

Spring 2009

**FDA REQUIRES BOXED WARNING AND RISK MITIGATION STRATEGY FOR METOCLOPRAMIDE-CONTAINING DRUGS****Agency warns against chronic use of these products to treat gastrointestinal disorders**

The U.S. Food and Drug Administration announced recently that manufacturers of metoclopramide, a drug used to treat gastrointestinal disorders, must add a boxed warning to their drug labels about the risk of its long-term or high-dose use. Chronic use of metoclopramide has been linked to tardive dyskinesia, which may include involuntary and repetitive movements of the body, even after the drugs are no longer taken.

Manufacturers will be required to implement a risk evaluation and mitigation strategy, or REMS, to ensure patients are provided with a medication guide that discusses this risk.

“The FDA wants patients and health care professionals to know about this risk so they can make informed decisions about treatment,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research. “The chronic use of metoclopramide therapy should be avoided in all but rare cases where the benefit is believed to outweigh the risk.”

Current product labeling warns of the risk of tardive dyskinesia with chronic metoclopramide treatment. The development of this condition is directly related to the length of time a patient is taking metoclopramide and the number of doses taken. Those at greatest risk include the elderly, especially older women, and people who have been on the drug for a long time.

Tardive dyskinesia is characterized by involuntary, repetitive movements of the extremities, or lip smacking, grimacing, tongue protrusion, rapid eye movements or blinking, puckering and pursing of the lips, or impaired movement of the fingers. These symptoms are rarely reversible and there is no known treatment. However, in some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

Metoclopramide works by speeding up the movement of the stomach muscles, thus increasing the rate at which the stomach empties into the intestines. It is used as a short-term treatment of gastroesophageal reflux disease in patients who have not responded to other therapies, and to treat diabetic gastroparesis (slowed emptying of the stomach’s contents into the intestines). It is recommended that treatment not exceed three months.

Metoclopramide is available in a variety of formulations including tablets, syrups and injections. Names of metoclopramide-containing products include Reglan Tablets, Reglan Oral Disintegrating Tablets, Metoclopramide Oral Solution and Reglan Injection. More than two million Americans use these products.

Recently published analyses suggest that metoclopramide is the most common cause of drug-induced movement disorders. Another analysis of study data by the FDA showed that about 20 percent of patients in that study who used metoclopramide took it for longer than three months. The FDA has also become aware of continued spontaneous reports of tardive dyskinesia in patients who used metoclopramide, the majority of whom had taken the drug for more than three months.

Consumers and health care professionals are encouraged to report adverse events to the FDA’s MedWatch program at 800-FDA-1088, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, Md. 20852-9787, or online at: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

**HOW TO GET THAT SECOND WIND****Feeling run-down?**

You can turn up the energy in five minutes if you...

**Refuel.**

Snack on fiber-rich munchies, such as dried apricots, celery sticks, an apple or a few pistachio nuts.

**Breathe Deeply.**

Every 1-2 hours, spend 5 minutes inhaling and exhaling deeply. It will help you feel calmer and more mentally focused, with renewed energy.

**Take A Visual Vacation.**

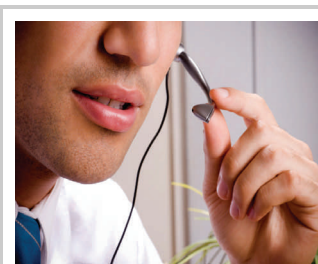
Close your eyes and mentally escape by imagining a peaceful scene on an island, in a meadow or by the ocean. “Seeing” yourself relaxed can be rejuvenating.

**Snap Out Of It.**

Splash cold water on your face or pop a breath mint—mint flavors are stimulating.

**Take A “Good News” Inventory.**

At the end of the day, write down all the good things that happened. You will be surprised at how much went right. Plus, you will set yourself up for a good night’s sleep... and energize yourself for tomorrow.



## PLAN B UPDATE

Plaintiffs who challenged FDA's denial of a Citizen Petition, which requested the FDA to make Plan B available without a prescription to women of all ages, won their case. The FDA was also ordered to permit Barr Pharmaceuticals, Inc. the Plan B drug sponsor, to make Plan B available to 17 year olds without a prescription, under the same conditions as Plan B is now available to women over the age of 18. The latter order should be complied with **within thirty days**. More information will be available soon.

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## LEGISLATIVE UPDATE

### **Senate Bill 76**

#### **RE: Donation of Unused Prescription Drugs (by Sen. Stewart Greenleaf, et al)**

Amends the Pharmacy Act to provide for the donation of unused prescription drugs by requiring the Department of Health, the board and the Health Care Cost Containment Council to develop a pilot project by which unused prescription drugs, other than controlled substances, be transferred from nursing facilities to pharmacies for the purpose of distributing the prescription drugs to residents who are Medically indigent (i.e. have no health insurance). The bill also calls for a review and report of the program after 18 months.

**Refiled from 2007 session.**

**Referred to Senate Consumer Protection & Prof. Licensure Committee, 1/30/2009**

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## MEDICATIONS—GOING GREEN?

The environment is getting a lot of attention these days. Topics such as global warming and climate change may have been relegated to scientific circles just a few years ago, however, now it is part of mainstream discussions. "Going Green" is certainly a concept gaining momentum, and likely will continue to do so.

Less publicized as an environmental threat, but no less critical, are improperly disposed drugs, such as prescription medications. This is a situation that can no longer be disregarded. It is important to get unused medications out of homes, but not at the risk of placing them into the water supply. For years, unused prescription medications have been dumped in drains and in the trash, often seeping into the water supply. The Environmental Protection Agency found that estrogens cause male fish to become female; antidepressants cause lobsters to become more aggressive; and fluoxetine induces reproduction in shellfish.

Along with the problem of drugs in the water, there is also a problem of unused prescription medications in households. It is estimated that more than 20,000 unintentional drug poisonings occur in the United States every year.

Pharmacy is a highly respected profession, and by helping solve the problems caused by unused and improperly disposed prescription medications, this can only add to the industry's stature.

Following are five steps to starting a take back program:

1. Order a collection bin or ask a local post office to donate an old mailbox, which can be painted.
2. Make a sign for the collection bin that states "Pharmaceutical Disposal." Since laws and regulations vary by state—ensure that appropriate wording, indicating what items are not accepted, is present. For example: controlled substances, sharps, inhalers, etc.
3. Determine the state's definition of pharmaceutical waste by soliciting feedback from the local household hazardous waste department or health department. If pharmaceutical waste is classified as universal waste, a Pharmacy may have to send their collected items via common carrier to a reverse distributor. If it is considered medical waste, a Pharmacy must have a medical waste carrier.
4. Send out a press release to get local media coverage.
5. Contact the local water department, household hazardous waste and

## ORGANIZING PHONE CALLS 1-2-3

### **Prepare, Before You Call.**

Before you make a phone call, do a little preparation. Gather anything you need to refer to, jot down any questions, keep a pen and paper handy to write down any notes and if necessary, practice what you are going to say to the person who answers the call.

### **Consolidate.**

If you have to make a lot of phone calls during your day, designate an hour as your "phone hour" and make all your calls during that time.

### **Eliminate Interruptions.**

The telephone is one of the biggest reasons why it is so difficult to get anything done. It usually rings at an unexpected time and interrupts project that you are working on. When you are working on something important, allow your voicemail or answering machine to field your calls for you. Then, you can call back at your convenience.

## WORDS OF WISDOM

*Genius is only the power of making continuous efforts. The line between failure and success is so fine that we scarcely know when we pass it; so fine that we are often on the line and do not know it. How many a man has thrown up his hands at a time when a little more effort, a little more patience, would have achieved success... a little more persistence, a little more effort, and what seemed hopeless failure may turn to glorious success. There is no failure except in no longer trying. There is no defeat except from within, no really insurmountable barrier save our own*

4. Send out a press release to get local media coverage.
5. Contact the local water department, household hazardous waste and environmental Websites to ensure they are aware of the Pharmacy's drug take-back program. Also contact local hospices.

NCPA is expanding its Protect Your Pharmacy Now! Initiative to include a new Prescription Disposal Program with information and resources for community pharmacies to create consumer drug disposal program. Go to [www.ncpanet.org](http://www.ncpanet.org) for more information.

## NEW DRUG APPROVALS

### **Afinitor (everolimus) Tablets**

#### **Treatment for: Renal Cell Carcinoma**

Afinitor (everolimus) is an oral once-daily inhibitor of mTOR indicated for the treatment of patients with advanced Renal Cell Carcinoma after failure of treatment with sunitinib or sorafenib.

### **AllerNaze (triamcinolone acetonide) Nasal Spray**

#### **Treatment for: Allergic Rhinitis**

AllerNaze, formerly Tri-Nasal (triamcinolone acetonide, USP) is a reformulated aqueous intranasal steroid nasal spray indicated for the once-daily treatment of nasal symptoms associated with both seasonal and perennial Allergic Rhinitis in adults and children twelve years of age and older.

### **ATryn (Antithrombin [Recombinant])**

#### **Treatment for: Antithrombin III Deficiency**

ATryn (Antithrombin [Recombinant]) is a recombinant form of human Antithrombin for the prevention of peri-operative and peri-paltum thromboembolic events in hereditary Antithrombin Deficient patients.

### **Degarelix for Injection**

#### **Treatment for: Prostate Cancer**

Degarelix is an injectable gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for patients with advanced Prostate Cancer. Potential trade names for Degarelix are still under review with the FDA.

### **Edluar (zolpidem) Sublingual Tablets—formerly Sublinox**

#### **Treatment for: Insomnia**

Edluar (formerly Sublinox) is a fast-acting sublingual tablet formulation of the widely used drug zolpidem. Edluar is approved for the short term treatment of Insomnia characterized by difficulties with sleep initiation.

### **Epiduo (adapalene and benzoyl peroxide) Gel**

#### **Treatment for: Acne**

Epiduo (adapalene and benzoyl peroxide) Gel is a once-daily topical acne treatment that combines the well-tolerated retinoid adapalene and benzoyl peroxide, a well-known antimicrobial.

### **Gelnique (oxybutynin hydrochloride) Topical Gel—formerly OTG**

#### **Treatment for: Overactive Bladder**

Gelnique (oxybutynin hydrochloride) Gel is a transdermal antispasmodic, which is applied to the skin once daily for the treatment of Overactive Bladder with symptoms of urge urinary incontinence, urgency and frequency.

### **Kapidex (dexlansoprazole) Delayed Release Capsules— formerly TAK-390MR**

#### **Treatment for: Erosive Esophagitis, Gastroesophageal Reflux Disease**

Kapidex (dexlansoprazole) is a proton pump inhibitor with a novel delivery system approved for the treatment of Erosive Esophagitis and heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD).

### **Latisse (bimatoprost) Ophthalmic Solution**

#### **Treatment for: Hypotrichosis of Eyelashes**

Latisse (bimatoprost ophthalmic) is a prostamide indicated for the treatment of Hypotrichosis (or reduced amount of hair) of the eyelashes. Growth of the eyelashes is a well documented side effect of bimatoprost, which is currently approved as Lumigan for the treatment of Glaucoma.

### **Nexterone (amiodarone HCl) Injection**

#### **Treatment for: Ventricular Fibrillation, Ventricular Tachycardia**

*really insurmountable barrier save our own inherent weakness of purpose.*

– Elbert Hubbard

## IMPROVING YOUR GOLF SWING

*Golfing experts offer these tips to help perfect your golf swing:*

Wear single-function glasses or contact lenses. Bifocals distort the sight line and upset the swing.

Don't grip the club too tightly. Proper tension in the hands will facilitate proper arm movement.



Keep your chin up. If you tuck your chin against your chest, it limits the rotation at the shoulders, lessens the force generated at impact and shortens the ball's flight.

Shift your weight from your back leg to the front as you swing and stand tall after hitting the ball.

## “QUOTE IT”

*Of all the things you wear, your expression is the most important*

– Unknown

## HERBS, SPICES AND ANTIOXIDANTS

*Recent studies indicate that those herbs and spices we use, might not just be giving our taste buds a boost.*

Scientists at the University of Oslo in Norway have reasons to believe that herbs and spices should be a part of an antioxidant-

### **Nexterone (amiodarone HCl) Injection**

#### **Treatment for: Ventricular Fibrillation, Ventricular Tachycardia**

Nexterone (amiodarone HCl) Injection is a cosolvent free formulation of the antiarrhythmic agent Amiodarone IV. Nexterone is indicated for the treatment and prophylaxis of frequently recurring Ventricular Fibrillation and Hemodynamically Unstable Ventricular Tachycardia in patients refractory to other therapy.

### **Oral Fludarabine (fludarabine phosphate) Tablets**

#### **Treatment for: Chronic Lymphocytic Leukemia**

Oral Fludarabine (fludarabine phosphate) is an oral nucleoside analogue approved as a single agent for the treatment of adult patients with B-cell Chronic Lymphocytic Leukemia.

### **Rapaflo (silodosin)**

#### **Treatment for: Benign Prostatic Hyperplasia (BPH)**

Alpha-blocker indicated for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH)

### **RiaSTAP (Fibrinogen Concentrate [Human])**

#### **Treatment for: Congenital Fibrinogen Deficiency**

RiaSTAP (Fibrinogen Concentrate [Human]) is lyophilized fibrinogen for the treatment of acute bleeding episode in patients with Congenital Fibrinogen Deficiency, including Afibrinogenemia and Hypofibrinogenemia.

### **Ryzolt (tramadol HCl) Extended Release Tablets**

#### **Treatment for: Pain**

Ryzolt (tramadol HCl) Extended Release Tablets is a once-daily analgesic indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.

### **Savella (milnacipran)**

#### **Treatment for: Fibromyalgia**

Savella (milnacipran) is a selective serotonin and norepinephrine reuptake inhibitor indicated for the management of Fibromyalgia.

### **Uloric (febuxostat) Tablets**

#### **Treatment for: Gout**

Uloric (febuxostat) is a xanthine oxidase inhibitor indicated for the chronic management of hyperuricemia in patients with Gout.

### **Vectical (calcitriol) Ointment**

#### **Treatment for: Psoriasis**

Vectical Ointment is a Vitamin D analog indicated for the topical treatment of mild to moderate plaque Psoriasis in adults—18 years and older.

### **Zolpimist (zolpidem tartrate) Oral Spray**

#### **Treatment for: Insomnia**

Zolpimist is an oral spray formulation of zolpidem, the drug contained in Ambien. Zolpimist is indicated for the short term treatment of Insomnia characterized by difficulties with sleep initiation.

herbs and spices should be a part of an antioxidant-rich diet.

Only 1 gram (half a teaspoon) of cloves will render the same antioxidant benefits that a half cup of blueberries or cranberries would.

Blueberries and cranberries are known for their high level of antioxidants. A half cup of dried oregano is the antioxidant equivalent of a half cup of sweet potatoes.

Both fresh and dried herbs and spices contain significant levels of antioxidants and are good sources to add to your diets.

Following is a list of dried and fresh herbs and spices that are rich in antioxidants:

#### **Fresh**

Marjoram  
Lemon Balm  
Thyme  
Peppermint  
Sage  
Oregano

#### **Dried**

Basil  
Tarragon  
Oregano  
Saffron  
Marjoram  
Thyme  
Rosemary  
Cinnamon  
Allspice  
Cloves

