# P.R.N.

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**What's Inside…**



## FDA Warning

In 2005, the FDA issued a warning concerning the use of atypical antipsychotics in patients with dementia-related psychosis. At that time the agency noted that such patients are at an increased risk of death. In a June, 2008 update, the FDA has widened the scope of that warning to include conventional antipsychotics as well. The revision is based on several large retrospective studies which showed conventional antipsychotics increased the risk of death as much, or more, than did atypical agents. Neither class of drugs is FDA-indicated for use in dementia-related psychosis. The complete list of affected drugs follows:

***Atypical Agents:***

| | |
|---|---|
| **Abilify** | **Risperdal** |
| **Clozaril** | **Seroquel** |
| **Geodon** | **Symbyax** |
| **Invega** | **Zyprexa** |

***Conventional Agents:***

| | |
|---|---|
| **Compazine** | **Orap** |
| **Haldol** | **Prolixin** |
| **Loxitane** | **Stelazine** |
| **Mellaril** | **Thorazine** |
| **Moban** | **Trilafon** |
| **Navane** | |

## ……RX NEWS……RX NEWS……RX NEWS……RX NEWS……

**PrandiMet Approved:** Novo Nordisk has been granted approval to market **PrandiMet**, a combination of the meglitinide Prandin (repaglinide) and the biguanide metformin. PrandiMet is indicated for use in patients with Type II diabetes already treated with a meglitinide and metformin or those who have inadequate control on a meglitinide or metformin alone. PrandiMet should not be used with gemfibrozil or NPH insulin. Adverse effects include hypoglycemia, headache, diarrhea, nausea. PrandiMet will be available in doses of 1mg/500mg and 2mg/500mg. PrandiMet should be taken within 15 minutes before meals and not taken if a meal is skipped.

**Risperdal Generic Approved:** The FDA has approved the first generic version of **Risperdal** (Risperidone), made by TEVA Pharmaceuticals. Interestingly, though this product is AB-rated to Janssen's Risperdal, it is not labeled for all the same indications. This is because some of the newer FDA-approved indications are protected by patents and exclusivity rights. So, while the generic is indicated for the treatment of schizophrenia and bipolar mania in adults, it can not be labeled for use in schizophrenia in pediatric patients aged 13 to 17, bipolar mania in patients aged 10 to 17, or irritability associated with autistic disorder in patients aged 5 to 16 years — all of which appear in the labeling of the brand-name product. Of course, this difference is offset by the fact that physicians may legally prescribe medications for off-label uses.

**Regranex Warning:** The FDA has issued a follow-up to the safety review communication of March, 2008 regarding Ortho-McNeil's **Regranex Gel** (becaplermin). The safety review was prompted by a post-marketing study which followed subjects of two randomized, controlled trials of Regranex for approximately 20 months. That study revealed an increased risk of cancer in patients who used Regranex compared to control groups. Following this result, a retrospective study, using a health insurance database, compared 1,622 patients who had used Regranex to 2,809 comparable subjects who had not. This study did not confirm the increased cancer risk, although the duration of follow-up was not long enough to detect new cancers. The results did show, however, that patients using 3 or more tubes of Regranex had a *five times greater risk of death from cancer* than those in the control group. In response to these results, a boxed warning has been added to the labeling of the product. Regranex is a recombinant human platelet-derived growth factor indicated for the treatment of lower extremity diabetic neuropathic ulcers. Since growth factors cause more rapid division of cells, Regranex should be used with caution, if at all, in patients with known malignancies.

**Yasmin Generic:** Bayer, maker of the oral contraceptive **Yasmin**, has reached an agreement to supply Barr Pharmaceuticals with an "authorized generic" version for sale in the U.S. Barr had sued successfully to invalidate Bayer's patent.

## JAMA Study: Pharmacist-Assisted Care Improves Blood Pressure Control

A study published in the June 25th edition of the Journal of the American Medical Association (JAMA) concludes that participation by pharmacists in the care of hypertensive patients significantly improved blood pressure control. The Electronic Communications and Home Blood Pressure Monitoring (e-BP) study[1] was conducted at Group Health, a large, nonprofit group practice serving patients in Washington and Idaho. A total of 778 patients with uncontrolled hypertension, defined as mean systolic reading between 140 and 199 mm Hg or mean diastolic reading between 90 and 109 mm Hg, were randomized to one of three groups. One group received the usual care offered by the practice. A second group received training in home BP monitoring and the use of a secure patient Web site, which allowed patients to view portions of their medical record, refill prescriptions, and email health care team members. The third group received the BP monitoring and Web site training *plus* pharmacist care management delivered through Web communications. Pharmacists took detailed medication histories, reviewed allergies and intolerances, recommended medication changes, and discussed lifestyle goals. The results at 1-year follow-up were striking: the percentage of patients with controlled blood pressure (<140/90 mm Hg) differed only slightly in the second group as compared to the first (36% vs.31%), but increased significantly in the third group (56%). A subgroup of patients with baseline systolic pressure over 160 mm Hg benefited even more from pharmacist intervention (54% controlled vs. 20% and 26% controlled in groups 1 and 2). These results highlight the important role pharmacists play in achieving beneficial outcomes for patients under their care.

# MEDICAID UPDATE

*Information Regarding the New York State Medicaid Program*

**Important Additions to the Clinical Drug Review Program**

In last month's issue we discussed the Clinical Drug Review Program (CDRP) instituted by New York State Medicaid in 2006. This month we report on the addition of four new drugs to the program, two of which are commonly prescribed agents. ***Effective July 30, 2008***, the following drugs will be subject to CDRP prior authorization protocols:

**Byetta** (exenatide)
Prescribers will be asked to certify that patients have a diagnosis of Type II diabetes and that they are currently receiving oral antidiabetic therapy. If authorized, prescriptions may be issued for a 30-day supply with 5 refills.

**Lidoderm Patch** (lidocaine)
Prescribers are asked if the patch is being used to treat post-herpetic neuralgia or some other condition, if the condition is one that can not be adequately controlled by another medication, and if the dose is within the FDA recommended limits of 3 patches per day and 90 per month. Authorization allows for dispensing of a 30-day supply with 5 refills.

**Actiq** (fentanyl lozenge)
**Fentora** (fentanyl buccal tablets)
For these agents, prescribers must indicate if the patient is being treated for breakthrough cancer pain, if an oncologist or pain management specialist has been consulted, if the patient is receiving long-acting opioids for underlying persistent pain, and if the patient is tolerant to that opioid therapy.

Prior authorizations numbers issued for CDRP drugs will end with a "W" and must be validated by the pharmacist before dispensing. To validate a prior authorization, pharmacists are directed to call 1-877-309-9493 and chose option 2.

# LAW REVIEW

*Regulatory Issues Affecting Pharmacy in New York State*

**Pharmacy Staffing: Rules and Regulations**

New York State law contains specific regulations regarding who may work in a registered pharmacy and what functions they may or may not perform. The relevant sections include Article 137 of the Education Law, Part 29 of the Rules of the Board of Regents, and Part 63 of the Commissioner's Regulations.

**Supervising Pharmacist**

Every registered pharmacy in New York State must be under the personal supervision of a pharmacist, designated as the supervising pharmacist (SP). The SP must be a full-time employee of the pharmacy, full-time being defined as a minimum of 30 hours per week. If the pharmacy is open less than 30 hours weekly, the SP must work a majority of the operating hours. The State Board of Pharmacy should be notified within 7 days of any change in the identity of the SP. Such notification must be made by the pharmacy owner, although it is recommended that the departing SP also notify the Board for his or her own protection. A pharmacist may not serve as SP for more than one pharmacy at a time. The SP is responsible for the proper conduct of the pharmacy in every particular, including, but not limited to, ensuring that the pharmacy is under the supervision of a licensed pharmacist at all times when open, and that the pharmacy is in compliance with all applicable laws and regulations.

**Pharmacy Interns**

A limited permit to practice as a licensed pharmacy intern (PI) may be issued to applicants who have completed the first 3 years of an approved program in pharmacy education. The permit is valid for 5 years and may be renewed only once, for an additional 2 year period. A PI may practice as a pharmacist, performing all functions designated to pharmacists by law, under the immediate personal supervision of a licensed pharmacist. PIs are licensed professionals and, as such, are *not* included in the ratio of unlicensed persons allowed to assist a pharmacist in the filling of prescriptions.

**Pharmacy Technicians**

Pharmacy technicians (PTs) are unlicensed persons who assist pharmacists in the filling and dispensing of prescriptions. No pharmacist shall obtain the assistance of more than 2 PTs in the performance of the activities listed below under the title "What PTs CAN do." This 2 to 1 ratio does NOT include pharmacy interns or staff members not directly involved in the filling of prescriptions, such as cashiers, delivery personnel, etc. The duties and prohibitions relating to PTs are listed below:

| What PTs CAN do… | What PTs can NOT do… |
|---|---|
| **Receive written prescriptions** | **Receive oral prescriptions from prescribers** |
| **Type prescription labels** | **Interpret prescriptions for authenticity, accuracy, or interactions** |
| **Key data for entry and retrieve data from computer file** | **Make determinations of therapeutic equivalency (i.e. generic substitution)** |
| **Get and return drugs from stock** | **Measure, weigh, compound or mix ingredients** |
| **Get prescription files from storage and locate prescriptions** | **Sign or initial any record of dispensing required to be maintained by law** |
| **Count dosage units of drugs and place in appropriate container** | **Counsel patients** |
| **Affix prescription label to container** | **Perform any other function involving the exercise of professional judgment** |
| **Prepare manual records of dispensing** | |
| **Deliver prescription to patient and make the offer to counsel (on refill Rxs only)** | |

*Feature Article..*

# Summer's Here! Sunscreens and Sunburns

**The Summer Solstice** having come and gone, we are now at the start of sunburn season, and rare is the community pharmacist who will not see his or her share of lobster-colored beachgoers in search of pharmaceutical relief. To assist in the aid and comfort of these sun worshipers, we have prepared a quick review of the relevant topics.

## UVA vs. UVB

Ultraviolet (UV) radiation from the sun is measured in wavelengths and divided into two broad categories: **UVA** for wavelengths between 320 and 400 nm and **UVB** for wavelengths between 290 and 320 nm. UVA is further divided into **UVA I** (340-400 nm) and **UVA II** (320-340 nm). While both UVA and UVB are implicated in skin cancer and aging of the skin, UVB is the primary cause of **sunburn,** and for this reason chemical sunscreens were originally developed to block only UVB. More recently, broad spectrum UVA/UVB blockers have become popular in response to increased awareness of the dangers of UVA exposure. In addition to skin damage and cancer, UVA is primarily responsible for drug-induced photosensitivity reactions.

## Which Sunscreens Are Best?

The most effective sunscreens are those which meet the following 3 criteria:

- **SPF of 15 or higher**
- **Very water resistant ("waterproof")**
- **Broad spectrum UVA/UVB coverage (look for ingredients such as Oxybenzone, Avobenzone [*Parsol 1789*], Ecamsule [Mexoryl SX], Zinc Oxide and Titanium Dioxide)**

## Drugs Which Cause Photosensitivity

The following drug categories are known to cause either phototoxic (common) or photoallergic (uncommon) reactions:

**Amiodarone**

**Diuretics** (Furosemide, HCTZ)

**Fluoroquinolones**

**Hydroxychloroquine**

**NSAIDs**

**Phenothiazines**

**Quinidine**

**Retinoids**

**Sulfonamides**

**Sulfonylureas**

**Tetracyclines**

## The Math Behind Sunburn Protection Factors (SPFs)

Sunscreens are rated for effectiveness in blocking UVB by a calculation that yields a sunburn protection factor (SPF). SPF is defined as the minimal dose of UV light required to produce erythema on skin protected by 2 gm/cm$^2$ of sunscreen divided by the minimal dose required to produce erythema on unprotected skin. If, under a particular set of conditions, a person would burn after 10 minutes of sun exposure, application of an SPF 15 product would extend that time by a factor of 15, to 150 minutes. Several factors influence the rate of erythema production, including skin type and environmental conditions (see tables 1 and 2 below). In August, 2007, the FDA proposed new regulations for sunscreens that would add a UVA rating scale to the current UVB SPF system. Products would be graded between one star (lowest) and four stars (highest) for UVA protection. In addition, when the rule becomes final, the term "waterproof" would be removed from product labels and replaced with either "water resistant" (retains SPF after 40 minutes in water) or "very water resistant" (retains SPF after 80 minutes in water).

**TABLE 1**

**Fitzgerald Skin Phototypes**

| | | |
|---|---|---|
| I | Pale, white skin | Always burns |
| II | Fair skin | Burns easily |
| III | Darker white skin | Tans after burn |
| IV | Light brown skin | Burns minimally |
| V | Brown skin | Rarely burns |
| VI | Dark brown or black skin | Never burns |

*Source: Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. Arch Dermatol. 1988. 124:869-871*

**TABLE 2**

**UV INDEX SCALE***

| | |
|---|---|
| 0-2 | Low– no danger |
| 3-5 | Moderate risk of harm |
| 6-7 | High risk of harm |
| 8-10 | Very high risk of harm |
| ≥11 | Extreme risk of harm |

*Risk of unprotected exposure

*Source: epa.gov/sunwise/uvindex.html*

## Treatment of First and Second Degree Sunburns

Most sunburns are first-degree (no blisters) or second-degree (blistering) burns and can be treated at home. Burns accompanied by fever, chills, headache, confusion, or dehydration require medical attention. For minor sunburns, most experts recommend the following treatments:

**First, get out of the sun!**

**Cool water compresses, cool baths**

**Topical application of aloe vera lotion or hydrocortisone cream**

**Use of NSAIDs such as ibuprofen**

The use of topical antihistamines (diphenhydramine) and/or anesthetics (lidocaine, benzocaine) is **not recommended**, as these agents may lead to hypersensitivity reactions.

If blisters develop, they should be allowed to heal on their own and should not be broken. They may be covered loosely with gauze to prevent irritation by clothing. If blisters break open, an antibiotic cream should be applied to prevent infection.

Further sun exposure should be avoided until after the sunburn has healed.

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## NATURAL PRODUCTS: ALOE VERA

**Uses/claimed benefits:** Aloe Vera has long been used topically in the treatment of minor burns, and claims have been made for its effectiveness in treating psoriasis, genital herpes, and wounds. Orally, aloe vera has been used as a laxative, and for the treatment of colitis, diabetes, and hyperlipidemia.

**Evidence:** There is a relative lack of controlled clinical trials of aloe vera for many of its proposed uses. A systemic review of studies appearing in a British medical journal[2] concluded that aloe vera showed promising results for use in psoriasis and genital herpes, and may lower blood sugar and lipid levels, but cautioned that clinical effectiveness is not yet sufficiently defined. A more recent review[3] in the journal *Burns* indicated that evidence supports the use of aloe vera in burn wound healing for first and second degree burns. It should be noted that there are two distinct forms of aloe vera: the gel extracted from the center of the leaf, and the latex form found in the lining of the leaf. Topical products, and most oral forms, are made from the gel. The latex was, for many years, available as an OTC laxative, but was removed from the market in 2002, along with the related compound cascara sagrada, when the FDA ruled that these products had not been shown to be safe and effective.

**Precautions:** High doses of oral aloe vera should not be used; aloe-induced hepatitis has been reported.[4] Aloe should not be used internally in children or pregnant or lactating women due to lack of safety data.

**Interactions:** Aloe vera may interact with **digoxin**, **diuretics**, and **antidiabetic drugs**.

## DID YOU KNOW?

DID YOU KNOW that many famous people throughout history started out as pharmacists or apothecaries before making their mark in other fields of endeavor? The great English Romantic poet John Keats trained as an apothecary, and an unkind critic once urged him to return to "plasters, pills, and ointment boxes." The American short story writer O. Henry, author of "The Gift of the Magi," was a licensed pharmacist, as was Vice President Hubert Humphrey. And, of course, there are the inventors of virtually every major soft drink available: John Pemberton (Coca-Cola), Caleb Bradham (Pepsi), Charles Alderton (Dr. Pepper), and Charles Elmer Hires (Hires Root Beer).

## PHARMACY FUN

**This month's puzzle involves probability and the unfortunate knack some patients have for mixing different medications in the same bottle. You receive a call from a patient who, just the day before, had stopped in and picked up a refill of her prescription for 30 tablets of Hybridium, the new drug indicated for the treatment of excessive fear of petroleum prices (EFOPP). Upon arriving home that night, she added what she thought were the 10 remaining Hybridium tablets from her last fill to the new bottle. Unfortunately, they were not Hybridium, but instead an eerily similar-looking placebo tablet left over from her last clinical trial! The next day, she takes 1 tablet every 8 hours, shaking the bottle vigorously each time to randomize the tablets (people are strange!). Finally, the question: what are the chances, in terms of percentage, that our subject has managed to take the correct tablet all 3 times, thereby avoiding a calamity upon hearing that the price of crude has hit $150 a barrel? The first reader to submit the correct answer (and no, you don't have to show your work!) to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.**

Answers to last month's **PHARMACY FUN**:
**Zyloprim**/Allopurinol **Ziagen**/Abacavir **Zovirax**/Acyclovir **Zorprin**/Aspirin
**Ambien**/Zolpidem **Accolate**/Zafirlukast

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