P.R.N.

ISSN # 1941-9481 www.prnnewsletter.com

No. 68 The Newsletter for Community Pharmacists Jan/Feb, 2020

What's Inside…

FDA NEWS

FDA Warns of Serious Breathing Problems with Gabapentinoids

The Food and Drug Administration has issued a Drug Safety Communication regarding the risk of serious breathing difficulties associated with the use of gabapentinoids (**Neurontin, Lyrica**). Data from the years 2012 to 2017 identified 49 cases of respiratory depression with gabapentinoids (15 involved gabapentin, 34 were linked to pregabalin), with 12 cases resulting in death. In 92% of these cases, the patient had at least one respiratory risk factor, or were also using another drug known to cause CNS depression, such as an opioid. The FDA will update the drug labels for this class, and recommend initiating gabapentinoids at the lowest dose when co-prescribing with other CNS depressants or in patients with underlying respiratory impairment.

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

REYVOW (Lasmiditan).
Category: Serotonin (5-HT) 1F receptor agonist for the acute treatment of migraine.
Initial Dose: 50 to 200 mg as needed, taken with or without food. No more than one dose should be administered in 24 hours.
MDD: 200 mg.

The Eli Lilly company has been granted FDA approval for Reyvow (lasmiditan), a novel agent for the treatment of migraine headache. Reyvow is the first serotonin (5-HT) 1F receptor agonist, and is indicated for the treatment of acute migraine with or without aura in adults. The recommended dose is 50, 100, or 200 mg taken orally, as needed, no more than once per 24 hours. Reyvow should not be taken unless the patient can wait at least 8 hours between dosing and driving or operating machinery. The DEA has classified Reyvow as a schedule V controlled substance.

UBRELVY (Ubrogepant).
Category: Calcitonin gene-related peptide receptor (CGRP) antagonist for the acute treatment of migraine.
Initial Dose: 50 mg as needed. A second dose may be given at least 2 hours later, if needed.
MDD: 200 mg in a 24 hour period.

Allergan will market Ubrelvy (ubrogepant), the first oral CGRP antagonist for the acute treatment of migraine headache. Previous CGRP agents (Aimovig, etc.) are injectable agents used for prevention only. Ubrelvy is indicated for the acute treatment of migraine and can be taken as needed, with an initial dose of 50 to 100 mg. A second dose, if needed, may be taken at least 2 hours after the initial dose.

XENLETA (Lefamulin).
Category: Antibiotic.
Initial Dose: 600 mg every 12 hours for 5 days.
MDD: 1200 mg.

Nabriva Therapeutics has announced FDA approval of Xenleta (lefamulin), a new antibiotic with a unique mechanism of action, indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP). Xenleta is a systemic pleuromutilin antibiotic which inhibits bacterial protein synthesis at the 50S subunit. In IV or oral dosage form, Xenleta is effective against the following organisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenza, Legionella pneumophilia, Mycoplasma pneumoniae, and Chlamydophilia pneumoniae*. The oral dose is one 600 mg tablet every 12 hours for 5 days. Xenleta tablets should be taken at least 1 hour before, or 2 hours after, a meal.

CAPLYTA (Lumateperone).
Category: Atypical antipsychotic.
Initial Dose: 42 mg once daily with food.
MDD: 42 mg.

Intra-Cellular Therapies, Inc. has developed and will market Caplyta (lumateperone), a new atypical antipsychotic, indicated for the treatment of schizophrenia in adults. The recommended dose is 42 mg once daily, taken with food; dose titration is not required. As with other antipsychotics, the Caplyta label will contain a **black-box warning** stating that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Caplyta is not approved for the treatment of patients with dementia-related psychosis.

New York Times Investigation Exposes "Chaos" at Chain Pharmacies

A recent New York Times article (link at ***www.prnnewsletter.com***) revealed an ongoing crisis at chain pharmacies across the country. The exposé, entitled "How Chaos at Chain Pharmacies Is Putting Patients at Risk[1]," combined medication error case reports with interviews of pharmacists to paint a disturbing picture of the dangerous working conditions at many chain pharmacies, including CVS, Walgreens, and Rite-Aid. Examples of medication errors highlighted in the article include a 4 month old child mistakenly given an oral steroid for 2 months instead of the prescribed anti-reflux medication, and a woman in Florida to whom methotrexate was dispensed instead of the antidepressant she was prescribed, leading to her death. A quote from the article, written by Times reporter Ellen Gabler, sums up what many believe is the cause of all the "chaos" at these pharmacies:

"They (pharmacists) struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients, and call doctors and insurance companies, ...all the while racing to meet corporate performance measures that they characterized as unreasonable and unsafe in an industry squeezed to do more with less."

CVS pharmacy

Walgreens

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York State Enacts Sweeping Changes to Pharmacy Technician Regulations

On October 25, 2019, New York governor Andrew Cuomo signed State Senate bill S6517 into law, updating the regulations regarding pharmacy technicians and their role in the practice of pharmacy in New York State. The legislation represents the most significant changes to the rules on technicians in decades, and was occasioned, in part, by the effort of hospital pharmacists to more clearly define the role technicians can play in the compounding of medications. Some of the highlights of the new law, which goes into effect on April 25, 2021, include:

- **Registered Pharmacy Technicians (RPTs):** the law creates a framework for the licensure of registered pharmacy technicians. Requirements will include: 18 years of age or older, a high school diploma or equivalent, national certification (e.g., PTCB), initial licensure fee and triennial registration fee. RPTs must also receive appropriate training from the facility at which they practice.
- **RPTs may assist in compounding:** the current regulations state that pharmacy technicians are unlicensed persons and cannot "measure, weigh, compound, or mix ingredients." The new law will allow RPTs to assist pharmacists in "compounding, preparing, labeling, or dispensing of drugs" under the direct supervision of a licensed pharmacist. Such activities are authorized only in Article 28 facilities (e.g., hospitals), not in the community pharmacy setting.
- **Increase in pharmacist/technician ratio:** currently, a pharmacist may be assisted in unlicensed activities by no more than 2 technicians at any time. Under the new law, up to 4 technicians at a time may assist a pharmacist, and this applies to all settings, including community or "retail" pharmacies. In the case of Article 28 facilities, no more than 2 of the 4 technicians may perform the duties of a registered pharmacy technician (i.e., assisting the pharmacist in the compounding of medications).
- **Pharmacy technicians added to the Board of Pharmacy:** the current New York State Board of Pharmacy consists of 9 licensed pharmacists and 2 public members. The new law will add 2 registered pharmacy technicians to the board.

FOCUS ON: OTC COUNSELING

by Sasha Budhram, PharmD

The availability of over-the-counter (OTC) medications provides a safe, effective, and easily accessible means of self care in the treatment of a variety of minor conditions. Safety and efficacy, however, depend largely upon the ability to appropriately select and properly use these agents. Warnings, directions for use, active ingredients and their concentrations are all components of labeling intended to protect and promote public safety. Unfortunately, this information is often ignored by the average consumer in a desperate rush to eradicate symptoms. The role of a pharmacist is indispensable in preventing OTC misuse. Identification of patients who are eligible for self care through knowledge of exclusion criteria in addition to familiarity with the range of products available are essential in achieving the best possible outcomes. Below is a set of questions that should be incorporated into the conversation when approached by patients seeking to use OTCs.

- **Do you have any medical conditions? Do you use any other medications?** Screen patients for drug-drug and drug-disease interactions.
- **Are you allergic to any medication?** Some drug-allergy interactions, such as salicylates in patients allergic to aspirin, may be challenging to identify without the aid of a pharmacist.
- **Are you pregnant or nursing?** (females) Patients may be unaware of risk of fetal/infant harm associated with OTC drug use during pregnancy/lactation.
- **Do you have any other symptoms, such as…?** Be specific to avoid a blanket "no" response. For example, a sore throat complaint should be followed up with questions regarding fever, headache, and/or nausea/vomiting, the presence of which would warrant a visit to the doctor.
- **How long have you had these symptoms?** Prolonged duration of symptoms may be an exclusion to self care.
- **Have you tried anything else?** Patients may have inappropriately utilized other agents, resulting in treatment failure. Counseling on proper usage may promote success. This is also important in preventing duplication of therapy and/or potential drug interactions.
- **Age?** This is a must if the patient is pediatric to ensure proper product selection and dosage.

After gathering the necessary information, determine if the patient is a candidate for self care and inform them of the available options, including **nonpharmacological** interventions. If a product is chosen, review the **directions** for use. **Duration** of therapy should also be discussed, along with advice on when to seek further medical attention.

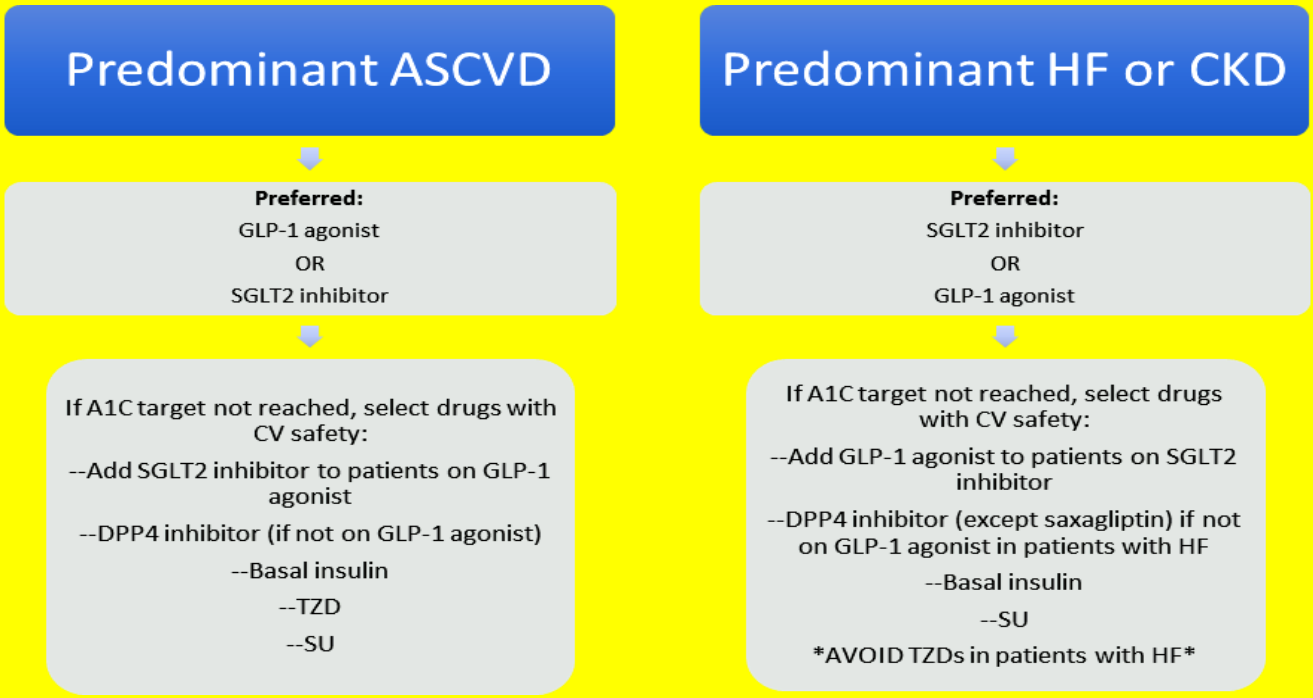
FEATURE ARTICLE...

PRACTICE UPDATES IN THE TREATMENT OF DIABETES

by Sasha Budhram, PharmD

Latest Recommendations from the American Diabetes Association

The *2020 Standards of Medical Care in Diabetes* published by the ADA reveals new recommendations for drug therapy in patients with type 2 diabetes. Metformin is still considered first line along with lifestyle changes. However, in type 2 patients with concomitant atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), or chronic kidney disease (CKD), treatment with SGLT2 inhibitors or GLP-1 agonists, regardless of their A1C, is recommended. This change is the result of evidence from clinical trials demonstrating a decrease in cardiovascular events associated with use of the SGLT2 inhibitors empagliflozin (Jardiance), canagliflozin (Invokana), and dapagliflozin (Farxiga), and the GLP-1 agonists liraglutide (Victoza), semaglutide (Ozempic), and dulaglutide (Trulicity).



As always, patients receiving diabetes treatment should be counseled on the potential for hypoglycemia (signs and symptoms, rule of 15 for treatment [see below]) as well as the risk for increased yeast/urinary tract infections associated with use of SGLT2 inhibitors and pancreatitis with GLP-1 agonists.

***Key*: ASCVD:** atherosclerotic cardiovascular disease **HF:** heart failure **CKD:** chronic kidney disease **GLP-1:** glucagon-like peptide 1 **SGLT2:** sodium-glucose transporter 2 **CV:** cardiovascular **DPP4:** dipeptidyl peptidase 4 **TZD:** thiazolidinedione **SU:** sulfonylurea

First Ever Oral GLP-1 Analog Approved

Novo Nordisk has produced the first oral glucagon-like peptide-1 analog for the treatment of adults with type 2 diabetes mellitus. **Rybelsus** is an orally active form of semaglutide, available as **Ozempic** in its once-weekly injectable form. The recommended dosing is as follows:

- **3 mg once daily for 30 days, then increase to 7 mg once daily.**
- **If needed, may increase to 14 mg once daily after at least 30 days on the 7 mg dose.**
- **Instruct patients to take Rybelsus at least 30 minutes before the first food, beverage, or other oral medications of the day with a sip of water (no more than 4 ounces of plain water only). Failure to follow this regimen will lessen the effect of Rybelsus. Eating 30 to 60 minutes after dosing is recommended.**

The Rule of 15

Diabetic patients should be educated to recognize hypoglycemia (blood glucose <70 mg/dL); signs and symptoms include dizziness, tremors, sweating, hunger, and palpitations or increased heart rate. Patients should be taught the Rule of 15 to treat hypoglycemia:

- **Consume 15 grams of simple carbohydrates (glucose tablets or gel, 4 ounces of juice or soda [except diet], 1 tablespoon of sugar or honey, etc.).**
- **Wait 15 minutes, then retest blood glucose.**
- **If blood glucose is still <70 mg/dL, consume an additional 15 grams of carbohydrates, followed by another blood glucose test. Repeat cycle until blood glucose is 70 or above.**
- **Report all episodes of hypoglycemia to physician.**

P.R.N.

P.R.N. (ISSN # 1941-9481)
is published bi-monthly by:
PRN Publishing LLC
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Forest Hills, New York 11375
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ASK PRN...

The new pharmacy technician law takes effect in 2021. In the meantime, what are the specific duties that pharmacy technicians are permitted to perform under current law?

For now, pharmacy technicians are "unlicensed persons," and, as such, are only allowed to perform the following tasks in assisting a licensed pharmacist:

- **Receiving written or electronically transmitted prescriptions**
- **Typing prescription labels**
- **Keying prescription data into a computer-generated file or retrieving prescription data from the file, provided that such computer-generated file shall provide for verification of all information by a licensed pharmacist prior to the dispensing of the prescription**
- **Getting drugs from stock and returning them to stock**
- **Getting prescription files and other manual records from storage and locating records**
- **Counting dosage units of drugs**
- **Placing dosage units of drugs in appropriate containers**
- **Affixing the label to the containers**
- **Preparing manual records of dispensing for the signature or initials of the licensed pharmacist**
- **Handing or delivering completed prescriptions to the patient or the person authorized to act on behalf of the patient, and advising the patient of the availability of counseling to be conducted by the licensed pharmacist or pharmacy intern**

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 amphetamine produced and marketed in the United States was sold as on over-the-counter nasal inhaler for stuffy nose? In 1933, the Philadelphia-based pharmaceutical firm of Smith, Kline, and French (now part of the British company GlaxoSmithKline) started selling the **Benzedrine inhaler** to treat nasal congestion. The active ingredient in Benzedrine was amphetamine, and within 3 years the company started selling an oral tablet version which they recommended for the treatment of mild depression. For many years following the classification of amphetamines as Schedule II controlled substances, a number of OTC nasal inhalers still contained amphetamine-like compounds, such as l-methamphetamine in the Vicks Inhaler.

PHARMACY FUN

For this issue we revisit our most popular game, something we call pharmacy word play. Untangle the following literary doodles to reveal the names of some common pharmaceuticals. The first reader to submit the correct answers to us at *puzzle@prnnewsletter.com* wins a set of PRN stylus pens.

1. **Star Trek Klingon Lieutenant ____ + Yankee OF ____ Judge**
2. **____ the Fifth + ____ Karenina**
3. **Singer ____ Fitzgerald + Pop ____**
4. **____ or false + Legal + Earl Grey, for example**
5. **Not ortho or para + Not amateur + Laughing out loud**
6. **Nicholas II + French fashion mag + Pedal digit**

Answers to last month's ***PHARMACY FUN***:
1. Eucrisa 2. Mylicon 3. Benzamycin 4. Livalo

References:
1. Gabler, Ellen. "How Chaos at Chain Pharmacies is Putting Patients at Risk." *New York Times*, January 31, 2020.