P.R.N.

ISSN # 1941-9481

www.prnnewsletter.com

No. 41 | **The Newsletter for Community Pharmacists** | **November/December, 2011**

What's Inside…

BREAKING NEWS

Governor Cuomo Signs Law Prohibiting Mandatory Mail Order Prescriptions

On December 12, 2011, New York governor Andrew Cuomo signed into law Assembly bill 5502-B, which prohibits health insurers from mandating that prescriptions be filled through mail order pharmacies. The bill also bans the practice of charging higher co-payments for prescriptions filled at community pharmacies rather than through mail order. The bill was opposed by pharmacy benefit managers (PBMs), as well as the Federal Trade Commission, on the grounds that it would increase overall prescription costs. Addressing these concerns, the governor prompted lawmakers to amend the legislation to include a provision that requires community pharmacies to agree to accept reimbursement rates equal to those of mail order pharmacies. The law will not affect prescription benefits provided by unions through collective bargaining agreements. The governor also signed a similar measure, Assembly bill 7779, which states that any policy that covers prescription fertility drugs through mail order must also cover these drugs, and charge the same price, at community pharmacies.

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

INTERMEZZO (Zolpidem Tartrate). **C-IV**
Category: Non-Benzodiazepine Hypnotic.
Initial dose: 1.75 mg for women and 3.5 mg for men taken once only if at least 4 hours remain before the planned time of waking .
MDD: 1.75 mg (women) or 3.5 mg (men).

The FDA has approved Trancept Pharmaceuticals' Intermezzo for use as needed to treat insomnia characterized by middle-of-the-night awakening followed by difficulty returning to sleep. Intermezzo is an orally disintegrating sublingual form of zolpidem, which should only be used if there are at least 4 hours remaining before the planned time of waking. The recommended dose for women is half that of the dose for men because women clear zolpidem from the body at a lower rate than men.

ONFI (Clobazam). **C-IV**
Category: Benzodiazepine Anticonvulsant.
Initial dose: 5 mg daily (patients ≤30 kg), 10 mg daily (patients >30 kg). Doses above 5 mg/day should be administered in two divided doses.
MDD: 20 mg (patients ≤30 kg), 40 mg (patients >30 kg).

The FDA has approved Lundbeck Inc.'s Onfi, a benzodiazepine indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older. Onfi tablets can be administered whole, or crushed and mixed in applesauce. Dose titration should not proceed more rapidly than weekly, because serum concentrations of Onfi and its active metabolite require 5 and 9 days, respectively, to reach steady-state.

ANTUROL (Oxybutynin 3% Topical Gel).
Category: Urinary Antispasmodic.
Initial dose: 84 mg (3 pumps) applied once daily.
MDD: 84 mg.

Antares Pharma, Inc. and Watson Pharmaceuticals have been granted approval to market Anturol, a topical form of the antispasmodic oxybutynin indicated for the treatment of overactive bladder. Anturol will be dispensed in a pump, which must be primed by pumping 4 times before first time use. The recommended dose is 84 mg (3 pumps) once daily applied to *one* of the following areas: abdomen, upper arms, shoulders, or thighs. Anturol may be applied with the hands, which should be washed with soap and water immediately after application of the dose.

FORFIVO XL (Bupropion HCl Extended).
Category: Antidepressant.
Initial dose: 450 mg once a day, taken with or without food.
MDD: 450 mg.

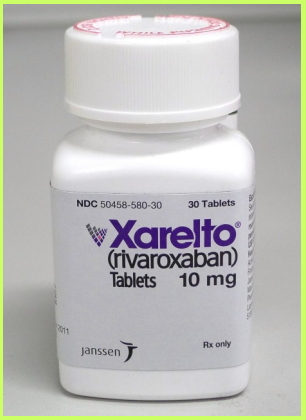
IntelGenx Corp. will introduce Forfivo XL, the first single-dose 450 mg formulation of the antidepressant bupropion. Forfivo XL is a once-daily, extended release formulation which may be taken without regard to food. Forfivo XL should not be used to initiate treatment, but can be used in patients receiving 300 mg/day of bupropion for at least 2 weeks and who require a dosage of 450 mg/day. Patients who are currently taking 450 mg of another form of bupropion can be switched to Forfivo XL once daily. Availability is expected by the second quarter of 2012.

FDA Approves Xarelto for Stroke Risk Reduction in Atrial Fibrillation

As expected, the Food and Drug Administration (FDA) has approved the factor Xa inhibitor **Xarelto** (rivaroxaban) to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Xarelto thus becomes a second available alternative to warfarin, following the introduction of **Pradaxa** (dabigatran). The drug was previously approved for deep vein thrombosis (DVT) prophylaxis, at a dose of 10 mg daily, with or without food. At the higher dose required for stroke reduction (15 to 20 mg daily), bioavailability is affected by food, and atrial fibrillation patients should be counseled to take Xarelto as follows:

Patients with CrCl >50 mL/min: **20 mg once daily *with the evening meal***

Patients with CrCl 15 - 50 mL/min: **15 mg once daily *with the evening meal***



MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Limit on Monthly Fills of Opioids

Effective December 29, 2011, the New York State Medicaid Program will impose a limit on the number of times per month a beneficiary may fill a prescription for an opioid analgesic. As of that date, prescriptions for opioid analgesics will be limited to four fills every thirty days. In cases where it has been determined that an additional opioid prescription is necessary, the prescriber may obtain prior authorization by calling the Medicaid clinical call center at **(877) 309-9493**.

Atypical Antipsychotic Exemption Ends

Also effective December 29, 2011, the exemption from prior authorization for drugs in the atypical antipsychotic class will end. This exemption was eliminated in the 2011 Executive Budget, but implementation was delayed for this particular drug class in order to allow for the grandfathering of patients already stabilized on non-preferred atypical antipsychotics. Once the exemption is lifted, claims for non-preferred drugs will be denied, and prior authorization required, unless the patient meets the clinical criteria for being stabilized on the non-preferred drug. Prior authorization may be obtained by prescribers through the Medicaid clinical call center at **(877) 309-9493**. The current list of preferred and non-preferred atypical antipsychotics is as follows:

ATYPICAL ANTIPSYCHOTICS

Preferred	Non-Preferred
Clozapine	Abilify
Fanapt	Clozaril
FazaClo	Invega
Geodon	Latuda
Risperidone	Risperdal
Saphris	Zyprexa
Seroquel	
Seroquel XR	

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Major Changes in EPIC Begin January 1, 2012

The New York State Executive Budget, passed on March 31, 2011, contains provisions that will effect substantial changes in the Elderly Pharmaceutical Insurance Coverage (EPIC) program. Effective January 1, 2012, EPIC will no longer be "creditable" coverage, meaning it is not superior to Medicare Part D, and therefore EPIC will only be available to those who have Medicare Part D as their primary drug coverage. Beginning with the new year, EPIC will provide supplemental coverage ***only during the Medicare Part D coverage gap ('donut hole")***. These and other changes are summarized below:

- **EPIC will be free. There will be no fees or deductibles.**
- **EPIC will only be available to patients with Medicare Part D coverage.**
- **EPIC will only cover Part D covered drugs and will cover them only during the coverage gap, or "donut hole." Before reaching the coverage gap, patients will be responsible to pay the full price charged by their Part D plan, including any Part D deductible, co-payment, or coinsurance.**
- **EPIC will continue to cover the specific Medicare Part D "excluded" drugs listed below, but will cover them only during the coverage gap.**

Medicare Part D "excluded drugs"

- Benzodiazepines (e.g., alprazolam for anxiety)
- Prescription vitamin and mineral preparations
- Barbiturates (e.g., phenobarbital for seizure control)
- Agents such as tretinoin and finasteride for dermatological uses
- Agents used for anorexia, weight loss, or weight gain (e.g., orlistat)
- Agents used for relief of cough and colds (e.g., guaifenesin/codeine)

- **During the coverage gap, EPIC co-payments will remain the same ($3.00 to $20.00 depending on the cost of the drug). The EPIC co-payment schedule appears below:**

EPIC Prescription Co-Payment Schedule	
Prescription Cost:	Co-Payment
Up to $15.00	$3.00
$15.01 to $35.00	$7.00
$35.01 to $55.00	$15.00
$55.01 and over	$20.00

- **EPIC will pay the Medicare Part D plan premium for single patients with incomes up to $23,000 and married patients with incomes up to $29,000.**
- **All claims should be submitted to EPIC, even before the coverage gap begins, to ensure that accumulations and patient records are up to date and accurate.**
- **Medicare Part D "excluded drugs" can be billed to EPIC during the coverage gap using an Other Coverage Code (OCC) of 3 (claim not covered).**

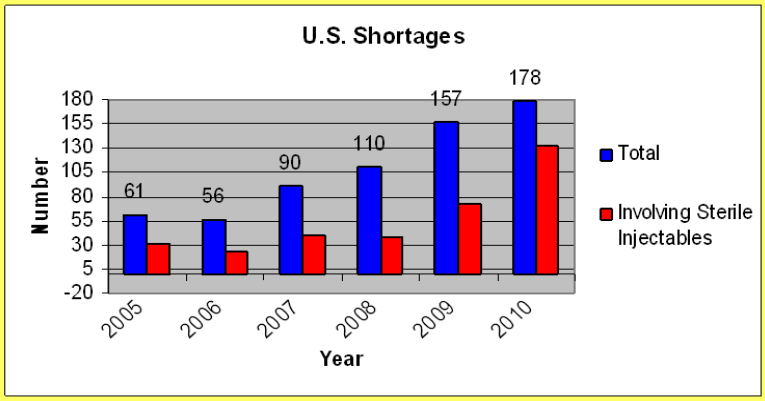
Feature Article..

GOVERNMENT RESPONSE TO DRUG SHORTAGES

The National Media have recently discovered a fact that pharmacists have long been aware of: drug shortages have become epidemic in the United States. National news broadcasts and major newspapers nationwide have started covering this problem, as severe shortages of some life-saving chemotherapeutic agents have come to light. Pharmacists are on the front lines of this burgeoning disaster, and our patients are looking to us for answers. This month we take a look at the steps the Food and Drug Administration, Congress, and the President are taking to address the problem of drug shortages.

The Basics: What Causes Drug Shortages?

At the end of October of this year, the FDA issued a report reviewing the agency's approach to medical product shortages. The report identified the causes of drug shortages, and found that fully 43% of shortages were due to problems at manufacturing facilities. Another 15% resulted from other delays in manufacturing or shipping, and 10% were caused by a shortage of the Active Pharmaceutical Ingredient (API). Furthermore, the report measured the magnitude of the increase in drug shortages, which have tripled between 2005 and 2010, growing from 61 to 178:



Congress Proposes a Solution

On June 21, 2011, Representatives Diana DeGette (D-Colorado) and Thomas Rooney (R-Florida) introduced the *Preserving Access to Life-Saving Medications Act*, designated H.R. 2245. The bill contains the following provisions:

- **All manufacturers would be required to notify the FDA of any discontinuance, interruption, or adjustment in the manufacture of a drug that may result in a shortage.**
- **If the manufacturer plans on discontinuing a drug, they must notify the FDA at least 6 months in advance.**
- **For other disruptions in manufacturing, the manufacturer must notify the FDA as soon as they become aware of the problem, but within 6 months.**
- **Manufacturers who do not comply with the reporting requirements are subject to penalties of up to $10,000 for each day the violation continues, up to 1.8 million dollars.**

Not surprisingly, the current congress, which has passed the fewest bills of any congress in at least 10 non-election years, has yet to take action on this legislation, notwithstanding the fact that is appears to have broad bi-partisan support.

The FDA Approach to Drug Shortages

The FDA has a two-pronged approach to the problem of drug shortages: prevention and response. The agency claims to have prevented 137 shortages since 2010, most commonly through the following actions:

- **Expediting review of new manufacturing sites, new suppliers, and specification changes** (71% of cases)
- **Exercising regulatory flexibility and discretion** (20% of cases)
- **Asking other firms to increase production** (7% of cases)

In response to drug shortages, FDA's most common actions were:

- **Asking other firms to increase production** (31% of cases)
- **Working with manufacturers to identify means to mitigate the dangers of products with quality issues** (28% of cases)
- **Expediting review of regulatory submissions** (26% of cases)

The President's Response

On October 31, 2011, the White House issued an Executive Order, entitled "Reducing Prescription Drug Shortages," aimed at enhancing the FDA's response to the crisis, as well as addressing the problem of price gouging. The key points include:

- **Broader Reporting of Manufacturing Discontinuances:** directs the FDA to use its authority to require advanced notice of manufacturing discontinuances that may lead to drug shortages.
- **Expedited Regulatory Review:** directs the FDA to expand current efforts to expedite regulatory reviews to help mitigate drug shortages.
- **Review of Certain Behaviors by Market Participants:** directs the FDA to report to the Department of Justice any findings of stockpiling of drugs or charging of exorbitant prices.

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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 have recently seen prescriptions for high dose cimetidine from a local podiatrist. The prescriber indicated that the patient was being treated for warts. What is the rationale for this therapy?

The H2 antagonist cimetidine (Tagamet) has been prescribed off-label for the treatment of various dermatological conditions. Most often it is used to treat common warts and plantar warts, although it has also been utilized for the treatment of genital warts, papillomatosis, and molluscum contagiosum. The proposed mechanism of action for cimetidine in treating these viral conditions is immunomodulation. Cimetidine has been shown to block suppressor T cells and increase the number of certain types of lymphocytes. The suggested dose for these treatments ranges between 25 and 40 mg/kg/day, although most studies have been done with a dose of either 30 or 40 mg/kg/day. The total daily dose is usually divided into TID or QID intervals. Unfortunately, the results of these studies have been mixed, with many early trials showing promise, and later placebo-controlled studies demonstrating no effect. The evidence of effectiveness was somewhat stronger for children than for adults; in fact, cimetidine is considered a safe alternative to cryotherapy in treating small children with molluscum contagiosum.[1] A number of other off-label uses for cimetidine have developed over the years, including the treatment of **androgenic hair loss in women** (300 mg five times daily), treatment of **urticaria** in conjunction with an H1 blocker (300 mg q6h), and the **prevention of dapsone-induced methemoglobinemia** (400 mg TID).

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 anticoagulant warfarin was named after the laboratory where it was discovered? In the 1940s, Karl Link, working at the University of Wisconsin, developed the drug, based on the naturally occurring plant product coumarin, and named it *W*isconsin *A*lumni *R*esearch *F*oundation-*arin*, or warfarin for short!

PHARMACY FUN

The introduction of *Intermezzo* (see New Drugs on page 1) brought to mind the fact that a number of drugs have names that are either ordinary words (an intermezzo is a short musical piece separating the major sections of a larger work), or words that are already in use for other products. Based on the descriptions or definitions below, can you name the drug that shares the same name? The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **This drug shares its name with a brand of cigarettes introduced by R. J. Reynolds in 1969.**
2. **Definition: a source of inspiration to a creative artist, especially a poet.**
3. **This drug has the same name as a car made by Hyundai and is also the name of a type of musical composition, usually for piano.**
4. **Definition: of, relating to, or affecting mice or related rodents (this one is OTC)**
5. **This drug's name is also the name of the state-sponsored, hangover-free hallucinogen in Aldous Huxley's influential novel, *Brave New World*.**

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

References:
1. CDC article: Molluscum Contagiosum. Accessed 12/17/2011 at: www.*cdc.gov/ncidod/dvrd/molluscum/clinical_overview.htm*