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What's Inside…

FDA NEWS

FDA Requires Label Changes for all Opioids

The Food and Drug Administration (FDA) has announced that it will require new warnings to be added to the labels of all opioid medications. The safety issues identified in the FDA warning are as follows:

- **Opioids can interact with antidepressants and migraine medications to cause a serious central nervous system reaction called serotonin syndrome, in which high levels of serotonin build up in the brain and cause toxicity.**
- **Taking opioids may lead to a rare, but serious condition in which the adrenal glands do not produce adequate amounts of the hormone cortisol. Cortisol helps the body respond to stress.**
- **Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as reduced interest in sex, impotence, or infertility.**

Some of the above warnings are already in place for specific opioid agents, but will now be added to the labels

.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

GILEAD INTRODUCES 3 NEW FIXED-DOSE HIV TREATMENTS CONTAINING A NOVEL FORM OF TENOFOVIR

Gilead Sciences, Inc., has developed a next-generation oral prodrug of tenofovir (Viread) called tenofovir alafenamide (TAF). TAF is effective at 1/10th the dose of tenofovir, appears to enter infected cells more efficiently, and causes less renal toxicity and decreases in bone mass density compared to tenofovir. Gilead began introducing TAF in fixed-dose combination at the end of 2015, and has now marketed a total of 3 TAF-containing products, which are discussed below.

GENVOYA
(Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide 150/150/200/10 mg tablets)
Category: Treatment of HIV-1 infection
Initial Dose: One tablet taken once daily with food
MDD: One tablet

Genvoya is a 4 drug combination of an integrase strand inhibitor, CYP3A inhibitor, and 2 NRTIs. It is indicated for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older who have no history of antiretroviral treatment or to replace current antiretroviral treatment in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL). Before starting Genvoya, patients should be tested for hepatitis B infection, since discontinuation of Genvoya in HBV patients can lead to severe exacerbation .

ODEFSEY (Emtricitabine/Rilpivirine/Tenofovir Alafenamide 200/25/25 mg tablets)
Category: Treatment of HIV-1 infection
Initial Dose: One tablet taken once daily with food
MDD: One tablet

Odefsey is a 3 drug combination of two NRTIs and one NNRTI, indicated for the treatment of HIV-1 infection in patients 12 years of age and older, either as initial treatment or as a replacement for a stable antiretroviral regimen (HIV-1 RNA less than 50 copies per mL). As with all tenofovir-containing products, patients should be tested for hepatitis B infection before initiating therapy.

DESCOVY (Emtricitabine/ Tenofovir Alafenamide 200/25 mg tablets)
Category: Treatment of HIV-1 infection
Initial Dose: One tablet taken once daily with or without food
MDD: One tablet

Descovy is a 2 drug combination of 2 NRTIs indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. The recommended dose is one tablet once daily with or without food for patients weighing at least 35 kg and having a creatinine clearance greater than or equal to 30 mL per minute. Although Descovy is the TAF analogue of Truvada, it does not share that agent's indication for use as pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.

FDA Advises Restricting Fluoroquinolone Use for Some Indications

The Food and Drug Administration (FDA) is now advising physicians to avoid the use of fluoroquinolones for certain common infections, except for patients for whom there is no alternative treatment option (see chart below). An FDA safety review indicated that systemic use of fluoroquinolones is associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system. Signs and symptoms include tendon, joint, and muscle pain, a "pins and needles" tingling or pricking sensation, confusion, and hallucinations.

For these infections….	Avoid these drugs….
Acute Sinusitis	Avelox (moxifloxacin)
Acute Bronchitis	Cipro (ciprofloxacin)
Uncomplicated Urinary Tract Infection	Factive (gemifloxacin)
	Levaquin (levofloxacin)
	Ofloxacin

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Override Options for Ordering/Prescribing/Referring/Attending (OPRA) Providers

Since January, 2014, the New York State Medicaid program has required that all prescriptions billed to the program be issued by a Medicaid-enrolled (OPRA) prescriber. However, many prescriptions issued in the hospital setting are written by unlicensed providers, including residents, interns, and foreign physicians in training programs. Since these physicians are not eligible for enrollment into the Medicaid program, the Department of Health has developed an override for pharmacy providers filing prescriptions written by these prescribers. The override for rejection 56 (non-matched prescriber ID) requires the following 3 codes:

- In the **Reason for Service Code** field (439-E4), also known as the Drug Utilization Conflict field,— enter **"PN**" (Prescriber Consultation)
- In the **Result of Service Code** field (441-E6)— enter one of the following applicable values (**1A, 1B, 1C, 1D, 1E, 1F, 1G, 1H, 1J, 1K, 2A, 2B, 3A, 3B, 3C, 3D, 3E, 3F, 3G, 3H, 3J, 3K, 3M, 3N,** or **4A**)
- In the **Submission Clarification Code** field(420-DK), also known as the Drug Prescription Override filed,— enter **"02"** (Other Override)

(If a DUR is also generated for the prescription, an override code will need to be entered in the Professional Service Code field). This option may also be used as an emergency override for prescriptions written by New York State licensed physicians who have not yet registered with the New York State Medicaid program. When using the override in this situation, the pharmacist should notify the prescriber and the Medicaid member that OPRA enrollment is required to ensure Medicaid reimbursement for future prescriptions.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York State Expedited Partner Therapy Program for STIs

In January of 2009, New York State enacted the Expedited Partner Therapy (EPT) law, which permits health care providers (physicians, nurse midwives, nurse practitioner, and physician assistants) to provide treatment to sex partners of persons diagnosed with *Chlamydia trachomatis* (Ct) without a prior medial examination or clinical assessment of those partners. The intention of the law is to reduce the morbidity caused by Ct infection and re-infection. Ct is the most commonly reported sexually transmitted infection (STI) nationwide, and is a leading cause of infertility, pelvic inflammatory disease, chronic pelvic pain, and ectopic pregnancy. The regulations pertaining to EPT (section 23.5 of Title 10 NYCRR) include the following provisions:

- **The use of EPT is limited to Ct infection only. The recommended EPT treatment for Ct is *1 gram of azithromycin in a single oral dose*.**
- **EPT should not be provided to Ct patients concurrently infected with gonorrhea or syphilis.**
- **EPT is *not* recommended for treating men who have sex with men due to a high risk of HIV co-morbidity in partners.**
- **EPT prescriptions must include the phrase "EPT" in the body of the prescription above the name and dosage of the medication. Prescriptions can be provided to patients without the name, address, or date of birth of the sex partner; the written designation "EPT" shall be sufficient for the pharmacist to fill the prescription. If needed, this information can be obtained when the prescription is dropped off at the pharmacy.**
- **Health care providers or pharmacists who dispense EPT in accordance with this law shall not be subject to liability or be deemed to have engaged in unprofessional conduct.**
- **EPT issued as medication or as a prescription to the original patient must be accompanied by written materials for patients and partners, addressing possible side effects and contraindications to EPT medication.**

Frequently Asked Questions for Pharmacists

Q: Who will assume the cost of the sex partner's medication?

A: Medication costs may be self-pay (paid by the person who picks up the prescription) or paid by the sex partner's health insurance. Billing the sex partner's prescription under the original patient's name would be considered fraudulent.

Q: Are EPT prescriptions exempt from mandatory electronic prescribing?

A: Yes. In a letter dated March 16, 2016, New York State Health Commissioner Howard A. Zucker specifically waived the requirement for electronic prescribing for physicians when prescribing under approved protocols for expedited partner therapy

Q: If a sex partner is allergic to azithromycin, what are the alternatives?

A: If the sex partner is known to be allergic to macrolides, azithromycin should not be given and the partner should be instructed to see a physician for appropriate treatment.

Q: What if the sex partner is taking a medication that interacts with azithromycin?

A: EPT should not be dispensed, and the partner should be referred to a physician or emergency room for appropriate treatment.

Feature Article..

The Zika Virus: A Primer For Pharmacists

Mosquito Season is fast approaching in the United States, and this year it is accompanied by a dark cloud known as the Zika virus. If and when Zika arrives on our shores, pharmacists will be on the front lines of the battle. In preparation for such an event, we offer the following review of what is currently known about the virus.

What is Zika?

The Zika virus is a single-stranded RNA virus of the *Flaviviridae* family, genus *Flavivirus*. It was discovered in 1947 in the Zika forest in Uganda. The first human cases were discovered in 1952, and since then, outbreaks have been recorded in tropical Africa, Southeast Asia, and the Pacific Islands. The current outbreak is centered in Brazil, and encompasses Mexico, Central America, South America, and the Caribbean Islands. Some Pacific Islands and Papua New Guinea are also affected. There are currently 591 travel-associated cases in the United States, including 168 cases involving pregnant women. New York State currently has the greatest number of cases with 127.

Symptoms, Diagnosis, and Treatment

Most people who become infected with Zika virus will be asymptomatic or will exhibit only mild symptoms. The most common symptoms include **fever**, **rash**, **joint pain**, and **conjunctivitis**. Some patients may also experience **muscle pain** and **headache**. There have been rare reports of Guillain-Barre syndrome in Zika-affected areas. The incubation period following exposure is likely a few days to a week, and the illness is generally mild, lasting for several days to a week. It is believed that infection confers immunity against future exposures. Clinical diagnosis is based on symptoms, recent travels and activities. There is now also a blood test available which can confirm the diagnosis. Treatment is supportive, and includes rest, fluids, and acetaminophen for pain and fever. Aspirin and NSAIDs should be avoided if the patient has travelled to areas where dengue fever is present, since the symptoms are similar and these agent would increase the risk of hemorrhage in patients with dengue.

Microcephaly

The most serious consequence of Zika virus infection is the link between the virus and the birth of children with microcephaly, which has transformed what was a rather mild illness into a world health crisis. The CDC has recently confirmed the link between Zika virus in pregnant woman and this severe birth defect. Microcephaly is a condition in which a baby's brain and head fail to grow to normal size, which can lead to intellectual disability, developmental delay, seizures, hearing and vision problems, and difficulty with feeding, movement and balance. Microcephaly can sometimes be detected by ultrasound during the late 2nd or early 3rd trimester. The CDC is recommending that non-pregnant women who become infected with Zika virus wait at least 8 weeks before attempting to become pregnant.

How is Zika Transmitted?

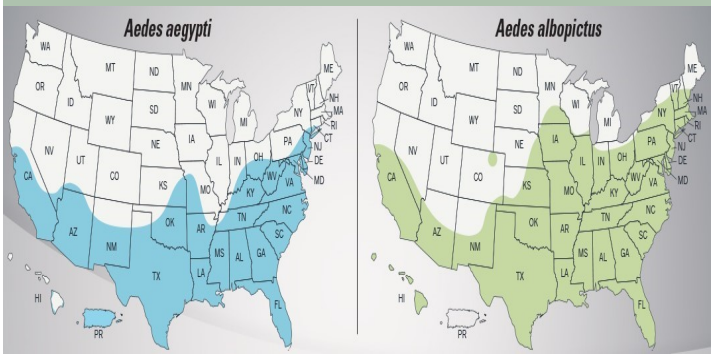
Zika virus is primarily spread to people through the bite of an infected mosquito of the Aedes species (*Aedes aegypti* and *Aedes albopictus* — see map below for U.S. states these species are known to inhabit). The mosquitos that carry Zika virus are aggressive daytime biters, but they can also bite at night. The virus can also be transmitted during sex with a man infected with Zika, from a pregnant woman to her fetus during pregnancy or around the time of birth, and possibly through a blood transfusion.

Prevention

The best way to prevent Zika virus transmission is to protect yourself from mosquito bites. The CDC recommends the following practices:

- **Wear long-sleeved shirts and long pants**
- **Use window and door screens to keep mosquitos outside**
- **Use EPA-registered insect repellents (e.g., DEET). When used as directed, these products are safe, even for children and pregnant and breast-feeding women.**
- **Do not use insect repellents on babies younger than 2 months old. Mosquito netting can be used on cribs and strollers for children < 2 months old**
- **Do not use products containing oil of lemon eucalyptus or para-menthane-diol on children younger than 3 years old**
- **Sleep under mosquito netting if air conditioned or screened rooms are not available or if sleeping outdoors.**
- **Prevent sexual transmission of Zika virus by using condoms or abstaining**

ESTIMATED range of Aedes albopictus and Aedes aegypti in the United States, 2016[1]



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ASK PRN...

When refilling a prescription for a controlled substance in New York State, are pharmacists still required to pull the original hard-copy prescription and endorse it with the amount and date dispensed and pharmacist's signature?

No. When using an electronic recordkeeping system it is no longer required that the pharmacist refilling a controlled substance prescription pull and sign the original hard-copy prescription. The regulations regarding refilling Schedule III, IV, and V prescriptions were amended and became effective on March 27, 2013. The pertinent section now reads as follows:

Part 80 Rules and Regulations on Controlled Substances

Section 80.69 - Schedule III, IV and V substances (i):

When refills are recorded in an electronic recordkeeping system:

(1) pharmacist shall ensure that the computer application used for such recordkeeping shall: (i) provide online retrieval of original prescription information; and (ii) provide online retrieval of the current refill history for Schedule III, IV, and V controlled substance prescriptions.
(2) each time an official New York State prescription or an out-of-state written prescription for a Schedule III, IV, or V controlled substance is refilled, the dispensing pharmacist shall document that the refill information entered into the computer has been reviewed and is correct by manually signing: (i) a hard-copy printout of each day's controlled substance refill data, or; (ii) a bound log book containing a statement that the refill information entered into the computer that day has been reviewed and is correct as shown.

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 study of phosphodiesterase inhibitors for pharmacologic purposes was inspired by the effects of a good hot cup of coffee? Henry Hyde Salter (1823-1871), a physician and asthma sufferer, noticed that both he and his patients breathed more freely after a dose of coffee, preferably served black and hot. In his landmark book, *On Asthma: Its Pathology and Treatment* (1860), he further described the effects of coffee as follows: "It produces rapidity of thought, vivacity of spirit, clearness of apprehension, greatly increases the working powers, and altogether intensifies mental processes." A hundred years would pass before the science caught up with Dr. Salter's observations, when caffeine and its chemical cousin theophylline were shown to be non-selective inhibitors of phosphodiesterase, an enzyme predominant in cells implicated in inflammatory airway disease

PHARMACY FUN

Tax season has come and gone once again (hope you all survived!), and that got us thinking about how many drugs contain the word "tax" in their name. In between filling out our state and federal returns, we managed to come up with six drugs that fit the bill. How many can you name? (for hints, see below) The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **Topical antifungal (brand name)**
2. **Beta blocker (generic name)**
3. **Cephalosporin (generic name)**
4. **Antineoplastic agent (brand name)**
5. **Muscle relaxant (generic name)**
6. **PDE-5 ODT (brand name)**

Answers to last month's **PHARMACY FUN**:
Ambien/Zolpidem **Ziagen**/Abacavir **Zithromax**/Azithromycin **Zovirax**/Acyclovir **Zyloprim**/Allopurinol **Bonus answer: Accolate**/Zafirlukast

References:
1. Accessed from CDC website at ***www.cdc.gov/zika/vector/range.html*** on May 1, 2016.