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What's Inside…

FDA NEWS

First Colchicine Approval: The FDA has, for the first time, approved a single-ingredient colchicine product, **Colcrys**, by Mutual Pharmaceutical Company, Inc. Although colchicine has been on the market for many years, none of the available products had ever received FDA approval. Colcrys is indicated for the treatment of acute flares of gout and for familial Mediterranean fever (FMF). The agency also approved a new dosing regimen for the drug that is as effective as the old regimen, but much less toxic. Previously, patients were instructed to take a dose of colchicine every hour until the flare subsided or until they could no longer tolerate the dose due to nausea and vomiting. A dosing study required for the approval process showed that an initial dose of 1.2 mg followed by a single additional dose of 0.6 mg in one hour was effective for treating acute gout attacks. The FDA also identified serious drug interactions between colchicine and CYP3A4 inhibitors. In particular, there were 60 deaths reported in patients taking colchicine and **Biaxin** (clarithromycin). Patients taking colchicine should also avoid consuming grapefruit and grapefruit juice.

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New Statin: The FDA has approved Kowa Pharmaceuticals' **Livalo** (pitavastatin) for the treatment of primary hyperlipidemia and mixed dyslipidemia. Livalo is an HMG-CoA reductase inhibitor, or statin, and will be the seventh such drug on the market in the U.S. In five comparative clinical trials, Livalo was shown to be superior to **pravastatin** and **simvastatin**, and comparable to **atorvastatin**, in lowering LDL-C. Livalo is only minimally metabolized by CYP2C9 and CYP2C8, and may have less clinically significant drug interactions than some other statins During clinical trials, the most common adverse effects were myalgia, back pain, diarrhea, constipation, and extremity pain. Liver enzymes must be monitored before and during treatment, and patients should be advised to report any unexplained muscle pain, tenderness, or weakness, since these may be signs of myopathy and may require discontinuation of treatment. Like all statins, Livalo is rated pregnancy category X, and is also contraindicated in breastfeeding. Livalo should not be taken with **Kaletra** or **cyclosporine**. If taken with **erythromycin**, Livalo dose should be limited to 1 mg daily. When used with **rifampin**, no more than 2 mg of Livalo should be taken daily. Livalo may be taken at any time of day, with or without food. The recommended starting dose is 2 mg once daily, and the maximum daily dose is 4 mg once daily. For patients with moderate renal impairment, the starting dose is 1 mg once daily and the maximum dose is 2 mg once daily.

New Atypical: Schering-Plough has received FDA approval to market its new atypical antipsychotic, **Saphris** (asenapine). Saphris is indicated for the treatment of schizophrenia in adults and for manic or mixed episodes associated with bipolar I disorder in adults. In common with other atypicals, Saphris labeling will contain warnings about the possibility of neuroleptic malignant syndrome, tardive dyskinesia, orthostatic hypotension, hyperglycemia, white blood cell disorders, QT prolongation, weight gain, and will require a **black box warning** about increased mortality in elderly patients with dementia-related psychosis. Saphris is *not indicated for use* in patients with dementia-related psychosis. The most common adverse effects reported with the use of Saphris were akathisia, oral hypothesthesia, somnolence, and weight gain. Saphris is metabolized by CYP1A2, and may interact with strong inhibitors of this enzyme, specifically with the SSRI **fluvoxamine**. The recommended starting and target dose of Saphris for schizophrenia is 5 mg sublingually twice daily. The recommended starting dose for bipolar disorder is 10 mg sublingually twice daily. This dose may be decreased to 5 mg twice daily if the patient experiences adverse effects. Patients should be instructed to handle the tablet with dry hands and place it under the tongue, allowing it to dissolve completely. Tablets *should not* be crushed, chewed, or swallowed, and no food or drink should be consumed for at least 10 minutes following administration. Saphris should be available sometime during the fourth quarter of 2009.

New York City Officials Announce New Swine Flu Strategy

New York City Mayor Michael Bloomberg held a press conference on September 1st detailing the city's plans for dealing with the return of the swine flu, now known as novel H1N1. New York was the epicenter of the outbreak in the U.S. last spring, and city officials have worked over the summer to create a strategic citywide response to the expected return of the pandemic virus this fall. Some of the key initiatives include:

- **The city will provide free novel H1N1 vaccinations to all elementary school students, public and private, whose parents give permission**
- **A daily public report will list all schools reporting 5 or more cases of flu-like illness**
- **To decrease the burden on hospital emergency departments, the city will designate some community-based primary care clinics as "flu centers"**
- **Expansion of the city's influenza website, *www.nyc.gov/flu*, to include a locator, searchable by zip code, to find vaccination centers, "flu centers," and pharmacies**
- **During an emergency, the city would provide free telephone consultations, with trained nurses, through the 311 system**

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Improper Use of MMIS Numbers

In the August edition of the New York State Medicaid Update, the problem of improper use of hospital Medicaid Management Information System (MMIS) numbers is discussed. The update correctly points out that many interns and residents working in hospitals, who do not have license numbers, are improperly recording their hospital's MMIS number on their prescriptions as a license number. However, it is the pharmacy filling the prescription that is penalized, if audited, for the physician's error (after extrapolation, pharmacy fines for just a few improper license numbers often total thousands of dollars).

Rules for Interns and Residents

When writing prescriptions, interns and residents are required to indicate upon the prescription the license number or MMIS number of their *supervising physician*. In practice, this is not being done consistently, and some hospitals need to do a better job of informing their employees of this requirement. On most hospital prescriptions, the physician's name is stamped on the Rx, and does not indicate if the prescriber is an intern or resident, making it difficult for the pharmacist filling the prescription to know if the "license number" indicated is appropriate. Compounding the problem is the fact that there is now overlap between MD's license numbers and hospital MMIS numbers, so it is no longer possible to easily differentiate between the two.

Burden on Pharmacists

Medicaid expects pharmacists filling prescriptions written by interns and residents to track down the prescribing physician by phone (not always an easy task) and ascertain the name of their supervising physician, and then manage to find out the license or MMIS number of that physician before filling the prescription. Failing that, the pharmacist is put in the untenable position of having to either refuse to supply needed medication to their patients, or risk devastating financial penalties if they fill the prescription.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New Pharmacy Rules Adopted

In the May issue of ***PRN***, we reported on four proposed rule changes affecting pharmacy practice in New York State. These rules have now been adopted and became effective on August 19, 2009. Changes made to section 29.7 of the Regents Rules and sections 63.3 and 63.6 of the Commissioner's Regulations are summarized below:

- **For oral prescriptions, a pharmacist may choose to create an electronic record, rather than a written one, which shall also contain the electronic equivalent of the signature or readily identifiable initials of the pharmacist receiving the oral order**
- **For electronically transmitted prescriptions, an electronic record, stored securely and permanently, may be kept in lieu of printing out a hard copy**
- **Rather than printing out a daily register, an electronic record of all prescriptions filled and refilled each day, signed electronically by the pharmacist whose initials appear on the record, will be sufficient**
- **As an alternative to taking Part III of the New York State pharmacy licensure examination (the compounding and pharmacy practice exam), candidates may submit certification of competency received through an approved residency program in pharmacy practice (certification shall be completed by the residency program director)**

It should be noted that, at this time, the New York State Medicaid Program continues to require maintenance of hard copies of oral and electronic prescriptions.

Emergency Rule Issued on Health Care Personnel Vaccination

The New York State Department of Health has issued an emergency rule, effective August 13, 2009, regarding influenza vaccination requirements for health care personnel. The new rule mandates annual influenza vaccination(s) for all personnel working in health care facilities who have direct contact with patients. The department defines "health care facilities" as including general hospitals, diagnostic and treatment centers, certified home health agencies, long term home health care programs, AIDS home care programs, and licensed home care service agencies. The rule was developed in response to low vaccination rates among health care workers and the advent of the novel H1N1 influenza virus.

Change to Official New York State Prescription

The New York State Department of Health has announced a change to the Official New York State Prescription. In an effort to decrease medication errors, a patient safety feature has been added to the back of each prescription (seen here at right). The check box, featuring 9 treatment categories, allows the prescriber to communicate to the pharmacist the general purpose for which the prescription was written. The utilization of the check box is optional, but strongly encouraged. Since completion of the check box by the prescriber is *not* mandatory, prescriptions may still be filled if the check box has not been used, and older prescription blanks which do not contain the check box are still valid for use. For answers to any questions about the Official Prescription, prescribers and pharmacists can call the New York State Official Prescription Program at (866) 811-7957 (option 2).

	Cardiovascular
	Gastrointestinal
	Antibiotic/ Anti-Infective
	Pain/ Inflammation
	Cough/Cold
	Respiratory
	Central Nervous System
	Genital/ Urology
	Endocrine
	Other_____

Feature Article..

PREPARING FOR FLU SEASON

As Flu Season Approaches, healthcare providers in the United States are preparing for a unusual scenario. In addition to readying for the seasonal flu, doctors, nurses, and pharmacists are bracing for the return of the "swine" flu, now known as **novel H1N1**. The pandemic, which began in North America last spring, has circled the globe, and, even as cases begin to subside in the Southern Hemisphere, new outbreaks are already appearing in the southeastern United States. This month we review the latest information available from the Centers for Disease Control (CDC).

The Virus

Novel H1N1 is a "quadruple reassortant" virus containing genes from European and Asian swine viruses, as well as avian and human influenza viruses. Symptoms of novel H1N1 are similar to those of seasonal flu (fever, cough, sore throat, headache, etc.), but may also include diarrhea and vomiting. The virus is believed to be transmitted in the same way as seasonal flu, through coughing and sneezing of infected persons and through contact with infected surfaces followed by touching of the eyes, nose, or mouth. Unlike the seasonal flu, however, novel H1N1 affects younger people more than it does people aged 65 and older, who may have some immunity due to exposure to a similar virus in the past. So far, this virus has caused mild illness in most patients, but more severe disease in some populations, including pregnant women, people under the age of 25, and people with certain pre-existing medical conditions, including asthma, diabetes, and heart disease. Patients with novel H1N1 infection are believed to be able to spread the virus to others from 1 day before getting sick until 5 to 7 days after. The current CDC recommendation is that infected patients stay home for at least 24 hours after the are completely free of fever *without* the use of fever reducing medications, such as acetaminophen and ibuprofen. Everyday steps to prevent infection include frequent hand-washing with soap and water, use of alcohol-based hand cleaners, and avoiding touching of the eyes, nose, and mouth.

The Vaccine

Clinical trials of the vaccine for novel H1N1, involving approximately 4,500 volunteers, began on August 7th. The trials will answers questions as to safety, dose (15 mcg vs. 30 mcg), and the number of doses required. While many experts predicted that 2 doses of the new vaccine would be required, initial results from Australian trials indicate that a single dose may suffice for adults. The vaccine is expected to be available in limited supply by the middle of October, although White House advisers recently requested that manufacturers have some doses ready in September. While there should eventually be enough supply for everyone who wants the vaccine, initially those groups at greatest risk will be prioritized. The CDC has identified 5 groups as being at higher risk for complications from novel H1N1, and these groups will be the first to be vaccinated:

- **Pregnant women**
- **Healthcare workers**
- **People who live with or care for children less than 6 months old**
- **People between the ages of 6 months and 24 years of age**
- **People aged 25 to 64 years of age with chronic health disorders**

The novel H1N1 vaccine does *not* protect against the seasonal influenza virus, so the regular flu vaccine is still needed, especially for people aged 50 and older and those with chronic illnesses.

The Treatment

The novel H1N1 virus is resistant to both **amantadine** and **rimantadine**, but can be treated with either **Tamiflu** (oseltamivir) or **Relenza** (zanamavir). Treatment is most effective if begun within 48 hours of the onset of illness. Due to greater ease of administration (capsule or liquid vs. inhalation), Tamiflu is the preferred drug. The recommended dose of Tamiflu is as follows:

Adults: 75 mg BID for 5 days

Children at least 1 year of age:

≤15 kg: 30 mg BID for 5 days

16 to 23 kg: 45 mg BID for 5 days

24 to 40 kg: 60 mg BID for 5 days

>40 kg: 75 mg BID for 5 days

Tamiflu is also indicated for chemoprophylaxis following close contact with infected persons. The dose is half the total daily treatment dose (see above), administered once daily, and the recommended duration of prophylaxis is for 10 days after the last known exposure (e.g., for adults, 75 mg QD for 10 days). The FDA has issued an Emergency Use Authorization allowing for Tamiflu suspension to be given to children less than 1 year of age (see table below). During last spring's outbreak, there were sporadic shortages of Tamiflu suspension; should this occur again, the FDA has indicated that the capsules (available in 30, 45, and 75 mg) may be opened and mixed with sweetened liquids, such as regular or sugar-free chocolate syrup.

***Emergency Use* TAMIFLU (oseltamivir) Dosing for Swine Flu in Children Less Than 1 Year of Age**

Patient Age	Treatment Dose	Prophylaxis Dose
< 3 Months	12 mg BID x 5 days	Not recommended unless situation judged critical
3 - 5 Months	20 mg BID x 5 days	20 mg QD x 10 days
6 - 11 Months	25 mg BID x 5 days	25 mg QD x 10 days

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ASK PRN...

During the swine flu outbreak this past spring, there were shortages of both Tamiflu suspension and Tamiflu low-dose capsules (30 and 45 mg). Should this happen again, is there a formula for preparing a Tamiflu suspension from the 75 mg capsules?

Yes. The FDA has approved a formula for use in emergency situations only, when the commercially prepared suspension is unavailable. The formula calls for preparation of a 15 mg/mL suspension using either Cherry Syrup (Humco®) or Ora-Sweet SF (sugar-free) (Paddock). The procedure is as follows: transfer the contents of the required number of 75 mg capsules to a mortar and triturate to a fine powder. Add 1/3 of the specified amount of vehicle and triturate to uniform suspension. Transfer to amber glass or PET bottle. Add another 1/3 of vehicle to rinse mortar, transfer to bottle, and repeat with final 1/3 of vehicle. Shake bottle well to dissolve drug and attach "Shake Gently Before Use" label. Suspension is stable for 5 days at room temperature or 35 days under refrigeration. Excess volume is provided (final volumes 30, 40, 50, and 60 mL), so attach label informing parents to discard any remaining liquid after completion of therapy.

Dose in mg	Dose in mL	Number of 75 mg capsules	mL of vehicle to add
30 mg BID	2 mL BID	6	29
45 mg BID	3 mL BID	8	38.5
60 mg BID	4 mL BID	10	48
75 mg BID	5 mL BID	12	57

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
askprn@prnnewsletter.com

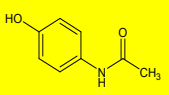
PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the first college of pharmacy opened in the United States was the Philadelphia College of Pharmacy?[1] The college, founded in 1821, is still in operation today, and is now known as the University of the Sciences of Philadelphia. The second pharmacy school to open in the U.S. was the College of Pharmacy of the City of New York, which began training pharmacists in 1829. In 1904, the college was incorporated into Columbia University, and was eventually renamed the Columbia University College of Pharmaceutical Sciences. Unfortunately, following years of financial problems, the college closed its doors for good in 1976 after losing its accreditation with the American Council of Pharmaceutical Education.

PHARMACY FUN

September has arrived and that means it's time for our second annual Back to School Quiz! Cast your mind back to those heady days spent in Med Chem and Pharmacology—how many of the following structures can you name correctly? The first reader to send the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.



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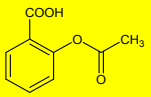

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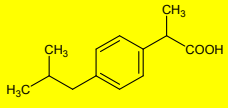
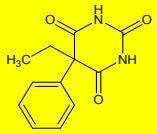


C



D

Answers to last month's ***PHARMACY FUN***:
Use the balance to split the 300 mg into 2 portions of 150 mg each. Place the 30 mg weight on the right pan, then transfer powder to the left pan until equilibrium, resulting in 165 mg on the left pan and 135 mg on the right. Use the same method with the 165 mg portion, splitting it between pans, then using both the 30 mg and the 5 mg weights to separate the powder in to **100 mg** and 65 mg portions. Then use both weights to separate the 65 mg portion into a **50 mg** and a 15 mg portion. Finally, add the 15 mg portion to the 135 mg portion to get **150 mg**.

References:
1. Glenn Sonnedecker, *Kremers and Urdang's History of Pharmacy* (Madison, WI: American Institute of the History of Pharmacy, 1976), 227.