Maryland Pharmacy Program

Pharmacy News and Views

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Brand Name Drug Dispensing

Dispensing of brand name drugs, which are available as multi-source generics, are no longer available by overriding claims in the point-of-sale system.

As of the first of November, prescriptions for these drugs require special prior authorization. The completion of a DHMH Medwatch form is necessary to demonstrate an adverse effect, allergy or a clear lack of efficacy of the generic drug. Copies of DHMH Medwatch forms can be found at www.dhmh.state.md.us/mma/mpap/fda.htm.

DHMH Medwatch forms must be completed by the prescriber and faxed to the Maryland Pharmacy Program at 410-333-5398 for review. Prescribers must write "Brand Medically Necessary, DHMH Medwatch Form Submitted" on the prescription order. Strict criteria will be used to review all requests. If the authorization for dispensing the brand has been approved by the Maryland Pharmacy Program, the prescription may be filled by entering DAW = 1 in the brand/generic indicator field.

Any questions regarding prior authorization of multi-source brand name medications should be directed to the Maryland Pharmacy Program at 410-767-1455.

Excepted Drugs

According to the July 2004 Maryland Board of Pharmacy Newsletter, the drug products listed below are non-substitutable in Maryland. The Maryland Pharmacy Program does not assign an interchangeable drug cost (IDC) to non-substitutable drug products and consequently the MedWatch requirement would not apply.

- Dilantin® - Phenytoin Sodium Extended Oral Capsules 100mg
- Mysoline® - Primidone Oral Tablets 250mg
- Depakene® - Valproic Acid Oral Capsules 250mg
- Theophylline Extended Release - Oral Tablets 100mg, 200mg and 300mg
- Coumadin® - Warfarin Sodium Oral Tablets 2mg, 2.5mg and 5mg ℞

Pharmacy News and Views is now on the Web

A copy of this newsletter and the previous editions of the ***Pharmacy News and Views*** newsletter can now be found on the HealthChoice Managed Care Organization website at www.mdmahealthchoicerx.com.

Preferred Drug List

It has been over a year since the first drugs were selected for inclusion on the Preferred Drug List (PDL). The process has now progressed to re-reviewing all classes of drugs on the PDL and making modifications where appropriate. The first 17 drug classes included on the original PDL were reviewed at the September 23, 2004 Pharmacy and Therapeutics Committee meeting. Changes were made within 12 classes of the PDL. These were implemented the first week in November 2004. Updates to the PDL are included on page 5 of this newsletter. The complete PDL can be viewed at: http://www.dhmh.state.md.us/mma/mpap/prefdruglist.html . ℞

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STATE OF MARYLAND DHMH

Step Therapy Criteria for COX-II Inhibitors

In addition to selecting preferred agents for the PDL, the Maryland Pharmacy Program is developing other processes that will help promote cost-beneficial prescribing without impacting recipient outcomes. Step therapy guidelines for the drug class of COX-II Inhibitors have been created and will be implemented. Step therapy is a means of assuring that the most cost-beneficial medications are the first line of therapy prior to utilizing more costly or non-preferred agents.

Up until this time, the use of any COX-II inhibitor required a prior authorization. However, no specific criteria for approval were necessary. In the past, prescribers only needed to ask for the non-preferred agent, and it was approved. With the development of step therapy, there is a new requirement before COX-II Inhibitors may be dispensed. Recipients must first fail a trial with a generic NSAID. Effective November 15, 2004 the "Non-steroidal Anti-inflammatory (NSAID)/COX-II Inhibitor" class of drugs became subject to a three-tier step therapy protocol. All new Pharmacy Program prescriptions in this class will be affected.

The three tiers of NSAID/COX-II Inhibitors are:

- **Tier One:** Preferred NSAIDs

  All of the drugs in Tier One are generic NSAIDs. With few exceptions, it is required that drugs from Tier One must be tried first, before drugs in other Tiers may be prescribed without preauthorization.

- **Tier Two:** Preferred COX-II Inhibitors and Prevacid Naprapac

  If the therapeutic responses of Tier One drugs are not satisfactory, Tier Two drugs may be considered. When a recipient has had a prescription for a Tier One drug within the previous 45-day period, prior to a new prescription for a Tier Two drug, he or she will be eligible for a Tier Two agent. This step therapy will allow for prescriptions for Tier Two drugs to be automatically accepted with out preauthorization as they are adjudicated on-line. The preferred drugs in Tier Two are Bextra®, Celebrex®, and Prevacid Naprapac®.

  In the event of such diagnoses as esophageal reflux disease, asthma, rhinitis, nasal polyps, NSAID hypersensitivity and GI ulceration, bleeding or perforation, a Preferred Tier Two agent may be prescribed with prior authorization, absent NSAID failure.

- **Tier Three:** Non-Preferred NSAIDs

  Finally, after a Tier Two preferred agent has failed, a Tier Three non-preferred non-steroidal anti-inflammatory agent may be prescribed. However, pre-authorization will be necessary. The agents in Tier Three are Arthrotecer®, Mobic®, and Ponstel®.

If you have any questions, please call the Maryland Pharmacy Program at 410-767-1455. ℞

Quantity Limits for Atypical Antipsychotic Agents

One of the goals of the Maryland Pharmacy Program is to ensure that Medical Assistance recipients receive optimal drug therapy at the lowest reasonable cost.

The Program has evaluated the use of multiple daily doses of selected atypical antipsychotic agents. These drugs are widely utilized and have a high cost. In many cases, the price of dosage units is not proportionate to the increase in strength, e.g. the price of two 5mg tablets of a selected drug substantially exceeds the price of one 10mg tablet.

In addition, some of these agents have a relatively long halflife and are indicated for once a day dosing which also increases compliance. Therefore, for a selected drug, one 10mg tablet taken once a day is preferable to one 5mg tablet taken twice a day.

In order to maximize the therapeutic benefits of these costly agents, the Program will be implementing the following maximum daily dosing limits for patients age 18 and older, effective December 14, 2004.

- Risperdal® 2 doses per day/ 68 tablets per month of 0.25mg; .5mg; 1mg; 2mg
- Abilify® 1 tablet per day/ 34 tablets per month of 5mg; 10mg; 15mg
- Geodon® 2 doses per day/ 68 capsules per month of 20mg; 40mg
- Zyprexa® 1 tablet per day/ 34 per month of 2.5mg; 5mg; 7.5mg and Zyprexa® Zydis® 5mg
- Seroquel® 4 tablets per day/ 136 per month of 25mg

In an effort to educate prescribers, the Maryland Pharmacy Program is sending letters to prescribers to alert them of their patients who would be affected by the quantity limitations requirement. Prior authorization will be required to dispense atypical Antipsychotic agents in excess of these limits. Prescribers should contact First Health Services Corporation for prior authorization at 800-932-3918.

Full consideration for the recipient continues to be a top priority. Recipients having problems obtaining prescribed medications from the pharmacy may call the Maryland Pharmacy Access Hotline at 1-800-492-5231. ℞

Contact Information

First Health			
First Health ProDur Help Desk	800-884-7387	First Health Technical Help Desk	800-884-3238
First Health PDL PA Phone	800-932-3918	First Health PDL PA Fax	800-932-3921

Managed Care Organizations Pharmacy Benefits Manager or MCO Contact			
AMERIGROUP Corporation	800-454-3730	Maryland Physicians Care	800-953-8854
Diamond Plan for Coventry Health Care	877-215-4100	Priority Partners	888-819-1043
Helix Family Choice	800-905-1722	United HealthCare	800-922-1557
Jai Medical Systems, Inc.	800-213-5640		

HealthChoice (MCO) Inquiries/Complaints			
Provider Hotline	800-766-8692	Recipient Hotline	800-284-4510

Eligibility Verification System (EVS)
410-333-3020 (Balto Metro) or 800-492-2134 (Available 24 hours a day / 7 days a week)

Main Department Numbers	
Department of Health and Mental Hygiene	877-4MD-DHMH
Division of Pharmacy Services	877-4MD-DHMH, x71455, or 410-767-1455
Division of Eligibility Services (Pharmacy Only)	800-226-2142 or 443-263-7090
Pharmacy/Nutritional Preauthorization Line	800-492-5231 Option 3 or 410-767-1755
Growth Hormone/Synagis Preauthorization Line	800-492-5231 Option 3 or 410-767-1755
Pharmacy Access Hotline for recipients	800-492-5231 Option 3 or 410-767-5800

Miscellaneous Numbers			
AIDS Administration	800-205-6308	Md. AIDS Drug Assistance Program	410-767-6535
Dental, Audiology and Vision	410-767-1485	Medicaid, Mental Health	410-767-1442
Department of Veterans Affairs	877-222-8387	Paid Claim Status	410-767-5987
DME/DMS	410-767-1739	Pharmacy Assistance Eligibility	800-226-2142
HealthChoice Enrollee Action Line	800-284-4510	Pharmacy Assistance Policy	410-767-1455
Free-Standing Clinics	410-767-1489	Physician Services	410-767-1722
First Call for Help	800-492-0618	Provider Enrollment	410-767-5340
Hospital Services	410-767-1722	Provider Relations	800-445-1159 ext 5503
Kidney Disease Program	410-767-5000	Transportation	410-767-1436
MED Bank of Maryland	410-821-9262	- *This number is for physicians only.*	

Newsletter Website and Contact Information	
DHMH Website	*http://www.dhmh.state.md.us/*
HealthChoice Website	*http://www.dhmh.state.md.us/mma/healthchoice/*
HealthChoice MCO Formulary Website	*http://www.mdmahealthchoicerx.com/*
Maryland Pharmacy Program	*http://www.dhmh.state.md.us/mma/mpap/*
First Health Website	*http://mdmedicaidrx.fhsc.com/*
Provider Synergies Website	*http://www.providersynergies.com/pages/medicaid_maryland_pdl.html*

For comments to help improve this newsletter please contact Health Information Designs, Inc. at 443-260-2555 or toll free 1-866-260-2555, or e-mail to mdmahealthchoicerx@hidinc.com

Retrospective Drug Utilization Review:
Over-utilization of Controlled Substances

Pharmacists play a key role in identifying over-utilization of medications by patients. For this reason, pharmacists were recently included in a provider letter intervention program undertaken to identify recipients who may be over-utilizing controlled substances.

A retrospective review of over-utilization of controlled substances was performed by evaluating fee-for-service claims for recipients who have utilized multiple prescribers and pharmacy providers to obtain controlled substances. Both prescribers and pharmacy providers received copies of the intervention letter, a response form and a copy of the recipient drug history profile. A total of 885 prescriber letters and 746 pharmacy letters were mailed, which included 362 recipients. Letters were mailed in May of 2004.

Prescriber and pharmacy provider responses to the letter intervention program were quite favorable. Approximately 40% of the prescriber responses and 65% of pharmacy provider responses indicated that some positive action as a result of the intervention letter had been or would be taken. A vast majority of the respondents, 90% of prescribers and 77% of pharmacy providers, found the information to be useful or extremely useful. We thank you for your responses and ask for your cooperation with regard to future provider letter intervention programs.

Recipients identified during this review may be followed for continued over-utilization of controlled substances, and additional interventions may be necessary. Some recipients may be referred for inclusion in the Pharmacy Corrective Management Care Program, otherwise know as the Pharmacy Lock-In Program, when this program is reintroduced in the near future. ℞

Retrospective Drug Utilization Review:
Therapeutic Duplication of Atypical Antipsychotic Agents

The use of atypical antipsychotic agents has dramatically altered the treatment of schizophrenia. These agents produce fewer adverse effects than traditional antipsychotic agents, and therefore, are better tolerated by patients, leading to increased compliance and improved responses. However, some patients may still be refractory to treatment with these agents.

Despite the fact that there is little data in the medical literature to support the use of two concurrent atypical agents, some patients are taking two agents. Duplicate therapy may offer some benefits in very few refractory patients. Routine duplicate therapy with atypical agents should be discouraged, since two agents may not offer improved responses in all patients. Adverse effects are more likely with two agents which are very costly.

In an effort to promote monotherapy of these agents, a retrospective drug use review program is underway to alert prescribers of recipients taking two concurrent atypical antipsychotic agents. Emphasis is on those who are utilizing two different prescribers.

Educational letters are being sent to prescribers along with a brief summary of clinical information about the atypical agents as well as a treatment plan to promote rational monotherapy prescribing. There are no plans at this time to require prior authorization of a second atypical agent. ℞

Dosage Form Limitations for Ranitidine and Fluoxetine

There are a few generic drugs for which there is a tremendous difference in the cost of various solid oral dosage forms. There is nothing in the literature that indicates one dosage form is any more effective than the other dosage form. Two of these agents are ranitidine and fluoxetine. Ranitidine capsules are five times more expensive than ranitidine tablets and fluoxetine 20 mg tablets are 15 times more expensive than fluoxetine capsules.

In an effort to reduce costs associated with the use of these dosage forms, as of December 1, 2004 the Maryland Pharmacy Program will no longer reimburse claims for ranitidine capsules or fluoxetine tablets without the prescriber requesting prior authorization. ℞

Maryland Preferred Drug List

(Italics show changes as a result of the September 23, 2004 Pharmacy and Therapeutics Committee Meeting)

CARDIOVASCULAR

ACE Inhibitor/Calcium Channel Blocker Combination

Preferred
Lotrel
Tarka
Requires Prior Authorization
Lexxel

ACE Inhibitors (Hypotensives,

Preferred
benazepril, HCTZ (Lotensin, HCT)
captopril, HCTZ (Capoten, Capozide)
enalapril, HCTZ (Vasotec, Vaseretic)
lisinopril, HCTZ (Prinivil, Zestril, Prinzide, Zestoretic)
moexipril (Univasc)
quinapril (Accuretic)
Aceon
Mavik
Monopril, HCT
Uniretic
Requires Prior Authorization
Accupril
Altace

Angiotensin Receptor Blockers (Hypotensives, Angiotensin Receptor Antagonist)

Preferred
Avapro, Avalide
Benicar, HCT
Cozaar, Hyzaar
Diovan, HCT
Micardis, HCT
Teveten, HCT
Requires Prior Authorization
Atacand, HCT

Beta Blockers (Alpha/ Beta-Adrenergic Blocking Agents, Beta Adrenergic Blocking Agents)

Preferred
acebutolol (Sectral)
atenolol (Tenormin)
betaxolol (Kerlone)
bisoprolol (Zebeta)
labetalol (Normodyne, Trandate)
metoprolol (Lopressor)
nadolol (Corgard)
pindolol (Visken)
propranolol (Inderal)
sotalol, AF (Betapace, AF)
timolol (Blocadren)
Coreg
Inderal LA

Beta Blockers (*continued*)

Requires Prior Authorization
Cartrol
Levatol

Calcium Channel Blocking Agents

Preferred
diltiazem (Cardizem)
diltiazem SR, ER (Cardizem SR CD, Dilacor XR, Tiazac)
nicardipine (Cardene)
nifedipine, SR (Adalat, CC, Procardia, XL)
verapamil (Calan)
verapamil ER, SR (Calan SR, Verelan)
Cardizem LA
Dynacirc, CR
Norvasc
Sular
Requires Prior Authorization
Cardene SR
Covera-HS
Nimotop
Plendil
Vascor
Verelan PM

Lipotropics, Other (Lipotropics, Bile Salt Sequestrants)

Preferred
cholestyramine (Questran, Light)
gemfibrozil (Lopid)
niacin (Niacor)
Colestid
Lofibra
Niaspan
Tricor
Zetia
Requires Prior Authorization
Welchol

Lipotropics, Statins (Lipotropics)

Preferred
lovastatin (Mevacor)
Advicor
Altoprev
Caduet
Crestor
Lescol, XL
Lipitor
Pravachol
Zocor
Requires Prior Authorization
Pravigard PAC

ENDOCRINE

Hypoglycemics, TZDs (Hypoglycemics, Insulin-Response Enhancers)

Preferred
Actos
Avandia

GASTROINTESTINAL

Proton Pump Inhibitors (Gastric Acid Secretion Reducers)

Preferred
Nexium
Prevacid
Prilosec OTC
Requires Prior Authorization
omeprazole
Aciphex
Protonix

RESPIRATORY

Leukotriene Receptor Antagonists

Preferred
Accolate
Singulair

Nasal Corticosteroids (Nasal Anti-Inflammatory Steroids)

Preferred
flunisolide (Nasalide)
Flonase
Nasarel
Requires Prior Authorization
Beconase AQ
Nasacort AQ
Nasonex
Thinocort Aqua

UROLOGIC

Benign Prostatic Hyperplasia

Preferred
doxazosin (Cardura)
terazosin (Hytrin)
Avodart
Flomax
Proscar
Uroxatral

Maryland Pharmacy Program Proposed Quantity Limits for Anti-emetic Drugs

The Maryland Pharmacy Program has begun to review selected drug classes where instituting prescription quantity limitations may be beneficial in reducing wastage of costly medications. One such class of drugs are the newer anti-emetic agents such as Anzemet® (dolasetron), Emend® (aprepitant), Kytril® (granisetron), Marinol® (dronabinol) and Zofran® (ondansetron). These agents offer advantages over traditional anti-emetics but are very costly and are only indicated for use for a few days post chemotherapy or radiation therapy. Prescription quantity limitations for these agents have been developed that will provide for adequate treatment for recipients while they are receiving chemotherapy or radiation therapy. Prior authorizations for quantities in excess of the limits will be available if needed. Quantity limitations are as noted on the following table. These limits will be implemented within the next few months.

PRODUCT (Preferred in bold)	STRENGTHS / DOSAGE FORMS	APPROVED ADJUNCTIVE CHEMO REGIMENS	30 DAY QUANTITY LIMITS
Emend® (aprepitant)	• 80 & 125 mg caps • 125mg/80mg Trifold Pack (3's)	• Chemo: 125mg 1 hour pre-treatment, then 80mg daily for 2-3 days in combination with dexamethasone	• 15 tabs
Marinol® (dronabinol)	• 2.5, 5, & 10mg caps	• Chemo: 2.5 to 40mg per day in divided doses every 4 to 6 hours	• 60 caps
Zofran®, Zofran ODT® (ondansetron)	Zofran: • 4 & 8mg tabs - 30s, 100s, & 1x3 daily UD packs • 24 mg tabs - 1x1 daily UD packs • Oral soln. (4mg/5ml)- 50 ml bottles	• Chemo: 8mg, 30 min. pre-treatment, and 8mg, 8 hrs. later; then 8mg q 12 hrs for 1 to 2 days post treatment. • Radiation: 8mg, 1 to 2 hrs. pre-treatment, then up to q 8 hrs. for 1 to 2 days post-treatment.	• 15 tabs (4 or 8mg) • 10 tabs (24mg) • 100ml
	Zofran ODT (orally disintegrating tabs): • 4mg - UD 30s • 8mg - UD 10s & 30s		• 15 tabs (4 or 8mg)
Anzemet® (dolasetron)	• 50mg tabs -5s, blister pack 5s, and UD 10s • 100mg tabs - 5s, blister pack 5s, and UD 10s	• Chemo: 100mg within 1 hour of chemo.	• 10 tabs
Kytril® (granisetron)	• 1mg tab - 2s and 20s • 1mg/5ml oral soln. - 30ml	• Chemo: 2mg q d within 1 hour of treatment or 1 mg(5ml) 1 hour prior to treatment and 1 mg (5ml) 12 hours later. • Radiation: 2mg within 1 hour of treatment.	• 15 tabs • 90ml

Atypical Antipsychotic Agents and Risk of Diabetes

The use of atypical antipsychotic agents has been associated with worsening hyperglycemia in patients with diabetes and possible development of dibetes in patients with risk factors for diabetes. Pharmacists can help identify patients at risk for diabetes who are taking atypical antipsychotic agents.

The Food and Drug Administration (FDA) has asked manufacturers of all atypical antipsychotic drugs to add a new warning to the drug labeling about the increased risk of hyperglycemia and diabetes. Atypical antipsychotic agents include: Clozaril® (clozapine), Risperdal® (risperidone), Zyprexa® (olanzepine), Seroquel® (quetiapine), Geodon® (ziprasidone), and Abilify® (aripiprazole).

Part of the warning is reprinted below:

"Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing."

Additional information can be found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=28#4 .

Actiq® (Fentanyl Transmucosal System)

Actiq® is a novel dosage of fentanyl that is only indicated for the treatment of breakthrough cancer pain in recipients over age 16 who are also taking long acting opioids. The labeling for the drug is noted below:

Actiq® (transmucosal fentanyl) is indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. The drug is not indicated in the management of acute or post-operative pain. This medication must not be used in opioid non-tolerant patients. Transmucosal fentanyl is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are experienced in the use of Schedule II opioids to treat cancer pain.

Several recipients have been identified who are utilizing large quantities of the drug and are not taking any other opioid agent for pain management. As a result, beginning November 15, 2004 special prior authorization for the use of Actiq® will be required. Actiq® will only be approved for recipients who meet the following criteria:

- Diagnosis of cancer
- Patient over 16 years of age
- Management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy.

In addition, FDA cautions the recipient:

- Be under the care of an oncologist or pain specialist who is experienced in the use of Schedule II opioids to treat cancer pain;
- Should not have any of the following contraindications: hypersensitivity to opiates; hypoxia/hypercapnia; severe asthma or chronic obstructive pulmonary disease; paralytic ileus.

Approval of prior authorization for Actiq® may be granted for up to 6 months. Prescribers may contact First Health Services at 1-800-932-3918 to request prior authorization. The prior authorization form is available from First Health and the Maryland Pharmacy Program and will soon be available on the program's website.

Women's Health Initiative Hormone Replacement Therapy Study

The question of the risks versus benefits of estrogen therapy in post-menopausal women is often posed by patients to their healthcare providers. Pharmacists often may find themselves being asked by their patients if they should continue on estrogen therapy. In an effort to answer the questions about the effects of long term estrogen therapy, a large clinical trial was undertaken several years ago.

The Women's Health Initiative (WHI) is a major 15-year research program undertaken to address the most common causes of death, disability and poor quality of life in postmenopausal women and evaluate any increased risk of cardiovascular disease, cancer, and osteoporosis associated with hormone replacement therapy. The WHI was launched in 1991 and consists of a set of clinical trials and an observational study, which together involve more than 161,000 generally healthy post-menopausal women.

The clinical trials were designed to test the effects of postmenopausal hormone replacement therapy, diet modification, and calcium and vitamin D supplements on the incidence of heart disease, fractures, breast cancer and colorectal cancer.

The hormone trial had two studies: the estrogen-plus-progestin study of women with an intact uterus and the estrogen-alone study of women without a uterus (post hysterectomy). Women with a uterus were given progestin in combination with estrogen, a practice known to prevent endometrial cancer. In both hormone therapy studies, women were randomly assigned to either the hormone medication being studied or to a placebo.

Summaries of the findings are given below. However, be aware that the findings for the two studies should not be compared directly, because of differences in the women's characteristics at the time of their enrollment in the studies. For example, those in the estrogen-alone study had a higher risk of cardiovascular disease than those in the estrogen-plus-progestin study. Women in the estrogen-alone study were more likely to have heart disease risk factors, such as high blood pressure, high cholesterol, diabetes, and obesity.

Compared with the placebo, estrogen plus progestin resulted in:

- Increased risk of heart attack
- Increased risk of stroke
- Increased risk of blood clots
- Increased risk of breast cancer
- Reduced risk of colorectal cancer
- Fewer fractures
- No protection against mild cognitive impairment and increased risk of dementia (study included only women 65 and older)

Compared with the placebo, estrogen alone resulted in:

- No difference in risk for heart attack
- Increased risk of stroke
- Increased risk of blood clots
- Uncertain effect for breast cancer
- No difference in risk for colorectal cancer
- Reduced risk of fracture (Findings about memory and cognitive function are not yet available.)

More information concerning the WHI can be found at http://www.nhlbi.nih.gov/whi/index.html.

Pharmacy News and Views
Maryland Department of Health and Mental Hygiene
Office of Operations, Eligibility and Pharmacy

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New Labeling for Use of Antidepressants in Pediatric Patients

Over the past several months there has been an increasing debate over the role that anti-depressants play in increasing the risk of suicide or suicidal thoughts in pediatric patients. Although much of the debate has focused on the SSRIs, there is evidence that any antidepressant has the potential to increase the risk of suicide or suicidal thoughts in the adolescent population. Based on recent recommendations made to the FDA by the Psychopharmacologic Drugs and Pediatrics Advisory Committee, the FDA has taken the following steps to insure the safe use of antidepressants in the pediatric population:

- Recommend a new warning be included in the labeling of all antidepressants which discusses the increased risk of suicide or suicidal thoughts in pediatric patients. The labeling will be applied to all anti-depressants, not just SSRIs.
- Requires the development of a patient information sheet or medication use guide to be distributed to patients at time of dispensing.
- Did not recommend that anti-depressants be contraindicated in pediatric patients, since a contraindication in the labeling may result in a decrease in the treatment of depression.

In addition, all pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Ideally, such observation would include at least weekly face-to-face contact with patients or their family members or care-givers with their physician during the first 4 weeks of treatment, then biweekly visits for the next 4 weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. Additional contact by telephone may be appropriate between face-to-face visits.

Adults with major depressive disorder or co-morbid depression in the setting of other psychiatric illness being treated with anti-depressants, should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

Despite the added precautions which are now being added to the labeling for antidepressants, the consequence of not treating depression with antidepressant medications at all would be far more serious with respect to adverse outcomes for patients and their families. The pharmacist plays a vital role in monitoring not only patient compliance with anti-depressant medications but also in observing and assessing patients for changes in behavior that may indicate clinical worsening of depression.

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All Program information and updates featured in this issue of ***Pharmacy News and Views*** are the best information available at the time of printing. Any updates that became effective after the date of printing will be included in the next issue of our newsletter.