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.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

New Combo for HTN: The FDA has approved a new antihypertensive combination product, **Valturna** (aliskiren/valsartan), by Novartis Pharmaceuticals. Valturna combines the direct renin inhibitor aliskiren (**Tekturna**) with the angiotensin II receptor blocker valsartan (**Diovan**). Valturna is indicated for the treatment of hypertension in people not adequately controlled with monotherapy, and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. In clinical trials, the most common adverse effects were fatigue and nasopharyngitis. Valturna has been assigned pregnancy category D and should be avoided in pregnant and breastfeeding women. Rarely, head and neck angioedema has been seen in patients taking aliskiren; Valturna should be discontinued if angioedema occurs. Hyperkalemia has occurred in patients taking Valturna. Since aliskiren may interact with cyclosporine, concomitant use with Valturna is not recommended. Potassium sparing diuretics, potassium supplements, or salt substitutes may lead to increases in serum potassium in patients taking Valturna. The initial dose of Valturna is one 150/160 mg tablet daily, which may be titrated up to a maximum of one 300/320 mg tablet daily if needed. Valturna should be taken with a routine pattern as regard to meals, either always with food or always on an empty stomach. Valturna will be available in tablets of 150 mg aliskiren/160 mg valsartan and 300 mg aliskiren/320 mg valsartan.

New Ophthalmic: ISTA Pharmaceuticals has received FDA approval to market **Bepreve** (bepotastine) ophthalmic solution for the treatment of allergic conjunctivitis. Bepreve is a direct H₁-receptor antagonist and an inhibitor of the release of histamine from mast cells. The most common adverse effect reported in clinical trials was a mild taste following instillation. Other adverse reactions included eye irritation, headache, and nasopharyngitis. To minimize contamination, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Patients should be advised not to wear contact lenses if their eyes are red and Bepreve should not be used to treat contact lens-related irritation. The recommended dose of Bepreve is one drop into the affected eye(s) twice a day. Patients should be advised to remove contact lenses prior to instillation of Bepreve. Lenses may be reinserted after 10 minutes following administration of Bepreve.

NYC H1N1 Program Begins: New York City officials announced plans to begin a program to offer free H1N1 vaccinations to all schoolchildren in the city. Phase I, which covers elementary schools with fewer than 400 students, is set to start on October 28. Phase II, covering elementary schools with more than 600 students, is scheduled to begin on November 4. The city also plans to hold free public vaccination programs on weekends for middle and high school students. For more information, visit www.nyc.gov/flu.

BREAKING NEWS

Mandatory Vaccination Rule Suspended

On October 22, New York State Governor David Paterson announced the suspension of a new state regulation mandating influenza vaccination for all health care workers. The Governor cited the current shortage of the H1N1 vaccine as the reason, saying that it is more important to use the limited supply to vaccinate those most at risk of complications, namely pregnant women and children and young people between the ages of 6 months and 24 years. The controversial regulation, detailed in last month's issue of *PRN*, was already the subject of a lawsuit brought by 3 nurses who objected to mandatory vaccination. The Centers for Disease Control (CDC) had originally projected that 120 million doses of the vaccine would be available by the end of October. The CDC has now acknowledged that less than 30 million doses will be ready by the end of the month, and less than 70 million doses will be available by the end of November.

FDA Warns of Potential Dosing Errors Involving Tamiflu Oral Syringe

The FDA has issued a public health warning regarding reports of errors in dosing of Tamiflu suspension. The oral syringe supplied by the manufacturer is calibrated in **milligrams** only, which has led to confusion when a prescription is issued with the dose written in **milliliters**. In cases where the prescriber has written the dose in milliliters, the agency recommends that the syringe provided in the Tamiflu package be discarded and replaced by the pharmacist with a standard oral syringe calibrated in milliliters. There are two other cases where the oral syringe supplied by the manufacturer **should not be used**:

- If the prescription is written for a child less than 1 year of age, the dose in mg will not correspond to any of the doses on the Tamiflu syringe and should be converted to mL for use with a standard oral syringe
- If, due to a shortage of commercially prepared Tamiflu suspension, a pharmacist compounds the suspension from capsules (see Sept. *PRN* for the approved formula), the Tamiflu syringe can not be used because the concentration of the compounded suspension differs from that of the commercially prepared product (15 mg/mL vs. 12 mg/mL)



Use Tamiflu syringe when dose is written in **mg**

Use standard syringe when dose is written in **mL**

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Medicaid Preferred Diabetic Supply Program

Effective October 1, 2009, the New York State Medicaid program has instituted a Preferred Diabetic Supply Program (PDSP). The program establishes a preferred supply list (PSL) of blood glucose monitors and strips which will not require prior authorization or use of the Dispensing Validation System (DVS). Most major brands are covered, including **Accu-Chek, Ascensia, Freestyle, Nova Max, One Touch, Precision, Truetest, and Truetrack**. The complete list of preferred products is available at <https://newyork.fhsc.com>.

Bill by NDC Number

Previously, blood glucose monitors, regardless of brand, were billed by product code (E0607) and reimbursed at a flat rate of \$76.58. Similarly, blood glucose strips were billed as code A4253 and reimbursed at a rate of \$38.79 per 50 strips. Under the PDSP, monitors and strips must be billed by their actual NDC number and will be reimbursed based on the current maximum Medicaid fee for the individual product dispensed (see our website, www.prnnewsletter.com for the latest available fee schedule). The PDSP *does not* apply to those beneficiaries enrolled in both Medicare and Medicaid.

Additions to the Preferred Drug Program (PDP)

Several changes to the Medicaid Preferred Drug Program go into effect on October 21, 2009:

Non-Preferred Agents:

Cedax

Preferred Agents:

Diclofenac Ophthalmic

Renvela

Treximet

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Scheduling of Drugs by the Drug Enforcement Administration (DEA)

The Federal Controlled Substance Act (CSA), which took effect on October 27, 1970, established five schedules of controlled substances, based on relative potential for abuse and physical or psychological dependence. Schedule I drugs (e.g., heroin, LSD) have no currently accepted medical use and may not be prescribed. Schedule II, III, IV, and V drugs have medical uses and may be prescribed by practitioners registered with the DEA.

Scheduling of Drugs by Individual States

Individual state legislatures and health departments may choose to impose different, generally stricter, schedules upon individual drugs. Pharmacists practicing in New York are familiar with special handling of anabolic steroids and benzodiazepines in their state (see below). Across the country, there are a number of interesting cases of drugs with schedules that differ from those of the DEA:

Examples of Drugs with Differing State and Federal Schedules^{1,2,3}

Drug Name	DEA Schedule	State Schedules
Carisoprodol (Soma)	Not scheduled	C-III in West Virginia C-IV in AL, AR, AZ, FL, GA, HI, IN, KY, LA, MA, MN, NV, NM, OK, OR, TX
Chorionic Gonadotropin (Novarel, Pregnyl)	Not scheduled	C-III in New York
Pseudoephedrine (Sudafed, etc.)	A "List I" chemical, available OTC from registered sellers in restricted quantities (maximum of 3.6 gm/day, 9 gm/30 days)	C-III in Oregon C-V in AR, IL, IA, KS, MN, MO, NM, OK, WV, WI
Tramadol (Ryzolt, Ultram)	Not scheduled	C-IV in Arkansas and Kentucky

Special Case I: Anabolic Steroids are Schedule II in New York State

In January, 1990, anabolic steroids became schedule II controlled substances in New York State. The following year, federal law placed anabolic steroids in schedule III of the controlled substance act (CSA). The difference is important because, under New York State law, prescriptions for anabolic steroids **are never refillable**. Some of the most commonly prescribed anabolic steroids are listed below:

Androderm (testosterone patch)	Striant (testosterone buccal)
Androgel (testosterone gel)	Testim (testosterone gel)
Android (methyltestosterone)	Testosterone Injection
Oxandrin (oxandrolone)	Testred (methyltestosterone)

Special case II: Benzodiazepines in New York State

Benzodiazepines, such as **Valium** (diazepam) and **Xanax** (alprazolam), are schedule IV controlled substances both federally and in New York State. However, since 1989, benzodiazepines have been regulated in New York under the rules and regulations pertaining to schedule II drugs and, therefore, prescriptions for benzodiazepines **are never refillable**.

PEDIATRIC COUGH AND COLD MEDICINES

A Lot Has Changed since this time last year in the world of pediatric OTC cough and cold medications. Following an FDA public meeting in October, 2008, the makers of children's cough and cold OTCs announced a voluntary relabeling of their products. The new labels, which were phased in over the past year, caution that these medications should not be used in children under 4 years of age. These changes have left many parents with questions about how to treat colds in younger children, and which medications are safe for use in older children. We provide some answers below.

Children Under 4 Years of Age

With two exceptions (see *Exceptions to the Rule*, below), all major pediatric OTC cough and cold medications have been relabeled **"Do Not Use In Children Under 4 Years Of Age."** So how should pharmacists counsel parents seeking to treat a young child with a cold? We suggest the recommendations of the American Academy of Pediatrics:

- For stuffy nose, try using saline nasal drops, followed by gentle bulb suction
- A cool mist humidifier may help clear nasal passages and ease chest congestion. Be sure to clean humidifiers often
- To reduce fever, use acetaminophen or ibuprofen (do not use ibuprofen in children less than 6 months of age and do not use aspirin in children of any age)
- For cough, try half a teaspoonful of honey for children ages 2 to 5, one teaspoonful for children ages 6 to 11, and two teaspoonfuls for children age 12 and older (do not give honey to children less than 1 year of age)

Exceptions to the Rule

A year after the announcement regarding label changes to pediatric OTC cough and cold medicines, almost all products on pharmacy shelves conform to the new recommendations. There are, however, two major exceptions: Wyeth's **Children's Advil Cold** and McNeil's **Children's Motrin Cold**, both of which contain ibuprofen and pseudoephedrine, and both of which are labeled for use in children **2 to 11 years of age**. To understand why this exception persists, we spoke with Linda Mayer at Wyeth and Marc Boston at McNeil. They explained that, unlike the vast majority of OTC medications, these products are not regulated under the FDA OTC monograph system, but were actually approved under a New Drug Application (NDA), the same way prescription drug products are approved, which requires the manufacturer to conduct studies demonstrating the safety and efficacy of the drug and its dosing. Pharmacists providing these products to patients should keep in mind the possibility of ingredient duplication with other products containing ibuprofen, pseudoephedrine, or phenylephrine.



Children 4 Years of Age and Older

The following cough and cold active ingredients can be labeled with directions for use in children 4 years of age and older:

- | | |
|-------------------------|------------------------|
| Dextromethorphan | Phenylephrine |
| Guaifenesin | Pseudoephedrine |

For specific sets of symptoms, the following products are available:

Nasal Congestion only:

- Children's Sudafed Nasal Decongestant
- Children's Sudafed PE Nasal Decongestant

Cough only:

- Mucinex Liquid
- Mucinex Cough Liquid
- Robitussin Children's Cough Long Acting
- Triaminic Long Acting Cough

Cough and Nasal Congestion:

- Children's Sudafed PE Cold & Cough
- Robitussin Children's Cough & Cold CF
- Triaminic Chest & Nasal Congestion
- Triaminic Day Time Cold & Cough

Note: Both Tylenol and Triaminic offer products combining the above ingredients with acetaminophen, which, while offering convenience, can lead to inadvertent overdoses of acetaminophen if parents combine these products with fever reducers

Children 6 Years of Age and Older

Over the counter products which contain first generation antihistamines (**Brompheniramine, Chlorpheniramine, Diphenhydramine**) are labeled for use in children 6 years of age and older. Some of the products available with these ingredients include:

Nasal Congestion and Runny Nose/Sneezing:

- Children's Dimetapp Cold & Allergy
- Triaminic Cold & Allergy

Cough and Runny Nose/Sneezing:

- Robitussin Children's Cough & Cold Long Acting
- Triaminic Night Time Cold & Cough

Cough, Nasal Congestion, and Runny Nose/Sneezing:

- Children's Dimetapp Cold & Cough
- Triaminic-D Multi-Symptom

Note: Both Tylenol and Triaminic offer products combining the above ingredients with acetaminophen, which, while offering convenience, can lead to inadvertent overdoses of acetaminophen if parents combine these products with fever reducers



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Recently, a physician called our pharmacy to ask what condition code to place on a prescription in order to prescribe a 90-day supply of Ambien (zolpidem). Is there a code that would allow for such a prescription?

No. New York State law allows for the prescribing of a 90-day supply (180-day supply for steroids) of controlled substances for the treatment of certain diseases or conditions. If a drug is not indicated for one of these specific conditions, that drug may not be written for more than a 30-day supply at a time. Since Ambien is indicated for insomnia, and insomnia is *not* one of the specified conditions, a prescription for Ambien may not exceed the 30-day maximum. For those drugs that are indicated for one of these conditions, prescribers may indicate on the prescription either the name of the condition or one of the following codes:

New York State Condition Codes

- A. Panic disorder
- B. Attention deficit disorder
- C. Chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive, or spasm activity
- D. Relief of pain in patients suffering from conditions or diseases known to be chronic or incurable
- E. Narcolepsy
- F. Hormone deficiency states in males; gynecological conditions that are responsive with anabolic steroids or chorionic gonadotropin; metastatic breast cancer in women; anemia and angioedema

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 two women considered to be the first female pharmacists in the United States shared the same first name? Elizabeth Greenleaf opened an apothecary shop in Boston in 1727, where she practiced with her husband, Daniel, also an apothecary. Elizabeth Marshall, granddaughter of Irish immigrant and American patriot Christopher Marshall, who established the Marshall Apothecary Shop in Philadelphia in 1729, apprenticed in her grandfathers shop and opened her own store in 1804. Today, women represent 65 to 67% of pharmacy school graduates, according to the American Association of Colleges of Pharmacy.

PHARMACY FUN

October is American Pharmacists Month, and to mark the celebration this month's quiz tests your knowledge of famous pharmacists in history. A number of pharmacists have made their mark in other professions; for each category below, identify the one luminary who was once a member of our profession. The first reader to submit the correct answers to puzzle@prnnewsletter.com will receive a custom-printed PRN binder.

1. **Politicians:** Lyndon Johnson, Hubert Humphrey, Gerald Ford
2. **Poets:** John Keats, William Butler Yeats, Robert Frost
3. **Writers:** William Faulkner, John Steinbeck, O. Henry



Answers to last month's **PHARMACY FUN**:

1. Acetaminophen 2. Aspirin 3. Ibuprofen 4. Phenobarbital

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1. Drugs and Chemicals of Concern section of DEA Office of Diversion Control website (www.deadiversion.usdoj.gov), accessed 10/16/2009.
2. New York State Rules and Regulations on Controlled Substances (Part 80), accessed 10/16/2009 at www.health.state.ny.us/professionals/narcotic.
3. Overview of State Legislative/Regulatory Restrictions on Over-the-Counter Sales/Purchases of Products Containing Pseudoephedrine. A report of the National Alliance for Model State Drug Laws (NAMSDL), accessed 10/16/2009 at www.namsdl.org.