P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

No. 40 **The Newsletter for Community Pharmacists** **September/October, 2011**

What's Inside…

FDA NEWS

Additional FDA Approvals

Cialis (tadalafil) has been approved for two additional indications: treatment of the signs and symptoms of benign prostatic hyperplasia (BPH), and treatment of erectile dysfunction (ED) and the signs and symptoms of BPH (ED/BPH). The approvals were based on three studies which demonstrated statistically significant improvement in BPH and ED/BPH patients treated with Cialis.

The FDA has approved two new hydrocodone-containing cough and cold preparations, the first such approvals since 1990. **Rezira** is a combination of hydrocodone 5 mg/5 mL and pseudoephedrine 60 mg/5 mL. **Zutripro** contains hydrocodone 5 mg/5 mL, chlorpheniramine 4 mg/5 mL, and pseudoephedrine 60 mg/5 mL. Both products are Schedule III controlled substances indicated for patient 18 years and older. The recommended dose is 5 mL every 4 to 6 hours as needed (MDD of 20 mL).

.....NEW DRUGS.....NEW DRUGS.....NEW DRUGS.....

XARELTO (Rivaroxaban).
Category: Factor Xa Inhibitor.
Initial dose: 10 mg once a day, taken with or without food.
MDD: 10 mg.

Janssen Pharmaceuticals has announced the FDA approval of Xarelto, a novel, once-daily oral anticoagulant for the prevention of deep vein thrombosis (DVT) in patients undergoing knee or hip replacement surgery. Xarelto is recommended to be taken for 12 days in knee replacement, and for 35 days in hip replacement. The most common adverse reaction seen in clinical trials was bleeding. On September 8, 2011, an FDA advisory panel voted 9 to 2 to recommend approval of Xarelto for use in preventing strokes and blood clots in patients with atrial fibrillation. If the FDA does grant approval for this indication, Xarelto would represent a second alternative to **warfarin**, the first being **Pradaxa**.

RECTIV (Nitroglycerin 0.4% Ointment).
Category: Vasodilator for Anal Fissure.
Initial dose: 1 inch of ointment (1.5 mg of nitroglycerin) intra-anally every 12 hours for up to 3 weeks.
MDD: 3 mg.

The FDA has approved ProStrakan Group's Rectiv, a nitroglycerin ointment for the treatment of moderate to severe pain associated with chronic anal fissure. For years, pharmacists have compounded a 0.2% ointment for the same purpose, but Rectiv is the first commercially available product for this indication. The product packaging contains a guide to facilitate measurement of the 1 inch dose.

LAZANDA (Fentanyl Nasal Spray).
Category: Opioid Analgesic.
Initial dose: One spray in one nostril (100mcg).
MDD: Four doses per 24 hours (doses range between 100 mcg and 800 mcg each).

Archimedes Pharma has received approval to market Lazanda, the first fentanyl nasal spray, for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and already tolerant to opioid therapy for their underlying persistent cancer pain. Lazanda will be available through a Risk Evaluation and Mitigation Strategy (REMS) which will require prescribers, pharmacies, and patients to enroll in the program before prescribing, dispensing, or receiving the drug. Pharmacists can enroll by reviewing educational materials and answering a 10-question knowledge assessment at ***www.lazandarems.com***.

JUVISYNC (Sitagliptin and Simvastatin).
Category: DPP-IV and HMG-CoA Reductase Inhibitor combination product.
Initial dose: 100 mg/40 mg once a day in the evening.
MDD: 100 mg/40 mg.

A new combination product by Merck Sharp & Dohme has been approved for the treatment of both type 2 diabetes and high cholesterol. Juvisync is a combination of Januvia and Zocor and will be available in fixed-dose combinations of 100 mg/10 mg, 100 mg/20 mg, and 100 mg/40 mg (a version containing only 50 mg on Januvia will be available at a future date). Juvisync is not indicated for use in Type 1 diabetes, and should not be used with drugs that interact with simvastatin (see our interaction chart in ***PRN*** # 38).

Ban on Primatene Mist Takes Effect December 31, 2011

Armstrong Pharmaceuticals' **Primatene Mist**, the only over-the-counter inhaler for the treatment of asthma symptoms, can not be manufactured or sold in the U.S. after December 31, 2011, according to the FDA. The ban is the result of compliance with the *Montreal Protocol on Substances that Deplete the Ozone Layer*, an international treaty signed by the United States in 1987. The treaty calls for the phasing out of products containing ozone-depleting chlorofluorocarbons (CFCs). The maker of Primatene Mist is currently developing a CFC-free version, but does not expect to receive FDA approval until some time after the ban goes into effect. Patients who rely on Primatene Mist should be advised to speak to a healthcare professional about switching to a prescription inhaler containing albuterol (**ProAir HFA, Proventil HFA, Ventolin HFA**). In a related development, Boehringer Ingelheim announced the approval of **Combivent Respimat**, a propellant-free replacement for **Combivent**, which contains CFCs and which will be phased out by December 31, 2013.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Transition to Managed Care Pharmacy Benefit

Effective October 1, 2011, New York State Medicaid beneficiaries enrolled in Medicaid and Family Health Plus managed care plans will receive pharmacy benefits through their health plan, rather than through Medicaid. Some key points for pharmacists with managed care patients include:

- **Managed care patients will receive new health plan prescription cards, but if the card is unavailable pharmacists can determine which health plan to bill either by swiping the patient's Medicaid card and performing an eligibility transaction, or by calling the MEVS eligibility line at (800) 997-1111.**
- **Co-payments will remain the same as under Medicaid, with one exception: there will be no co-payments for supplies for managed care members. As is the case with Medicaid, pharmacies may not refuse to provide a drug solely because the managed care member cannot affords the co-payment. However, any legal means may be employed to collect unpaid co-payments.**
- **The OMIG card swipe requirement *will not* apply to managed care members.**

Medicare Part D "Wrap Around" Coverage Discontinued

Since 2006, New York State Medicaid has provided "wrap around" coverage for dual-eligible patients in the following 4 categories of drugs:

- **Atypical antipsychotics**
- **Antidepressants**
- **Antiretrovirals used in HIV/AIDS**
- **Antirejection drugs for transplants**

As of October 1, 2011, this coverage will be discontinued, and non-covered drugs will require Medicare Part D prior authorization.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

New York State Expedited Partner Therapy Program for STIs

In January of 2009, New York State enacted the Expedited Partner Therapy (EPT) law, which permits health care providers (physicians, nurse midwives, nurse practitioner, and physician assistants) to provide treatment to sex partners of persons diagnosed with *Chlamydia trachomatis* (Ct) without a prior medial examination or clinical assessment of those partners. The intention of the law is to reduce the morbidity caused by Ct infection and re-infection. Ct is the most commonly reported sexually transmitted infection (STI) nationwide, and is a leading cause of infertility, pelvic inflammatory disease, chronic pelvic pain, and ectopic pregnancy. The regulations pertaining to EPT (section 23.5 of Title 10 NYCRR) include the following provisions:

- **The use of EPT is limited to Ct infection only. The recommended EPT treatment for Ct is *1 gram of azithromycin in a single oral dose*.**
- **EPT should not be provided to Ct patients concurrently infected with gonorrhea or syphilis.**
- **EPT is *not* recommended for treating men who have sex with men due to a high risk of HIV co-morbidity in partners.**
- **EPT prescriptions must include the phrase "EPT" in the body of the prescription above the name and dosage of the medication. Prescriptions can be provided to patients without the name, address, or date of birth of the sex partner; the written designation "EPT" shall be sufficient for the pharmacist to fill the prescription. If needed, this information can be obtained when the prescription is dropped off at the pharmacy.**
- **Health care providers or pharmacists who dispense EPT in accordance with this law shall not be subject to liability or be deemed to have engaged in unprofessional conduct.**
- **EPT issued as medication or as a prescription to the original patient must be accompanied by written materials for patients and partners, addressing possible side effects and contraindications to EPT medication.**

Frequently Asked Questions for Pharmacists

Q: Who will assume the cost of the sex partner's medication?

A: Medication costs may be self-pay (paid by the person who picks up the prescription) or paid by the sex partner's health insurance. Billing the sex partner's prescription under the original patient's name would be considered fraudulent.

Q: How should pharmacists conduct patient record keeping for "EPT" prescriptions?

A: EPT prescriptions should be documented/filed like any other non-controlled substance prescription.

Q: If a sex partner is allergic to azithromycin, what are the alternatives?

A: If the sex partner is known to be allergic to macrolides, azithromycin should not be given and the partner should be instructed to see a physician for appropriate treatment.

Q: What if the sex partner is taking a medication that interacts with azithromycin?

A: EPT should not be dispensed, and the partner should be referred to a physician or emergency room for appropriate treatment.

Guest Editorial: **Daniel A. Hussar**

The Large Chains are Making a Mockery of Our Profession– And Our Profession is a Co-Conspirator Through Our Silence!

October is American Pharmacists Month, and to mark the ocassion we have chosen to present the following editorial, reprinted with permission from the April, 2011 edition of ***The Pharmacist Activist***, which addresses a growing crisis that threatens the future of the profession of pharmacy. Daniel A. Hussar is the Remington Professor of Pharmacy at the Philadelphia College of Pharmacy, a former Dean of that institution, the author of the New Drugs and Comparison Ratings series, and a powerful advocate for our profession. (Due to space limitations, the complete editorial could not be reproduced here; the full text may be accessed at ***www.pharmacistactivist.com***)

LOOK! OVER ON THE CORNER! It's a fast-food drive-through! It's a photo center! It's a tobacco shop! It's a supermarket! IT'S SUPERMEGACHAINPHARMACY! (with apologies to Superman).

It used to be that the large chain pharmacies like CVS Caremark, Walgreens, and Rite Aid would be satisfied to expand their lines of retail merchandise while permitting the Pharmacy department to function in as professional a manner as possible in an environment that increasingly resembles a convenience store or mini-mall. However, in recent years, they have commercialized, discounted, and demeaned the importance and risks of prescription medications, as well as the value of the professional role and services of their own pharmacists. Many of these actions insult and make a mockery of the profession of pharmacy – the very profession that has made possible what they might count as their success.

Rite Aid coupons

The chains have used various strategies to increase the speed of dispensing prescriptions as one measure of evaluating their pharmacists. However, Rite Aid has added an additional incentive for speed by promoting to consumers that, if their prescription is not ready within 15 minutes, they will receive a $5 coupon for store merchandise. How can this promotion not place added pressure and stress on the already-busy pharmacist whose performance might be evaluated negatively by management if too many $5 coupons have to be given to customers on her/his shift?

Many Rite Aid employees have concerns about and even ridicule this promotion, but their management does not listen to them.

Some customers play games with the promotion and "hide out" in a corner of the store or step outside until the 15 minutes elapse to increase their likelihood of obtaining the $5 coupon. The employees in the front end of the store chide those in the Pharmacy department that there is not a similar $5 coupon incentive to help customers speed their way through the lines at the front of the store.

As people learn of this promotion, the instant recall for many is the Domino Pizza promotion to deliver pizzas within 30 minutes, one of the consequences of which was an increased number of accidents of Dominos' delivery vehicles. I would contend that the Rite Aid promotion has serious negative implications with respect to patient safety.

CVS Caremark steals patients

Caremark is one of the largest administrators of prescription benefit programs. It establishes the criteria and policies of these programs that local pharmacies can accept or reject, but not negotiate or collaborate. Many of these programs require participating patients to obtain their medications for chronic conditions from a Caremark mail-order pharmacy or a local CVS pharmacy. Unless a patient is willing to incur financial penalties for not abiding by the conditions of the prescription program, they are forced to obtain these medications from a pharmacy other than the one that they might have been using for decades and in which they have a long-standing and trusted relationship with the pharmacist. CVS Caremark is stealing these patients from their local pharmacies and, by fragmenting their care by having them use additional pharmacies, is placing them at greater risk of drug interactions and other drug-related problems. Legislative initiatives that would prevent these practices are being pursued in many states and at the national level and require extensive support from the profession.

Lawsuits

The most recent public embarrassment for CVS and our profession is the announcement that CVS will pay $17.5 million to the federal government and 10 state governments to settle allegations that it overcharged Medicaid programs. A CVS pharmacist was a whistleblower in this case and must have provided compelling evidence, even though CVS provided its standard response when they settle allegations for millions of dollars-acknowledging no wrongdoing but agreeing to settle to avoid additional expense and uncertainty. In my opinion, the federal and state governments should not settle cases such as this, but rather should continue to investigate and prosecute these situations so that innocence or guilt can be clearly determined. If there is guilt, the participation of the guilty party/company in the government prescription program should be terminated.

It was only in October that CVS agreed to pay $75 million in civil penalties following its admission that it unlawfully sold pseudoephedrine to criminals who made methamphetamine (please see the editorial in the November, 2010 issue of *The Pharmacist Activist*). It is bad enough that CVS is engaged in such activities. Unfortunately, our entire profession is the victim of the negative publicity that results.

Public opinion

Situations such as the above through which large chain pharmacies make a mockery of the profession of pharmacy are not only of concern to those in our profession, but are also increasingly evident to patients and others outside the profession. The May 2011 issue of *Consumer Reports* includes an article, "Best Drugstores," in which more than 43,000 readers rate pharmacies on factors such as accuracy, knowledge, helpfulness, and personal service. Thirty-three pharmacy chains and other entities were evaluated and the five receiving the lowest ratings are the following:

29-31 - tie between CVS, Giant Eagle, and Walgreens
32 - Rite Aid
33 - Walmart

The five receiving the highest ratings are the following:

1 - Independent drugstores
2-3 - tie between Health Mart and The Medicine Shoppe
4-5 - tie between Bi-Mart and Publix

The silence of our profession

Many of the situations described above might be expected to generate outrage from within our profession. Are these the ways in which we want our profession to be known to the public? Are these the types of practice situations in which we want pharmacists and student pharmacists to be employed? Are patients not being placed at excessive risk of drug-related problems? Are these not situations that severely compromise the attainment of the vision for the profession that we rally around?

What are our national and state pharmacy associations, our state boards of pharmacy, and our colleges of pharmacy saying about these situations? With few exceptions, SILENCE has been their response. To give credit where credit is due, the National Community Pharmacists Association has been highly active in addressing the concerns associated with CVS Caremark operations, Mike Cohen and the Institute for Safe Medication Practices have been exceptional in addressing patient safety issues including the Rite Aid coupons, and the New York Board of Pharmacy has been bold in prohibiting the Rite Aid coupon program.

Where are all the other boards, colleges, and pharmacy associations? Our profession has become a co-conspirator through our silence!

Daniel A. Hussar

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P.R.N. (ISSN # 1941-9481)
is published bi-monthly by:
PRN Publishing LLC
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375
Phone & Fax (718) 263-4632

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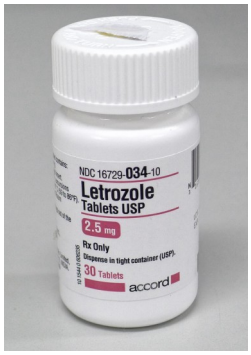
ASK PRN...

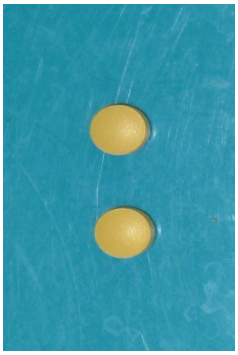
I recently dispensed a new generic for Femara, letrozole by Accord Healthcare, and noticed something very unusual: the tablets had no markings or imprint of any kind. Doesn't the FDA require all prescription drug tablets or capsules to be imprinted for identification purposes?

Yes. 21 CFR Part 206.10 reads:

Unless exempted under §206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product.

Exemptions to 206 include products with "unique physical characteristic" which would preclude imprinting. This is not the case with Accord's letrozole (see below); what appears to have been an oversight by the manufacturer is now being corrected through a supplemental application to the FDA. The new version will be imprinted with the letters "LT" on one side.





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 Speedy, the iconic animated spokesman for Alka Seltzer, was brought to life by the Academy Award-winning animator and filmmaker George Pal? Pal would later produce and/or direct such classics as *War of the Worlds*, *The Time Machine*, and *The Seven Faces of Dr. Lao*. Speedy, who was originally intended to be named Sparky, first appeared in 1951 and was featured in 212 commercials for Alka Seltzer, finally "retiring" in 1964. Speedy returned to print advertisements in 2008, and then made his television comeback in 2010.

PHARMACY FUN

Autumn has arrived and that means it's time for our fourth annual Back To School Quiz! This one should be a snap for those of you who attended pharmacy school back in the 20th century: match the archaic term on the left with the corresponding modern nomenclature on the right. The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. Carbolic Acid	**a. Ammonium Chloride**
2. Oil of Vitriol	**b. Mercury (I) Chloride**
3. Calomel	**c. Phenol**
4. Sal Ammoniac	**d. Hydrochloric Acid**
5. Lugol's Solution	**e. Sulfuric Acid**
6. Muriatic Acid	**f. Iodine/Potassium Iodide**

Answers to last month's **PHARMACY FUN**:
What's interesting about the sentence in last issue's Pharmacy Fun is that each word has exactly one more letter than the previous word, starting with "I" (1) and ending with "incomprehensibleness" (20).

Photographs by James Murphy