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What's Inside…

Rx News……...1

Medicaid Update…….2

Law Review……2

Feature Article:
Mpox: Etiology, Symptoms, and Prevention.... 3

Ask PRN……...…4

Did You Know?..... 4

Pharmacy Fun……4

FDA NEWS

FDA Warns CGM Users of Missed Safety Alerts

The FDA is warning patients who are currently using smartphone-compatible devices about missed safety alerts due to hardware and software changes, updates, and configurations. Many diabetics rely on continuous glucose monitors (CGM), insulin pumps, and automated insulin dosing systems. Most of these devices depend on a smartphone to deliver critical safety alerts. The agency has identified a number of issues which can lead to missed critical alerts, including:

- Software configuration settings, such as app notification permissions, using "do not disturb" mode, or the app entering "deep sleep" mode
- Connecting to new hardware, such as car audio or wireless earphones
- OS updates that do not support the medical device app

……RX NEWS……RX NEWS……RX NEWS……RX NEWS……

SYMBRAVO (Meloxicam and rizatriptan tablets).
Category: Anti-migraine.
Initial Dose: One tablet by mouth as needed.
MDD: One tablet (20 mg meloxicam and 10 mg of rizatriptan).

Axsome Therapeutics, Inc. has received approval to market a new combination therapy for the acute treatment of migraine with or without aura in adults. Each Symbravo tablet contains 20 mg of the NSAID meloxicam and 10 mg of the 5-HT receptor agonist rizatriptan. The recommended dose is one tablet as needed for the acute treatment of migraine. Symbravo may be taken with or without food. Tablets should be taken whole; do not crush, divide, or chew the tablets. The maximum daily dose should not exceed one tablet, and the safety of treating more than 7 headaches in a 30-day period has not been established. Contraindications include the use of propranolol, recent (within 24 hours) use of ergotamine-containing medications, and concurrent administration or recent discontinuation (within 2 weeks) of drugs containing an MAO-A inhibitor.

MIEBO (Perfluorohexyloctane ophthalmic solution).
Category: Treatment of dry eye disease.
Initial Dose: One drop in each eye four times a day.
MDD: One drop in each eye four times a day.

The FDA has approved Bausch and Lomb's Miebo (perfluorohexyloctane) eye drops for treatment of the signs and symptoms of dry eye disease (DED). Miebo is a first-in-class therapy targeting tear evaporation, a significant cause of DED. Perfluorohexyloctane is a semifluorinated alkane which forms a monolayer at the air-liquid interface of the tear film which can reduce tear evaporation. The recommended dosage of Miebo is one drop into each eye four times daily. Patients should be advised not to administer while wearing contact lenses; contact lenses should be removed prior to and for at least 30 minutes after administration of Miebo. To administer Miebo, remove cap and gently squeeze the bottle while holding upright. While squeezing, turn the bottle upside down and release the pressure (drawing air into the bottle). Keeping the bottle upside down, place above eye and squeeze again to release a drop into eye.

FDA Approves New Non-Opioid Medication for Moderate to Severe Pain

Vertex Pharmaceuticals, Inc. has announced FDA approval of its new, first-in-class pain reliever, **Journavx** (suzetrigine). Journavx is the first Nav1.8 pain signal inhibitor to reach the market, and the first new non-opioid pain medication approved in more than 20 years. Nav1.8 is a sodium channel, expressed in peripheral sensory neurons, which transmits pain signals to the spinal cord and brain. Since Journavx works in the periphery, not in the brain, it lacks the addictive potential of opioids. In clinical trials, Journavx was shown to be as effective as Vicodin (hydrocodone/apap) in relieving post-surgical pain. The recommended dosage is as follows: Starting dose is 100 mg (2 tablets) on an empty stomach at least 1 hour before or 2 hours after food. Clear liquids may be consumed at this time (water, apple juice, tea, black coffee). Starting 12 hours after the initial dose, take 50 mg (1 tablet) every 12 hours, with or without food. Avoid food or drink containing grapefruit.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Changes to NY Medicaid Preferred Diabetic Supply Program

Effective January 1, 2025, **One Touch** glucose monitoring supplies have been excluded from the Preferred Diabetic Supply Program and will no longer be covered by Medicaid in New York State. Products currently covered under the program are as follows:

Preferred Meters

CONTOUR METER
CONTOUR NEXT GEN
CONTOUR NEXT EZ
CONTOUR NEXT ONE
FREESTYLE LITE
FREESTYLE FREEDOM LITE
FREESTYLE PRECISION NEO
PRECISION XTRA

Preferred Test Strips

CONTOUR TEST STRIPS
CONTOUR NEXT TEST STRIPS
FREESTYLE TEST STRIPS
FREESTYLE LITE TEST STRIPS
FREESTYLE PRECISION NEO TEST STRIPS
FREESTYLE INSULINX TEST STRIPS
PRECISION XTRA TEST STRIPS
PRECISION XTRA B-KETONE STRIPS

Preferred Continuous Glucose Monitors include **Dexcom**, **Freestyle Libre**, **Omnipod**, **Cequr**, and **V-Go**. Prior Authorization, when required, may be obtained by prescribers by calling 877-309-9493. In addition, Medicaid has adjusted its coverage limits for diabetic supplies to align with *Medicare* coverage of diabetic supplies:

- **For patients who use insulin:** allowed up to 300 test strips and lancets every 90 days
- **For patients who do not use insulin:** allowed up to 100 test strips and lancets every 90 days

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Update to Regulations on Hypodermic Syringes and Needles

Since January, 2001, New York State has permitted pharmacies to sell hypodermic syringes and needles without a prescription under the Expanded Syringe Access Program (ESAP). Originally a public health demonstration project, the program became permanent in 2009. ESAP allowed for the sale of up to 10 syringes, as long as the pharmacy was registered with the program and a safety pamphlet was provided to the purchaser. These long-standing rules were amended in October, 2021. Senate bill 2523, signed by the governor on 10/7/21, removed the limit of 10 syringes/needles per sale, ended the ban on pharmacies advertising such sales, and discontinued the need for pharmacies to register with the program. The safety pamphlet, available at www.health.ny.gov/publications/9539.pdf, must still be supplied to each purchaser. Thanks to Stephen at NYRXLAW.com for this belated update.

Pharmacists in New York State Authorized to Administer Mpox Vaccine

On August 20, 2024, the New York State Department of Health in partnership with the New York State Education Department have determined that pharmacists can administer the Mpox vaccine (JYNNEOS) to patients 18 years of age and older pursuant to patient specific and non-patient specific orders consistent with the Advisory Committee for Immunization Practices' recommendations. This determination shall remain in effect until such time as it may be rescinded by the Commissioner of Health. Current pharmacist-administered vaccines include:

VACCINE	PHARMACIST'S RESTRICTIONS
INFLUENZA	Patients 2 years of age and older.
COVID-19	Patients 18 years of age and older (Federal law 3 years of age and older).
PNEUMONIA	Patients 18 years of age and older (under 50 years of age qualifying medical condition required).
TDAP	Patients 18 years of age and older. Pregnant women, with each pregnancy, between 27 and 36 weeks gestation.
MENINGITIS	Patients 18 years of age and older.
SHINGLES	Patients 50 years of age and older
HEPATITIS A	Patients 18 years of age and older.
HEPATITIS B	Patients 18 years of age and older.
HPV	Patients 18 to 45 years of age.
MMR	Patients 18 years of age and older.
VARICELLA	Patients 18 years of age and older.
RSV	Patients 75 years of age and older, 60 to 74 years at high risk, and pregnant women 32 to 36 weeks gestation (Abrysvo only).
MPOX	Patients 18 years of age and older in at-risk groups.

FEATURE ARTICLE...

Mpox: Etiology, Symptoms, and Prevention

Mpox: Etiology and Nomenclature

Mpox disease is caused by the *monkeypox* virus (**MPV**), a double-stranded DNA virus of the genus *Orthopoxvirus*, a group which also includes *variola*, the causative agent of smallpox. MPV was first discovered in laboratory monkeys in 1958, hence the name. In 2002, the name of the disease caused by MPV was changed to Mpox, to avoid "discrimination and stigma." MPV is divided into two clades, or types. **Clade I**, which has a higher mortality rate, originated in Central Africa, while the less severe **Clade II** is endemic to West Africa. The global outbreak which reached the U.S. in 2022 was caused by Clade II. The first U.S. case of Clade I was reported in November, 2024.

Mpox: Signs and Symptoms

The incubation period for Mpox is 3 to 17 days, and symptoms usually start within 21 days of exposure to the virus. Mpox often begins with a prodromal period of fever, malaise, headache, sore throat, cough, and swollen lymph nodes. This is followed by the characteristic rash, which may develop in the mouth, or on the face, hands, feet, or genital areas, and spread to other parts of the body. The rash initially presents as flat, red bumps, which are sometimes painful, then progresses to pus-filled blisters, which eventually crust over and fall off. Patients with Mpox are considered contagious until the scabs have fallen off and the skin has healed. Mpox is spread in the following manner:

- Sexual contact, intimate activities, prolonged face-to-face contact
- Direct skin-to-skin contact with Mpox rash or scabs from a person with Mpox
- Contact with objects, fabrics, and surfaces that have not been disinfected after use by someone with Mpox
- Pregnant women with Mpox can pass the virus to the fetus during pregnancy or to the newborn during or after birth

Vaccination Against Mpox

Currently, there is no vaccine specifically designed to immunize against Mpox on the market. However, **JYNNEOS**, a smallpox vaccine produced by Bavarian Nordic, has been approved for the prevention of smallpox *and* Mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or Mpox infection.

Administration: Give 2 doses (0.5 mL each) of JYNNEOS by subcutaneous injection, preferably into the upper arm, 4 weeks apart. Swirl the vial gently before use for at least 30 seconds.

Description: JYNNEOS is a live, non-replicating vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated orthopoxvirus grown in chicken embryo fibroblast cells. The vaccine is formulated without preservatives, and the vial stoppers do not contain latex. When thawed, JYNNEOS is a milky, light yellow to pale white colored suspension.

Storage: JYNNEOS should be kept frozen at -25°C to -15°C (-13°F to +5°F). Allow the vaccine to thaw and reach room temperature before use. Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 4 weeks. Do not refreeze.

ACIP Recommendations: The Advisory Committee on Immunization Practices recommends a 2-dose series of JYNNEOS for persons at risk for Mpox infection, which includes:

Persons who are gay or bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:

- A new diagnosis of at least one sexually transmitted disease
- More than 1 sex partner
- Sex at a commercial sex venue
- Sex in association with a large public event in a geographic area where Mpox transmission is occurring
- Persons who are sexual partners of the persons described above
- Persons who anticipate experiencing any of the situations described above

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Founder and Editor:
James Murphy, RPh

Contributor
Sasha Budhram, PharmD

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

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editor@prnnewsletter.com

Contributors can inquire about submissions to the newsletter at:
james@prnnewsletter.com

Visit us on the web at:
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ASK PRN...

What is the current status of the Federal Public Readiness and Emergency Preparedness (PREP) Act, specifically as it relates to the practice of pharmacy?

The PREP Act for Medical Countermeasures Against COVID-19 was declared by the Secretary of Health and Human Services in March, 2020 in response to the COVID-19 pandemic. The Act eventually came to include a number of provisions expanding the authority of pharmacists, pharmacy interns, and pharmacy technicians beyond the scope of many state laws. For example, PREP authorized pharmacists, interns, and technicians in all 50 states to administer not only COVID-19 vaccines, but any and all ACIP-approved childhood vaccines to children aged 3 years and up. In May of 2023, the public health emergency was declared ended, and many of the provisions of PREP expired at that time. Several key pharmacy-related permissions, however, were renewed. Specifically, the authorization for pharmacists, interns, and certified technicians to administer COVID-19 and influenza vaccines to patients ages 3 and older. The permission for other childhood vaccines was not renewed. The remaining pharmacy authorizations were set to expire on December 31, 2024, but were once again renewed by the Secretary, and will now remain in effect until at least December 31, 2029.

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the first ACE inhibitor marketed, Captopril, was synthesized from the venom of a deadly South American snake known as *Bothrops jararaca*? One bite from this feared pit viper was enough to cause severe hypotension, among other life-threatening symptoms. Brazilian scientist Sergio Ferreira isolated a compound from the venom which proved to be an angiotensin converting enzyme (ACE) inhibitor. Researchers at the E. R. Squibb company later developed an orally available analogue, which was approved in 1981 under the brand name Capoten[1].

PHARMACY FUN

Name That Drug! **is the category of this month's Pharmacy Fun. There is a life-saving drug, carried by most pharmacies, which can be identified by using some simple math (or *maths*, as the Brits say). The middle four numbers of the NDC of this product follows this rule: the first digit is one fourth of the last digit, the second digit is six times the first digit, and the third digit is equal to the second digit plus three. What is the number, and what is the drug? The first reader to submit the correct answers to us at puzzle@prnnewsletter.com will receive a $25 gift card from Amazon.**

Answers to last month's **PHARMACY FUN**:
The **NOTABLE** compounding pharmacist was **NOT ABLE** to prepare the product because she had **NO TABLE**.

References:
1. Li, Jie Jack. Laughing gas, viagra, and lipitor: the human stories behind the drugs we use. New York, Oxford University Press, 2006.