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No. 47 **The Newsletter for Community Pharmacists** **November/December, 2012**

What's Inside…

FDA NEWS

FDA Warns Against Use of Pradaxa in Patients with Mechanical Heart Valves

The Food and Drug Administration (FDA) has issued a Drug Safety Communication regarding the anticoagulant Pradaxa (dabigatran). A European clinical trial called RE-ALIGN was recently halted because patients with mechanical prosthetic heart valves given Pradaxa were found to be more likely to experience strokes, heart attacks, and blood clots than were patients given warfarin. Although Pradaxa is not approved for use in patients with atrial fibrillation caused by heart valve problems, the FDA is now requiring a contraindication be included in the label. The agency recommends that any patient with a mechanical heart valve who is taking Pradaxa be promptly transitioned to another medication. In addition, the use of Pradaxa in patients with another type of valve replacement, known as a bioprosthetic valve, has not been evaluated and cannot be recommended. The FDA suggests that patients who have had any type of heart valve replacement surgery, and are taking Pradaxa, speak to their health care professional as soon as possible about their treatment.

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

FLUCELVAX (Influenza Virus Vaccine).
Category: Trivalent Inactivated Influenza vaccine (TIV).
Initial dose: 0.5 mL intramuscularly.
MDD: One dose annually.

Novartis has been granted FDA approval to market Flucelvax, the first TIV produced using mammalian cell cultures rather than fertilized chicken eggs. Growing the virus in cultured canine kidney cells allows for much faster production, and eliminates the risks involved in vaccinating patients with egg allergies. Flucelvax will be available in limited supply for 2012-13 flu season and will come in prefilled syringes. The prefilled syringe contains no thimerosal, but the tip caps may contain natural rubber latex which can cause allergic reactions in latex-sensitive individuals.

QUILLIVANT XR (Methylphenidate Extended-Release Oral Suspension).
Category: CNS Stimulant for the treatment of ADHD.
Initial dose: 20 mg once daily in the morning.
MDD: 60 mg once daily.

NextWave Pharmaceuticals has received FDA approval for Quillivant XR, the first once-daily, extended-release liquid methylphenidate available for patients with Attention Deficit Hyperactivity Disorder (ADHD). The recommended starting dose for children 6 years and above is 20 mg given once daily in the morning, with or without food. Dosage may be increased weekly in increments of 10 to 20 mg per day up to a maximum of 60 mg daily. Quillivant XR is supplied as a powder for reconstitution by the pharmacist; after reconstitution, the product should be kept in the original container and is stable at room temperature for up to 4 months.

XELJANZ (Tofacitinib).
Category: Janus Associated Kinases (JAKs) Inhibitor.
Initial dose: 5 mg twice daily.
MDD: 5 mg twice daily.

Pfizer has introduced Xeljanz, a new treatment for adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate. Xeljanz is an inhibitor of Janus Associated Kinases (JAKs), a family of intracellular enzymes which transmit cytokine-mediated signals that affect immune cell function. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Xeljanz should not be used in combination with biologic DMARDS (e.g., Enbrel, Humira) or potent immunosuppressants such as azathioprine and cyclosporine. Xeljanz therapy should be interrupted during an active infection. Lymphomas and other malignancies have been observed in patients treated with Xeljanz. Regular laboratory monitoring is recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids. Live vaccines should not be given concurrently with Xeljanz. The dose of Xeljanz should be reduced to 5 mg once daily in patients:

- with moderate or severe renal insufficiency
- with moderate hepatic impairment
- receiving potent inhibitors of CYP3A4 (e.g., ketoconazole)
- receiving mediations that result in both moderate inhibition of CYP3A4 and potent inhibition of CYP2C19 (e.g., fluconazole)

FDA Approves Use of Tamiflu in Children Younger Than 1 Year Old

The FDA has announced the expansion of the approved uses of Tamiflu (oseltamivir) to include the treatment of children as young as two weeks old who have shown symptoms of flu for no more than two days. Previously the drug was approved for use only in patients 1 year of age and older. Unlike the fixed dosing regimen for children 1 year and older, the dosing for children younger than 1 must be calculated for each patient based on their exact weight. These patients should receive 3 mg per kg twice a day for 5 days. These smaller doses may require a different measuring device than the one supplied by the manufacturer; pharmacists dispensing Tamiflu for children less than 1 year of age should supply an appropriate device for measuring the correct dose. At this time, Tamiflu is *not* approved for prophylactic use to prevent flu infection in children less than 1 year old.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Brand Less Than Generic Program Update

In April, 2010, New York State Medicaid initiated the Dispense Brand Name Drugs When Less Expensive Program, also known as Brand Less Than Generic, or BLTG. The program promotes the dispensing of brand name drugs over generics when their cost to the program is less (for example, due to brand name manufacturer's rebates to Medicaid being larger than those of generic manufacturers). Since the dispensing of the lower cost drug is in conformance with New York State Education law, prescriptions for drugs in this program:

- Do not require "Dispense as Written" (DAW) or "Brand Medically Necessary" on the prescription
- Have a generic copayment
- Will be paid at the Brand Name Drug reimbursement rate or usual and customary price, whichever is lower
- Do not require a new prescription if the drug is removed from the program

The BLTG program is revised frequently due to fluctuations in brand name and generic drug prices (visit ***https://newyork.fhsc.com*** for the latest updates). Effective November 29, 2012, the BLTG program includes the following brand name drugs:

Actos	**Epivir**
ActoPlus Met	**Geodon**
Adderall XR	**Kadian**
Astelin	**Lexapro**
Carbatrol	**Lovenox**
Catapres-TTS	**Nasacort AQ**
Combivir	**Sanctura XR**
Concerta	**Symbyax**
Diastat	**Valtrex**
Diovan HCT	**Ziagen**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Changes to Controlled Substance Schedules in New York State

As a result of recent legislation, a number of drugs have been scheduled, or re-scheduled, as controlled substance in New York State. The changes which will have the greatest impact on community pharmacy practice involve hydrocodone and tramadol, and these are discussed in detail in this month's Feature Article (see page 3). The complete list, as published by the Bureau of Narcotic Enforcement (BNE) on their website (***www.health.ny.gov/professionals/narcotic***) is as follows:

1. Effective November 25, 2012:

Schedule II Additions:

- Tapentadol **(Nucynta)** [editor's note: already schedule II federally]
- Immediate precursor to fentanyl: (ANPP)
- Boldione
- Desoxymethyltestosterone
- 19-nor-4,9(10)-androstadienedione

Schedule II Amendments:

- Language defining an anabolic steroid was amended: Unless specifically excepted or listed in another schedule, "anabolic steroid" shall mean any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone).

Schedule III Amendments:

- Language to clarify the description of dronabinol.

Schedule IV Additions:

- Fospropofol **(Lusedra)** [editor's note: already schedule IV federally]
- Carisoprodol **(Soma)** [editor's note: already schedule IV federally]

Schedule V Additions:

- Ezogabine **(Potiga)** [editor's note: already schedule V federally]
- Lacosamide **(Vimpat)** [editor's note: already schedule V federally]

2. Effective February 23, 2013:

Schedule II Additions:

- Hydrocodone (dihydrocodeinone) **(Vicodin, Lortab, Tussionex) This action renders all products containing hydrocodone, including but not limited to hydrocodone in combination with acetaminophen or ibuprofen, schedule II.**

Schedule III Deletions:

- Hydrocodone (dihydrocodeinone) **(Vicodin, Lortab, Tussionex) This action renders all products containing hydrocodone, including but not limited to hydrocodone in combination with acetaminophen or ibuprofen, schedule II.**

Schedule IV Additions:

- Tramadol **(Ultram, Ultracet, Ryzolt)**

Editor's note on electronic prescribing: The BNE has confirmed that electronic prescribing of controlled substances *is not yet permissible* in New York State. As a result, prescriptions for tramadol submitted electronically prior to 2/23/13 will no longer be valid for filling or refilling as of that date.

Feature Article..

RESCHEDULING OF HYDROCODONE AND TRAMADOL IN NEW YORK STATE

On August 27, 2012, New York Governor Andrew Cuomo signed The Prescription Drug Reform Act (Chapter 447 of the Laws of 2012). Part C of the Act authorizes the rescheduling of hydrocodone and tramadol. Effective February 23, 2013, all hydrocodone-containing products will become schedule II controlled substances and all tramadol-containing products will become schedule IV controlled substances. The Bureau of Narcotic Enforcement has issued the following questions and answers regarding these changes (the complete FAQ can be viewed on the Bureau's website at ***www.health.ny.gov/professionals/narcotic***):

1. HYDROCODONE:

Q: Effective 2/23/13, are all strengths, formulations, and combination products of hydrocodone a schedule II controlled substance in New York State?

A: Yes

Q: Are refills allowed for hydrocodone prescriptions?

A: No. Effective 2/23/13, hydrocodone is a schedule II controlled substance in New York State.

Q: Are existing refills on a hydrocodone prescription valid on or after 2/23/13?

A: No. As with all prescriptions for schedule II drugs, hydrocodone prescriptions shall not be refilled.

Q: Can a pharmacist dispense an original fill on a prescription for hydrocodone with refills issued prior to 2/23/13 but presented on or after 2/23/13?

A: Yes, provided the prescription is presented within 30 days from the date of issue and meets all laws and regulations for a schedule II controlled substance in New York State. However, any refills authorized on the prescription cannot be honored.

Q: Is there any instance where a prescription for hydrocodone that exists in the pharmacy file, issued prior to 2/23/13, may be refilled on or after 2/23/13?

A: No.

Q: Can a pharmacist create a new prescription and give it a new prescription number for the authorized refills written on a prescription for hydrocodone issued prior to 2/23/13?

A: No. All authorized refills are null and void on or after 2/23/13.

Q: Is a DEA-222 form required when placing an order for hydrocodone on or after 2/23/13?

A: No. Hydrocodone is still listed as a schedule III controlled substance in the federal Code of Regulations.

Q: Where should a hydrocodone prescription, dispensed on or after 2/23/13, be filed?

A: Hydrocodone prescriptions should be filed with the other schedule II prescriptions.

2. TRAMADOL:

Q: Can a pharmacist dispense a prescription for tramadol issued prior to 2/23/13 but presented on or after 2/23/13?

A: Yes, provided the prescription is presented within 30 days from the date of issue and meets all laws and regulations for a schedule IV controlled substance on New York State, and provided the pharmacist dispenses consistent with such laws and regulations.

Q: Can a pharmacist dispense authorized refills on a prescription for tramadol that was issued prior to 2/23/13?

A: Yes, provided the pharmacist dispenses consistent with all laws and regulations for a schedule IV controlled substance, and provided the prescription meets all such laws and regulations including but not limited to:

- The prescription is not older than 6 months from the date of issue
- The number of authorized refills does not exceed five
- The prescription is issued by a DEA registered practitioner
- The DEA number is indicated on the prescription

Q: Can a pharmacist dispense authorized refills on an oral prescription for tramadol phoned in prior to 2/23/13?

A: No.

Q: Does an inventory for tramadol need to be done on 2/23/13?

A: Yes. An initial inventory of all stocks of tramadol on hand must be taken on or before 2/23/13.

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ASK PRN...

What is the status of Suboxone tablets? Recently, it seems, most patients have been switched to the film formulation.

In September, 2012, Reckitt Benckiser, the maker of Suboxone, announced that it was voluntarily withdrawing the tablet formulation from the U.S. market in response to reports of accidental ingestion by children. The tablet formulation was much more likely to be involved than was the film formulation. The company released the following statement:

"Reckitt Benckiser Pharmaceuticals, Inc. received an analysis based on data from the U.S. Poison Control Centers on September 15, 2012 that found consistently and significantly higher rates (7.8 to 8.5 times greater depending on the study period) of accidental pediatric exposure with SUBOXONE tablets as compared with SUBOXONE sublingual film. In the interest of public health, Reckitt Benckiser Pharmaceuticals, Inc. decided to inform the U.S. Food and Drug Administration (FDA) that it will discontinue the supply of SUBOXONE tablets in a manner that ensures patients will have time to transition to SUBOXONE film. Reckitt Benckiser Pharmaceuticals, Inc. will be working closely with the FDA and the broader healthcare community to ensure patients currently taking SUBOXONE tablets have sufficient time and notification to appropriately transition to the same active ingredient with SUBOXINE film and to minimize any risk of impacting patient's continuity of treatment. Reckitt Benckiser Pharmaceuticals, Inc. anticipates that discontinuation of the tablet formulation will occur within the next 6 months, possibly sooner."[1]

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 world's 10th largest pharmaceutical company was founded by a Civil War colonel, former prisoner-of-war, pharmacist, and chemist who turned to drug manufacturing only after a failed attempt at growing cotton? Eli Lilly enlisted in the Union Army at the start of the war, and spent the last months of the conflict as a prisoner of the Confederate army. After the war, he tried his hand at farming, but eventually returned to his home in Indianapolis to open a drug store. Dissatisfied with the quality of pharmaceutical products available at the time, he started his own manufacturing business, naming it Eli Lilly and Company. The rest, as they say, is history.

PHARMACY FUN

It's that time of year again when lists proliferate: the best of, the worst of, the wildest, and the wackiest of 2012. Well, we have a list of our own: new drugs of 2012; for each clue below, name the new agent (hint: all of them have appeared in the pages of this journal, and if you take the first letter of each answer you will spell out something that every letter needs!). The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. NSAID nasal spray
2. Anticholinergic inhalation
3. Oral MS agent
4. Beta-3 Agonist for overactive bladder
5. Topical for actinic keratoses
6. New PDE-5 inhibitor for ED

Answers to last month's **PHARMACY FUN**:
1. **A**cetyl **P**ara **A**mino **P**henol 2. 5-**A**mino **S**alicylic **A**cid 3. **A**zidothymidine 4. **B**acille **C**almette-**G**uerin 5. **I**so**n**icotinyl**h**ydrazine 6. **K**indly **O**blige **W**ith 7. **N**eutral **P**rotamine **H**agedorn 8. **P**ro **R**e **N**ata 9. **Q**uantity **S**ufficient 10. **S**aturated **S**olution of Potassium (**K**) **I**odide

References:
1. Update on Suboxone Tablet. Accessed at ***www.suboxone.com/hcp***