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What's Inside…

Fluoroquinolone Warning

On July 8, 2008, the FDA issued an alert regarding the use of fluoroquinolone antibiotics. The agency announced that manufacturers will be required to add a ***boxed warning*** to the prescribing information about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones. In addition, a Medication Guide for patients must be developed. This represents a strengthening of a previously known warning, and applies only to systemic use of the drugs, not to ophthalmic or otic preparations. Three groups of patients considered most at risk for tendon problems are those over age 60, recipients of kidney, heart, or lung transplants, and patients using corticosteroids. The list of affected drugs follows:

Ciprofloxacin (CIpro, Cipro XR, Proquin XR)

Gemifloxacin (Factive)

Levofloxacin (Levaquin)

Moxifloxacin (Avelox)

Norfloxacin (Noroxin)

Ofloxacin (Floxin)

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Stavzor Approved: The FDA has approved Noven Pharmaceuticals' **Stavzor** (Valproic Acid Delayed Release Capsules). Stavzor is indicated for use in the acute treatment of manic episodes associated with bipolar disorder, as monotherapy and adjunctive therapy of complex partial seizures and absence seizures, and for prophylaxis of migraine headaches. Stavzor will carry the same black box warnings as Abbott's **Depakote** (Divalproex Sodium Delayed Release Tablets) regarding hepatotoxicity, teratogenicity, and pancreatitis[1]. The most common adverse effects of Stavzor include nausea, somnolence, dizziness, asthenia, abdominal pain, and tremor. Drug interactions include increased clearance in the presence of enzyme-inducing drugs (phenytoin, carbamazepine, phenobarbital, rifampin), decreased clearance with enzyme inhibitors (felbamate). Aspirin may lead to valproic acid toxicity. The combination of valproic acid and topiramate has been associated with cases of hyperammonemia and encephalopathy. Stavzor will be available in soft gel capsules, said to be smaller and easier to swallow than Depakote tablets, in strengths of 125 mg, 250 mg and 500 mg. Since Stavzor was approved through the 505(b)(2) process, it is not expected to be AB rated to Depakote or to Depakote generics (see the May, 2008 issue of *PRN* for a discussion of the 505(b)(2) pathway). As for **Depakote generics**, the FDA has just granted eight manufacturers approval to market Divalproex Sodium Delayed Release Tablets: U.S. firms Sandoz and Upsher-Smith, Genpharm and Nu-Pharm of Canada, Israel's Teva, and Dr. Reddy's, Sun, and Lupin of India.

FDA/CDC On Gardasil Safety: The FDA, in conjunction with the Centers for Disease Control (CDC), released a statement reaffirming its position that Merck's **Gardasil** vaccine is safe and effective. The joint announcement was issued in response to reports of serious adverse events, including deaths, following administration of the vaccine. Gardasil was approved in June of 2006 for use in girls and women aged 9 through 26 years to prevent infection with human papillomavirus (HPV) types 6, 11, 16, and 18. HPV types 6 and 11 are the cause of 90% of cases of genital warts, while types 16 and 18 are implicated in about 70% of cases of cervical cancer. Since approval, the manufacturer has distributed more than 16 million doses of Gardasil and, as of June 30, 2008, there have been a total of 9,749 reports of adverse events following vaccination. Of these, the FDA classifies 94% as non-serious and 6% as serious. Included in the 6% considered serious were cases involving thromboembolic disorders, Guillain-Barre Syndrome (GBS), and reports of some 20 deaths. The agency found no common pattern to the deaths that would suggest they were caused by the vaccine, and in cases where autopsy results, death certificates and medical records were available, the cause of death was explained by other factors. Regarding GBS, the FDA believes the data do not currently support an association between the disorder and the vaccine. Thromboembolic disorders are being assessed by the CDC through previously planned controlled studies. Based on their review of all the available information, the FDA and CDC continue to consider Gardasil as safe and effective, with proven benefits outweighing possible risks.

Chantix vs. Nicotine Patch: No Significant Difference in Long-Term Efficacy

The results of a 52-week head-to-head comparison between Chantix and Nicoderm CQ patches showed no statistically significant difference in quit rates at 6 month and 12 month follow up. The study, published in the journal *Thorax* and funded by Pfizer, Inc., maker of Chantix, was conducted at sites in the United States, United Kingdom, France, The Netherlands, and Belgium[2]. A total of 757 participants were randomized to receive either Chantix (varenicline) for 12 weeks or transdermal nicotine replacement therapy (NRT), in this case Nicoderm CQ, for 10 weeks. The primary endpoint of the study, continuous abstinence rate (CAR) during the last four weeks of treatment, did establish a significant advantage of Chantix over NRT (CAR of 55.9% vs. 43.2%, $p<0.001$). However, in the long-term arm of the study, the CAR at 6 months and 12 months, the advantage of Chantix over NRT was not significant (32.4% vs. 27.3%, $p=0.118$ at 6 months and 26.1% vs. 20.3%, $p=0.056$ at 12 months). These results, as well as the recent FDA warning about the possible behavioral side effects of Chantix (see the June, 2008 issue of *PRN),* may result in a decrease in the number of physicians and patients considering Chantix for smoking cessation therapy.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Change in Pharmacy Co-payment

The Department of Health has announced that, effective July 1, 2008, the co-payment for "preferred" brand-name prescription drugs has been reduced from $3.00 to $1.00. (See the February, 2008 issue of ***PRN*** for details on the Preferred Drug Program). Non-preferred brand-name drugs will continue to generate a co-pay of $3.00, while generics have a co-pay of $1.00. Certain drug categories remain exempt from co-pays, including **psychotropics, anti-tuberculosis agents,** and **contraceptives**. In addition, beneficiaries who are younger than 21 years of age, those who are pregnant, and those who reside in nursing homes, adult care facilities, or Office of Mental Health Residences are exempt from having to pay co-payments for drugs.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Changes to Condition Code "D" Announced

New York State's Bureau of Narcotic Enforcement (BNE) has announced two changes to the wording of **condition code "D"**, which allows for the prescribing of up to a 90-day supply of controlled substances used in the treatment of pain [see Title X, Sections 80.67(d)1(iv) and 80.69(d)1(iv)]. Previously, these sections allowed a three month supply for "relief of pain in patients suffering from diseases known to be chronic and incurable." The revised wording states "relief of pain in patients suffering from **conditions *or* diseases** known to be **chronic *or* incurable**." This change gives practitioners more latitude when prescribing controlled substances for patients suffering pain due to conditions, rather than diseases, which may or may not be incurable. Such prescriptions must specify, on the face of the prescription, either code "D" or the name of the condition being treated.

Partial Filling of Schedule II Extended

BNE has also published a change that will allow partial fillings of Schedule II and benzodiazepine prescriptions issued for more than a 30-day supply for patients in residential healthcare facilities or hospice programs to occur within **60 days** from the date the prescription was issued. Pharmacists partially filling such orders must record on the prescription the date of partial filling, quantity dispensed, quantity remaining, and their signature. This should not be confused with "partial filling" of an outpatient C-II prescription at the patient's request, which requires authorization by the prescriber and which voids any remaining quantity not dispensed.

The remainder of this month's Law Review is dedicated to providing pharmacists with a list of important addresses and phone numbers relevant to their practice.

PHARMACIST'S CONTACT LIST

NEW YORK STATE CONTACTS

State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000
Phone: (518) 474-3817 ext. 130
Fax: (518) 473-6995
email: *pharmbd@mail.nysed.gov*

Bureau of Narcotic Enforcement
433 River Street, Suite 303
Troy, New York 12180-2299
Phone: (866) 811-7957
Fax: (518) 402-0709
email: *narcotic@health.state.ny.us*

Medicaid Program

Claims:	800-343-9000
Prior Approval:	800-342-3005
Pharmacy Policy:	518-486-3209
Fraud Hotline:	877-873-7283
Medicaid Help Line:	800-541-2831

EPIC Program
Pharmacy Help Line: 800-634-1340

FEDERAL CONTACTS

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (888) INFO-FDA (463-6332)
Website: *www.fda.gov*

Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, Virginia 22301
Phone (NY Office): (212) 337-3900
Website: *www.usdoj.gov/dea*

To Order 222 Forms: (800) 882-9539

New York Mailing Address
(For forwarding completed "reverse" 222 forms from returns):

Drug Enforcement Administration
New York Field Division
99 Tenth Avenue
New York, New York 10011

Medicare Part D Program
Phone: (800) MEDICARE
(800) 633-4227

MISCELLANEOUS CONTACTS

Poison Control Centers

National Number:	(800) 222-1222
New York City:	(212) POISONS
	(212) 764-7667

N.Y. State Colleges of Pharmacy

Long Island University
75 DeKalb Avenue, Brooklyn, NY 11201
(718) 488-1004

St. John's University
8000 Utopia Pkwy, Jamaica, NY 11439
(718) 990-6411

SUNY at Buffalo
126 Cooke Hall, Buffalo, NY 14260
(716) 645-2823

Albany College of Pharmacy
106 New Scotland Ave, Albany, NY 12208
(888) 203-8010

St. John Fisher College
3690 East Avenue, Rochester, NY 14618
(585) 385-8430

Feature Article..

FIRST AID: REVIEW AND RECOMMENDATIONS

"Ah, Summer, what power you have to make us suffer and like it." When Russell Baker wrote those words he may have had in mind all the bites, stings, sprains, strains, and rashes the season brings. It's the time of year when a little knowledge of first aid can go a long way, and since pharmacists are the first line of defense against the slings and arrows of outrageous summer, ***PRN*** presents the following review of current recommendations.

Bee and Wasp Stings

Most bee or wasp stings require only simple home treatment. Individuals known to have severe or anaphylactic reactions to stings should use EpiPen or a similar product (adults and children ≥30kg 0.3 mg IM, children <30 kg 0.15 mg IM) and call emergency services immediately. Those without severe allergy should follow the procedure below:

1. If the stinger is still present, remove it immediately by scraping it with a hard-edged object such as a credit card.

2. Apply an ice pack or cold water for 10 to 30 minutes.

3. Wash the area and apply either hydrocortisone cream, calamine lotion, or a baking soda and water paste.

4. If needed, antihistamines (diphenhydramine) and pain relievers (acetaminophen, ibuprofen) may be used.

Poison Ivy, Oak, and Sumac

The rash caused by poison ivy, oak, and sumac, known as Rhus Dermatitis, is due to contact with an oily plant resin called urushiol. After exposure, a reaction is likely unless the oil can be washed off immediately (less than 10 minutes). The rash is self-limiting, generally resolving in 1 to 3 weeks. Treatments to relieve symptoms include:

1. Hydrocortisone cream may be helpful if used early in the course of the rash.

2. Cool compresses several times a day and cool water baths with colloidal oatmeal (Aveeno) may reduce symptoms.

3. Oral antihistamines (diphenhydramine) can be used to reduce itching.

In more severe cases, oral steroids may be prescribed. In that case it is important that treatment continue for at least 2 to 3 weeks, as use of short-course "dosepacks" can lead to a severe rebound of symptoms.

Cuts and Scrapes

Minor cuts and scrapes can be self-treated. Deep wounds, puncture wounds (especially of the feet), and dirty wounds may require medical care and a tetanus shot. For minor cuts, treat as follows:

1. Stop any bleeding by applying pressure continuously. If after 20 minutes of pressure, bleeding continues, seek medical attention.

2. Clean the wound with soap and water or plain water.

3. Apply antibiotic ointment. If previous use led to a rash, this was likely due to neomycin; in that case use plain bacitracin.

Insect and Spider Bites

The majority of insect and spider bites are not serious and respond to self-treatment. The two exceptions are bites from either Black Widow and Brown Recluse spiders, which require immediate medical attention. The Black Widow spider is recognizable by the red hourglass marking on its belly, and the Brown Recluse by the violin-shaped mark on its upper back area. Bites from mosquitoes and other non-venomous insects can be treated as follows:

1. Wash the area of the bite with soap and water.

2. Apply an ice pack or cold compress.

3. Oral antihistamines (diphenhydramine) or topical corticosteroids may be used if needed.

4. In more severe reactions, a short course of oral steroids may be necessary.

Sprains and Strains

Sprains are stretched or torn *ligaments*, while **strains** are stretched or torn *muscles*. Minor injuries can be self-treated, but more severe sprains and strains may require professional evaluation. Immediate medical care is indicated if a popping sound is heard when the injury occurs, if the affected limb is unstable, if the area becomes hot and red and a fever develops, or if there is no improvement after 2 to 3 days. Minor sprains and strains can be treated at home using the **PRINCE** protocol:

- **P**rotect the injured area.
- **R**est the injured area. This protects against further injury and facilitates healing.
- **I**ce the injured area for up to 20 minutes at a time every 1 to 2 hours while awake for the first 24 to 48 hours (use an ice pack or slush bath; do not apply ice directly to the skin).
- **N**SAIDs or acetaminophen may be used to relieve pain.
- **C**ompression: an elastic compression wrap (e.g. ACE bandage) reduces swelling and should be worn for the first 24 to 36 hours. The wrap should be applied to fit snugly, but not too tightly, as circulation may be restricted.
- **E**levation: elevation of the injured area above the level of the heart whenever possible reduces swelling by allowing edema fluid to drain.

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OFF-LABEL USE: AMITRIPTYLINE

Amitriptyline is tricyclic amine indicated for the treatment of depression. However, a study published in the *Journal of Clinical Psychiatry* reported that 81% of prescriptions filled for amitriptyline were written for off-label uses[3]. And so it is particularly important for pharmacists counseling patients about this agent to be familiar with its most common unlabeled uses.

Chronic and Neuropathic Pain: Amitriptyline has been used for post-herpetic neuralgia, diabetic neuropathy, and fibromyalgia. Doses range from 0.5 to 2 mg/kg given at bedtime, with a suggested maximum dose of 150 mg QD.

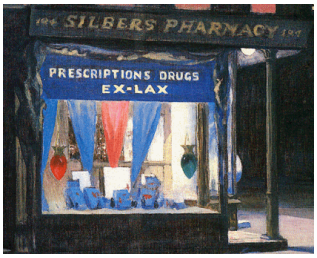
Migraine Headache: Amitriptyline is used for migraine headache prevention at a dose of 10 to 150 mg daily.

Attention Deficit Hyperactivity Disorder: Given an hour before bedtime, amitriptyline is used as adjunct therapy in ADHD and may be especially beneficial in children with significant sleep problems.

Nocturnal Enuresis: Due to its anticholinergic activity, amitriptyline has been used to treat bedwetting in children. Doses range from 10 mg to 50 mg at bedtime.

DID YOU KNOW?

DID YOU KNOW that for centuries apothecaries, chemists, and more recently, druggists and pharmacists displayed large glass vessels filled with colored water to distinguish their shops as places of healing? Like the barber's striped pole and the cigar store Indian, these "show globes" were unmistakable symbols of the profession practiced within. Appearing first in 17th century England, show globes could still be seen in American pharmacies as late as the1950's. Pharmacists took great pride in using their knowledge of chemistry to create unique and interesting colors. One famous example of show globes in art appears in Edward Hopper's 1927 painting "Drug Store," which features red and green colored globes suspended in the store window.



Detail from Edward Hopper's *Drug Store* (1927). Museum of Fine Arts, Boston.

PHARMACY FUN

This month's puzzle revolves around August, that most holiday-less of months and the namesake of the first Roman emperor, Augustus. Note that there are eight letters in the name of the eighth month's eponym. But that wasn't his real name—you get a new one when you become emperor! His original name also contained eight letters, but was even "eight-ier" than Augustus. Those who solve for the following clues will find the emperor's real name spelled out by the first letters of the correct answers. The first reader to submit the correct answers to us at *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder. By the way, we wrote this puzzle on 8/8/08!

1. Somatostatin analogue
2. Methylmorphine
3. Beta-2 tocolytic
4. First trademarked in Germany in 1899
5. Can cause "red man syndrome"
6. Patent ductus arteriosus treatment
7. Gallstone dissolver
8. Drug of choice for plague

Answers to last month's **PHARMACY FUN**:
Our patient has a 41% chance of taking the right tablet all 3 times. The probability is calculated this way: 30/40 x 29/39 x 28/38 = 0.41 or 41%

References:
1. Stavzor [package insert]. New York, NY: JDS Pharmaceuticals, LLC; July, 2008.
2. Aubin H-J, et al. Varenicline versus nicotine transdermal patch for smoking cessation: results from a randomized open label trial. *Thorax* 2008;63:717-724.
3. Chen H, et al. Off-label use of antidepressant, anticonvulsant, and antipsychotic medications among Georgia Medicaid enrollees in 2001. *J Clin Psychiatry.* 2006, June;67(6):972-82.