P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

No. 64 | **The Newsletter for Community Pharmacists** | **Sept/Oct, 2018**

What's Inside…

Rx News……...1

Medicaid Update…….2

Law Review……2

Feature Article:
Update on Influenza Vaccines for 2018-19….3

Ask PRN……...…4

Did You Know?..... 4

Pharmacy Fun……4

FDA NEWS

FDA Warns of Serious Infections Linked to Popular Diabetic Medications

The U.S. Food and Drug Administration (FDA) has issued a Drug Safety Announcement regarding the possibility of a rare but serious infection linked to the use of a popular class of type 2 diabetes medications. The agency cited reports of necrotizing fasciitis of the perineum (also known as Fournier's gangrene) in patients taking sodium-glucose cotransporter-2 (SGLT2) inhibitors (**Farxiga**, **Jardiance**, **Invokana**, and **Steglatro**). Fournier's gangrene is a rare but life-threatening bacterial infection of the tissue under the skin of the perineum. Between 2013 and 2018, the FDA identified 12 cases of the infection in SGLT2-treated patients (7 male and 5 female); all 12 patients were hospitalized and required surgery, and one died. Health care professionals should assess patients for Fournier's if they present with tenderness, erythema, swelling in the genital or perineal area, fever, malaise, and have pain out of proportion to the physical exam. If Fournier's is suspected, discontinue the SGLT2 inhibitor and institute prompt treatment with antibiotics and surgical debridement, if appropriate.

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

AJOVY (Fremenezumab-vfrm).
Category: Migraine preventative.
Initial Dose: 225 mg once monthly.
MDD: 675 mg every 3 months.

The FDA has approved Ajovy, the second in a new class of drugs, calcitonin gene-related peptide (CGRP) antagonists, which are indicated for the preventative treatment of migraine headaches in adults. CGRP is a protein thought to be involved in migraine headache through cerebral vasodilation, release of inflammatory mediators, and transmission of pain signals. Ajovy is administered by subcutaneous injection and can be given in either one of two dosing regimens: 225 mg once monthly or 675 mg every 3 months (the 675 mg dose is administered as three consecutive injections of 225 mg each). The injection may be given in the abdomen, thigh, or upper arm as follows:

- **Leave the prefilled syringe at room temperature for 30 minutes before injecting.**
- **Remove needle cap, gently pinch up at least 1 inch of skin at the cleaned injection site, and insert needle at a 45 or 90 degree angle.**
- **Push the plunger slowly all the way down as far as it will go to inject all of the medicine.**
- **After injecting all of the medicine, pull the needle straight out of the skin and dispose of the syringe.**

EMGALITY (Galcanezumab-gnlm).
Category: Migraine preventative.
Initial Dose: 240 mg loading dose.
MDD: 120 mg once monthly.

Emgality injection has been FDA approved and represents the third CGRP antagonist for migraine prevention to reach the market. Unlike the first two agents in this class, **Aimovig** and **Ajovy**, Emgality will require a loading dose of 240 mg (administered as two consecutive injections of 120 mg each). The maintenance dose is then 120 mg monthly. Emgality will be available in a single-dose prefilled pen as well as a single-dose prefilled syringe. The subcutaneous injection may be given in the abdomen, thigh, back of the upper arm, or buttocks as follows:

- **Leave the pen or pre-filled syringe at room temperature for 30 minutes.**
- **Patient may self-inject in abdomen or thigh; another person must administer injection if using upper arm or buttocks.**
- **For PREFILLED SYRINGE, pinch skin at cleaned injection site and insert needle at 45 degree angle. Slowly push plunger all the way in until all medicine is injected.**
- **For PEN, twist off base cap and hold pen flat and firmly against skin; press and hold the teal injection button (you will hear a click) for 10 seconds. A second click indicates the injection is complete.**

FDA Approves First New Influenza Treatment in Nearly 20 Years

On October 24, The U.S. Food and Drug Administration (FDA) approved Genentech's **Xofluza** (baloxavir marboxil), a novel antiviral for the treatment of influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. Unlike **Tamiflu** and **Relenza** (both approved in 1999), which treat influenza by inhibiting viral neuraminidase, Xofluza works by blocking viral polymerase, resulting in inhibition of influenza virus replication.

Dosing: Give a single dose of Xofluza orally within 48 hours of symptom onset, with or without food. Avoid co-administration of Xofluza with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc), The dose of Xofluza depends on weight:

Patient Body Weight (kg)	Recommended Oral Dose
40 kg to less than 80 kg	Single dose of 40 mg
At least 80 kg	Single dose of 80 mg

Adverse reactions: Events reported in at least 1% of patients included diarrhea (3%), bronchitis (2%), nasopharyngitis (1%), headache (1%), and nausea (1%).

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Prescriptions Transfers in Medicaid Fee for Service

In April, 2015, the New York State Department of Health (DOH) announced that it would begin allowing prescription transfers for patients using Medicaid Fee for Service (FFS, sometimes referred to as "straight Medicaid"). Previously, New York State Medicaid prohibited the transfer of prescriptions from one pharmacy to another. Although it has been more than 3 years since the change, there is still some confusion among pharmacists. Recently, DOH published guidelines for refill transfers on Medicaid as a reminder to practitioners. All eligible non-control prescription drug and over-the-counter (OTC) drug transfers should be done in accordance with New York State Education Department (NYSED) prescription requirements. In addition, some of the key points to remember when transferring a prescription for a Medicaid patient:

- **Only one fill at a time may be transferred from either a new unfilled non-control electronic prescription or refill remaining on a prescription from the original pharmacy.**
- **Submit non-control prescription drug and OTC transfers with an origin code of 5 in the origin code field.**
- **Submit a serial number of TTTTTTTT in the serial number field to indicate a prescription transfer, in lieu of reporting the original prescription's Official Prescription Form Serial Number.**
- **Prescriptions may be refilled no more than 180 days after being written by prescriber. The original prescribing date must be submitted on the claim. Changing the written date to bypass the rejection is considered fraudulent billing and is subject to audit.**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Five New York Physicians, and One Pharmacist, Arrested for Illegal Distribution of Oxycodone

On October 11, 2018, the U.S. Drug Enforcement Administration (DEA) announced the arrests and indictments of several New York physicians, and one pharmacist, in connection with investigations into the illegal distribution of the potent narcotic oxycodone. The cases were collaborative efforts, involving the DEA, the U.S. Attorney for the Southern District, and the New York City police department, among other agencies. The alleged crimes involve health care professionals knowingly prescribing and/or dispensing large amounts of oxycodone strictly for financial gain and without legitimate medical need. Those arrested include the following:

- **Dr. Dante A. Cubangbang**, who operated a medial clinic in Queens, is alleged to have prescribed over 6 million oxycodone pills to individuals that he knew did not need the medication for any legitimate medical reason. Dr. Cubangbang, along with a nurse practitioner in his employ, together prescribed more than twice as many oxycodone pills than the next highest prescriber in New York, while collecting more than 5 million dollars in all-cash office visit fees.
- **Dr. Carl Anderson**, a physician practicing in Staten Island, was charged with prescribing over a million oxycodone pills to patients he knew had no legitimate medical need for the medication. He was said to have seen patients without appointments and with little notice, in the middle of the night, requiring that they pay hundreds of dollars in cash for each prescription. On more than one occasion, noisy crowds of pill-seeking patients gathered outside of Anderson's office prompted 911 calls from neighbors. Dr. Anderson did not alter his prescribing practices even after some of his patients died of drug overdoses.
- **Dr. Anthony Pietropinto**, a Manhattan psychiatrist, is alleged to have written thousands of medically unnecessary oxycodone prescriptions in exchange for $50 to $100 in cash per visit, instructing patients not to fill the prescriptions at large chain pharmacies like CVS and Walgreens because pharmacists at those pharmacies would call and question Pietropinto about the prescriptions.
- **Dr. Nadem J. Sayegh**, a physician with offices in the Bronx and Westchester, was charged with conspiring to issue oxycodone prescriptions without medical need in exchange for thousands of dollars in cash, expensive dinners, high-end whiskey, cruises, and all-expense-paid trips. Sayegh allegedly wrote some of these prescriptions for individuals who did not visit his medical office, including a patient who was overseas and another patient who was in jail at the time.
- **Dr. Nkanga U. Nkanga**, a Staten Island physician, is alleged to have written thousands of oxycodone prescriptions, in exchange for cash payments, without conducting any physical examination or even seeing the patients in an examination room. Nkanga regularly prescribed over 100 oxycodone pills per patient per month until July, 2018, when he reduced all patients' monthly allotment, telling one patient he was "very worried" about scrutiny from law enforcement.
- **Marc Klein**, a pharmacist in White Plains, has been indicted and charged with filling oxycodone prescriptions that he knew were illegitimate, including prescriptions filled by a customer in multiple variations of his name and date of birth. Klein is said to have filled thousands of these oxycodone prescriptions, "fronted" controlled substances, and made false reports to New York State authorities, in exchange for cash payments and a vacation. Klein admitted, in substance, that he and his employees could be called "licensed drug dealers" because "oxy pays the bills" at Klein's pharmacy.

FEATURE ARTICLE...

Update on Vaccines for the 2018-19 Flu Season

Flu season is upon us once again, which means it's time for our annual review of the latest vaccines and recommendations. Since the majority of vaccines administered these days are quadrivalent, we will focus on those products for this review. A new wrinkle for pharmacists in New York State this year is the fact that they are now authorized to administer influenza vaccine to children age 2 years and older; to address this we have included, for the first time, information on the administration of vaccines to children.

Quadrivalent Inactivated Influenza Vaccine (IIV4)

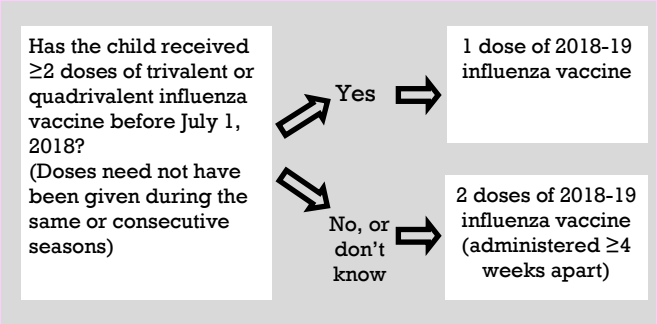
The 2018-19 quadrivalent influenza vaccine contains the following 4 antigens:

- **A/Michigan/45/2015 (H1N1)pdm09-like virus**
- **A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus**
- **B/Colorado/06/2017-like virus (Victoria lineage)**
- **B/Phuket/3073/2013-like virus (Yamagata lineage)**

To permit time for production of protective antibody levels, vaccination should optimally occur before the onset of influenza activity in the community. Vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available. Of the five IIV4s available this season, all but one are prepared in fertilized eggs. The exception, **Flucelvax**, is prepared in mammalian cells, but may still contain some egg proteins due to the fact that some of the initial viruses provided to the manufacturer are egg-derived. Only **Flublok** (RIV) is considered an egg-free vaccine.

Special Considerations for Pediatric Patients

Legislation signed into law in April of this year authorizes pharmacists in New York State to administer influenza vaccine to patients 2 years of age and older (previously, pharmacists were limited to patients 18 years old and up). There are several clinical issues pharmacists must familiarize themselves with in regard to vaccinating this population. For example, children under the age of 9 ***may*** require 2 doses of the influenza vaccine, administered at least 4 weeks apart, depending on prior history. Here is an algorithm to determine if a child under age 9 will need 2 doses of vaccine[1]:



Quadrivalent Influenza Vaccines for the 2018-2019 Season

Vaccine Trade Name (Manufacturer)	Presentation	Age Indication	Thimerosal Content (mcg/0.5 mL)
AFLURIA (Seqirus)	0.5 mL Syringe	≥5 years old	0.0
	5.0 mL Multi-dose vial	≥5 years old	24.5
FLUARIX (GlaxoSmithKline)	0.5 mL Syringe	≥6 months old	0.0
FLULAVAL (ID Biomedical)	0.5 mL Syringe	≥6 months old	0.0
	5.0 mL Multi-dose vial	≥6 months old	<25
FLUCELVAX (Seqirus)	0.5 mL Syringe	≥4 years old	0.0
	5.0 mL Multi-dose vial	≥4 years old	25
FLUZONE (Sanofi Pasteur)	0.25 mL Syringe	6 through 35 months old	0.0
	0.5 mL Syringe	≥3 years old	0.0
	0.5 mL Single-dose vial	≥3 years old	0.0
	5.0 mL Multi-dose vial	≥6 months old	25

P.R.N.

P.R.N. (ISSN # 1941-9481)
is published bi-monthly by:
PRN Publishing LLC
7636 113th Street
Suite 6C
Forest Hills, New York 11375
Phone & Fax (718) 263-4632

Founder and Editor:
James Murphy, RPh

Interns
Sarah Manrakhan
Ashley Raghubir

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

The information contained in P.R.N. is for educational purposes only. Always use professional judgment in clinical practice.

The entire collection of ***PRN*** back-issues is now available in PDF format on the Archive page of our website:
www.prnnewsletter.com

Contact Us

We welcome your input. Please forward any comments, suggestions, or questions to us at:
askprn@prnnewsletter.com

Visit us on the web at:
www.prnnewsletter.com

Or, if you prefer, write us at:
PRN Publishing
7636 113th Street
Suite 6C
Forest Hills, New York 11375

ASK PRN...

What is the current recommendation regarding the administration of influenza vaccine to patients with egg allergy?

The Advisory Committee on Immunization Practices (ACIP) has made the following recommendations (based upon the severity of the patient's previous reactions after egg exposure):

- **Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive influenza vaccine.**
- **Persons who report having had reactions to egg involving symptoms other than urticaria (hives), such as angioedema, respiratory distress, lightheadedness, or recurrent emesis, or who have required epinephrine or another emergency medical intervention, may receive any licensed influenza vaccine. For these patients, the vaccine should be administered in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices), and supervised by a health care provider who is able to recognize and manage severe allergic reactions.**

A previous severe allergic reaction to influenza vaccine is a **contraindication** to future receipt of the vaccine.

Currently available influenza vaccines, with the exception of **Flublok** and **Flucelvax**, are prepared by propagation of virus in embryonated eggs. However, since one of the four viruses in Flucelvax is egg derived, only Flublok, which is produced by recombinant technology, can be considered completely egg-free.

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 influenza vaccine was developed by Jonas Salk, who would later gain international fame as the inventor of the first vaccine against polio? Working with his mentor, Dr. Thomas Francis, at New York University, and later at the University of Michigan, Salk helped produce the original influenza vaccine, which was initially used to protect United States troops fighting in World War II. Salk would go on to become a household name in the U.S. after developing the first polio vaccine in 1952, during a time when it was said that, apart from the atomic bomb, polio was America's greatest fear.

PHARMACY FUN

Last month's Pharmacy Fun was so popular, we decided to give it another go! It's something we call pharmacy word play, a sort of crossword puzzle/rebus hybrid. The answer to each clue below is a drug name (could be brand name or generic, prescription or OTC). The first reader to submit all the correct answers to *puzzle@prnnewsletter.com* wins a set of PRN stylus pens.

1. **One watt ÷ one amp = one _____ + Vice-President _____ Burr.**
2. **Current British P.M. + Smoked salmon.**
3. **Actual pharmaceutical with the same name as the "ideal pleasure drug" in Aldous Huxley's *Brave New World.***
4. **Anthracite, for example + Tennis-playing Evert**
5. **Magazine abbreviation Nat ___ + Ad man Draper**
6. **_____ Carlo + ___ Gehrig + "____ and crew."**

Answers to last month's **PHARMACY FUN**:
1. Lansoprazole 2. Metformin 3. Hyzaar 4. Sonata 5. Beladonna 6. Coreg

References:
1. CDC Morbidity and Mortality Weekly Report. August 24, 2018, Page 8. Retrieved from www.cdc.gov/mmwr