P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

Volume 3, Number 5 | A Monthly Newsletter for Community Pharmacists | May, 2009

What's Inside…

Rx News……...1

Medicaid Update…….2

Law Review……2

Feature Article:
Allergic Rhinitis: Review of Rx Nasal Sprays…....3

Ask PRN……...…4

Did You Know?..... 4

Pharmacy Fun……4

FDA NEWS

Recent FDA actions include:

Prevacid OTC: Novartis has announced FDA approval of an over-the-counter version of the company's proton pump inhibitor **Prevacid** (lansoprazole delayed-release capsules). *Prevacid 24HR* will be available in 15 mg capsules and is expected to reach pharmacy shelves later this year.

Creon Now FDA-Approved: The FDA announced approval of a new, not yet marketed, formulation of **Creon,** making it the only approved pancreatic enzyme product (PEP). All other PEPs on the market, including the current version of Creon, are unapproved products. The FDA announced in 2004 that PEPs, many of which became available before enactment of federal legislation mandating proof of safety and efficacy, must be submitted for approval within 4 years or be removed from the market. That deadline was later extended to 2009 and Creon represents the first such approval. The new formulation, expected to be available later this year, will contain 6,000, 12,000, or 24,000 units of lipase. The currently marketed product, which will be phased out, contains 5,000, 10,000 or 20,000 units of lipase.

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

Novel Treatment for Diabetes: The FDA has approved VeroScience LLC's **Cycloset** (bromocriptine mesylate) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. The active ingredient in Cycloset has been marketed since 1978 as **Parlodel** for the treatment of hyperprolactinemia, acromegaly, and Parkinson's disease. While the exact mechanism of action in diabetics is not known, it is believed that a once-daily morning dose of Cycloset provides a boost of dopaminergic activity which resets circadian activity in the hypothalamus, resulting in improved post-prandial glucose levels without increasing plasma insulin levels. Cycloset is the first drug approved under new FDA guidelines, published in December, 2008, that require new agents for type 2 diabetes to demonstrate cardiovascular safety. In clinical trials, the most common adverse reactions were nausea, fatigue, dizziness, vomiting and headache. Cycloset can cause orthostatic hypotension and syncope, especially during initiation or dose escalation, and should be used with caution in patients taking antihypertensive medications. Cycloset is contraindicated in patients allergic to ergot-related drugs, in patients with syncopal migraines, and in nursing women. Cycloset will be available in 0.8 mg tablets and the recommended initial dose in 0.8 mg taken within 2 hours after waking in the morning with food. The dosage should be increased by 0.8 mg weekly until reaching the maximal tolerated daily dose of 1.6 to 4.8 mg.[1]

First Triple Therapy for HTN: The FDA has granted approval to Novartis Pharmaceuticals' **Exforge HCT** (amlodipine, valsartan, hydrochlorothiazide), the first product to combine three antihypertensive agents in a single tablet. Exforge HCT combines a dihydropyridine calcium channel blocker (amlodipine), an angiotensin receptor blocker (valsartan), and a thiazide diuretic (hydrochlorothiazide). Exforge HCT is indicated for the treatment of hypertension and may be used as add-on/switch therapy for patients not adequately controlled on any two of the following antihypertensive classes: calcium channel blockers, angiotensin receptor blockers, and diuretics. This combination drug is not indicated for the initial therapy of hypertension. Dosing is once daily, with or without food. Exforge HCT will be available in the following strengths: **5/160/12.5 mg**, **10/160/12.5 mg**, **5/160/25 mg**, **10/160/25 mg**, and **10/320/25 mg**.

New Atypical Antipsychotic Approved: The FDA announced approval of **Fanapt** (iloperidone), a new drug for the treatment of schizophrenia. Fanapt is a mixed dopamine type 2 (D_2)/serotonin type 2 (5-HT_2) receptor antagonist.[2] As with other atypical antipsychotics, Fanapt carries a black box warning regarding increased risk of death associated with use in elderly patients with dementia-related psychosis. The recommended initial dose is 1 mg BID, titrated up by 1 mg per dose per day until reaching the 12 to 24 mg/day dose range. Fanapt will be available in **1, 2, 4 ,6, 8, 10, and 12 mg tablets.**

Healthfirst Easy OTC Plan Anything But Easy, Pharmacists Say

Beginning on April 22, pharmacists in New York began processing over-the-counter purchases through their pharmacy computers for members of the Healthfirst New York Medicare program. The program, known as **Healthfirst Easy OTC**, was unveiled with little fanfare and even less guidance for pharmacists, who have complained of vague coverage categories and a lack of specific information, leading to confusion among both providers and patients. After speaking with representatives of both Healthfirst New York and the program processor, Express Scripts, we have compiled the following list of key points for pharmacists participating in the program:

"Dual-Purpose" OTC Items Which Require A Prescription For Easy OTC Program

Acne Medications

Acne Treatment

Blood Pressure Monitors

Diagnostic Products

Multivitamins and Multivitamins with Minerals

Urine Testing

- **Process purchases with a "dummy" prescriber utilizing the pharmacy's DEA number.**
- **Prescriptions *are required* for so-called "dual-purpose" OTC items (see complete list at left).**
- **According to the program's processor, Express Scripts, insurance log signatures are *not required*.**
- **The current list of covered categories, as well as a paper claim reimbursement form for patients who forget their card, is available at: *www.healthfirstny.org***

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Change to Post and Clear System

Certain prescribers in New York State are required by the Medicaid Program to "post" all their orders for prescriptions, fiscal orders, and medical-surgical supplies. Posting entails entering the patients Medicaid ID number and sequence number, as well as the number of prescriptions issued, into the Medicaid system either through their terminal or via ePACES. Effective **June 1, 2009**, these prescribers must also enter the number of *orders* for each prescription (original plus the number of refills). Currently, if a pharmacist attempts to fill a new prescription from a posting provider that has not been posted, a two-letter rejection code containing a **D** in the *second position*, such as **AD or DD,** appears and the prescriber must be contacted to post the prescription. After June 1, pharmacists *refilling* prescriptions posted after that date may see rejections if the prescriber failed to include the number of refills in the posting. The rejection will read **edit 00746 "No Service Authorization on File."** A complete list of prescribers required to post can be found at:

www.emedny.org/info/posting.html

Serial Number Requirement

The Bureau of Pharmacy Policy and Operations for the New York State Medicaid Program has clarified an issue regarding the use of Official New York State Prescription serial numbers on refills of certain prescriptions. When billing Medicaid for a refill of a prescription that was originally billed only to a third party that *did not* require the serial number, pharmacies *must include the original serial number from the hard copy or fax prescription*. In this case, the use of any of the serial number override codes is not permitted. Pharmacists must retrieve the serial number from the original prescription and submit it when billing Medicaid.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Four New Proposed Rules Regarding Pharmacy Practice and Licensure

The New York State Department of Education has published the text of four proposed rules in the May 6, 2009 edition of the State Register. The rules, concerning maintenance of electronic records by pharmacists and licensure requirements for pharmacists, are subject to a 45-day public comment period. If adopted, the rules become effective August 20, 2009.

Maintenance of Electronic Records by Pharmacists

Section 29.7(a)(2) of the Regents Rules on unprofessional conduct would be amended to read (changes in italics):

Failure by a pharmacist to reduce to writing, *either through written communication or electronic record*, a prescription transmitted orally, which writing *or electronic record* shall include all the information required by paragraph (1) of this subdivision and the signature, *or the electronic equivalent of a signature*, or readily identifiable initials of the receiver of the oral prescription….

Section 29.7(a)(8)(v) would be amended to read:

For all refills of a prescription, the records introduced into the system shall be sufficient if:

(a)…

(b) a printout *or electronic record* is produced of all prescriptions filled and refilled each day and the pharmacist(s) whose initials appear(s) on the printout sign(s), *either manually or electronically*, the printout *or electronic record* to indicate that it is [a] *an* accurate record.

Section 63.6(a)(7)(ii) of the Regulations of the Commissioner of Education regarding electronically transmitted prescriptions would be amended to read:

(c) a permanent hard copy of an electronically transmitted prescription *or a copy of an electronically transmitted prescription stored securely and permanently by electronic means* shall be produced and maintained at the pharmacy for a period of five years from the date of the most recent filling.

Licensure Requirements for Pharmacists

Amendment of section 63.3(b) of the Regulations of the Commissioner of Education would allow for an alternative to Part III of the state licensure examination, also known as prescription compounding and pharmacy practice. In lieu of sitting for the exam, the department may accept certification that the applicant has achieved competency in the following areas as part of an approved residency program in pharmacy practice:

sterile product preparation and technique

non-sterile compounding preparation and technique

dosing calculations (including aliquot, proportions, and drip-rates)

medication safety procedures (including look–alike and sound-alike drugs and other medication error prevention techniques)

drug distribution (including preparing, dispensing, and verifying the accuracy of filled prescriptions and medication orders)

such other competencies as may be required by the department

(ii) Such certification shall be on a form prescribed by the commissioner and shall be completed by the residency program director who supervised the applicant's performance in such residency program, attesting that the applicant has successfully achieved such competencies and that in the supervisor's judgment the applicant is competent to practice pharmacy.

Feature Article..

ALLERGIC RHINITIS: REVIEW OF PRESCRIPTION NASAL SPRAYS

Millions Of Americans suffer with allergic rhinitis every year. According to the American Academy of Allergy, Asthma, and Immunology, between 10 and 30% of adults and as many as 40% of children are affected, leading to more than 12 million office visits yearly. Although there are many treatments available for allergic rhinitis, recent research has shown nasal sprays, specifically corticosteroids, to be the most effective therapy. Below is a review of available products.

Steroid Nasal Sprays

Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Beconase AQ (beclomethasone 42 mcg/spray)	No	6-12 yo: 1 to 2 sprays in each nostril BID	1 to 2 sprays in each nostril BID	Shake well before use
Flonase (fluticasone propionate 50 mcg/spray)	Yes	4-12 yo: 1 to 2 sprays in each nostril QD	2 sprays in each nostril QD	Shake gently before use
Nasacort AQ (triamcinolone 55 mcg/spray)	No	2-5 yo: 1 spray in each nostril QD 6-12 yo: 1 to 2 sprays in each nostril QD	1 to 2 sprays in each nostril QD	Shake before use
Nasarel (flunisolide 29 mcg/spray)	Yes	6-14 yo: 2 sprays in each nostril BID *or* 1 spray TID	2 sprays in each nostril 2 to 3 times a day	Does not need shaking
Nasonex (mometasone 50 mcg/spray)	No	2-12 yo: 1 spray in each nostril QD	2 sprays in each nostril QD	Shake well before use
Omnaris (ciclesonide 50 mcg/spray)	No	≥6 yo: 2 sprays in each nostril QD	2 sprays in each nostril QD	Shake gently before use
Rhinocort Aqua (budesonide 32 mcg/spray)	No	6-12 yo: 1 to 2 sprays in each nostril QD	1 to 4 sprays in each nostril QD	Shake gently before use
Veramyst (fluticasone furoate 27.5 mcg/spray)	No	2-11 yo: 1 spray in each nostril QD	2 sprays in each nostril QD	Shake well before use

Antihistamine Nasal Sprays

Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Astelin (azelastine 137 mcg/spray)	No	5-11 yo: 1 spray in each nostril BID	1 to 2 sprays in each nostril BID	May cause drowsiness
Astepro (azelastine 137 mcg/spray)	No	≥12 yo: 1 to 2 sprays in each nostril BID	1 to 2 sprays in each nostril BID	May cause drowsiness
Patanase (olopatadine 665 mcg/spray)	No	≥12 yo: 2 sprays in each nostril BID	2 sprays in each nostril BID	May cause drowsiness

Anticholinergic Nasal Sprays

Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Atrovent Nasal (ipratropium 0.03%)	Yes	***Perennial allergic or non-allergic rhinitis*:** ≥6 yo: 2 sprays in each nostril 2 to 3 times a day	***Perennial allergic or non-allergic rhinitis*:** 2 sprays in each nostril 2 to 3 times a day	May cause nasal dryness
Atrovent Nasal (ipratropium 0.06%)	Yes	***Seasonal allergic rhinitis*:** ≥5 yo: 2 sprays in each nostril 4 times a day	***Seasonal allergic rhinitis*:** 2 sprays in each nostril 4 times a day	May cause nasal dryness
		***Common cold*:** 5-11 yo: 2 sprays in each nostril 3 times a day	***Common cold*:** 2 sprays in each nostril 3 to 4 times a day	May cause nasal dryness

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...

As a pharmacist, am I required to send records of continuing education (CE) programs I have completed to the state board?

No. But such records must be available for inspection by the Education Department upon request. For every three-year registration period, a minimum of 45 hours of CE are required, the majority of which (23 or more) must be live courses. At least 3 hours (written or live) must involve strategies and techniques to reduce medication and prescription errors. Records of completed CEs must be kept for six years from the date completed and must include the following 5 items of information:

1. Course title and ID number
2. Number of hours completed
3. Sponsor's name and ID number
4. Verification by sponsor of attendance or completion
5. Date and location of the course

What's the difference between Astelin Nasal Spray and Astepro Nasal Spray? Both contain azelastine 137 mcg.

Meda Pharmaceuticals introduced Astepro, a reformulation of their existing product, Astelin, in January, 2009. As many as 20% of Astelin users had complained of an unpleasant or bitter taste. Meda reformulated the product, adding sucralose and sorbitol to improve taste and increase tolerability. Another possible reason for the change is the fact that a generic version of Astelin has been approved by the FDA. Introduction of Astepro will allow the company to retain some of the market share that would otherwise be lost when the generic hits the market. It should be noted that while Astelin is indicated for patients 5 years of age and older, Astepro is not yet approved for use in children.

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 a young Ohio artist's failure to find a job in his field eventually led to relief of suffering for millions of people with allergies around the world? George Rieveschl graduated from the Ohio Mechanics Institute of Technology in 1933 and set out to find work as a commercial artist.[3] After failing to secure a position, despite more than 200 job applications, George enrolled at the University of Cincinnati to study chemistry. While researching muscle-relaxing drugs, he synthesized a compound which he realized could have a completely different application. He took the drug to Parke-Davis for testing, and it went on sale by prescription in May of 1946. The chemical George Rieveschl had synthesized was diphenhydramine, later known as Benadryl.

PHARMACY FUN

The month of May is distinctive for any number of reasons: Mother's Day, Memorial Day, May Day, Cinco de Mayo, the Kentucky Derby, the Indy 500. It also happens to be the only 3-letter month, all the rest have 4 or more. A number of prescription drugs also have 3-letter (or number) names, or more correctly, acronyms. How many can you identify? The first reader to submit all the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. AZT	**4. 3TC**	**7. ADH**
2. BAL	**5. CPZ**	**8. d4T**
3. tPA	**6. THC**	**9. BCG**

Answers to last month's **PHARMACY FUN**:
1. Plavix 75 mg 2. Lipitor 10 mg 3. Diovan 80 mg 4. Lexapro 20 mg 5. Zyprexa 5 mg 6. Cozaar 50 mg 7. Avelox 400 mg 8. Zetia 10 mg

References:
1. Cycloset [package insert]. Tiverton, RI: VeroScience LLC; April, 2009
2. Fanapt [package insert]. Rockville, MD: Vanda Pharmaceuticals, Inc.; May, 2009.
3. Dennis Hevesi, "George Rieveschl; scientist who invented Benadryl; 91," *New York Times News Service*, October 3, 2007.