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FDA NEWS

FDA Statement on Opioid Addiction Medication Use in Patients on CNS Depressants

The FDA has released a drug safety communication addressing the use of the opioid addiction medications buprenorphine and methadone in patients using benzodiazepines and other CNS depressants. Although the combined use of these drugs increases the risk of serious side effects, the agency feels that the harm caused by untreated opioid addiction outweighs the risk. Recommendations for health care professionals include:

- **Medications for opioid addiction should not be automatically denied to patients taking benzodiazepines or other CNS depressants.**
- **Develop strategies to manage use of benzodiazepines or other CNS depressants at initiation of buprenorphine or methadone treatment.**

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

TRELEGY ELLIPTA (Fluticasone furoate, Umeclidinium, and Vilanterol).
Category: Inhaler for COPD.
Initial Dose: 1 inhalation once daily.
MDD: 1 inhalation once daily.

The FDA has approved the first once-daily, 3 active ingredient inhaler for the maintenance treatment of COPD, including chronic bronchitis and/or emphysema. Glaxo's Trelegy Ellipta contains an inhaled corticosteroid, an anticholinergic, and a long-acting beta-2 agonist (LABA), and is indicated for patients who are already on a fixed-dose combination of fluticasone furoate and vilanterol (Breo Ellipta) in whom additional treatment is desired. As with all products containing a LABA, Trelegy Ellipta contains a **black-box warning** regarding the fact that LABAs increase the risk of asthma-related deaths. Trelegy Ellipta is ***not*** indicated for the treatment of asthma. In order to prevent *Candida albicans* infection of the mouth or pharynx, patients should be advised to rinse his or her mouth with water without swallowing after inhalation. Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur.

SOLOSEC (Secnidazole).
Category: Nitroimidazole antibacterial.
Initial Dose: 2 grams once daily, without regard to meals, mixed in the appropriate vehicle (applesauce, yogurt, pudding).
MDD: 2 grams once daily.

Symbiomix Therapeutics will introduce Solosec, a single-dose oral therapy for the treatment of bacterial vaginosis in adult women. Solosec is a second generation nitroimidazole, closely related to metronidazole, which will be available in a 2 gram packet of granules to be taken once orally, without regard to meals. The manufacturer has supplied the following dosing instructions:

- **Open the SOLOSEC packet by folding over the corner (marked by an arrow) and tearing across the top.**
- **Sprinkle the entire contents of the SOLOSEC packet onto applesauce, yogurt, or pudding. The granules will not dissolve. Consume all of the mixture within 30 minutes without chewing or crunching the granules. A glass of water may be taken after the administration of SOLOSEC to aid in swallowing.**
- **The granules are not intended to be dissolved in any liquid.**

In Latest Scheme to Delay Generics, Allergan "Donates" its Patent

For many years now, brand name dug companies have been working overtime to figure out new ways to circumvent the process by which their blockbuster drugs become available as generics. The earliest attempts involved developing new, "long-acting" dosage forms. Then they moved on to "pay for delay," a scheme in which the brand name company pays generic manufacturers millions of dollars to delay the marketing of their lower-cost version of the drug in question. There are also the so-called "authorized generics," which are simply brand name drugs repackaged as generics to freeze out the competition. But the latest innovation in corporate greed takes the cake: Allergan has transferred the patents for its $1.5 billion ophthalmic drug Restasis to the Saint Regis Mohawk Native American Tribe of upstate New York. The point of this philanthropy is to prevent the drug's patents from being challenged through the Patent Trial and Appeal Board, since the Tribe can claim sovereign immunity from such challenges. The novelty of such an approach is matched only by its cynicism. Critics fear that if Allergan's tactic proves successful, it will set off a frenzy of drug patents being transferred to other sovereign groups. This bold move may not, in the end, work out for Allergan, since those very same patents are currently being contested in Federal court, where the immunity does not apply. As we go to press, the Judge in that case has just ruled that the Restastis patents are invalid, opening the door to approval of a generic version. Allergan has said it will appeal the ruling.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Updates to the Dispense Brand Name Drug when Less Expensive than Generic Program

There have recently been several updates to the Dispense Brand Name Drug when Less Expensive than Generic Program, including 1 addition and 3 deletions:

Addition (effective 10/19/2017)

Fosrenol chewable tablets

Deletions (effective 10/19/2017)

Differin

Strattera

Tazorac

Prescriptions for drugs in the program **do not require** *"DAW"* or *"Brand Medically Necessary"* on the prescription, and have a generic copayment. If a drug is removed from the program, a new prescription is not required. The current list of drugs in the program is as follows:

Adderall XR	**Aggrenox**
Alphagan P 0.15	**Benzaclin gel pump**
Butrans	**Catapres-TTS**
Cellcept Susp	**Copaxone**
Diastat	**Edecrin**
Exelon patch	**Focalin**
Focalin XR	**Fosrenol chew**
Gleevec	**Hepsera**
Kapvay	**Myfortic**
Pataday	**Patanase**
Protopic	**Pulmicort Resp**
Retin-A crm, gel	**Tegretol Susp**
Tegretol XR	**Tobradex Susp**
Trizivir	**Valcyte Tabs, Solution**
Voltaren Gel	**Vigamox**
Xeloda	**Xenazine**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

The Pharmacist's Rolodex: Updated

Pharmacy is among the most highly regulated professions in the United States, and, as such, it is vital that pharmacists have access to all the various agencies doing the regulating. To serve this purpose, we at ***PRN*** periodically publish a list of the phone numbers, addresses, and websites of those organizations most likely to affect the practice of pharmacy, both in New York State and at the Federal level. Here is the latest edition of *The Pharmacist's Rolodex*:

New York State Contacts

NY State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000
Phone: (518) 474-3817 ext. 130
Fax: (518) 473-6995
Website: www.op.nysed.gov/prof/pharm
Email: pharmbd@nysed.gov

Bureau of Narcotic Enforcement
Riverview Center
150 Broadway
Albany, NY 12204
Phone: (866) 811-7957
Fax: (518) 402-0709
Website:
www.health.ny.gov/professionals/narcotic
Email: narcotic@health.ny.gov

New York State Medicaid Program
Claims: (800) 343-9000
Prior Authorization: (877) 309-9493
Policy Questions: (518) 486-3209 or
email at: PPNO@health.ny.gov
Websites:
General:
www.health.ny.gov/health_care/medicaid/program/pharmacy.htm

Billing/Formulary/Updates:
www.emedny.org

Prior Authorization Programs:
newyork.fhsc.com

Federal Contacts

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: (888) INFO-FDA (463-6332)
Website: www.fda.gov
Email: druginfo@fda.hhs.gov

Drug Enforcement Administration
8701 Morrissette Drive,
Springfield, VA 22152
Phone (Main office): (202) 307-1000
Phone (NY office): (212) 337-3900
Phone (Order forms): (800) 882-9539
Website: www.dea.gov

New York Mailing Address (for forwarding "reverse" 222 forms):

Drug Enforcement Administration
New York Field Division
99 Tenth Avenue
New York, New York 10011

U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Phone: (800) MEDICARE (633-4227)
Website: www.medicare.gov

Centers for Disease Control and Prevention
Phone: (800) CDC-INFO (232-4636)
Website: www.cdc.gov

Miscellaneous Contacts

Poison Control Centers
Phone (National): (800) 222-1222
Phone (NYC): (212) POISONS
(212) 764-7667
Website: www.aapcc.org
Web tool: www.poisonhelp.org

Drug Information Centers
The International Drug Information Center at Long Island University
Phone: (718) 488-1064
Fax: (718) 488-1254
Website: www.liu.edu/pharmacy/idic
Email: IDIC@brooklyn.liu.edu

FEATURE ARTICLE...

Move Over Zostavax, Shingrix is Coming

New York pharmacists have been administering the zoster (shingles) vaccine since October, 2012. Up until now, there has been only one option, Merck's **Zostavax**, initially approved in 2006. But on October 20th of this year, Glaxo announced that the FDA had given the green light to **Shingrix**, making it the second vaccine against shingles to be approved. Based on the information available so far, the new entry may well go on to dominate the market.

The Virus

The varicella zoster virus (VZV), also known as human herpesvirus type 3, is the cause of both chicken pox and shingles. Shingles is a result of the reactivation of the dormant chicken pox virus, hence one can not get shingles if one has never had chicken pox. Although patients can develop shingles at any age post-chicken pox infection, it is most commonly seen in patients 50 years of age and older. The CDC estimates that 1 in 3 people age 60 or older will get shingles, accounting for the majority of the approximately 1 million cases in the U.S. every year. The most common complication of shingles is severe, and sometimes debilitating, pain where the shingles rash was located, known as postherpetic neuralgia.

The Vaccines

Zostavax: the first vaccine for shingles, approved by the FDA in 2006. Zostavax is a lyophilized preparation of the Oka/Merck strain of **live**, attenuated varicella zoster virus (VZV). Studies show the vaccine reduces the incidence of shingles by 51% and postherpetic neuralgia by 66%. After 4 years the effectiveness of Zostavax is reduced to approximately 35%.

Shingrix: in October, 2017, the FDA approved Shingrix as the second vaccine available for shingles. Shingrix is a **non-live**, lyophilized recombinant varicella zoster virus surface glycoprotein E antigen with adjuvant. In trials, Shingrix was found to reduce the incidence of shingles by 91% and postherpetic neuralgia by 85%, effects which were sustained over 4 years.

The Recommendations

On October 25, 2017, the Advisory Committee on Immunization Practices (ACIP) voted that **Shingrix** is:

- **Recommended for healthy adults aged 50 years and older to prevent shingles and related complications**
- **Recommended for adults who previously received Zostavax**
- **The preferred vaccine for preventing shingles and related complications**

While both vaccines are FDA-approved for people aged 50 years and older, ACIP has recommended Zostavax not be administered before age 60 due to its relatively short-lived effectiveness.

Comparison of Current Vaccines for Herpes Zoster (Shingles)

Vaccine	Storage	Reconstitution	Administration	Efficacy
Zostavax (Zoster Vaccine Live)	Zostavax should be stored frozen at a temperature between **–58°F and +5°F**.	Withdraw the entire contents of the supplied diluent into a syringe and *slowly* inject into the vaccine vial. Agitate gently to mix thoroughly. Withdraw entire contents (0.65 mL) into a syringe and inject immediately. Discard vaccine if not used within 30 minutes.	Administer Zostavax as a single 0.65 mL dose **subcutaneously** in the deltoid region of the upper arm (according to the package insert). Most clinicians prefer to inject Zostavax subcutaneously in the anterolateral aspect of the upper arm.	Studies have shown Zostavax to be 51% effective in preventing shingles, and 66% effective in preventing postherpetic neuralgia. The CDC states that the vaccine only protects against shingles for about 5 years, which is why they recommend waiting until age 60 to receive Zostavax.
Shingrix (Zoster Vaccine Recombinant, Adjuvanted)	Shingrix should be stored refrigerated at a temperature between **36°F and 46°F**.	Withdraw the entire contents of the vial containing the adjuvant (blue-green cap) into a syringe. *Slowly* transfer to the antigen component vial (brown cap). Gently shake the vial to thoroughly mix contents. Withdraw 0.5 mL from the vial and inject immediately or refrigerate and use within 6 hours.	Administer Shingrix **intramuscularly** in the deltoid region of the upper arm. Two doses are required. The second dose may be administered anytime between 2 and 6 months after the initial dose.	Studies have shown Shingrix to be over 90% effective in preventing shingles, and this effect was sustained over a follow-up period of 4 years. Shingrix was also demonstrated to be 85% effective in preventing post-herpetic neuralgia, a benefit attributable to the effect of the vaccine on the prevention of shingles.

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Founder and Editor:
James Murphy, RPh

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

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Suite 6C
Forest Hills, New York 11375

ASK PRN...

In administering vaccinations in New York, are pharmacists permitted to deviate from the current ACIP guidelines? For example, can Zostavax be administered to a patient 50 years of age?

In determining whether a pharmacist may administer a vaccine outside the recommendations of the Advisory Committee on Immunization Practices (ACIP), the deciding factor is the nature of the order, specifically whether it is patient specific. In the case of Zostavax, which is FDA-approved for patients 50 years of age and older but ACIP approved for 60 and older, a pharmacist may only administer it to patients under 60 years of age pursuant to a patient specific order. When administering under a non-patient specific protocol, ACIP recommendations must be adhered to. This became the law in New York State with the passage of Assembly bill *A00123B* in 2015. Some of the changes brought about by this bill included the following:

- **Pharmacists must "administer the immunization or immunizations according to the most current recommendations by the ACIP, provided, however, that a pharmacist may administer any immunization authorized under this section when specified by a patient specific order."**
- **"When administering an immunization in a pharmacy, the pharmacist shall provide an area for the immunization that provides for the patient's privacy. The privacy area should include a clearly visible posting of the most current "Recommended Adult Immunization Schedule" published by the ACIP."**

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 licensed pharmacist in the United States was a French immigrant names Louis Joseph Dufilho, Jr?[1] Dufilho, educated in France, was practicing in New Orleans when Louisiana passed the first law requiring a licensing examination for pharmacists. Dufilho was the first applicant to pass the test, and the pharmacy he opened in 1823 is now preserved as the New Orleans Pharmacy Museum. Incidentally, and in keeping with the season, it is said that the museum is haunted by the ghost of one Dr. Joseph Dupas, a physician of ill repute who owned the building after Dufilho sold it in 1857.

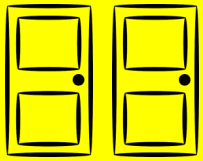
PHARMACY FUN

It's rebus time again here at Pharmacy Fun, and for those who don't know, a rebus is a picture puzzle, a word or phrase constructed from things instead of letters. The first reader to send the correct answers to *puzzle@prnnewsletter.com* will receive a *PRN* combination pen and touchscreen stylus.

1. 

\+ **D** +


2. 
\+


3. 
\+ **UH**

4. 
\+

\+


Answers to last month's ***PHARMACY FUN***:
1. 20 grains in a scruple 2. 3 scruples in a dram 3. 60 minims in a fluidram 4. C stands for gallon 5. aa stands for ana ana (of each) 6. ss stands for semis (one half) 7. d.t.d stands for dentur tales doses (give such doses) 8. 100 proof EtOH is 50% alcohol 9. -log of H+ conc. is pH 10. Density of water (4° C) is 1 gm/mL

References:
1. The history of Louis J. Dufilho, Jr., from the website of the New Orleans Pharmacy Museum at www.pharmacymuseum.org accessed 10/27/17.