P.R.N.

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What's Inside…

FDA NEWS

Propylthiouracil Alert: The FDA has issued a safety alert regarding the antithyroid agent Propylthiouracil (PTU). The agency reports that there is an increased risk of hepatotoxicity when compared to the other drug in its class, methimazole. PTU therapy was associated with 32 cases of serious liver injury, including 12 deaths and 5 liver transplants. Methimazole was associated with only 5 reports of serious liver injury. The agency noted that although now considered second-line therapy, PTU may still be appropriate for those patients allergic to or intolerant of methimazole, and for women in the first trimester of pregnancy who require antithyroid treatment. The agency recommends the following actions:

- **Closely monitor patients on PTU for signs of liver injury, especially during the first 6 months of therapy**
- **Counsel patients to promptly report any of the following signs or symptoms: fatigue, weakness, vague abdominal pain, loss of appetite, itching, easy bruising or yellowing of the eyes or skin**

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

New "Pink Eye" Treatment: The FDA has approved Bausch & Lomb's **Besivance** (besifloxacin ophthalmic suspension 0.6%) for the treatment of bacterial conjunctivitis, commonly known as "pink eye." Besivance is a fluoroquinolone with activity against many species of staphylococcus, streptococcus, and corynebacterium responsible for causing bacterial conjunctivitis. The recommended dose of Besivance is 1 drop in the affected eye(s) 3 times a day, four to twelve hours apart, for 7 days. Patients should be counseled to invert the closed bottle and shake once before use. Patients should also be advised not to wear contact lenses during the course of therapy with Besivance.

New Agent for PAH: United Therapeutics Corporation has received FDA approval to market **Adcirca** (tadalafil) for the treatment of pulmonary arterial hypertension (PAH). Adcirca is a phosphodiesterase type 5 (PDE5) inhibitor and contains the same active ingredient as Eli Lilly's **Cialis**, which is used to treat erectile dysfunction. Like other PDE5 agents, Adcirca is contraindicated in patients taking nitrates, and caution is advised in patients using alpha blockers. Patients should seek immediate medical attention if they experience sudden loss of vision or hearing. The recommended dose of Adcirca is 40 mg (given as two 20 mg tablets) once daily, with or without food.

Update on Citizen Petition: In the May, 2008 issue of ***PRN*** we announced our intention to petition the FDA to amend the law regarding the label on prescription drug products (the complete petition can be viewed on our website at ***www.prnnewsletter.com***). The goal of our petition is to make it possible to tell, from the manufacturer's label alone, the equivalence rating of any prescription drug product. This would be accomplished by stating the New Drug Application (NDA) number under which the drug was manufactured on the label. Pharmacists could then easily determine the equivalence status of the product by matching the label's NDA number to those listed in the FDA Orange Book. This change has been made necessary by the proliferation of mergers and acquisitions in the pharmaceutical industry, and the increasing availability of "authorized generics," which are not listed in the Orange Book but are, in fact, manufactured under the originator's NDA. Our petition was accepted for filing on May 6, 2008 and assigned docket # FDA-2008-P-0291-001/CP. We received an interim response on October 30, 2008 stating that the agency was still considering their decision and that further review and analysis was needed. We will continue to keep our readers updated on the FDA's response. For a more detailed discussion of many of the issues involved in this petition, please see the *Orange Book Special Edition* page of our website.

House Subcommittee Approves Bill Protecting Access to Generics

By a vote of 16 to 10, the House Subcommittee on Commerce, Trade, and Consumer Protection approved H.R. 1706, the Protecting Consumer Access to Generic Drugs Act of 2009. The bill will now be forwarded to the full House Energy and Commerce Committee for further consideration. The act, sponsored by Illinois congressman Bobby Rush, would make it illegal for brand name drug companies to compensate generic drug companies to delay the entry of generic drugs into the market. This increasingly common practice allows brand name drug companies to extend the life of products with expiring patents, thereby, critics say, unfairly denying consumers access to lower cost generic drugs. In this arrangement, the brand company basically pays the generic company to *not* market the generic version of the brand-name drug. Some generic manufacturers may find this preferable to actually marketing their product, since they are often undercut by the introduction of so-called "authorized generics," sold by the brand name company, shortly before the generic product comes to market. These "authorized generics" essentially erase the 180-day exclusivity granted to the first generic by the Hatch-Waxman Act, which was to serve as an incentive to the development of lower cost generic drugs. One infamous example of the type of deal which would be prohibited under this legislation is that involving Plavix (clopidogrel). A botched agreement between Bristol-Myers Squibb (BMS) and Apotex, a generic drug manufacturer, eventually led to federal charges against company executives and the short-lived appearance of generic Plavix in August, 2006. Former BMS executive Dr. Andrew Bodner was sentenced on June 8th of this year; in addition to imposing a fine and 2 years probation, the presiding judge in the case took the unusual step of ordering Dr. Bodner to write a book about his experiences connected to the case.[1]

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Changes to Preferred Drug Program

Effective June 10, 2009, the following drugs will no longer be covered by Medicaid without prior authorization:

Bactroban Oint.	**Denavir Cream**
Dovonex Scalp	**Patanase**
Taclonex Oint.	**Taclonex Scalp**
Vectical Oint.	**Zovirax Cream**

This is only a partial listing of the upcoming changes to the program. For a complete list of preferred and non-preferred drugs, visit:

http://newyork.fhsc.com

Benefit ID Card Changes

Starting in May, chronological sequence numbers (SEQs) will be replaced by randomly generated SEQs on new and replacement Benefit cards. In addition, new and replacement cards will include a date and time stamp located at the top of the card. This will help clients and pharmacists identify the most recently issued card, since the random SEQs will no longer be useful in determining which card is valid.

Quantity Limits Reduced for Diabetic Supplies

The maximum allowable monthly quantity for blood glucose (BG) test strips and lancets has been reduced as follows:

Supply	Old Max	New Max
BG strips	**250**	**200**
Lancets	**500**	**200**

Patients needing more than the new maximum quantities will require prior approvals. The reimbursement schedule for these items has also been updated. The price for blood glucose test strips has been reduced from $39.38 to $38.79 per box of 50 strips. The price for lancets has been increased from $6.06 to $6.56 per box of 100 lancets.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Legislative Proposals Involving Pharmacy in New York State

As we go to press, the New York State Legislature, specifically the New York State Senate, is in a state of chaos. What some have called a political coup by Republicans has left the doors of the senate chamber locked and brought the lawmaking process to a dead stop (although it is sometime hard to tell the difference between business as usual in Albany and a dead stop). Be that as it may, there are still a number of bills in both houses that would have a signicant effect on the practice of pharmacy in New York. Below is a selection of some of the more interesting proposals ("A" indicates Assembly bill, "S" indicates Senate bill).

- **A6848/S3292:** Would permit pharmacists practicing in health care facilities to engage in collaborative drug therapy management (CDTM). CDTM allows pharmacists to review, evaluate, and modify drug therapy in accordance with a written agreement or protocol with a physician or nurse practitioner. A version of this bill has been in the legislature for several years and was passed by the Senate on more than one occasion, but was never voted on in the Assembly. The Board of Pharmacy supports this legislation.
- **A5379:** Would require pharmacy technicians to be certified and registered with the Board of Pharmacy. In addition to becoming certified, pharmacy technicians would need to be at least 18 years of age, have a high school diploma or GED, and have no felony or drug-related convictions.
- **A7448/S4218:** Would amend the public health law regarding Medicaid audits of pharmacy providers. This bill would put limits on office of the Medicaid Inspector General (OMIG) audits, which many pharmacy owners believe have been inappropriate in numerous ways, including charging exorbitant fines and payment recoupments for administrative or clerical errors.
- **A1267A:** Would prohibit health insurers from requiring that prescriptions be filled through a mail order pharmacy or from charging a co-payment fee for purchases not made through mail order if a similar fee is not charged for drugs from a mail order pharmacy.
- **A3528/S5855:** Would prohibit pharmacists from substituting any anti-epileptic drug for the prescribed anti-epileptic drug without notification of and informed consent of the prescriber and patient, or such patient's parent, guardian, or spouse.
- **A4045:** Would authorize a pharmacist to substitute a brand-name prescription drug for the generic equivalent if requested to do so by the patient. The patient would be responsible for the cost difference between the brand and generic drug product.
- **A5890/S1234:** Would prohibit the sale of tobacco products by pharmacies.

Endorsing Controlled Substance Prescriptions

The Bureau of Narcotic Enforcement has released a statement clarifying the issue of pharmacists' endorsement of controlled substance prescriptions. In their Spring, 2009 Pharmacy Update (available at ***www.nyhealth.gov/professionals/narcotic***) the Bureau explains that while a computer-generated sticker may be used to indicate the date of dispensing and prescription number on a new prescription, the pharmacist's signature must be written *upon the actual prescription itself*. When refilling controlled substance prescriptions, the date dispensed, amount dispensed, and pharmacist's signature must be indicated upon the original prescription. Here again a computer-generated sticker will suffice for the date and amount dispensed, but the pharmacist's signature must be written on the original prescription itself, not on the sticker.

Feature Article..

REVIEW OF COMMON DERMATOLOGICAL CONDITIONS SEEN IN THE COMMUNITY PHARMACY

Skin Rashes and other dermatological conditions are commonly seen in community pharmacy practice. Patients frequently seek consultation from their pharmacist for such problems before planning a physician visit. While many skin disorders do require evaluation by a physician, there are a few common conditions which may be safely treated at home, and the community pharmacist is well placed to offer advice on their proper care. In addition to reviewing the treatment of some common skin rashes, we have also included a chart comparing the relative potencies of topical steroids. For a review of some summer-specific ailments, such as insect bites, bee stings, and poison ivy, see "First Aid: Review and Recommendations" on our website at ***www.prnnewsletter.com***.

Topical Steroid Potency Chart

Low Potency

Alclometasone
Desonide
Fluocinolone 0.01%
Hydrocortisone

Medium Potency

Betamethasone Dip L
Betamethasone Valerate C
Clocortolone
Desoximetasone 0.05% C
Fluocinolone 0.025%
Flurandrenolide
Fluticasone
Hydrocortisone Butyrate
Hydrocortisone Valerate
Mometasone
Prednicarbate
Triamcinolone 0.025%
Triamcinolone 0.1%

High Potency

Amcinonide
Betamethasone Dip C,O
Betamethasone Dip Aug C
Betamethasone Valerate O
Desoximetasone 0.05% G
Desoximetasone 0.25%
Diflorasone
Fluocinonide
Halcinonide
Triamcinolone 0.5%

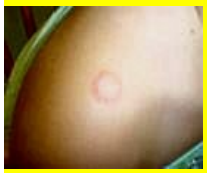
Very High Potency

Betamethasone Dip Aug O
Clobetasol
Halobetasol

KEY:
C = Cream
G = Gel
L = Lotion
O = Ointment

Aug = Augmented
Dip = Dipropionate

Where a form or strength is not specified, the rating applies to all forms and strengths available



RINGWORM

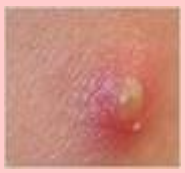
Ringworm, also known as *tinea corporis*, is a fungal infection caused by a dermatophyte which produces an itchy, circular rash, usually red on the perimeter and clear in the center. It is most commonly seen on the arms, legs, or trunk. Ringworm is related to other common fungal infections including *tinea pedis* (athlete's foot), *tinea cruris* (jock itch), *tinea barbae* (barber's itch), and *tinea capitis* (scalp ringworm).

Treatment: Ringworm can be treated with antifungal creams, including **clotrimazole**, **miconazole**, and **terbinafine**. Depending upon the agent selected, the cream should be applied once or twice a day, and treatment should continue for 2 to 4 weeks.

TINEA VERSICOLOR

Tinea versicolor is a fungal skin infection caused by *Malassezia furfur* which produces scaly patches of discolored skin, ranging from white to brown in color. It is most common in young adults, appearing on the back, neck, chest, or, rarely, the face, and is more prevalent during warm, humid weather. Because the affected area does not tan, it is often first noticed during the summer.

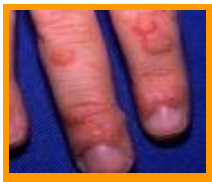
Treatment: Mild cases of tinea versicolor may be treated with an antifungal cream, such as **clotrimazole**, or with an antifungal shampoo, such as **selenium sulfide** (Selsun Blue). If using a cream, it is applied twice a day for 2 to 4 weeks. Shampoo is applied once daily for 7 days (leave on for 10 minutes before rinsing). Moderate to severe cases require evaluation by a physician and may benefit from prescription strength versions of selenium sulfide (2.5%) or ketoconazole (2%). The skin discoloration caused by tinea versicolor may linger for months after successful treatment. Recurrence is common.



BOIL

A boil, or *furuncle*, is a staphylococcal skin infection, often involving a follicle. They are most often found on the armpits, thighs, buttocks, neck, or face. Multiple connected furuncles are called *carbuncles*. Boils located on the nose or central face area, as well as carbuncles and very large boils, should be evaluated by a physician as systemic antibiotics may be necessary.

Treatment: Single boils, not located on the nose or central face area, may be treated with warm compresses applied for 10 minutes every few hours. This allows the boil to come to a head and drain; when draining begins an antibiotic ointment may be applied. Lancing or squeezing the boil is not recommended as this may spread the infection and necessitate medical treatment, including oral antibiotics.



WARTS

Common warts (*verrucae vulgaris*) are benign growths, caused by the human papillomavirus, which most often appear on the fingers, knees, elbows, and face. Warts are usually painless, but they may cause discomfort if located on a pressure point. Common warts normally resolve spontaneously within 2 years, but there are a number of over-the-counter products which offer effective treatment.

Treatment: Common warts can be self-treated using any of several methods:

- **Liquid wart removers** which contain 17% Salicylic Acid
- **Wart remover pads**, which contain 40% Salicylic Acid
- **Wart freeze off systems**, which contain propane and dimethyl ether
- **Duct tape** left on the wart for 6 days weekly may induce an effective immune response

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ASK PRN...

What reference materials are New York State registered pharmacies required to possess?

As stated in section 63.6(b)(4) of the Commissioner's Regulations, pharmacies shall possess:

> **"copies of laws, rules, and regulations governing the practice of pharmacy in New York, and other reference resources as may be necessary to carry on the practice of pharmacy."**

At a minimum, pharmacies should obtain a copy of the *Pharmacy Guide to Practice* and the *Rules and Regulations on Controlled Substances (Part 80)*, both of which can be downloaded from our website at ***www.prnnewsletter.com***. In addition, the latest edition of at least one reliable drug reference should be available, such as Lexi-Comp's *Drug Information Handbook* or WK Health's *Facts and Comparisons*.

When filling controlled substance prescriptions we affix a computer-generated sticker containing the prescription number and date filled on the back of the prescription, rather than on the face. Is this practice in compliance with regulations?

Yes. Originally, the Rules and Regulations on Controlled Substances (Part 80) specified that the prescription number and date of filling be endorsed on the "face" of the prescription. However, since the adoption of the Official New York State Prescription in 2006, the regulations have been changed; the word "face" was removed, making the back and front of the prescription equally acceptable for endorsement. In fact, the back may be preferable, since it is important not to obscure any information of the front of the prescription or interfere with any tamper-proof features.

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, in the not-too-distant future, New York may be home to 8 schools of pharmacy? That would represent a doubling of the number of schools existing just 3 years ago. In 2006, **St. John Fisher College** joined **Long Island University**, **St. John's University**, **SUNY Buffalo**, and **Albany College** in providing pharmacy education in the state. In 2008, **Touro College**, though not yet fully accredited, opened the first pharmacy school in Manhattan since **Columbia University** closed its pharmacy program in 1974. The Fall of 2009 will see the inaugural class for **D'Youville College** in Buffalo, and this past Spring the City University of New York (**CUNY**) expressed interest in initiating a pharmacy program.

PHARMACY FUN

It's rebus time again. Can you solve these 4 picture puzzles by naming the OTC products they represent? Send your answers to *puzzle@prnnewsletter.com* to win a custom-printed *PRN* binder!

1.  + 

2.  + 

3.  + 

4.  +  + 

Answers to last month's ***PHARMACY FUN***:
1. Zidovudine (formerly azidothymidine) 2. Dimercaprol (aka British Anti-Lewisite) 3. Alteplase (aka Tissue Plasminogen Activator) 4. Lamivudine 5. Chlorpromazine 6. Dronabinol (aka Tetrahydrocannabinol) 7. Vasopressin (aka Antidiuretic Hormone) 8. Stavudine 9. Bacillus Calmette-Guerin

References:
1. Natasha Singer, Judge Orders Former Bristol-Myers Executive to Write Book," *New York Times*, June 8, 2009.