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What's Inside…

FDA NEWS

.FDA Warns of Fracture Risk with PPI Use

The Food And Drug Administration has issued a Drug Safety Communication regarding the possible increased risk of fractures of the hip, wrist, and spine with the use of proton pump inhibitors (PPIs). Based on a review of seven epidemiological studies, the agency has revised the *Warnings and Precautions* section of the prescription label and the *Drug Facts* section of the OTC label for all PPIs. The studies evaluated individuals 50 years of age and older and found the greatest increased risk for fracture in patients who had been taking PPIs for at least one year or who had been taking high doses of the medications. The FDA recommends the following:

- **When prescribing PPIs, consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition**
- **Individuals at risk for osteoporosis should have their bone status managed and should take adequate vitamin D and calcium supplementation**

.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

NSAID/PPI Combination: AstraZeneca has received FDA approval to market **Vimovo** (naproxen and esomeprazole magnesium delayed release tablets). Vimovo is a combination product indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers. As with all NSAID-containing products, Vimovo carries a **black box warning** regarding increased risk of cardiovascular events and gastrointestinal bleeding. Vimovo is contraindicated in patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or NSAIDs, in late pregnancy, and during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. The most common adverse effects seen in clinical trials were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, and nausea. Vimovo may interact with **lithium**, **methotrexate**, **warfarin**, with drugs which require low gastric pH for absorption (**ketoconazole**, **iron salts**, **digoxin**), and may reduce the effects of antihypertensive drugs (ACE inhibitors, diuretics, beta blockers). The recommended dose of Vimovo is one tablet twice daily. Vimovo is not recommended in patients with moderate/severe renal insufficiency or severe hepatic insufficiency (consider dose reduction in mild/moderate hepatic insufficiency). Vimovo will be available in delayed release tablets, each containing naproxen and esomeprazole magnesium in strengths of 375 mg/20 mg or 500 mg/20 mg.

Higher Strength Zymar: The FDA has approved Allergan's **Zymaxid** (gatifloxacin ophthalmic solution), which is an increased strength version of the company's existing product, **Zymar** (0.5% vs. 0.3%). Zymaxid is a fourth-generation topical fluoroquinolone indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of *H. influenza, Staph. aureus*, *Staph. epidermidis*, *Strep. mitis* group, *Strep. oralis,* and *Strep. pneumonia*. The most common adverse reactions included worsening of conjunctivitis, eye irritation, dysgeusia, and eye pain. Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Zymaxid. The recommended dose of Zymaxid in patients 1 year of age or older is one drop every two hours in the affected eye(s) while awake, up to 8 times on Day 1, then one drop two to four times daily in the affected eye(s) while awake on Days 2 through 7.

Generic Yaz: Teva Pharmaceuticals has started shipping a generic version of Bayer's **Yaz** oral contraceptive under the name **Gianvi**. This action has prompted Bayer to sue Teva over patent infringement, noting that there was a pre-existing agreement between the two companies which would allow Teva to sell an authorized generic version of Yaz, supplied by Bayer, starting in July, 2011. Meanwhile, Bayer, looking to replace its lucrative Yaz and Yasmin line of OCs, has just received approval to market **Natazia**, a unique oral contraceptive combining the synthetic estrogen estradiol valerate with the progestin dienogest in a 26-day tetraphasic regimen, which is followed by 2 days of inert tablets.

McNeil Pediatric OTC Recall List Grows as Pediacare Products are Added

Blacksmith Brands, distributers of the **Pediacare** line of pediatric cold and cough products, has announce a voluntary recall of all lots of four of their products. The affected products were all manufactured for Blacksmith by McNeil Consumer Healthcare at their Fort Washington, PA plant. That facility failed an FDA inspection in April, leading to a massive recall of **Children's Tylenol Suspension, Children's Tylenol Plus Suspension, Tylenol Infants' Drops, Children's Motrin Suspension, Children's Motrin Cold Suspension, Motrin Infants' Drops, Children's Zyrtec Liquid,** and **Children's Benadryl Allergy Dye-Free Liquid**. The affected Blacksmith products are:

- **Pediacare Children's Decongestant**
- **Pediacare Children's Long-Acting Cough**
- **Pediacare Children's Multi-Symptom Cold**
- **Pediacare Children's Allergy & Cold**

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Brand Less Than Generic Initiative

Effective April 26, 2010, the New York State Medicaid Program implemented the Brand Less Than Generic Initiative, a new program designed to take advantage of cost savings associated with certain brand-name drugs. All drugs covered by Medicaid are subject to the Medicaid Drug Rebate Program created by OBRA '90. Since innovator drugs are required to offer a larger rebate (15.1%, or more if an authorized generic exists, vs. 11%), there are instances where a brand-name drug may be more cost-effective when dispensed through the Medicaid Program. Claims submitted for generic versions of drugs in this program will generate the following NCPDP rejection:

Code 78 Cost Exceed Maximum

Such generics will require prior authorization. Currently, there are 5 brand-name drugs covered by the program:

Adderall XR

Cozaar

Hyzaar

Mirapex

Valtrex

Brand-name drugs in the program:

- Have a generic copayment
- Have a generic dispensing fee
- Will be paid at the Brand Name Drug reimbursement rate
- Will not require prior authorization
- Will not require "DAW" or "Brand Medically Necessary"

This last point would seem to be in conflict with section 6810 of the Education law regarding "DAW." We have questioned the Board of Pharmacy regarding this seeming contradiction, and they informed us that they are now reviewing the matter.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

DEA Issues Interim Final Rule on Electronic Prescribing of Controlled Substances

The Drug Enforcement Administration (DEA) has issued an interim final rule which allows for the electronic prescribing of controlled substances. The new rule, which has a proposed effective date of June 1, 2010, was published in the March 31, 2010 edition of the Federal Register. The regulations for e-prescribing of controlled substances require electronic prescription or electronic health record software applications to be certified as compliant with the interim rule. This can be accomplished by hiring a qualified third party to audit the application or by having the application reviewed by an approved certification body. In addition, the rule mandates a two-factor credential system to authenticate the prescriber's digital signature. Any two of the following factors can be used: something you know (a PIN or password), something you have (a token or card), or something you are (a biometric, such as a fingerprint).

New York State Bureau of Narcotic Enforcement Statement on Electronic Prescribing of Controlled Substances

In anticipation of pharmacist's questions regarding the applicability of the new DEA rule in New York State, the Bureau of Narcotic Enforcement has issued the following statement, which will appear in the next edition of their Pharmacy Update Newsletter at ***www.health.state.ny.us/professionals/narcotic*:**

> *The March 31, 2010 Federal Register contains a Drug Enforcement Administration (DEA) Interim Final Rule with Request for Comment regarding Electronic Prescriptions for Controlled Substances. The DEA is revising its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will also permit pharmacies to receive, dispense and archive these electronic prescriptions. The proposed effective date of the DEA rule is June 1, 2010.*
>
> *In anticipation of adoption of the DEA final rule, the Department of Health, Bureau of Narcotic Enforcement, is working to update its regulations to allow for electronic prescribing of controlled substances in New York State. However, until such time as the corresponding State regulations are adopted,* ***electronic prescribing of controlled substances is not permissible in New York State****. (Please also note that electronic prescribing of hypodermic needles and syringes is also not permissible at this time).*

Questions and Answers for Pharmacists

Although it may be quite some time before all the necessary systems and regulations are in place to allow for e-prescribing of controlled substances, the DEA has already published advice for pharmacists on how to handle some unique situations:

Q: What should a pharmacist do if he or she receives a paper or oral prescription that was originally transmitted electronically?

A: The pharmacist must check the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

Q: What should a pharmacist do if he or she receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy?

A: The pharmacist must check with the other pharmacy to determine whether the prescription was received and dispensed. If it was received and not dispensed, that pharmacy must mark the electronic version as void or cancelled. If it was received and dispensed, the pharmacist with the paper version must not dispense the paper prescription and must mark the prescription as void.

Feature Article..

AUTHORIZED GENERICS: A CONTINUING CONTROVERSY

One Of The Best-Kept Secrets of the pharmaceutical industry, and your local drug store, is the proliferation of so-called "authorized generics" on the market. Authorized generics (AGs) are actually brand-name drugs re-dressed and relabeled as generics, and sold by, or licensed through, the original manufacturer. The generic drug industry believes they compete unfairly with first-to-market generics because they are not subject to the 180-day exclusivity rule granted by the Hatch-Waxman Act. Brand-name pharmaceutical companies, on the other hand, claim that AGs increase competition and promote lower prices.

Definition of "Authorized Generics" (AGs)

Authorized generics (AGs) are brand-name drugs which have been relabeled for sale as generics. They are produced under the original New Drug Application (NDA) of the innovator company and sold through a variety of arrangements between the brand-name manufacturer and its subsidiaries, licensees, or contract manufacturers, such as Prasco Laboratories. The official FDA definition of AGs appears in 21 CFR 314.3:

> *Authorized generic drug means a listed drug...approved under section 505c...marketed, sold, or distributed...with labeling, packaging, product code, labeler code, trade name, or trademark that differs from that of the listed drug.*

Since the FDA considers AGs *identical* to the brand-name drug, they *are not* listed in the Orange Book and do not require an AB rating to be substituted for the brand-name.

Federal Trade Commission Interim Report on Authorized Generics

In response to requests from Congress, the Federal Trade Commission (FTC) began a study of the short-term and long-term effects of AGs on competition in the prescription drug marketplace. The commission released an interim report in June of last year and the results were something of a split decision. The study found that the introduction of an AG in the 180-day exclusivity period led to a 4.2% decrease in retail drug prices. However, revenues for first-filer generic firms dropped substantially when an AG entered the market (between 47 and 51 percent on average). This may lead generic companies to enter into "pay for delay" agreements with brand-name companies, which can delay the entry of generics into the market, thereby increasing costs for consumers over a period of months to years.

Identification of Authorized Generics

There was a time when it was not always easy to spot the authorized generic among the many generic versions of a drug available. In the past, AGs usually had different identifying marks on them and no indication on the label of their true provenance. For example, Greenstone's **Azithromycin** is an authorized generic for Pfizer's **Zithromax** because Greenstone is a wholly owned subsidiary of Pfizer, but that information is not available anywhere on the label. An example of just how complicated the situation can become is the case of the AG for **Diabeta** (see our discussion on the Orange Book page of our website at: ***www.prnnewsletter.com***). Lately, however, identification of AGs has become much easier, as many brand-name manufacturers have done away with any attempt to disguise their AGs as generics. Recent example include **Protonix** and **Cozaar**, in which the brand-name bottle and AG bottle contain the *exact same* tablets (see below). In the case of Cozaar, Merck actually changed the color of the brand from green to white to match the color of the AG.

FDA Listing of Authorized Generics

As a result of the Food and Drug Administration Amendments Act (FDAAA) of 2007, the FDA is required to publish a complete list of all authorized generic drugs. Since the list contains only the drug trade name, brand company manufacturer, and date of market entry, it is of limited use in helping pharmacists determine what is and what is not an AG. Pharmacists will still have to determine which generic company is distributing the AG for the brand manufacturer. The list is currently available on the FDA website at: ***www.fda.gov/aboutfda/centersoffices/cder/ucm126391***

A Suggestion: Why Not Dispense AGs on Prescriptions Marked 'DAW'?

While AGs remain controversial, the one thing everyone agrees upon is the fact that AGs are actually brand-name drugs, in varying degrees of disguise. So it seems to us that pharmacists would be justified in dispensing an AG, where available, on a prescription marked 'DAW' without having to call the prescriber (while counseling the patient, of course). This would reduce costs for the patient, their insurance company, and the health care system as a whole, while still supplying the patient with the exact medication their doctor prescribed. We have forwarded this suggestion to the Board of Pharmacy for comment.

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ASK PRN...

Are there specific requirements for the type of identification used for the purchase of emergency contraception products in New York State?

The New York State Board of Pharmacy has issued guidelines for pharmacies on the sale of emergency contraception products (go to: ***op.nysed.gov/prof/pharm/pharmplanb.htm***). Regarding identification for the purchase of ***Plan B One-Step*** and ***Next Choice***, which are authorized for OTC sale to women and men ages 17 and older, the guidelines state:

- **An acceptable proof of age would be an I.D. that shows a person's date of birth, such as a driver's license, school I.D., passport, or other government-issued identification. If the I.D. card does not contain a photograph, the I.D. should included other identifying information, such as: name, date of birth, sex, height, color of hair, and address.**

Are compounded prescriptions eligible for refill transfer from one pharmacy to another?

There is nothing stated in the refill transfer regulations (Commissioner's Regulations, Part 63, section 63.6(a)[8]) that would prohibit the transfer of a refill of a compounded prescription. However, there are certain general restrictions that apply to refill transfers:

- **Prescriptions containing any controlled substances may not be transferred**
- **Prescriptions containing syringes and/or needles may not be transferred**
- **Prescriptions billed to the New York State Medicaid program may not be transferred**

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 man responsible for the introduction of Tylenol, originally as a prescription-only product, passed away this month? Robert L. McNeil, Jr. joined the family business in 1936, and helped transform the drug store founded by his grandfather in 1879 into McNeil Laboratories. McNeil championed the company's successful attempt to market a little-used chemical, first synthesized in 1877, as the successor to aspirin. It was McNeil himself who coined the generic name, acetaminophen (a contraction of sorts of the chemical name, N-***acet***yl-p-***aminophen***ol). The first Tylenol product, Elixir Tylenol for Children, was approved for sale by prescription in 1955. In 1960, Tylenol was approved for over-the-counter use and went on to become the best-selling pain reliever in the United States.

PHARMACY FUN

In Edgar Allan Poe's "The Purloined Letter," the sought-after missive is invisible to the experts searching for it because it is hidden in plain sight. Could the same be true for pharmacists and the tablets and capsules they dispense every day? Below are the imprints of 10 brand-name prescription drugs, all of which made the top 40 of IMS Health's list of the biggest selling drugs of 2009. Can you identify them? The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. PD 156	**3. A-008**	**5. Lilly 4115**	**7. FO**	**9. DV/NVR**
2. 1171/75	**4. MRK 117**	**6. FL/20**	**8. PGN 50**	**10. 277**

Answers to last month's ***PHARMACY FUN***:
1. Purple foxglove: Digoxin 2. *French lilac*: Metformin 3. *Rauwolfia serpentina*: Reserpine 4. *Deadly nightshade*: Atropine 5. *Chincona ledgeriana*: Quinine 6. *Papaver somniferum*: Morphine 7. *Ephedra sinica*: Ephedrine 8. *Autumn crocus*: Colchicine

Page 3 photographs by James Murphy