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What's Inside…

BREAKING NEWS

The Centers for Disease Control and Prevention (CDC) has confirmed that the **swine flu outbreak**, which appears to have begun in Veracruz state, Mexico, has spread to the U.S., with the greatest number of known cases found in Queens, New York. The virus, which is responsible for more than 100 deaths in Mexico, appeared in a cluster of cases at St. Francis Preparatory School, a Catholic high school located in Fresh Meadows. The outbreak is believed to have originated with several St. Francis students recently returned from a spring break trip to Mexico. As we go to press, there are 51 confirmed cases in New York City, mostly among students and faculty of the high school. A key fact for pharmacists to know is that, unlike this year's human type A, H1N1 flu virus, the swine flu (also A, H1N1) **is not resistant to Tamiflu** (oseltamivir). The virus is, however, resistant to both **rimantadine** and **amantadine**. Treatment of swine flu should, therefore, consist of either Tamiflu or **Relenza** (zanamavir). This story, like the virus itself, is still evolving; look for important updates on our website: ***www.prnnewsletter.com***. See page 3 for more details.

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New TNF Inhibitor Approved: The FDA has given the green light to Centocor Ortho Biotech's **Simponi** (golimumab), a new tumor necrosis factor (TNF) inhibitor. Like **Enbrel** and **Humira**, Simponi blocks the action of TNF, a protein that plays a key role in the inflammatory process and resulting joint damage of rheumatoid disorders. Simponi is FDA-approved for the following indications:

- **The treatment of adults with moderate-to-severe rheumatoid arthritis (in combination with methotrexate)**
- **The treatment of adults with active psoriatic arthritis (alone or in combination with methotrexate)**
- **The treatment of adult patients with active ankylosing spondylitis**

Simponi is unique in that it represents the first patient-administered TNF blocker that offers a once-monthly treatment option. Simponi is, unfortunately, not unique in that it carries the same serious risks as other TNF blockers: increased risk of bacterial, viral, and fungal infections, including tuberculosis and histoplasmosis, reactivation of Hepatitis B in patients who are carriers of the virus, increased risk of developing lymphoma and other cancers, and the development or worsening of heart failure. Patients taking Simponi should avoid concurrent administration of live vaccines. Simponi will be available in a 50 mg once monthly subcutaneous dose as either a prefilled syringe or in the Simponi SmartJect, an autoinjector designed to be easy to use for patients with reduced dexterity resulting from arthritis.

Plan B OTC Age Limit Lowered: In 2006, The Food and Drug Administration (FDA) approved the over-the-counter sale of the emergency contraceptive **Plan B** (levonorgestrel) to women aged 18 years and older. Last month, a Federal District Court judge in New York ruled that this decision was fraught with "political considerations, delays, and implausible justifications"[1] and ordered the FDA to lower the age limit to 17 within 30 days. The lower age limit is consistent with the scientific findings of the agency's Center for Drug Evaluation and Research. In a statement issued on April 22, the FDA announced that it would not contest the ruling, and informed the manufacturer, Teva Pharmaceuticals, that upon submission and approval of the appropriate application, they may market Plan B without a prescription to women 17 years of age and older. It is expected to take several months for the application and relabeling process to be completed.

Sublingual Zolpidem: The FDA has approved a sublingual form of the sedative hypnotic agent Zolpidem, which will be marketed by Orexo under the trade name **Edluar**. This fast-acting formulation will be available in 5 and 10 mg strengths and should be placed under the tongue right before getting into bed. Edluar should not be swallowed or taken with water, and should not be taken with, or right after, a meal. As with other forms of Zolpidem, there is a risk of patients getting out of bed while not fully awake and engaging in activities they are not aware of, such as "sleep-driving," sleep-walking, and making and eating food.

New York Pharmacy Chains Agree To Provide Language Services

New York State Attorney General Andrew Cuomo has reached an agreement with five major pharmacy chains regarding communication with patients whose primary language is not English. The agreement is the result of an undercover investigation which was prompted by the immigrant advocate organization *Make the Road New York*. The investigation found many cases where legally mandated pharmacist counseling was hindered by a language barrier, sometime leading to medication misuse by non-English speaking patients. The solution reached involves the installation of so-called "language lines," telephones in the pharmacy connected to interpreters of the estimated 170 languages spoken in New York State. Additionally, the pharmacies agreed to provide written drug information to customers in the five most common foreign languages spoken in New York: Spanish, Chinese, Italian, Russian, and French. The five pharmacy chains involved in the agreement are: Duane Reade, Target, Wal-Mart, Costco,, and A. & P. (operator of Pathmark pharmacies, among others). Two other major pharmacy chains in the state, CVS and Rite-Aid, are already providing these language services, based on an agreement with the attorney general reached last November.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

New York State Budget 2009-10: Changes in Medicaid Program

The New York State Health Budget for 2009-10, approved by the legislature on April 3, includes a number of reforms involving the Medicaid program. Along with changes which invest in primary and preventative care, the budget also contains several pharmacy initiatives which will directly affect pharmacists who participate in the program:

- **Quantity, frequency, and duration limits** will be instituted for certain drugs. These parameters will be set by the State's Drug Utilization Review Board.
- **Step therapy** programs, which require the use of less costly first-line agents before approval of second-line drugs, may be applied to some therapeutic categories.
- **Brand-name drugs** may be covered by Medicaid if they are less costly than their generic equivalents after rebates are applied.
- **The rebate program will be strengthened** by allowing Medicaid to negotiate directly with drug manufacturers. This change is expected to expand the Preferred Drug Program beyond the drug classes currently included and allow Medicaid to receive rebates on a greater number of preferred drugs.
- **E-prescribing** will be encouraged by providing an extra 80 cents per electronic prescription to prescribers and an additional 20 cents per electronic prescription to pharmacies. It is hoped that an increase in e-prescribing will reduce medication errors, produce better patient outcomes, and lead to savings in the long run.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Inventory Requirements for Controlled Substances

Pharmacies registered in New York State are required to take a complete inventory of all controlled substances in stock on May 1st of every odd-numbered year. This biennial inventory system dates back to a regulation, section 80.112 of the Rules and Regulations on Controlled Substances, which states, in part:

> **All pharmacies possessing, having under their control, selling, dispensing, or compounding any controlled substance in New York State shall as of May 1, 1975 and every two years thereafter, prepare and maintain am inventory of all controlled substances….**
>
> **Maintaining for inspection a biennial inventory of controlled substances prepared and maintained in compliance with federal statute and regulations shall be deemed compliance with this section.**

That second statement leads us to the federal rules on controlled substance inventories; this is an unusual case where it is necessary to combine both state and federal regulations in order obtain a complete understanding of what is required. The federal statutes are found in the Code of Federal Regulations, specifically 21 CFR 1304.11., the key points of which are:

- **Initial inventory: an inventory of all controlled substance stocks shall be taken on the date the pharmacy first engages in the dispensing of controlled substances.**
- **Bienniel inventory: After the initial inventory, a new inventory shall be taken at least every two years *(May 1st of odd-numbered years in New York State)*.**
- **The records of all controlled substance inventories shall be maintained at the registered location *(must be kept with other controlled substance records and be kept available for inspection for at least 5 years in New York State)*.**
- **The inventory shall be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.**
- **For Schedule II substances an *exact* count or measure must be taken.**
- **For Schedule III, IV, or V substances, an estimated count or measure may be taken, unless the container holds *more* than 1,000 tablets or capsules, in which case an *exact* count must be taken.**
- **On the effective date of a rule which changes the schedule of a substance from non-controlled to controlled, every registrant who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each biennial inventory.**
- **The inventory record must contain the name, address, and DEA registration number of the registrant.**
- **The inventory record should also contain the signature(s) of the person or persons or persons responsible for taking the inventory**

Feature Article..

CDC Update On Swine Flu Outbreak

Early In March of this year, 5 year-old Edgar Hernandez starting feeling sick; he had a fever, a cough, and stopped eating. Edgar, who lives in La Gloria, Mexico, near a large, industrial pig farm, has been identified by Mexican officials as patient zero in the current swine flu outbreak. Others believe there may have been an earlier case, in San Diego, California. Whatever the source, the swine flu quickly spread and there are now confirmed cases in 9 countries: the U.S., Mexico, Austria, Canada, Germany, Israel, New Zealand, Spain, and the United Kingdom. Much of the information below is derived from the CDC. The situation is evolving rapidly and we suggest that pharmacists keep up with the latest news by visiting our website (***www.prnnewsletter.com***), as well as that of the CDC (***www.cdc.gov***).

What Is The Swine Flu?

The current outbreak is caused by a unique virus which has been analyzed by the CDC and found to contain genetic components from four sources: North American swine influenza virus, North American avian influenza virus, human influenza virus, and swine influenza virus found in Asia and Europe. The virus is designated Type A, H1N1, but is genetically distinct from this year's human Type A, H1N1 virus and therefore previous vaccination against that strain will not prevent infection with the swine flu.

How Is Swine Flu Contracted?

It is believed that swine flu is spread from person to person in the same way the seasonal influenza is spread. People contract swine flu through the coughing and sneezing of infected persons. Swine flu may also be contracted by touching something contaminated with the virus and then touching the nose or mouth. "Close contact" is defined as being within 6 feet of an ill person during their infectious period. The infectious period is defined as from 1 day prior to the onset of illness to 7 days after the onset of illness.

What Are The Symptoms Of Swine Flu?

The symptoms of swine flu are indistinguishable from those of seasonal influenza, namely: fever, cough, sore throat, body aches, headache, chills, fatigue, and loss of appetite. Some patients have also reported diarrhea and vomiting.

How Is Swine Flu Treated?

Unlike this year's seasonal H1N1 flu virus, the swine flu virus can be treated with either **Tamiflu** or **Relenza**. The swine flu virus is resistant to both **rimantadine** and **amantadine**. Tamiflu is approved for use in adults and children aged 1 year and older. In response to the current outbreak, the FDA has issued an Emergency Use Authorization (EUA) allowing for the use of Tamiflu in children less than 1 year of age. Both Tamiflu and Relenza are also indicated for chemoprophylaxis following close contact with infected persons. Recommended duration of prophylaxis dose is for 10 days after the last know exposure to an ill confirmed case of swine flu influenza A (H1N1) virus infection.

TAMIFLU (oseltamivir) Dosing for Swine Flu in Adults and Children 1 Year of Age and Older

Patient Age	Treatment Dose	Prophylaxis Dose
Adults	75 mg BID x 5 days	75 mg QD x 10 days
Children ≥1 year 15 kg or less	30 mg BID x 5 days	30 mg QD x 10 days
Children ≥1 year 15 - 23 kg	45 mg BID x 5 days	45 mg QD x 10 days
Children ≥1 year 24 - 40 kg	60 mg BID x 5 days	60 mg QD x 10 days
Children ≥1 year >40 kg	75 mg BID x 5 days	75 mg QD x 10 days

***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...

Occasionally a prescriber will write "prn" as a refill instruction. Is this acceptable?

Yes, but it is only valid for one refill. Section 29.7(a)(4) of the Rules of the Board of Regents states that pharmacists may accept, as refill instructions, a specific number of times, a time period, such as one year, or the Latin phrase pro re nata (prn), in which case the pharmacist shall refill the prescription only once. This applies to prescriptions for non-controlled substances only. In the case of controlled substance prescriptions, section 80.69(b)(5) of the Rules and Regulations on Controlled Substances states that a prescription must contain "the *number* of times a prescription may be refilled indicated in both numerical and written word form." Furthermore, section 80.69(g) indicates that "prescriptions may be refilled, but not more than the number of times *specifically* authorized by the prescriber upon the prescription," up to a maximum of 5 times within 6 months of the date the prescription was signed.

We received a prescription at our pharmacy for Adderall XR 20 mg, Sig: 1 capsule QD, #90. There was, however, no code written on the prescription which would allow for the dispensing of a 90-day supply. Can this information be added to the prescription by the pharmacist?

Yes, after consultation with the prescriber. Pharmacists may add information missing from a controlled substance prescription, except in the case of unsigned or undated prescriptions, or those missing the name and/or quantity of the controlled substance, or where the name of the ultimate user is missing. The prescriber may orally provide the missing information to the pharmacist and authorize entry of the information on the Rx. The pharmacist must also enter the date he or she received the authorization and sign the Rx.

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 there was once a monoamine oxidase inhibitor (MAOI) on the market in the United States for the treatment of *hypertension*? Today, pharmacists are most familiar with MAOIs as antidepressants which carry a warning about hypertensive crisis if taken with certain other drugs or tyramine-rich foods and beverages. But back in 1964, when Abbott introduced **Eutonyl** (pargyline), it was touted as a powerful antihypertensive which did not cause depression, unlike some other popular agents of the day, such as reserpine. An ad in the Dec. 1964 *Diseases of the Chest* quotes Eutonyl users as saying they "feel like new" and "believe the future holds something for me."

PHARMACY FUN

How good is your visual memory? How well do you remember things you see every day? Would you make a good eyewitness? Answer these questions by taking our tablet imprint quiz! Below are the numbers and/or letters printed on 8 popular drugs (we used brand names only since different pharmacies carry different generics). How many can you name? The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **75/1171**
2. **PD155/10**
3. **DV/NVR**
4. **FL/20**
5. **Lilly 4115**
6. **MRK 952**
7. **BAYER/M400**
8. **414**

Answers to last month's **PHARMACY FUN**:
1. Rosuvastatin 2. Linezolid 3. Erythromycin 4. Escitalopram 5. Amoxicilln or Ampicillin 6. Ergotamine 7. Diltiazem 8. Inamnirone 9. Sitagliptin 10. Mercaptopurine 11. Lithium
Hidden Answer: EMERALD ISLE

References:
1. Kirk Semple, "Pharmacies Agree to Provide Prescription Data in Many Languages," *New York Times*, April 22, 2009.