FIRST ANNIVERSARY ISSUE

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What's Inside…

FDA NEWS

Recent FDA actions and approvals include:

Vimpat (lacosamide) is approved as adjunctive therapy for partial-onset seizures in patients ≥17 years old. Vimpat is a functionalized amino acid which enhances slow inactivation of voltage-gated sodium channels. It will be available in 50, 100, 150, and 200 mg tablets. The recommended initial dose is 50 mg twice a day.

LoSeasonique is a new lower dose formulation of the oral contraceptive **Seasonique**, which is taken for 91 consecutive days, reducing the number of menstrual periods to 4 per year. The new product contains 0.02 mg of ethinyl estradiol and 0.10 mg of levonorgestrel per tablet.

Astepro is a reformulation of **Astelin** (azelastine) nasal spray, approved for treatment of seasonal allergic rhinitis. According to the manufacturer, Meda, a study involving 1400 patients showed that Astepro was better tolerated than Astelin, with fewer reports of bitter taste and nasal discomfort.

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

Pediatric Cough/Cold Label Change: Following last month's FDA hearing on the safety and efficacy of pediatric cough and cold products (see October's ***PRN***), the Consumer Healthcare Products Association (CHPA) announced a voluntary relabeling of over-the-counter children's cold medicines. The CHPA, a trade group representing OTC drug makers, took a similar action last October, withdrawing infant cough and cold drops from the market shortly after an FDA panel urged the agency to ban all cold medicines for children under 6 years old. All major children's cough and cold products will be relabeled with the following statement:

Do Not Use In Children Under 4 Years Of Age

In addition, products containing certain antihistamines will contain the statement:

Do Not Use This Product To Sedate Or Make A Child Sleepy

Combination products containing first generation antihistamines (diphenhydramine, chlorpheniramine, etc.) will continue to be labeled with dosages for children 6 years and older only. Manufacturers also promised to provide dosing devices with all liquid pediatric medications, and have expanded their national education program, aimed at parents, caregivers, and healthcare professionals. Some key points to stress when counseling on pediatric OTCs include:

- **Always use a calibrated dosing device, *not* household teaspoons, and follow dosing recommendations exactly**
- **Read all product labels to prevent duplication of ingredients, such as acetaminophen, which could lead to unintentional overdose**
- **Keep all medicines out of the reach and sight of children**

The following product lines will be relabeled:

Children's Benadryl-D	**Delsym Children's**
Children's Dimetapp	**Pediacare**
Children's Mucinex	**Robitussin Pediatric**
Children's Sudafed	**Triaminic**
Children's Tylenol Plus	**Vicks Pediatric 44**
Children's Nyquil	**Vicks Casero**

New BPH Treatment: Watson Pharmaceuticals has been granted FDA approval to market **Rapaflo** (silodosin) for the treatment of benign prostatic hyperplasia (BPH). Rapaflo is a new alpha1A-adrenoreceptor-selective antagonist. Approximately 75% of the alpha receptors in the prostate are of the alpha1A subtype. The most common adverse effect seen in clinical trials was retrograde ejaculation. Other adverse effects included dizziness, light-headedness, diarrhea, and orthostatic hypotension. Rapaflo will be available in 4 mg and 8 mg capsules. The recommended adult dose is 8 mg once daily. In patients with moderate renal impairment, the recommended dose is 4 mg once daily. Rapaflo should not be used in men with severe renal or hepatic impairment.

New Pediatric Vitamin D Guidelines: The American Academy of Pediatrics (AAP) has doubled the amount of Vitamin D it recommends for infants, children, and adolescents. The new AAP guidelines are summarized below:

- **Breastfed and partially breastfed infants should receive 400 IU of Vitamin D daily, beginning in the first few days of life**
- **All non-breastfed infants, as well as older children, who consume less than 1 quart of Vitamin D-fortified formula or milk, should also receive 400 IU daily**
- **Adolescents who do not obtain 400 IU of Vitamin D through dietary sources should receive a 400 IU supplement**
- **Children with increased risk of Vitamin D deficiency, such as those taking certain mediations, may need higher doses of Vitamin D**

The revisions were prompted, in part, by continuing reports in the U.S. of rickets, a softening of bone caused by Vitamin D deficiency. Rickets can lead to impaired growth, increased fractures, and skeletal deformities such as bowed legs and abnormal curvature of the spine. Those at greatest risk for developing rickets are exclusively breastfed infants who are not supplemented with 400 IU of Vitamin D daily. The AAP also cited their review of new clinical trials on Vitamin D and the historical precedence of the safety of giving 400 IU daily to the pediatric population.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Mandatory Generic Drug Program Update

A number of drugs have been added to the New York State Medicaid Mandatory Generic Drug Program. Effective November 1, 2008, new prescriptions for the following drugs will require prior authorization:

Anestacon 2% Jel
Beta-Val 0.1% Cream
Brevicon 28 Tablet
Climara 0.0375 & 0.06 mg Patch
Emla Cream
Jolivette Tablet
Mononessa 28 Tablet
Naprelan 500 mg Tablet
Necon 7-7-7 28 Tablet
Nora-Be Tablet
Nor-QD Tablet
Omnipred 1% Eye Drops
Serophene 50 mg Tablet
Solia Tablet
SSD 1% Cream
Trinessa Tablet

Prescriptions, and refills of prescriptions, written before November 1, 2008 will not require prior authorization. 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:*

Clozaril	**L-Thyroxine Brands**
Coumadin	**Neoral**
Dilantin	**Sandimmune**
Gengraf	**Tegretol**
Lanoxin	**Zarontin**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

News from the 26th Annual Seminar on Pharmacy Laws and Regulations

The annual seminar on pharmacy law, sponsored by the Arnold and Marie Schwartz College of Pharmacy, was held on October 19th in East Elmhurst, New York. As usual, the most informative presentation was that given by speakers from the Board of Pharmacy, this year represented by board members Daniel J. Villa, RPh, and Daniel Molina, RPh. Some of the topics they discussed are summarized below.

Immunization by Pharmacists

As reported in the October issue of ***PRN***, the Pharmacist Vaccination Bill was signed into law by the governor on Sept. 5th. The specific regulations are expected to be finalized on November 18th and the proposed effective date is December 4th, 2008. Under this law, pharmacists will be able to administer influenza and pneumococcal vaccines to adults pursuant to a patient-specific order, or a non patient-specific order from a physician or nurse practitioner (RPAs are currently excluded from issuing such an order). The program is voluntary. Pharmacists wishing to provide immunizations must first become certified by completing a specified course of training and paying a $100 fee, which is renewable every 3 years. In addition, applicants must compete CPR/BLS training and receive the hepatitis B vaccine for self-protection.

Early Admission to the Compounding Exam (Part III)

In an effort to streamline the licensure process and encourage voluntary internships, the Board of Pharmacy will allow 6th year pharmacy students to take Part III of the New York State licensing exam *before* graduation. In order to sit for the January, 2009 compounding exam, students must be certified as being enrolled in their final year of study and must submit proof of completion of 1000 hours of independent internship practice (NOT required rotations). The deadline for application was November 1 , 2008. To see a FAQ sheet prepared by the Board of Pharmacy, go to our website at: ***www.prnnewsletter.com***.

Drug Disposal Sign Must be Posted in Pharmacy

The Drug Management and Disposal Act was signed into law on September 25th, 2008 and will take effect in March, 2009. The act requires all registered pharmacies in New York State to conspicuously display a sign containing information on the proper storage and disposal of drugs. The specific content and size of the required notice has yet to be announced. Proper disposal of drugs has become an environmental issue in recent years as a result of studies which found trace amounts of numerous prescription drugs in the nation's water supply. In 2007, the White House Office of National Drug Control Policy, in collaboration with the FDA, issued guidelines for the proper disposal of prescription drugs. The federal guidance suggests:

- **Remove unneeded or expired prescription drugs from their original containers and throw them in the trash**
- **Before discarding, mix prescription drugs (crush solid dosage forms first) with an undesirable substance, such as used coffee grounds or kitty litter, and place in impermeable, nondescript containers such as empty cans or sealable bags**
- **Flush prescription drugs down the toilet *only* if the accompanying patient information instructs doing so**

The FDA advises that the following drugs *should* be flushed down the toilet instead of thrown in the trash:

Actiq	**Daytrana**	**Meperidine**	**Reyataz**
Avinza	**Duragesic**	**Oxycontin**	**Xyrem**
Baraclude	**Fentora**	**Percocet**	**Zerit Solution**

Feature Article..

DIABETES REVIEW: DIAGNOSIS, TREATMENT, AND BLOOD GLUCOSE MONITORING

November is American Diabetes Month. According to the American Diabetes Association, 23.6 million Americans are diabetic, and, of those, almost 6 million are undiagnosed. Fortunately, a number of new and innovative treatments have been introduced in recent years, and several more are in the pipeline (see "New Treatments," below). Pharmacists are a key source of information for diabetic patients; one important example of this is in helping select and properly use a blood glucose monitor. Our up-to-date glucometer comparison chart incorporates all the recent changes and upgrades to the leading brand-name models.

Diagnosis and Screening

The current criteria for diagnosing diabetes mellitus, issued by the American Diabetes Association, are as follows:

1. Symptoms of diabetes (polyuria, polydipsia, etc.) and a random plasma glucose ≥ 200mg/dL

or

2. A fasting plasma glucose ≥ 126 mg/dL

or

3. A 2-hr plasma glucose ≥ 200 mg/dL during an oral glucose tolerance test (OGTT)

Two recent articles[1,2] disagree as to the usefulness of **HbA_{1c}** as a *screening* tool for diabetes, but it is well established as a measure of average blood glucose levels over the preceding two months:

HbA_{1c} %	Average Plasma Glucose (mg/dL)	Evaluation
4 to 5.9	50 to 117	Normal
6 to 8	120 to 180	Diabetic—Controlled
9 to 11	210 to 280	Diabetic—Action Suggested
12 to 14	300 to 380	Diabetic—Action Necessary

New Treatments

Recent innovations in the pharmacologic treatment of diabetes include incretin and amylin mimetics (**Byetta** and **Symlin**), and dipeptidyl peptidase IV (DDP-IV) inhibitors (**Januvia**). Some of the latest therapies working toward FDA approval include:

New DDP-IV Inhibitors: Alogliptin and Vildagliptin (**Galvus**) are being considered for the treatment of Type 2 diabetes.

New Incretin Mimetics: Liraglutide is a once-daily injectable glucagon-like peptide (GLP-1) analog. An oral GLP-1 analog, ORMD 0901, is also under development.

Oral Insulin: Generex's **Oral-Lyn** is an oral spray formulation of insulin, currently in Phase III clinical trials in the U.S., Canada, and Europe.

Non-TZD PPAR: INT131 is a non-thiazolidinedione selective peroxisome proliferator-activated receptor modulator which may cause less fluid retention and weight gain than TZD PPARs **Actos** and **Avandia**. INT131 is currently in Phase II clinical trials for Type 2 diabetes.

Blood Glucose Meter Comparison Chart

Meter *website address*	Manufacturer Information	Sample Size	Coding Required?	Memory Capacity	Special Features
ACCU-CHEK® Aviva *www.accu-chek.com*	Roche Diagnostics 800-858-8072	0.6 microliter	YES	500 readings	Wide-mouth strips quickly absorbs blood drop. Muliticlix preloaded 6-lancet drum saves time and the need to handle lancets.
ACCU-CHEK® Compact Plus *www.accu-chek.com*	Roche Diagnostics 800-858-8072	1.5 microliter	NO	500 readings	Drum containing 17 preloaded test strips reduces strip handling. Comes with detachable Softclix Plus lancing device.
BREEZE®2 *www.bayerdiabetes.com*	Bayer Diabetes Care 800-348-8100	1.0 microliter	NO	420 readings	Easy-to-load BREEZE 2 discs each contain 10 preloaded test strips for easy handling and less chance of dropping or losing strips.
CONTOUR® *www.bayerdiabetes.com*	Bayer Diabetes Care 800-348-8100	0.6 microliter	NO	480 readings	Offers two levels of testing— basic and advanced modes. Available in 4 different colors: purple, blue, green, and grey.
FreeStyle *Lite*™ & Freedom *Lite*™ *www.abbottdiabetescare.com*	Abbott Diabetes Care 888-522-5226	0.3 microliter	NO	400 readings	60-second reapplication time designed to reduce extra finger sticks and wasted strips. Freedom model has larger numeric display.
Nova Max® *www.novacares.com*	Nova Biomedical 800-681-7390	0.3 microliter	NO	400 readings	Nova Max test strips can also be used with the BD Logic® and Paradigm Link® monitors.
OneTouch®UltraMini® *www.lifescan.com*	LifeScan 800-227-8862	1.0 microliter	YES	500 readings	Smallest meter available. Comes in 6 different colors: Purple Twilight, Blue Comet, Limelight, Pink Glow, Silver Moon, and Jet Black.
OneTouch®Ultra2® *www.lifescan.com*	LifeScan 800-227-8862	1.0 microliter	YES	500 readings	Features two scrolling buttons and an optional backlight for ease in operation and reading of meter.
OneTouch®UltraSmart® *www.lifescan.com*	LifeScan 800-227-8862	1.0 microliter	YES	3000 readings	Most memory of any meter. Automatically converts results into easy-to-use charts and graphs, making it possible to see patterns and trends.

Note: All models listed above are approved for alternate site testing, deliver results in an average of 5 seconds, and are PC compatible.

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NATURAL PRODUCTS: CHROMIUM PICOLINATE

Uses/claimed benefits: Chromium picolinate has been used to lower blood glucose, insulin resistance, and HbA_{1c} in diabetics, to increase lean body mass, promote weight loss, and lower cholesterol and triglyceride levels.

Evidence: Chromium picolinate is a stable complex of trivalent chromium and picolinic acid, available in strengths ranging from 200 to 1000 mcg per tablet. While results have been inconsistent, a number of studies indicate that chromium may decrease fasting plasma glucose, insulin resistance, and HbA_{1c}. Two recent studies of a proprietary combination of 600 mcg Chromium and 2 mg Biotin (Diachrome®) demonstrated improved glycemic control in overweight patients and those poorly controlled on oral antidiabetic medications[3,4]. Neither study, however, proved that the combination product was any more effective than chromium alone. Overall, study results for other possible uses of chromium (weight loss, increased muscle mass, etc.) have been inconclusive.

Precautions: Long-term use of high doses of chromium has been associated with renal and hepatic toxicity. Do not use in pregnancy without medical supervision

Interactions: Antacids, **H-2 blockers**, and **Proton Pump Inhibitors** may decrease chromium absorption. **NSAIDs** may increase chromium absorption. Chromium may enhance the therapeutic effects of **Insulin**.

DID YOU KNOW?

DID YOU KNOW that NPH insulin was named after Hans Christian Hagedorn, co-founder of Nordisk, one of the world's first producers of insulin products? NPH stands for *Neutral Protamine Hagedorn*, which describes the process of adding a cationic peptide to regular insulin in order to prolong its duration of action. Incidentally, Nordisk's greatest competitor, Novo, was formed by Nordisk employee Harald Pederson after Hagedorn fired his brother! The two companies merged in 1989, becoming Novo Nordisk; their logo (pictured right) is the Apis bull, an ancient Egyptian deity said to represent the god Ptah (later linked to Osiris). As in the logo, the Apis bull was often pictured with the sun-disk between its horns.

PHARMACY FUN

Election season is upon us, and it's a season replete with initials and acronyms, whether you're a (D) democrat or (R) republican (or would you prefer GOP?), whether your main concern is GDP or the S&P. Pharmacy, too, has its share of abbreviations, symbols, and acronyms, which, though frowned upon by safety experts, still persist today. How many of the following drugs can you name? The first reader to submit all the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. APAP	**6. 5-FU**	**11. NSS**
2. ASA	**7. INH**	**12. SPS**
3. 5-ASA	**8. MOPP**	**13. SSKI**
4. CHOP	**9. 6-MP**	**14. TAO**
5. CBZ	**10. MTX**	**15. TCN**

Answers to last month's **PHARMACY FUN**:
1. Vancomycin (van + comb + ice + n) 2. Levofloxacin (leaf + o + flock + saws + n)
3. Kanamycin (can + a + mice + n)

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4. Albarracin C A, et al. Chromium picolinate and biotin combination improves glucose metabolism in treated, uncontrolled overweight to obese patients with type 2 diabetes. *Diabetes Metab Res Rev*. 2008 Jan-Feb;24(1):41-51.