic blacks (30.3%), and non-Hispanic whites (23.4%).

In the majority of locations examined, non-Hispanic blacks and Hispanics had a significantly higher prevalence of inactivity than non-Hispanic whites.

- 5 states and Puerto Rico had a physical inactivity prevalence of 30% or higher among non-Hispanic white adults;
- 22 states and Puerto Rico had a physical inactivity prevalence of 30% or higher among Hispanic adults;
- 23 states and the District of Columbia had a physical inactivity prevalence of 30% or higher among non-Hispanic black adults.

What More Can Be Done? The CDC is working with communities and partners across the country as part of the Active People, Healthy Nation[SM] initiative, to make it easier, safer, and more convenient for people to be active where they live, learn, work, and play. The overall goal of the initiative is to help 27 million Americans become more physically active by 2027 to improve overall health and quality of life and to reduce healthcare costs.

The Physical Activity Guidelines for Americans-2nd edition recommends that adults get at least 150 minutes of moderate-intensity physical activity each week. For example, this can be broken into smaller amounts such as 25 minutes every day or 30 minutes/5 times a week.

Individuals and families are encouraged to build physical activity into their day by going for a brisk walk or a hike, walking the dog, choosing the stairs instead of the elevator or escalator, parking further away in the parking lot, walking or cycling to run errands, and getting off the bus one stop early and walking the rest of the way. The key is to move more and sit less.

The initiative helps community leaders take advantage of proven strategies to make physical activity safe and enjoyable for people of all ages and abilities. Building active and walkable communities may also help support local economies and create more cohesive communities.

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

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

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

Government Agency News

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Alcohol-Related Deaths Increasing In The U.S.

On January 10, the National Institute on Alcohol Abuse & Alcoholism (NIAAA), part of the National Institutes of Health (NIH), announced that a new study and analysis of U.S. death certificate data by researchers found that nearly 1 million people died from alcohol-related causes between the years 1999 and 2017.

The number of death certificates mentioning alcohol more than doubled from 1999 (35,914 cases), to year 2017 (72,558 cases). In that year 2017, alcohol played a role in 2.6% of all deaths in the United States. The increase in alcohol-related deaths is consistent with reports of increases in alcohol consumption and alcohol-involved Emergency Department visits and hospitalizations during the same period.

Dr. George F. Koob, Director of the NIAAA, said: "Alcohol is not a benign substance and there are many ways it can contribute to mortality. The current findings suggest that alcohol-related deaths involving injuries, overdoses, and chronic diseases are increasing across a wide swath of the population. The report is a wakeup call to the growing threat alcohol poses to public health."

Aaron White, Ph.D., Senior Scientific Advisor to the NIAAA Director was part of the team analyzing the study's data. A death was identified as alcohol-related if an alcohol-induced cause was listed as the underlying cause or as a contributing cause of death. The researchers found that in 2017, nearly half of alcohol-related deaths resulted from liver disease (31%; 22,245), or overdoses on alcohol alone or with other drugs (18%; 12,954). People aged 45 to 74 had the highest rates of deaths related to alcohol, but the biggest increases over time were among people age 25 to 34. High rates among middle-aged adults are consistent with recent reports of increases in "deaths of despair," generally defined as deaths related to overdoses, alcohol-associated liver cirrhosis, and suicides, primarily among non-Hispanic whites. However, the authors report that by the end of the study period, alcohol-related deaths were increasing among people in almost all age and racial and ethnic groups.

As with increases in alcohol consumption and related medical emergencies, rates of death involving alcohol increased more for women (85%) than men (35%) over the study period, further narrowing once large differences in alcohol use and harms between males and females. The findings come at a time of growing evidence that even 1 drink per day of alcohol can contribute to an increase in the risk of breast cancer for women. Women also appear to be at a greater risk than men for alcohol-related cardiovascular diseases, liver disease, alcohol use disorder, and other consequences. Dr. Koob noted: "Alcohol is a growing women's health issue. The rapid increase in deaths involving alcohol among women is troubling and parallels the increases in alcohol consumption among women over the past few decades."

The authors note that previous studies have shown that the role of alcohol in deaths is vastly underreported. Since the present study examined death certificates only, the actual number of alcohol-related deaths in 2017 may far exceed the 72,558 determined by the authors.

Dr. Koob concluded: "Taken together, the findings of this study and others suggests that alcohol-related harms are increasing at multiple levels, from Emergency Department visits and hospitalizations to deaths. We know that the contribution of alcohol often fails to make it onto death certificates. Better surveillance of alcohol involvement in mortality is essential in order to better understand and address the impact of alcohol on public health."

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U.S. Trivia

Editorial Note: all of the below historical U.S. trivia is made available from "Profile America," now in its 20th year produced as a public service by the Center for New Media & Promotion within the U.S. Census Bureau.

Fluoridation Of Public Water Supplies

The first fluoridation law in the nation went into effect 53 years ago, on January 1, 1967.

At the start of the new law, the state of Connecticut required fluoridation of public water supplies serving 20,000 or more population, in order to combat tooth decay. The requirement was extended to the whole state later that year.

Water fluoridation began in 1945, when the cities of Newburgh, New York, and Grand Rapids, Michigan, began adding sodium fluoride to their public water systems. Nationwide today, there are 1.2 million miles of water supply lines.

Some two-thirds of America's 119-million occupied housing units are connected to public water lines. As most urban areas fluoridate their water, some three quarters of the U.S. population have such treated community water on tap.

First Woman Doctor

The nation's first woman doctor earned her M.D. in January of 1849, that started as the result of a joke.

Elizabeth Blackwell had applied to many medical schools but was rejected because of her sex. The faculty at Geneva Medical College in New York decided to let the students vote on her application, sure it wouldn't go through. But just meant to be a gag, the students voted: "Yes."

After attempting practice overseas, Dr. Blackwell moved to New York City, but found it hard be accepted at established hospitals. So, she opened her own dispensary in 1854, which 3 years later had grown to become the New York Infirmary For Women & Children.

Now, there are 763,000 doctors in the United States, and about 36% of them are women.

Federal Income Tax

It may be hard to credit, but there used to be a time when the public sphere wasn't filled with squabbling about income tax rates. The familiar noise began 107 years ago on February 3, when the 16th Amendment to the Constitution was ratified, authorizing Congress to levy taxes on income.

In its first 2 years, the tax was modest, affecting only a very few citizens and provided only a small part of the government's total revenue. But the need to fund our involvement in World War I then moved income taxes to the center of federal finances.

In our current year, about $2.6 trillion in federal income tax is anticipated. State and local income taxes lately amount to around $487 billion. Income taxes comprise over 37% of all state revenues.

Medicare

February 8, 1961 marks the anniversary of the date when the newly inaugurated **President John F. Kennedy** asked Congress to approve a health insurance program for 14.2 million Americans age 65 or older. It would be financed by an increase in Social Security taxes.

The 1961 proposal went nowhere until after Kennedy's assassination. What we know as Medicare passed through the House and Senate by July 27, 1965, and **President Lyndon Johnson** signed it into law on the 30th in the presence of former **President Harry Truman**.

Now, over 61 million people are enrolled, and 32% (nearly 20 million of them) have impaired health. Recent population estimates by the U.S. Census Bureau find 52 million Americans age 65 and older.

America's First Hospital

Among his very many achievements, **Benjamin Franklin** played a leading role in the founding of America's first hospital, decades before the Declaration of Independence. Together with **Dr. Thomas Bond,** he obtained a charter for a hospital to serve the poor, sick, and insane in the city of Philadelphia.

The Pennsylvania Hospital opened in a converted house on February 11, 1752. The hospital later developed at a location where a modern medical complex still serves the city. During its long history, the hospital's doctors have made advances in many fields, becoming known as "The Father" of both American psychiatry and of surgery.

Today, there are approximatelly 7,100 hospitals nationwide, employing over 6.1 million people in the $1 trillion per year business of healing.

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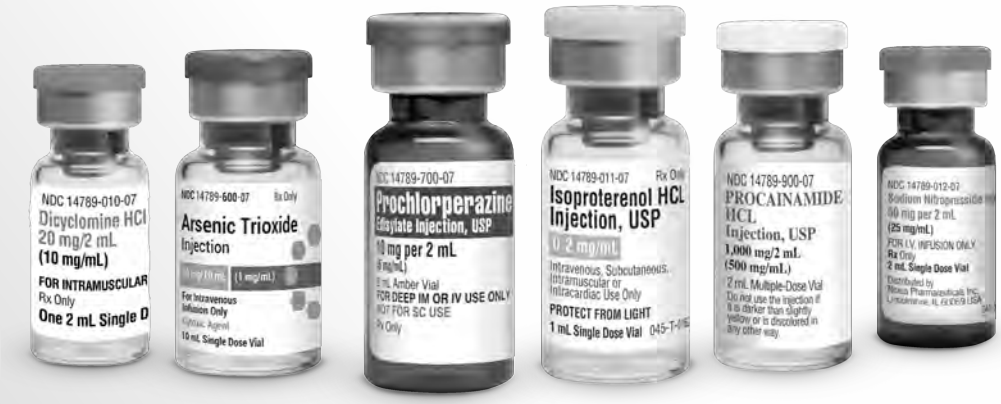

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or visit our website www.nexuspharma.net/products

References: 1. ASHP Website. https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortages-List?page=CurrentShortages&sort=1. Accessed July 24, 2019.

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Important Safety Information

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

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

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

To report SUSPECTED ADVERSE REACTIONS contact US WorldMeds at 1-888-900-8796 or MEDWATCH at 1-800-FDA-1088 (1-800-332-1088) or http://www.FDA.gov/medwatch/.

To see the full Prescribing Information visit revonto.com.

US WorldMeds

USWMREV-00004 02/20

Welcome, New NPPA Members!

Thanks and welcome to all listed below, for their new NPPA memberships! We encourage you to send feedback, and contribute articles for our member-publication here *(PPO)*. Also be aware of our "Pharmacy Buyer Forum" on the NPPA website (www.PharmacyPurchasing.com), that allows you to "chat" onlilne with your peers across the country for advice & assistance.

In addition, see here on the following pages, for our "NPPA Website Resources" (a regular column we print in each *PPO* edition). This provides you with your Member-Only page's login information, which has FDA shortage alerts, recalls, and more.

Full Pharmacy Members

Katie Pilcher, Pharmacy Purchasing Agent, St. Bernard's Medical Center, Jonesboro, AR

Stacey Wheeler, Pharmacy Supply Coordinator, Banner Health-Supply Chain, Chandler, AZ

Rosie Boyd, Pharmacy Buyer, Shasta Regional Medical Center, Redding, CA

Stephanie Cortez, Pharmacy Buyer, Adventist Health Saint Helena Hospital, St. Helena, CA

Roxanne Gura, Pharmacy Liaison, Yale New Haven Health, Plantsville, CT

Jessica Lillis, Central Pharmacy Purchasing Coordinator, Samaritan Lebanon Community Hospital, Lebanon, OR

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Associate Pharmacy Members

Jemma Carrillo, Pharmacy Technician, Torrance Memorial Medical Center, Torrance, CA

Rachael McKinley, Registered Nurse, Andrews Institute Ambulatory Surgery Ctr., Gulf Breeze, FL

Kim Brandt, Pharmacy Tech/Assistant Buyer, Bay Area Hospital, Coos Bay, OR

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Thanks To Renewing NPPA Members!

Full Pharmacy Members

Cindy Cragle, Pharmacy Inventory Analyst, RWJ University Hospital Somerset, Somerville, NJ

Karleen Mack-Brandt, Pharmacy Buyer, UnityPoint Health-Meriter Hospital, Madison, WI

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Taylor Beeler, National Accounts, US WorldMeds, LLC, Louisville, KY

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

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Terry Stein, Regional Account Manager, Virtus Pharmaceuticals, Alpharetta, GA

Brian Lynch, Senior Director of Hospital Marketing, Par Pharmaceutical, Inc., Chestnut Ridge, NY

Anthony Montanarella, Senior Graphic Designer & Marketing, X-Gen Pharmaceuticals, Inc., Horseheads, NY

Jessica Bellew, Managing Partner, Code Bellew Healthcare, Houston, TX

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NPPA Website Resources

New NPPA Members: here follows is all of the information about the resources you can find on the NPPA website, www.PharmacyPurchasing.com

NPPA is very proud of our Pharmacy Buyers Forum web page (an online "chat" forum); for you to be able to easily network with and get valuable information from your fellow Pharmacy Buyers across the country. We feel that our Buyers Forum is one of the most powerful and valuable tools NPPA provides to assist Pharmacy Buyers, because of the following.

- NPPA's online Forum is available to ***all*** Pharmacy Buyers, whether they are NPPA members or not.
- It addresses issues that are important to Pharmacy Buyers ***exclusively***.
- It is virtually unfiltered: anything and everything Pharmacy Buyer-related can be discussed there.
- It is ***Ad-free,*** and accessible to Pharmacy Buyers ***only***. The Forum is constantly monitored. Vendors, spam, objectionable material is deleted almost immediately. Vendors are permitted to read the Forum, but are prohibited from commenting.
- With NPPA being a national organization with Pharmacy Buyers all over the country, and beyond (NPPA even has some international members), the Buyers Forum is the loudest voice in our profession. Every Pharmacy Buyer can read it; every Pharmacy Buyer can offer their perspective on any issue.
- Posters on the Forum have asked for availability of shorted items, questioned a product in some way, inquired about career opportunities, asked questions regarding activities at the NPPA Annual Conference, and more. Check it out today!

Our site's "Member Only Resources" page password login information is: *"npparesources"* (as all 1 word, case-sensitive, and no "User ID" at all anymore). 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 the Member-Only Resources page, you will find the following sections & info.

1) The "Breaking News, Recalls & Alerts" section: for any important alerts and recalls that we feel is 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.

2) The "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. *(Also found from Home Page, under "What's New.")*

b) A live feed from FDA, with current product recalls and alerts from their MedWatch Safety Report.

c) A live feed from ASHP.org that lists the latest reported "Current" & "Resolved" Drug Shortages.

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Digital Version Of *PPO*

Continued from Page 1

option to provide their ad pages in color instead of black & white. Thank you for your patience on getting those updated while we wait to hear from our advertisers.

In addition, please understand that we will not be able to stop sending the hard copy versions of *PPO* if some of you prefer to only now receive the digital version; since our advertisers have already committed and paid for their 2020 advertsing pages in the publication itself.

Lastly, please note that the digital versions of *PPO* are ***only*** being provided to current paid members of NPPA. The PDF files and the web address of our private page we store them on, are ***not*** to be forwarded nor shared/distributed to others. Sharing with anyone other than current NPPA members is considered inappropriate and may affect your NPPA membership and our ability to provide them in the future. Thank you for your cooperation & understanding.

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NPPA Website Resources

Continued from Page 73

d) A live feed from ASHP.org that lists the latest reported "Discontinued Drugs."

3) The "Pharmacy Buyer Salary & Task Info" section:

a) NPPA's Pharmacy Buyer Wage & Task Report, which was based on a survey that NPPA conducted of their members and other Pharmacy Buyers, in 2008, now available to purchase to see where you stand among your colleagues' average salaries and responsibilities.

b) Data on the average salaries of Pharmacy Buyers (and other professions), as provided by SalaryExpert.com.

4) The "NPPA Publication Reprints" section: which includes previous articles printed in NPPA's official publication, *Pharmacy Purchasing Outlook*, that may be of interest to new members or a revisit by existing ones.

5) Lastly, the "Other Industry Resources & Links" section, which includes links to the following, and more:

a) Various websites for additional drug shortage references;

b) The latest flu & vaccine information from the CDC;

c) Information on Emergency & Pandemic Preparedness;

d) Recycling information for healthcare facilities;

e) Educational information;

f) Networking Tools, such as for inexpensive business cards to bring to the NPPA Conference;

g) Career Opportunity websites for your profession.

NPPA sincerely hopes these resources help you to be a better Pharmacy Buyer!

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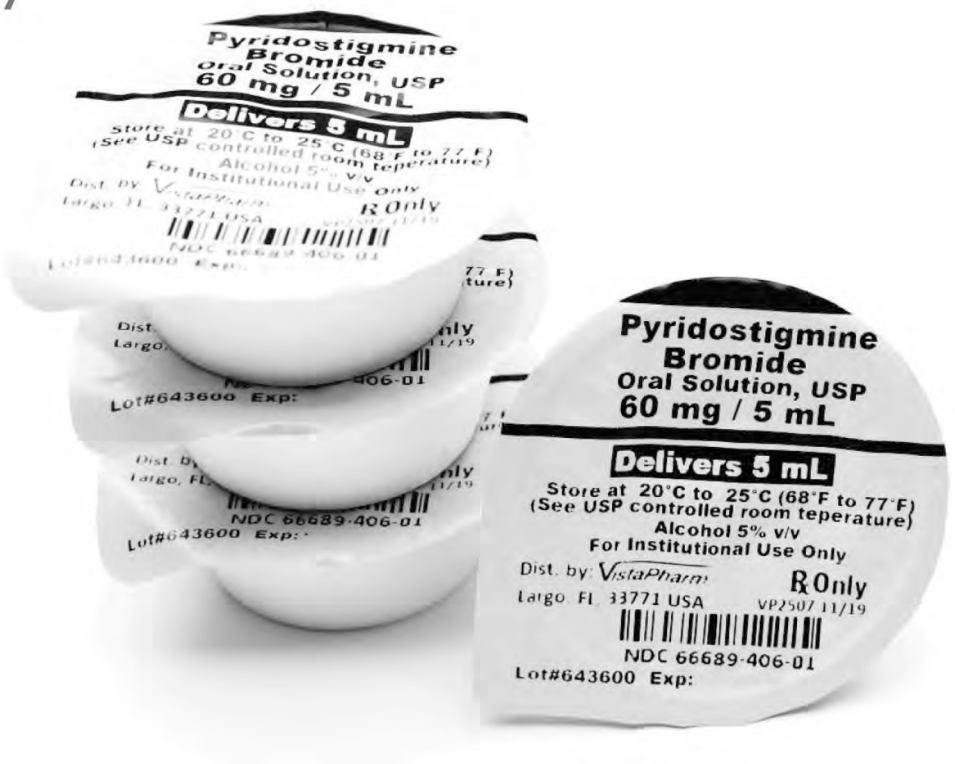

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