P.R.N.

Volume 1, Number 2 | A Monthly Newsletter for Community Pharmacists | December, 2007

What's Inside…

BREAKING NEWS

Chantix Safety Review

The FDA has released a statement regarding their ongoing safety review of Chantix (varenicline). The review was prompted in part by post-marketing data indicating cases of suicidal thoughts, aggressive and erratic behavior, and drowsiness. At this time, FDA recommends:

Healthcare professionals monitor patients taking Chantix for behavior and mood changes.

Patients taking Chantix contact their physician if experiencing behavior or mood changes.

Patients use caution when driving or operating machinery until they know how quitting smoking with Chantix may affect them.

**********RX NEWS**********

Zyrtec OTC: The FDA has granted nonprescription status to **Zyrtec** (certirizine), which will be marketed by McNeil Consumer Healthcare. The tablet, chewable tablet, and syrup formulations will be available in two different packages each, one labeled for treatment of hay fever and other respiratory allergies in adults and children 2 years of age and up, and one labeled for treatment of itching due to hives in adults and children 6 years of age and up. Both are expected to ship in late January, 2008. **Zyrtec-D** (certirizine and pseudoephedrine) has also been approved for OTC sale, subject to the restrictions mandated by the Combat Methamphetamine Epidemic Act.

Diovan Pediatric Use: A new indication has been approved for Novartis' ARB **Diovan** (valsartan): pediatric hypertension in children and adolescents 6 to 16 years of age. The starting dose is 1.3 mg/kg once daily (up to 40 mg total) and the dose range is 1.3 to 2.7 mg/kg once daily (up to 40 –160 mg total). A suspension may be prepared for those children who cannot swallow tablets or for doses that do not correspond to available tablet strengths. To compound 160 mL of a 4 mg/mL suspension, place 8 tablets of Diovan 80 mg in an amber glass bottle and add 80 mL of Ora-Plus®, shake for at least 2 minutes, then let stand for a minimum of 1 hour. Then add 80 mL of Ora-Sweet SF® and shake for 10 seconds. The suspension must be shaken well before each use and is stable for 30 days at room temperature or 75 days under refrigeration.[1] If the patient is later switched to tablets, the dose may have to be increased due to the fact that exposure to valsartan is 1.6 times greater with the suspension than with the tablet dosage form.[1]

Protonix Suspension: Wyeth Pharmaceuticals' PPI **Protonix** (pantoprazole) will soon be available in a new dosage form— enteric coated granules for delayed-release oral suspension for those patients unable to swallow tablets. Each unit dose packet contains 40 mg pantoprazole sodium and *must* be administered in either applesauce or apple juice. To prepare a dose in applesauce, the contents of one packet are to be sprinkled onto one teaspoonful of applesauce and consumed within 10 minutes. For apple juice, the contents of one packet should be emptied into 5 mL of apple juice, stirred for 5 seconds, and swallowed immediately. Protonix for suspension may also be administered via nasogastric tube utilizing several 10 mL aliquots of apple juice.

Mevacor OTC?: For the third time in the last 7 years, the FDA will consider an application to grant nonprescription status to Merck's HMG-CoA inhibitor **Mevacor** (lovastatin). A joint panel of FDA's Nonprescription Drugs Advisory Committee and Endocrine and Metabolic Drugs Advisory Committee will meet to review the petition on December 13, 2007.

FDA Panel Seeks New Warning on Influenza Drugs

An FDA advisory panel recently recommended that the agency demand a stronger warning label on Roche's neuraminidase inhibitor **Tamiflu** (oseltamivir). The advice was prompted by a review of almost 600 cases of psychiatric disturbances in patients taking Tamiflu, the majority of which were reported in Japan, where use of the drug is more common than in the United States. Delirium, hallucination, and self-injury were reported, including 5 children who died after jumping from windows or balconies or running into traffic. The panel also suggested new labeling for GlaxoSmithKline's **Relenza** (zanamivir), which has also been linked to neurologic disturbances, though no deaths have been reported. Roche has already announced that they would agree to the new labeling, while pointing out that no causal relationship between Tamiflu and psychiatric symptoms has yet been proven.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Mandatory Generic Drug Program Update

As of December 1, 2007, the following brand-name drugs will require prior authorization in order to be dispensed under the N.Y. State Medicaid Program:

Biaxin XL 500 mg
Cutivate Cream and Ointment
Cytotec 100 mg, 200 mg
Estrace 1 mg, 2 mg
Lithobid 300 mg
Metrogel Vaginal Gel
Tessalon 200 mg
Tiazac 240 mg

Prescriptions written before Dec. 1, 2007, including refills, will still be covered until the prescription expires, at which point a prior authorization will be required to fill any new prescription for the brand-name drug.

The Mandatory Generic Program, which began in 2002, allows coverage for a brand-name drug for 6 months following the release of an AB rated generic for that drug. After that period expires, prior authorization will be required for any prescriptions for the brand-name. There are 2 exceptions to this rule. One is that brand-name drugs that are on the ***Medicaid Preferred Drug List*** do not require prior authorization. The second exception is for any of the *brand-name drugs which have been exempted from requiring prior approval by order of the Commissioner of Health:*

Coumadin
Lanoxin
Dilantin
Clozaril
Tegretol
Gengraf
Neoral
Sandimmune
Zarontin
Levothyroxine Brands

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Year-end Review of Regulatory Changes

The past year saw several important changes to the laws, rules, and regulations governing the practice of pharmacy in New York State. Here are some of the highlights:

Hospital Prescribing Exemption Expires

On April 19, 2007 the exemption granted hospital prescribers from the requirement to write all prescriptions on the Official New York State Prescription (ONYSRx) expired. Henceforth all prescriptions, controlled and non-controlled, must be written using the ONYSRx. The exemption continues, however, for those hospitals and their affiliated clinics which have implemented an electronic prescribing system or a computerized provider order entry system that generates printed prescriptions. These facilities may continue to issue prescriptions on regular hospital blanks for **non-controlled drugs only**. The current list of exempt facilities may be accessed at: *www.health.state.ny.us/professionals/narcotic/facilities/exempted_list* or by calling the Bureau of Narcotic Enforcement at 866-811-7957.

Coupons for Controlled Substances Allowed

The Department of Health reversed its earlier ruling on the issue on coupons for controlled substance prescriptions. As of January 12, 2007, coupons, vouchers, and other programs reimbursing a pharmacy for the cost of a controlled substance are acceptable when accompanied by a valid prescription issued by an authorized prescriber.

Oral Prescriptions for Needles and Syringes Quantity Increased

Practitioners may now orally prescribe up to 100 hypodermic syringes and/or needles at a time. Previously, only a 10-day supply was allowed. Within 72 hours of authorizing such an oral prescription, the prescriber shall cause the written prescription to be delivered to the pharmacist. If the pharmacist does not receive the prescription, he or she must write “Prescription not received” on the oral memorandum and sign and date the statement.

Clarification on Faxing Controlled Substance Prescriptions

The Bureau of Narcotic Enforcement has clarified their policy on the acceptability of faxing prescriptions for controlled substances. Prescribers may fax *official prescriptions* for controlled substances to pharmacies for dispensing; such prescriptions **must comply with the requirements for oral prescriptions for controlled substances** (5-day supply maximum, except for non-benzodiazepine C-IV drugs, which are allowed a 30-day supply or 100 dosage units, whichever is less). Follow-up written prescriptions must be sent to pharmacy within 72 hours.

Continuing Education Required for Initial Registration Period

The exemption from completing continuing education credits during the initial registration period after licensure has been rescinded. All pharmacists licensed on or after 8/1/07 are now required to fulfill the mandatory continuing education requirements of 45 credits per 3 year registration period.

Physician Assistants May Prescribe Schedule II Drugs

Beginning on December 13, 2007, Registered Physician Assistants (RPAs) may prescribe Schedule II drugs for outpatients under the care of their supervising physician. As is the case with prescriptions for C-III, C-IV, and C-V drugs, **RPAs must use their own DEA numbers**, not that of their supervising physician.

Feature Article..

Community Acquired Pneumonia

Community Acquired Pneumonia (CAP) strikes between 4 and 5 million people a year in the United States and causes between 45,000 and 65,000 deaths annually. Mortality due to pneumonia and influenza combined represents the 7th leading cause of death in the U.S., with pneumonia accounting for the majority of fatalities. There are a number of causative agents (see table 1), with *Streptococcus pneumoniae* being the most common infection. In addition to bacteria, pneumonia may also be caused by viruses and fungi.

Clinical presentation may include cough, fever, dyspnea, malaise, tachypnea, tachycardia, and pleuritic chest pain. Diagnosis is made based upon clinical presentation and confirmed by chest x-ray. Treatment is usually empirical and over the years several organizations have distributed guidelines for the treatment of community acquired pneumonia. Two of those organizations recently convened a joint committee for the purpose of creating a single, unified set of recommendations (see below). One major break with past recommendations is that fluoroquinolones are no longer advised for use as initial therapy in previously healthy adults with no comorbidities or risk factors for drug-resistant infection. This change was made out of concern for increasing resistance developing to fluoroquinolones. Beta-lactam and macrolide resistant strains are also on the rise; however, with empiric treatment, 90% of patients with CAP will improve.[2]

Prevention of some forms of pneumonia is possible through vaccination. The use of the Influenza vaccine can reduce the incidence of secondary pneumonias and the Pneumococcal Polysaccharide Vaccine (PPV) protects against 23 types of pneumococcal bacteria that can cause *Streptococcus pneumoniae* infection. The current Centers for Disease Control (CDC) guidelines are found in table 2.

TABLE 1

Leading Causes of CAP

S. Pneumoniae	20-60%
H. Influenza	3-10%
S. aureus	3-5%
Legionella	2-8%
Chlamydia	4-6%
Mycoplasma	1-6%
Viral	2-15%

Adapted from Applied Therapeutics, Eighth Edition, 2005

TABLE 2

CDC Guidelines on Pneumococcal Vaccine: Who Should get PPV?

All adults 65 years of age or older

Anyone over 2 years of age with long term health problems such as:
- Heart disease
- Lung disease
- Sickle cell disease
- Diabetes
- Alcoholism
- Cirrhosis
- Leaks of cerebrospinal fluid

Anyone over 2 years of age with a condition that lowers the body's resistance to infection

Alaskan Natives and certain Native American populations

Current Guidelines for Treatment:

Community Acquired Pneumonia in Outpatient Setting*

Patient Population	Treatment Recommendations
Previously healthy adults with no risk factors for drug-resistant *Streptococcus pneumoniae* (DRSP) infection	**A. Macrolides:** **Azithromycin** 500 mg x 1 day, then 250 mg x4 days **OR** **Azithromycin ER** 2 gm x 1 **Clarithromycin** 500 mg BID **OR** **Clarithromycin ER** 1 gm q24 **B. Doxycycline** 100 mg BID
Adults with comorbitities: chronic heart, lung, liver, or renal disease; diabetes; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials in previous 3 months **In regions with a high rate (>25%) of high-level macrolide-resistant *S. pneumonia,* consider comorbidity recommendations for all patients**	**A. Fluoroquinolones:** **Levofloxacin** 750 mg q24 **Moxifloxacin** 400 mg q24 **Gemifloxacin** 320 mg q24 **B. β-lactam PLUS Macrolide** **Amoxicillin** 1 gm TID **OR** **Augmentin** 2 gm BID **PLUS** **Azithromycin or Clarithromycin** **OR** **Doxycycline** if Macrolide allergy

* Based on Infectious Disease Society of America/American Thoracic Society Consensus Guidelines, 2007.

P.R.N.

P.R.N. is published monthly by
PRN Publishing LLC
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375
Phone & Fax (718) 263-4632

Founder and Editor:
James Murphy, R.Ph

Contributors:
Loriann Irving, Pharm. D.
Margaret Irving, Pharm. D.
Lilian Bejarano, R.Ph

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

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

askprn@gmail.com

SUBSCRIPTION INFORMATION

Subscriptions are available:
One year (12 issues)…….$48.00

Payable by check or money order
Please write to:

askprn@gmail.com

NATURAL PRODUCTS: GINGER

Uses/claimed benefits: Ginger is thought to be an effective herbal antiemetic; it has been used to relieve symptoms of nausea and vomiting associated with motion sickness, pregnancy, and surgery. It is also believed to possess anti-inflammatory and anti-thrombotic properties, as well as aid in the treatment of many gastrointestinal disorders, such as abdominal pain and indigestion.

Evidence: Numerous studies, of varying quality, have demonstrated the efficacy of ginger as an anti-emetic. A systematic review of only double-blind, randomized controlled trials published in *Obstetrics and Gynecology*[3] found ginger to be an effective treatment for pregnancy-induced nausea and noted no adverse effects on pregnancy outcomes. Evidence for use in motion sickness and some non-GI uses is not as compelling. However, a review of recent studies in an upcoming issue of the *International Journal of Cardiology* points to renewed interest in pursuing the use of ginger for anti-platelet and hypolipidemic effects.

Precautions: Ginger is generally considered safe in doses under 5 grams daily. Woman who are pregnant should consult their physician before taking any medication, including herbal products.

Interactions: The ability of ginger to inhibit platelet aggregation could lead to an interaction with anti-platelet and anticoagulant drugs, such as **aspirin, clopidogrel, ticlopidine, warfarin, heparin, enoxaparin, and dalteparin**.

DID YOU KNOW?

DID YOU KNOW that the Christmas Factor, also known as coagulation factor IX, was named not for this month's holiday, but for a 5 year-old Canadian boy named Stephen Christmas? Suffering from hemophilia, he was being studied by doctors at Oxford, England because he was *not* deficient in factor VIII, the traditional cause of the disease. Instead, it was discovered that another coagulation factor deficiency was the cause and that factor was named after the patient. His physicians published their discovery in the British Medical Journal on December 27, 1952— the Christmas issue.

PHARMACY FUN

The following clues refer to commonly prescribed medications. After solving all eight (using generic names), use the first letter of each correct answer to make a word that is an old English term for the holiday season (you may have to rearrange the eight letters!) The first person to email the correct answer to *askprn@gmail.com* wins a P.R.N. binder and a complimentary copy of each of our next three issues.

1. **Reverse Transcriptase Inhibitor; may cause abnormal dreams**
2. **Methylxanthine for asthma**
3. **Antitubercular hydrazide**
4. **Liquid osmotic laxative; also for encephalopathy**
5. **The original macrolide**
6. **Alpha-2 blocker; found in tree bark**
7. **Treatment for acute malignant hyperthermia**
8. **Dissolves gallstones**

Answers to last month's PHARMACY FUN:

KETEK LEXXEL LOZOL RAXAR XANAX

References:
1. Diovan [package insert]. East Hanover, NJ: Novartis; revised 2007.
2. *The Merck Manual.* Whitehouse Station, NJ: Merck Research Laboratories; 2006: 430.
3. Borrelli F, Capasso R, Aviello G, Pittler MH, Izzo AA. Effectiveness and safety of ginger in the treatment of pregnancy-induced nausea and vomiting. *Obstet Gynecol*. 2005;105:849-56.