P.R.N.

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

What's Inside…

TABLE 1

List of Infant Cough and Cold Products in Voluntary Recall:

DIMETAPP:
- Decongestant Infant Drops
- Decongestant Plus Cough Infant

LITTLE COLDS:
- Decongestant Plus Cough
- Multi-Symptom Cold Formula

ROBITUSSIN:
- Infant Cough DM Drops

TYLENOL:
- Conc. Infants' Drops Plus Cold
- Conc. Infants' Drops Cough/Cold

TRIAMINIC:
- Infant Thin Strips Decongestant
- Infant Thin Strips Plus Cough

PEDIACARE INFANT DROPS:
- Decongestant-pseudoephedrine
- Decongestant-phenylephrine
- Decongestant Plus Cough -pseudoephedrine
- Decongestant Plus Cough -phenylephrine
- Long-Acting Cough

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

Exubera Discontinued: On October 18, Pfizer announced that it will stop production of its inhaled insulin **Exubera**. The decision was based on lackluster sales of the long-anticipated product, not on any safety concerns. Supplies are expected to last an additional three months; physicians and patients are urged to discuss replacement therapy during the interim. Questions can be referred to Pfizer at 1-800-EXUBERA (1-800-398-2372).

Plavix 300 mg Approved: The FDA has approved a new strength of **Plavix** (clopidogrel). The 300 mg tablet is indicated for use as a loading dose in patients with acute coronary syndrome (ACS). It will be available in unit-dose packages of 4, 30, and 100 tablets.

New CCB/ARB Combo: A new combination antihypertensive, **Azor**, is being marketed by Daiichi Sankyo. Azor combines the dihydropyridine calcium channel blocker **amlodipine** with angiotensin II receptor blocker **olmesartan** in strengths of 5/20 mg, 5/40 mg, 10/20 mg, and 10/40 mg. The most common adverse reaction in clinical trials was edema.

Topical Voltaren: Novartis has received FDA approval for **Voltaren Gel** (diclofenac sodium 1%) to treat joint pain due to osteoarthritis. Dosing is four times daily, using 2 grams for upper extremities or 4 grams for lower extremities (maximum daily dose of 32 grams). A special dosing card will be included to facilitate proper use.

New Warnings on PDE-5 Inhibitors: The FDA is revising warning labels for **Viagra, Levitra, Cialis,** and **Revatio** to include possible sudden hearing loss, sometimes accompanied by tinnitus and/or vertigo. Of the 29 reported cases, only one-third of patients have recovered full function to date. Advise patients to contact their physician immediately upon discovering any of these symptoms.

COUGH AND COLD RECALLS

Wyeth Consumer Healthcare has recalled six products in their **Robitussin** line of cough and cold liquids. The recall is not due to product safety, but rather because the dosage cups do not include a half-teaspoon mark, which is the appropriate dose for children aged 2 to 6 years. The affected products are **Robitussin PE, CF, DM, Sugar-Free DM, Chest Congestion,** and **Cough and Congestion**. Added to the recent voluntary recall of infant cough and cold medicine (see complete list in Table 1), this will make for some pretty bare shelves during cold and flu season this year. When counseling parents on treating their children under 2 years of age for colds, we suggest the recommendations of the American Academy of Pediatrics:

***Fluids to prevent dehydration**
***Acetaminophen of ibuprofen for fever**
***Saline nose drops with suction for congestion**
***Cool-mist humidifier in the child's room**

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Medicare Part "D"

As the Medicare Part D enrollment period nears, it is important to note the categories of drugs which can be billed *directly* to Medicaid for dual-eligible recipients:

Benzodiazepines
Barbiturates
Covered OTC drugs
Covered prescription vitamins

In addition, Medicaid provides, under certain circumstances, "wrap-around" coverage for 4 categories of drugs:

Atypical Antipsychotics
Antidepressants
Antiretrovirals
Anti-Rejection Drugs

In the case of these drug classes, Medicaid may be billed for dual-eligibles only after every attempt has been made to verify Part D coverage and the recipient is still unable to obtain the medication through their Medicare plan.

Profession Codes

In order to bill Medicaid for prescription services using a practitioner's license number, a 3 digit profession code prefix* is required. Below are the codes for the most commonly seen practitioners:

Physicians	**060**
Dentists	**050**
Physician Assistants	**023**
Nurse Midwife	**028**
Optometrist	**056**
Podiatrist	**065**
Nurse Practitioner**	

* Insert '00' between prefix and license number ('0F' for Nurse Practitioners and Nurse Midwives)

** For Nurse Practitioners, the 3 digit code consists of a leading zero plus the first two digits of their license number (i.e., 030 to 045)

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

News from the Seminar on Pharmacy Law

The 25th Annual Seminar on Pharmacy Laws and Regulations, sponsored by the Arnold and Marie Schwartz College of Pharmacy, was held in New York on November 4th. Speakers included **Susan Ksiazek** and **John Carlo**, Chair and Vice-Chair of the N.Y. State Board of Pharmacy, and **Mark Haskins**, Senior Investigator for the Bureau of Narcotic Enforcement, N.Y. State Department of Health. The panelists discussed two bills, recently signed into law, of interest to pharmacists. The first, which amends section 3703 of the Public Health Law, **authorized Registered Physician Assistants (RPAs) to prescribe Schedule II drug for outpatients**. This change takes effect on December 13, 2007. As with prescriptions for C-III, IV, and V drugs, ***RPAs must use their own DEA numbers*** on these Rxs. A second new regulation, which became effective on August 1, 2007, amends section 6827 (b) of the education law to eliminate the exemption from mandatory continuing education (CE) requirements during the first triennial registration period after initial licensing of pharmacists. **All pharmacists licensed on or after 8/1/07 are now required to fulfill the mandatory CE requirements of 45 credits per 3 year registration period**. (At least 23 credits must be live and 3 credits on Medication Error Reduction are required).

Clarification of the "7 Day Rule"

Section 80.69 (h) of Part 80 (Rules and Regulations on Controlled Substances) states:

> ***"Unless an earlier refilling is authorized by the prescriber, no prescription shall be refilled earlier than seven days prior to the date the previously dispensed supply would be exhausted if used in conformity with the directions for use."***

Over the years there has been some confusion as to the exact interpretation of this regulation. In a recent discussion with the Bureau of Narcotics, **P.R.N.** has confirmed the following: **the 7 day rule applies for the *life of the drug,* not simply to each individual refill or even to each individual prescription**. That means, for example, if the first refill of a controlled substance prescription is filled 7 days early, *no subsequent refills can be filled early at all*. This also applies to new prescriptions filled for the same drug, strength, and directions for that same patient (this piece was also confirmed by Mark Haskins of the Bureau at the seminar mentioned above). Any combination of early refills which add up to 7 days (e.g., refill #1— 5 days early, refill # 2 — 2 days early) exhausts the "grace period" and disallows any future early fills. If, however, a subsequent fill or refill is filled 7 days *late,* then the clock is reset to zero and a refill up to 7 days early would be allowed.

Physician's Signature

A recent update distributed by the New York State Department of Health discusses the requirements related to the physician's signature on prescriptions. The following is excerpted from the Summer, 2007 Practitioner Update:

All written prescriptions— for both controlled and non-controlled substances— are required to contain the *handwritten signature* of the prescribing practitioner. Prescriptions containing a stamped or computer-generated practitioner's signature do not meet the requirement and are not valid for dispensing.

Feature Article...

COLD AND FLU SEASON

Fall's arrival signals the beginning of the cold and flu season, and although both maladies are viral in nature, they differ greatly in terms of incidence, severity, and mortality.

The Common Cold is caused by any one of over 200 viruses, most often by one of the 100 serotypes of Rhinoviruses. According to some estimates, Americans suffer up to 1 billion colds per year. The average adult catches 2 to 4 colds each year, while children have between 6 and 10. Preventive measures include hand washing and use of disinfectants on contaminated surfaces. Treatment is symptomatic and consists of acetaminophen or ibuprofen for aches and pains, decongestants for stuffy nose, first-generation antihistamines for rhinorrhea (second-generation agents are not as effective for colds), and cough suppressants. Single-agent products are preferred as they minimize adverse effects and reduce the possibility of therapeutic duplication and overdose. As always, it is important to ascertain any existing medical conditions which may be aggravated by OTCs before recommending their use (see OTC Focus, below). Echinacea use has become popular as a cold remedy, but the research is mixed as to efficacy (see Natural Products, page 4).

The Flu is caused by one of three influenza viruses, designated A, B, and C. The yearly outbreaks seen in the U.S. are due to either A or B; type A generally causes more severe illness and is responsible for the worldwide pandemics that occasionally strike. Between 5 and 20 percent of Americans contract the flu each year, leading to, on average, 200,000 hospitalizations and 36,000 deaths. When combined with pneumonia, a possible complication of the flu, it represents the 7th leading cause of death in the U.S. Prevention consists of the yearly vaccine (usually a combination of A and B strains), as well as the neuraminidase inhibitors Tamiflu (oseltamivir) and Relenza (zanamivir), which are active against both influenza A and B. These agents are also used to treat influenza (prophylactic dose is QD x 10 days, treatment dose is BID x 5 days). It is important to note that the Centers for Disease Control no longer supports the use of amantadine or rimantadine for prevention or treatment of influenza due to high levels or resistance.

The chart below was adapted from one published by the National Institute of Allergy and Infectious Disease. More info at **www.niaid.nih.gov**

Symptoms	Cold	Flu
Fever	Rare	Characteristic; high (102-104°F); lasts 3-4 days
Headache	Rare	Prominent
General Aches, Pains	Slight	Usual; often severe
Fatigue, Weakness	Sometimes	Usual; can last up to 2-3 weeks
Extreme Exhaustion	Never	Early and prominent
Stuffy Nose	Common	Sometimes
Sneezing	Usual	Sometimes
Sore Throat	Common	Sometimes
Chest Discomfort, Cough	Mild to moderate Hacking cough	Common; can become severe
Prevention	Hand washing, avoid close contact with anyone with a cold	Annual vaccination; Tamiflu® (oseltamivir) Relenza® (zanamivir)
Treatment	Antihistamines Decongestants APAP/NSAIDs	Tamiflu® (oseltamivir) Relenza® (zanamivir)
Complications	Sinus congestion Middle ear infection Asthma	Bronchitis, pneumonia; can be life-threatening

OTC FOCUS

Contraindications for use of over-the-counter cold and flu remedies:

DECONGESTANTS:
Consult a physician before use if you have:

- **Heart Disease**
- **Hypertension**
- **Thyroid Disease**
- **Diabetes**
- **Trouble urinating due to an enlarged prostate**

ANTIHISTAMINES
Consult a physician before use if you have:

- **Glaucoma**
- **A breathing problem such as emphysema or chronic bronchitis**
- **Trouble urinating due to an enlarged prostate**

P.R.N.

P.R.N. is published monthly by
Pharmacy Associates, L.L.C.
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.

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)……..$50.00

Payable by check or money order
Please write to:

askprn@gmail.com

NATURAL PRODUCTS: ECHINACEA

Uses/claimed benefits: Echinacea is believed to be an immunostimulant, capable of either preventing colds or shortening their duration, or both.

Evidence: Thus far, the results are conflicting. A major study reported in the New England Journal of Medicine in 2005 showed the herb ineffective in either preventing or shortening the duration of the common cold. More recently, a meta-analysis published in The Lancet Infectious Disease for July, 2007 showed a significant benefit in both preventing and treating colds. One reason often given for these contradictory results is that different researchers have used different species of echinacea as well as different parts of the plant. The 2005 study was of Echinacea angustofolia, while many of the more positive studies utilized Echinacea purpurea.

Precautions: Serious reactions have occurred in patients allergic to members of the *Asteraceae/Compositae* plant family (ragweed, chrysanthemums, daisies, and marigolds).

Interactions: Echinacea products may interfere with immunosuppressant agents such as **cyclosporine, tacrolimus, sirolimus, azathioprine,** and **corticosteroids,** among others. Echinacea seems to have mixed effects on CYP3A4 isoenzymes and could theoretically affect blood levels of drugs such as **lovastatin, indinavir, clarithromycin, diltiazem,** and many others.

DID YOU KNOW?

DID YOU KNOW that the antifungal agent Nystatin was named after the Empire state? This breakthrough drug was discovered in 1950 by Elizabeth Lee Hazen and Ruth Fuller Brown, both of whom worked for the New York State Department of Health. E.R. Squibb purchased the patent rights and marketed the drug as Mycostatin. The two women donated their royalties to science through the Brown-Hazen Research Fund and decided to name the drug **NY-STAT-in** in honor of the New York State Department of Health.

PHARMACY FUN

A palindrome is a word of phrase that reads the same forward and backward, such as 'civic' or 'Madam I'm Adam.' Can you name 5 prescription drug names that are palindromes?

Hint: all 5 are brand names and 1 was recalled due to QT interval prolongation

P.S., if you can think of more than 5, let us know at askprn@gmail.com

Answers in next month's issue

A Note from the Editor…

Welcome to the first issue of P.R.N., a monthly newsletter for community pharmacists practicing in New York State. The name, of course, is shorthand for "pro re nata," the Latin for "as needed." Why prn? We hope to provide you with quick and convenient access to the latest information from all the fields that impact our profession: the newest drug approvals, changes in law, third party billing, clinical updates, natural products, and OTC news, to name but a few. So we hope you use P.R.N. *as needed*, when you're searching for that piece of information and don't have time to look through the 5 pharmacy magazines, 3 CE booklets, and 2 medical journals piled up on the living room table!

We need to hear from YOU! What did you like or not like about this issue? What do you suggest for future issues? Drop us a note at **askprn@gmail.com**

Thanks!