P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

Volume 3, Number 3 | **A Monthly Newsletter for Community Pharmacists** | **March, 2009**

What's Inside…

FDA NEWS

The FDA has issued safety warnings on the following drugs:

Metoclopramide: the FDA has informed manufacturers of metoclopramide that a boxed warning must be added to their labels regarding the risks of long-term or high-dose use of the drug. In addition, drug makers will be required to implement a risk evaluation and mitigation strategy (REMS). Metoclopramide use has been associated with the development of tardive dyskinesia, a movement disorder which is often irreversible. The majority of patients who developed this disorder had taken the drug for more than 3 months. Older woman seem to be at greatest risk of this adverse effect of metoclopramide.

Zonisamide: the FDA, after reviewing the latest clinical data, has determined that Zonisamide use may lead to metabolic acidosis in some patients. Younger patients appear more susceptible to this effect. Those with predisposing conditions, such as renal or pulmonary disease, may also be at increased risk. The FDA recommends that patient's serum sodium bicarbonate be measured before starting treatment and periodically during treatment.

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

New Aspirin Recommendations: The U.S. Preventative Services Task Force (USPSTF) has issued new recommendations on the use of daily **aspirin** for the prevention of cardiovascular disease. For the first time, the guidelines now urge daily aspirin use for most men aged 45 to 79 years and women aged 55 to 79 years. The recommendations are based on the benefit of heart attack (men) or stroke (women) reduction versus the risk of potential gastrointestinal hemorrhage. In men aged 45 to 59 years, for example, the benefits of aspirin outweigh the risks of G.I. bleeding if the patient's 10-year risk of coronary heart disease (CHD) is equal to or greater than 4%. For an understanding of which patients have at least this level of risk, consider an example: *a 45-year old man, non-smoker, non-diabetic, with a BP of 120/80, total cholesterol of 180, and HDL of 50 has a 10-year CHD risk of 4%.* The risk calculation does not apply to patients taking NSAIDs of those with a history of upper GI pain or ulcers. For women aged 55 to 59 years, the cutoff is a 10-year stroke risk of 3% or higher. CHD and stroke risk for individual patients can be calculated using tools available at the following websites:

10-year CHD Risk Tool:

http://healthlink.mcw.edu/article/923521437.html

10-year Stroke Risk Tool:

http://www.westernstroke.org/PersonalStrokeRisk1.xls

New Psoriasis Treatment: The FDA has approved Galderma Laboratories' **Vectical** (calcitriol ointment) for the topical treatment of mild to moderate plaque psoriasis in adults 18 years and older. Vectical contains an active form of vitamin D_3 and will be available in a 3mcg/gm ointment. Since Dovonex is no longer marketed in ointment form (except in combination with betamethasone as **Taclonex**), Vectical represents the only vitamin D_3 psoriasis treatment available as an ointment. Vectical should be applied to the affected area twice daily (morning and evening). The maximum weekly dose should not exceed 200 grams. Excessive exposure to natural or artificial sunlight should be avoided.[1]

FDA Public Health Advisory: The FDA is warning of the risk of burns to patients having MRI scans while wearing certain transdermal patches. Some patches contain metal in their backing layer which may overheat during an MRI scan, causing a skin burn in the area of the patch. The agency is currently working with the manufacturers of these patches to update labeling to include appropriate warnings. In the meantime, the FDA urges patients who use medicated patches to tell the doctor referring them, as well as the staff of the MRI facility, about any patches they are using. The list of patches available in the U.S. identified by the FDA as containing metal components includes:

Androderm	**Fentanyl**
Catapres TTS	**Transderm Scop**

CDC Cautions Supermarket Pharmacies About Free Antibiotic Programs

The Centers for Disease Control (CDC), in cooperation with the Infectious Diseases Society of America (ISDA), has written to several major supermarket pharmacy chains concerning their free antibiotic programs. In letters to ShopRite, Stop and Shop, Wegmans, and Giant, the federal agency urged the chains to promote responsible use of antibiotics. As Dr. Laurie Hicks of the CDC told the New York Times, "If a patient believes that they can get an antibiotic quite easily or for free, then it may increase the pressure on health care providers to prescribe it."[2] And in a press release, ISDA president Dr. Anne Gershon said "Taking an antibiotic when you don't need it won't help you, and may in fact do more harm than good. At a time when antibiotic overuse is helping to create drug-resistant superbugs such as MRSA and few new antibiotics are being developed, supermarkets need to be responsible in how they promote antibiotics." Of particular concern is the fact that some of the chains offering free antibiotics have linked the promotion to cold and flu season, disregarding the fact that these are viral illnesses which do not respond to antibiotics, and further confusing the public regarding the appropriate use of antibiotics. In addition to fostering bacterial resistance, antibiotic overuse also contributes to approximately 142,000 emergency department visits each year traceable to adverse reactions and allergies to antibacterial drugs.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Medicaid Resources on the Web

In the not-too-distant past, pharmacists practicing in New York State had to rely upon their copy of the Medicaid Provider Manual (that green binder that you were never sure was up-to-date) to provide guidance on policy questions and other practical matters regarding Medicaid prescriptions. That has all changed with the advent of the internet and, more specifically, the **eMedNY** website:

www.emedny.org

Under the heading **Information**, pharmacists will find a number of valuable resources, including a link to the *Medicaid Update website*, which contains all the monthly updates from 1999 to the present. Also in this section is the *Formulary File*, a complete listing of all prescription and over-the-counter drugs covered by Medicaid, with current reimbursement rates and valid NDC numbers. Also available here are lists of prescribers who are required to post, disqualified prescribers, and deceased prescribers.

Click on **Provider Manuals** to access the latest, updated version of both the *Pharmacy manual* and the *Durable Medical Equipment (DME) manual*, both of which contain valuable information of policies and procedures for dispensing Medicaid prescriptions. Pharmacists should periodically check the **What's New** section of the website to determine if there have been any important changes to either of these manuals. For example, a February 17, 2009 update to the *Pharmacy manual* contains the latest enteral products classification list, which provides the correct billing codes for dispensing Ensure, Pediasure, etc.

The eMedNY home page also contains a link the *New York Medicaid Preferred Drug Program* website, where the latest listing of preferred and non-preferred drugs can be accessed and downloaded.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Rules on Transfers of Drugs Between Registered Pharmacies

One of the long-standing traditions in community pharmacy is the exchange of prescription drug stock between pharmacies. In the days before the ascendance of chain pharmacies, such an exchange was known as a KOW, which stood for "kindly oblige with." These transactions occurred when a pharmacy was out of stock of a particular product needed for a patient's prescription; in order to fill the prescription, the pharmacist would obtain the needed drug from a nearby, friendly competitor. Today, many such exchanges take place between locations within a pharmacy chain, and are usually referred to as "store transfers." Regardless of the nomenclature, these transactions are regulated by both state and federal law.

Transfers of Non-Controlled Substances

The regulation which allows for the transfer of non-controlled drugs between pharmacies, without either pharmacy being registered as a distributor, is contained in section 6810(1) of the Education Law. This section prohibits the dispensing or distributing of prescription drugs without a prescription, with the following exception:

> **"Nothing in this subdivision shall prevent a pharmacy from furnishing a drug to another pharmacy which does not have such drug in stock for the purpose of filling a prescription."**

Transfers of Controlled Substances

New York State regulations regarding the transfer of controlled substance drugs between pharmacies are more specific, and can be found in a Commissioner's Ruling on Exempt Distribution from August, 1998. The key points of the ruling are:

1. **Pharmacies licensed by the state and registered with the DEA may transfer or sell controlled substance stock to another pharmacy only to meet the immediate needs (e.g., a waiting prescription) of the pharmacy receiving the stock**
2. **This ruling shall apply only to transfers of controlled substances**
3. **A pharmacy may sell or transfer schedule III, IV, or V controlled substances to another pharmacy pursuant to a written request from the purchasing pharmacy, which must include the name, address, and DEA number of both pharmacies, as well as the date and name, strength, form, and quantity of the requested drug. Schedule II drugs may only be ordered using the official DEA 222 form.**
4. **The pharmacy furnishing the drug shall provide the receiving pharmacy with an itemized list of drugs sold. Such list shall contain all the information required in item 4 above, and must be signed and dated by the pharmacist upon receipt.**
5. **Both pharmacies shall maintain all required records of such transfers in a separate file or in such a manner as will make them readily available for inspection**

Federal Restriction on Controlled Substance Transfers

In addition to the New York State regulations listed above, transfers of controlled substances between pharmacies are also regulated by a federal rule found in 21 CFR 1307.11, which states:

- **The total number of dosage units of controlled substances distributed by a pharmacy in a calendar year may not exceed 5 percent of all the controlled substances dispensed and distributed by that pharmacy in that same calendar year. If the amount exceeds 5 percent, the pharmacy must obtain a registration to distribute controlled substances.**

Feature Article..

ASTHMA: CLASSIFICATION AND TREATMENT

Asthma affects more than 22 million Americans, including 6 million children, making it one of the most common chronic diseases of childhood.[3] According to the National Center for Health Statistics, asthma accounts for 1 out of every 4 emergency room visits in the U.S., and is the cause of more than 4,000 deaths each year. Asthma is currently defined as a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness, and an underlying inflammation.[3] Pharmacists play an important role in the management of this chronic disease, which is primarily treated by pharmacological means. By explaining the role of each of the various medications used, as well as the proper technique for use of inhalers, pharmacists can greatly improve treatment outcomes in patients with asthma. Below is a review of the current classification and treatment guidelines for asthma, adapted from the National Asthma Education and Prevention Program's Expert Panel Report 3 (2007), available online at ***www.nhlbi.nih.gov/guidelines/asthma/index.htm***.

CLASSIFICATION AND INITIAL TREATMENT OF ASTHMA

Classification	Symptoms/ Initial Treatment Step	Lung Function
Intermittent	Symptoms ≤ 2 days/week Nighttime awakenings ≤ 2 times/month Short-acting β_2 agonist use ≤ 2 days/week Effect on normal activity: none Initial treatment: **Step 1**	FEV_1 > 80% predicted *(normal between exacerbations)*
Mild Persistent	Symptoms > 2 days/week but not daily Nighttime awakenings 3 to 4 times/month Short-acting β_2 agonist use > 2 days/week but not daily Effect on normal activity: minor limitation Initial treatment: **Step 2**	FEV_1 > 80% predicted
Moderate Persistent	Symptoms daily Nighttime awakenings >1 time/week but not nightly Short-acting β_2 agonist use daily Effect on normal activity: some limitation Initial treatment: **Step 3**	FEV_1 > 60% but < 80% predicted
Severe Persistent	Symptoms throughout the day Nighttime awakenings often 7 times/week Short-acting β_2 agonist use several times/day Effect on normal activity: severe limitation Initial treatment: **Step 4 or 5**	FEV_1 < 60% predicted

FEV_1 = Force Expiratory Volume in 1 second

STEPWISE APPROACH FOR MANAGING ASTHMA IN ADULTS AND YOUTHS ≥ 12 YEARS OF AGE

STEP 1
Short-acting β_2 agonist prn

STEP 2
Preferred: Low-dose ICS
Alternative: LTRA, Cromolyn, Nedocromil, or Theophylline

STEP 3
Preferred: Low-dose ICS + LABA *or* Medium-dose ICS
Alternative: Low-dose ICS + either LTRA, Theophylline, or Zileutin

STEP 4
Preferred: Medium-dose ICS + LABA
Alternative: Medium-dose ICS + either LTRA, Theophylline, or Zileutin

STEP 5
Preferred: High-dose ICS + LABA
AND
Consider Xolair for patients who have allergies

STEP 6
Preferred: High-dose ICS + LABA + oral corticosteroid
AND
Consider Xolair for patients who have allergies

ICS= inhaled corticosteroid; LABA= long-acting β_2 agonist; LTRA= leukotriene receptor antagonist

INSTRUCTIONS FOR WEEKLY CLEANING OF HFA ALBUTEROL INHALERS

1. **Remove the canister and mouthpiece cap from the mouthpiece**
2. **Wash the mouthpiece through the top and bottom with warm running water for at least 30 seconds**
3. **Shake off excess water and allow the mouthpiece to air dry (this can be done overnight, for example)**
4. **If you need to use the inhaler before the mouthpiece is completely dry, shake off excess water, replace the canister, shake well, test spray twice into the air to remove most of the remaining water, and then take dose as prescribed**

P.R.N.

P.R.N. (ISSN # 1941-9481)
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, RPh

Associate Editor:
Margaret McDonald, PharmD

Contributors:
Loriann Irving, PharmD
Lilian Papacharalambous, RPh
Mila Sakhnovsky, PharmD

Medical Liaison:
Deborah Blenner, MD

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@prnnewsletter.com

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

SUBSCRIPTION INFORMATION

Subscriptions are available:
One year (12 issues)……..$48.00
(Student Discount Available Online)

To pay by credit card via secure server go to the **SERVICES** page of our website: **www.prnnewsletter.com**
or
Send a check or money order payable to PRN Publishing to:

PRN Publishing
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375

ASK PRN...

Oral prescriptions are often called in to pharmacists by staff members of a doctor's office, rather than by the physician. Is this practice acceptable for controlled substance prescriptions?

No. Sections 80.68 and 80.70 of the N.Y. State Rules and Regulations on Controlled Substances state that only a *practitioner* may orally prescribe a controlled substance. In the case of non-controlled substance prescriptions, the practice of staff members transmitting oral prescriptions to pharmacists is sanctioned by section 6810(4)(a) of the Education Law, which states, in part:

An oral prescription or an oral authorization for the refill of a prescription, other than a controlled substance, may be communicated by an employee of the prescriber.

The pharmacist should make a good faith effort to verify the employee's identity if the employee is unknown to the pharmacist.

We frequently receive prescriptions for controlled substances from local hospitals, which contain the hospital's DEA number, rather than the prescriber's. Which practitioners are authorized to use such institutional DEA numbers?

In New York State, the only prescribers authorized to utilize institutional DEA numbers when issuing prescriptions for controlled substances are interns, residents, and foreign physicians. These practitioners must also include the suffix they have been issued by the hospital authorizing them to prescribe controlled substances. Licensed physicians, physician assistants, nurse practitioners, and nurse midwives *must have their own personal DEA registration number in order to write outpatient prescriptions for controlled substances.*

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 Beers Criteria, the list of drugs that are potentially inappropriate for the elderly, was created by Mark H. Beers? Dr. Beers, a Brooklyn native, based his list on a study at Harvard of 850 nursing home residents, published in 1988. The original criteria was produced in 1991 and updated and expanded in 2003. Dr. Beers went on to become an editor at The Merck Manuals, contributing to both the *Merck Manual of Geriatrics* and the *Merck Manual of Medical Information: Home Edition*. Dr. Beers was diagnosed with diabetes as a child, and died of complications of the disease on February 28, 2009 at age 54.

PHARMACY FUN

In honor of Saint Patrick's Day, this month's puzzle has a bit o' the Irish in it. Solve each of the following clues to the names of prescription drugs (generic names, please), then rearrange the first letters of each correct answer to form a well-known two-word sobriquet for Ireland. The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. Most potent statin
2. Oral VRE treatment
3. Macrolide for gastroparesis
4. S-isomer of SSRI
5. Aminopenicillin
6. Alkaloid for migraine
7. Benzothiazepine CCB
8. Formerly amnirone
9. DPP-IV inhibitor
10. 6-MP
11. Carbonate or citrate for bipolar

Answers to last month's **PHARMACY FUN**:
1. Prilosec *was* Losec *similar to* Lasix 2. Lovaza *was* Omacor *similar to* Amicar 3. Altoprev *was* Altocor *similar to* Advicor 4. Razadyne *was* Reminyl *similar to* Amaryl 5. Inamnirone *was* Amnirone *similar to* Amiodarone

References:
1. Vectical [package insert]. Fort Worth, TX: Galderma; January, 2009.
2. Tara Parker-Pope, "Free Antibiotics May contribute to Drug resistance, Officials Say," *New York Times*, March 5, 2009.
3. National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Treatment of Asthma (2007).