P.R.N.

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What's Inside…

FDA NEWS

Propylthiouracil Warning

The FDA has added a **black box warning** to the label of the anti-hyperthyroid agent **propylthiouracil**. The warning includes information on reports of severe liver injury and death associated with the drug. The agency identified 34 cases of severe injury (23 in adults and 11 in children). Of the 23 adult cases, 13 deaths and 5 liver transplants were reported. In the 11 pediatric cases, there were 2 deaths and 7 transplants. Healthcare professionals should be aware of the following information regarding propylthiouracil:

- **Propylthiouracil should be reserved for patients who cannot tolerate methimazole**
- **Propylthiouracil is not recommended for pediatric patients , except in rare cases where other treatments are not appropriate**
- **Propylthiouracil may be the treatment of choice during the first trimester of pregnancy because fetal abnormalities have been seen with methimazole use in the first trimester**

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

New Treatment for Thrush: The FDA has approved the first local, oral formulation of miconazole for the treatment of oropharyngeal candidiasis, commonly known as thrush. Strativa Pharmaceuticals' **Oravig** (miconazole) buccal tablets are indicated for the local treatment of oropharyngeal candidiasis in adults and children aged 16 years and older. Oravig is contraindicated in patients with known hypersensitivity to miconazole or milk protein concentrate, which is used in the formulation of Oravig tablets. In clinical trials, the most common adverse effects seen were diarrhea, headache, nausea, dysgeusia, upper abdominal pain, and nausea. Miconazole may enhance the anticoagulant effect of warfarin; patients on warfarin taking Oravig should be monitored for evidence of bleeding and should have regular prothrombin time and INR testing. The recommended dose of Oravig is one 50 mg buccal tablet applied to the gum region once daily for 14 consecutive days. Patients should be instructed not to crush, chew, or swallow Oravig tablets. The tablet should be applied to the upper gum above the incisor tooth in the morning after brushing, and held in place for 30 seconds with slight pressure of the finger over the upper lip. Patients should alternate the application site on a daily basis.

Executive Order 29 Expires: As of April 17, 2010, New York State Executive Order 29 has expired. The Order, which had previously been extended on several occasions, authorized the suspension and modification of laws regulating vaccination in an effort to facilitate the timely distribution of H1N1 and seasonal influenza vaccine. The main provision involving pharmacists allowed certified RPh's to vaccinate children 6 months of age and older. Under the Education Law, now once again in full effect, pharmacists may only administer vaccinations to persons 18 years of age and older.

New Anti-Rejection Agent: Novartis Pharmaceuticals has received FDA approval to market **Zortress** (everolimus) oral tablets for the prevention of rejection of kidney transplants in adult patients at low-to-moderate immunologic risk. In clinical trials, Zortress prevented acute organ rejection and preserved kidney function while allowing, on average, 60% lower doses of cyclosporine to be used compared with the control regimen using **Myfortic** (mycophenolic acid). As with other agents in its class, Zortress can increase susceptibility to infection and can lead to the development of malignancies. The active ingredient in Zortress is also marketed as **Afinitor** for the treatment of advanced renal cell cancer.

FDA: Seven Metered-Dose Inhalers will be Removed from Market

The FDA has announced that seven metered-dose inhalers (MDIs) used to treat asthma and COPD will be gradually removed from the market. The agency's action is part of a continuing effort to enforce the Montreal Protocol on Substances that Deplete the Ozone Layer, an international treaty signed in 1987 which called for the discontinuation of products containing chlorofluorocarbons (CFCs). Single-ingredient albuterol MDIs were removed from the market on December 31, 2008, replaced by HFA-based products. The seven remaining CFC-based prescription inhalers are now scheduled for removal (see chart below). Over-the-counter CFC-based epinephrine MDIs (e.g., Primatene Mist) will be banned as of December 31, 2011.

Inhaler Product	Last date to be manufactured, sold , or dispensed in the United States
Tilade (nedocromil)	**June 14, 2010**
Alupent (metaproterenol)	**June 14, 2010**
Azmacort (triamcinolone)	**December 31, 2010**
Intal (cromolyn)	**December 31, 2010**
Aerobid (flunisolide)	**June 30, 2011**
Combivent (albuterol - ipratropium)	**December 31, 2013**
Maxair (pirbuterol)	**December 31, 2013**

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Pharmacist NPI Requirement Postponed

As reported here in the February issue of ***PRN***, the New York State Medicaid Program will begin requiring the dispensing pharmacist's NPI number on all electronic claims. The effective date of April 1, 2010 has been postponed to June 1, 2010 to allow pharmacies ample time to implement the change/

Reminder about Protopic Age Limitations

The Department of Health wishes to remind pharmacists validating prior authorizations for **Protopic** (tacrolimus) prescriptions that the following age restrictions are in effect:

Protopic 0.03% ointment:
Minimum age limit of 2 years

Protopic 0.1% ointment:
Minimum age limit of 16 years

Additions to the Mandatory Generic Drug Program

Effective April 15, 2010, *new* prescriptions for the following brand-name drugs will require prior authorization:

Calan SR 120 mg, 180 mg

Casodex 50 mg

Condylox 0.5% Solution

Depakote ER 250 mg, 500 mg

Phenergan 25 mg/mL Ampule

Reglan 10 mg

Temovate 0.05% Cream

Temovate 0.05% Ointment

Topamax 25 mg, 50 mg, 100 mg, 200 mg

Urso 250 mg

To receive prior authorization, prescribers must call 1-877-309-9493, and must indicate on the prescription *both* "DAW" and "BRAND MEDICALLY NECESSARY."

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Electronic Transmittal of Prescriptions in New York State

The use of electronic prescriptions has expanded rapidly in the past few years, and the trend shows no sign of waning. The emphasis on the use of electronic medical records by physicians has facilitated this change in prescribing habits. The New York State Board of Pharmacy recently answered a number of frequently asked questions regarding "e-prescriptions."

Definition:
An electronic prescription in one that is created, transmitted, recorded, and stored by electronic means such as facsimile or computer systems

Special Requirements:
Prescribers and pharmacists must have a secure system (encrypted or encoded) for electronic transmission from computer to computer. Electronically transmitted prescriptions must:

a. Contain the prescriber's signature or the electronic equivalent
b. Be protected from unauthorized access, alteration, or use
c. Have the initials of the pharmacist or pharmacy intern entered into the pharmacy's records to indicate acceptance of the prescription by the pharmacy

When can a pharmacy accept a prescription that contains an electronic signature and/or an electronic DAW?
ONLY when a prescription is electronically-generated *AND* electronically transmitted *by the prescriber* from the prescriber's computer or PDA to the computer or fax machine of the pharmacy of the patient's choice *[Editor's note: Notice that the board is covering a lot of ground in this answer, i.e., the prescriber him or herself must create and transmit the e-prescription, it must be electronically transmitted directly to the pharmacy's computer or fax machine, not a hard copy fax, which would require a handwritten signature and/or DAW, and prescribers may not "steer" prescriptions to a particular pharmacy]*.

Is the pharmacist responsible for determining the authenticity of a prescription transmitted electronically?
Yes. Pharmacists are responsible for assuring the validity of all written, oral, and electronically transmitted prescriptions. Pharmacists and prescribers must use compatible software programs, which may require passwords, PIN numbers, or other authentication of the prescriber. Faxed prescriptions require careful attention, and the board recommends the same steps used to verify phoned prescriptions, such as caller ID, calling back the office for verification if the prescriber is not known to the pharmacist, and asking for proof of identity if the person picking up the prescription is not known to the pharmacist.

Is a pharmacy required to print and maintain a hard copy of an electronically transmitted prescription?
No. Recently approved regulations allow for secure electronic storage of electronically transmitted prescriptions.

What if a pharmacist believes that dispensing a prescription will cause harm to the patient?
If a pharmacist believes that a prescription can cause harm to a patient, even after discussion with the prescriber, the pharmacist can choose not to fill the prescription.

What should a pharmacist do if he or she believes a prescriber is ordering a prescription that is not consistent with the prescriber's scope of practice?
If a prescriber cannot legally order the prescription based on the prescriber's scope of practice, the pharmacist must not fill the prescription.

Feature Article..

UPDATE: PRESCRIPTION NASAL SPRAYS FOR ALLERGIC RHINITIS

The 2010 Allergy Season is shaping up to be one of the worst on record. Across the country, the combination of a particularly wet winter followed by an early and warm spring has set the stage for record pollen counts. In New York City, there have already been reports of shortages of over-the-counter allergy remedies in many pharmacies. Prescription nasal sprays are among the most effective treatments available for allergy sufferers, and since there have been some product changes since we last published our chart on the subject, we have updated it for the 2010 season.

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	$\geq$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 to 2 sprays 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)	Yes	5-11 yo: 1 spray in each nostril BID	1 to 2 sprays in each nostril BID	May cause drowsiness
Astepro (azelastine 205.5 mcg/spray)	No	$\geq$12 yo: 1 to 2 sprays in each nostril BID (alt. 2 sprays in each nostril QD)	1 to 2 sprays in each nostril BID (alt. 2 sprays in each nostril QD)	May cause drowsiness
Patanase (olopatadine 665 mcg/spray)	No	6-11 yo: 1 spray 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***: $\geq$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***: $\geq$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

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ASK PRN...

When labeling a prescription for a controlled substance, is it required that the maximum daily dose (MDD) be written as part of the directions for use?

Yes. Sections 80.67 and 80.69 of the Rules and Regulations on Controlled Substances state that prescribers must indicate an MDD on all prescriptions for controlled substances. Sections 80.73 and 80.74 go on to say that pharmacists must label controlled substance prescriptions with the "specific directions for use as stated on the prescription." Therefore when filling a controlled substance prescription on which the prescriber has indicated an MDD, the pharmacist *must* include that MDD on the prescription label.

Can a pharmacist fill a prescription for a controlled substance if the prescriber has left the MDD box empty?

It depends on the particular prescription involved. If a prescriber fails to indicate an MDD on a prescription, but there is absolutely no question as to what the MDD is, the pharmacist may fill the Rx. For example:

Concerta 27 mg Sig: i QD in AM.

However, if there is any question as to the possible MDD, the prescriber should be contacted and an MDD documented and placed on the label. This is particularly true if the directions include a range of tablets to be taken and/or a prn indication. Every pharmacist has seen prescriptions like this one:

Vicodin ES Sig: i - ii q4-6h prn.

Failure to indicate an MDD on this Rx could lead to a patient taking 12 tablets per day, which represents an amount more than double the maximum daily dose of acetaminophen (9 gms vs. 4 gms/day), and could lead to severe liver damage and even death.

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 heroin was, at one time, marketed and sold in the United States, without a prescription, as a "non-addictive" cough suppressant? In 1897 Felix Hoffman, a chemist at the Bayer Company in Germany, first synthesized aspirin using a process developed by Arthur Eichengruen. Just 2 weeks later, in the same lab, Hoffman synthesized diacetylmorphine, which Bayer trademarked as "Heroin," because the some of the subjects who tested it said it made them feel "heroic."[1] Between 1898 and 1913 Bayer sold the narcotic for the treatment of cough due to bronchitis, whooping cough, etc., and discontinued its manufacture only after receiving overwhelming evidence of the true nature of their discovery.

PHARMACY FUN

It has been 40 years since Wisconsin Senator Gaylord Nelson called for the environmental "teach-in" that we now celebrate every April 22 as Earth Day. Earth being one of the finest planets we know of, we have decided to honor it in our own way by presenting a puzzle which asks the burning question: do you know where on Earth your drugs come from? For each of the following native species, name the drug extracted therefrom. The first reader to email the correct answers to *puzzle@prnnewsletter.com* wins a custom-printed PRN binder.

1. **Purple foxglove**
2. **French lilac**
3. **Rauwolfia serpentina**
4. **Deadly nightshade**
5. **Chincona ledgeriana**
6. **Papaver somniferum**
7. **Ephedra sinica**
8. **Autumn crocus**

Answers to last month's ***PHARMACY FUN***:
1. Cataflam 2. Dilantin 3. Glucotrol

References:
1, Askwith R. How aspirin turned hero. *Sunday Times [London]*. Sept. 13, 1998.

Front cover photograph by James Murphy