

**DSHS STATE HOSPITALS SECTION  
EXECUTIVE FORMULARY COMMITTEE MINUTES  
April 29, 2005**

The Executive Formulary Committee convened on Friday, April 29, 2005 in Room 295 - CO Building 2. The meeting was called to order by Dr. Ward, Interim Chair at 9:30 a.m.

Janet Adams, MSN, RN, CNS	√	Robert Kifowit	Absent
Rosha Chadwick, R.Ph.	√	Kenny Dudley	Absent
Jeanna Heidel, Pharm.D.	√	Mike Maples	Absent
Robin Mallett, M.D.	Absent	Michael Woolsey	Absent
Jack McCoy, M.D.	√	Barbara Otting, RN	Absent
Connie Millhollon, RN,	√	Camille Hemlock, M.D.	√
Victoria B. Morgan, M.D.	Absent	Nina Muse, M.D.	√
Ann L. Richards, Pharm.D.	√	Steven P. Shon, M.D.	√
Dan Still, Pharm.D.	√	Vacant Center Position	
Bernardo C. Tarin-Godoy, M.D.	Absent	Vacant Center Position	
Robert L. Ward, D.O.	√	Vacant State School Position	

**Guest Present: Sharon Tramonte, Pharm.D., San Antonio State School, Linda Ekezie, M.D., Resident**

**Roll Call, Introductions and Announcements**

Dr. Emilio Dominguez submitted his resignation due to his inability to regularly attend the meetings.

Dr. Shon provided a brief update on legislative issues.

**Approval of Minutes of February 4, 2005**

On a motion of Dr. McCoy, seconded by Ms. Chadwick, the minutes of the February 4<sup>th</sup> meeting were approved as previously distributed.

**Adverse Drug Reaction Reports**

The Executive Formulary Committee received many adverse drug reaction reports from several facilities. In the first case, a 35-year-old obese patient developed hyperglycemia secondary to quetiapine (Seroquel®). The patient had a normal baseline glucose level and HgA<sub>1c</sub> while on risperidone (Risperdal®). The patient was changed to quetiapine and approximately 22 days after the switch (which was 28 days after the normal fasting glucose and HgA<sub>1c</sub>) the fasting glucose became elevated. The patient was treated with metformin

(Glucophage®) and was eventually changed to aripiprazole (Abilify®).

In the second case, a 26-year-old male patient receiving aripiprazole (Abilify®) 30 mg/day developed severe cogwheeling dystonia with difficulty swallowing, excessive drooling with a rigid posture, stiff gait and arms stiff at side. The AIMS score was zero (0) on admission. The aripiprazole dose was decreased.

In another case, a 48 year-old patient receiving divalproex sodium (Depakote®) 3000 mg/day with a level of 87.9 mcg/ml had an ANC of 0.7. The divalproex was decreased to 2000mg/day and the ANC rebounded to 1.1.

A 44 year-old patient, already on hydrochlorothiazide developed acute mental status changes and weakness one week after the initiation of oxcarbazepine (Trileptal®) 600 mg/day. Labs obtained four days after the oxcarbazepine initiation showed a sodium level of 116 mEq/L. A previous sodium obtained three months earlier was 134 mEq/L. The patient was transferred to a medical facility for treatment of hyponatremia and the oxcarbazepine was discontinued. The sodium levels improved after the oxcarbazepine was discontinued.

A patient received tetanus toxoid vaccine as part of the hospital’s routine vaccination program. Within two hours after administration of the vaccine, the patient displayed difficulty breathing, swelling and a rash subsequently developed. The patient was rushed to a local emergency room for treatment. The patient received corticosteroids, antihistamines, albuterol inhalation and calamine lotion.

**Proposed changes to DSHS Standard Formulary Memo**

The reports from the three Work Groups were combined into one and submitted to Dr. Bell for his approval. The recommendations from these Work Groups will be implemented.

**Antipsychotic Audit Criteria**

Dr. Richards revised the audit criteria for the antipsychotics to match the article “Physical Health Monitoring of Patients with Schizophrenia” (Am J Psychiatry 161:8, August 2004) which was the recommendation by the Work Group. In comparing the previous audit criteria to the proposed, the following items were not addressed in the proposed audit criteria:

Antipsychotics	Pregnancy test – as clinically indicated
Antipsychotics- mesoridazine (Serentil®), thioridazine (Mellaril®)	Pregnancy test – as clinically indicated Serum potassium – baseline, every six months and as clinically indicated Serum magnesium level – baseline and as clinically indicated (especially if potassium level is low)
Decanoates	Pregnancy test – as clinically indicated Blood levels – as clinically indicated
Clozapine (Clozaril®)	Pregnancy test – as clinically indicated
Risperidone (Risperdal®), olanzapine (Zyprexa®), quetiapine (Seroquel®), ziprasidone (Geodon®) and aripiprazole (Abilify®)	Pregnancy test – as clinically indicated Patients at risk for hypokalemia (and/or hypomagnesemia) should have baseline serum potassium and magnesium before starting ziprasidone

The following changes were made to the Antipsychotic mesoridazine (Serentil®), thioridazine (Mellaril®) audit criteria:

- Added to Absolute Contraindications  
Known heart disease  
Personal history of syncope  
Family history of sudden death at an early age (under age of 40 years)  
Congenital long QT syndrome
- Deleted from the Relative Contraindication  
Severe cardiovascular diseases, including certain conduction disturbances  
(Note: this was added to Absolute Contraindications)

In reviewing the proposed Audit Criteria, the Committee recommended the following changes:

- Add pregnancy test – as clinically indicated to all the revised audit criteria
- Add serum potassium – baseline, every six months and as clinically indicated to the mesoridazine and thioridazine audit criteria
- Add serum magnesium level – baseline and as clinically indicated (especially if potassium level is low) to the mesoridazine and thioridazine audit criteria
- Add risperidone (Risperdal®) Consta to the listing that includes risperidone
- Define “at every visit” for the BMI measurement as “monthly for inpatients” to all revised audit criteria
- Change the “prolactin and sexual function questionnaire” to “Sexual function inquiry – inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly” to all revised audit criteria
- Define “at each visit” for the section for antipsychotics known for prolactin elevation under sexual function inquiry to “quarterly for inpatients” to all revised audit criteria
- Change prolactin level to if there is evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbance yearly to all revised audit criteria

On a motion of Dr. Still, seconded by Dr. Heidel the recommendation to approve the all of the antipsychotic audit criteria as revised was approved. See Attachment A. The revised audit criteria and guidelines will be distributed to the field.

### **Consent List for Psychoactive Medications**

Dr. Richards presented the revised consent list for psychotropic medications. The following additions were made to the list:

- Bupropion (Wellbutrin XL®) *nonformulary*
- Duloxetine (Cymbalta®)
- Escitalopram (Lexapro®)
- Remeron® SolTab to mirtazapine
- Paxil CR® to paroxetine
- Risperdal M-Tab® to risperidone
- Risperidone (Risperdal Consta®)
- Xanax XR to alprazolam
- Tegretol XR® and Carbatrol® to carbamazepine
- Depakote ER® to divalproex sodium
- Adderall XR® to amphetamine/dextroamphetamine mixture
- Atomoxetine (Strattera®)
- Olanzapine/fluoxetine (Symbyax®) *nonformulary*

On a motion of Dr. Heidel, seconded by Dr. Still, the recommendation to approve the psychotropic consent list as revised was approved. See Attachment B. The revised consent list will be distributed to the field.

## New Drug Applications

(Please refer to [Attachment C](#) for the monographs and applications that were considered when determining action by the committee.)

### **tegaserod (Zelnorm®) - discussed by Dr. Tramonte**

Serotonin has been shown to be involved in regulating motility, visceral sensitivity and intestinal secretion. Tegaserod is a 5-HT<sub>4</sub> receptor partial agonist that binds with high affinity. The activation of 5-HT<sub>4</sub> receptors in the gastrointestinal tract stimulates the peristaltic reflex and intestinal secretion, as well as inhibits visceral sensitivity. *In vivo* studies showed that tegaserod enhanced basal motor activity and normalized impaired motility throughout the gastrointestinal tract. In addition, studies demonstrated that tegaserod moderated visceral sensitivity during colorectal distension in animals. Tegaserod is indicated for the short-term treatment of women with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation.

**Following discussion, on motion of Ms. Chadwick, seconded by Dr. Ward, the request to add tegaserod (Zelnorm®) to the formulary was approved.** The Formulary CheckList was completed.

### **pioglitazone (Actos®) - discussed by Dr. Tramonte**

Pioglitazone is an oral antidiabetic agent that acts primarily by decreasing insulin resistance. Pioglitazone belongs to a different chemical class and has a different pharmacological action than the sulfonylureas, metformin, or the  $\alpha$ -glucosidase inhibitors. It is synthesized and used as the racemic mixture. The two enantiomers of pioglitazone inter-convert *in vivo*. No differences were found in the pharmacological activity between the two enantiomers. Pioglitazone is indicated for the treatment of Type 2 diabetes as monotherapy and in combination with a sulfonylurea, metformin, or insulin when diet and exercise plus the single agent does not result in adequate glycemic control. In reviewing potential medication errors, Actos® can be confused with Actidose® and Actonel®.

**Following discussion, on motion of Dr. Still, seconded by Dr. Heidel, the request to add pioglitazone (Actos®) to the formulary was approved.** The Formulary CheckList was completed.

### **montelukast (Singulair®) - discussed by Dr. Tramonte**

The cysteinyl leukotriene type-1 (CysLT<sub>1</sub>) receptor is found in the human airway (including airway smooth muscle cells and airway macrophages) and on other pro-inflammatory cells (including eosinophils and certain myeloid stem cells). Montelukast binds with high affinity and selectivity to the CysLT<sub>1</sub> receptor inhibiting the physiologic actions of LTD<sub>4</sub> without any agonist activity. In asthma, leukotriene-mediated effects include airway edema, smooth muscle contraction, and altered cellular activity associated with the inflammatory process. In allergic rhinitis, CysLTs are released from the nasal mucosa after allergen exposure during both early and late-phase reactions and are associated with symptoms of allergic rhinitis. Montelukast is indicated for the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older and for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older. In reviewing potential medication errors, Singulair® can be confused with Sinequan®.

**Following discussion, on motion of Dr. Ward, seconded by Ms. Chadwick, the request to add montelukast (Singulair®) to the formulary was approved.** The Formulary CheckList was completed.

## **Quarterly Non-Formulary Drug Justification Report**

The summary of the non-formulary drug report for the second quarter was reviewed. No action was taken as a result of this review.

## **Polypharmacy with Atypical Antipsychotics**

A polypharmacy survey was sent to the pharmacy directors at the state facilities. Each pharmacy director was asked to take a “snapshot picture” of patients on more than one atypical antipsychotic. In addition, each pharmacy director reported their policy for polypharmacy. Not all facilities submitted their reports.

For the mental health facilities, eight facilities reported. For these eight facilities, a total of 112 patients were on two atypical antipsychotics. Kerrville State Hospital had the most with 30 patients. One patient had three atypical antipsychotics.

For the State Schools, ten facilities reported. For these ten facilities, a total of 51 patients were on two atypical antipsychotics. San Angelo State School had the most with 11 patients. Three patients at one facility were on three atypical antipsychotics.

Most of the State Hospitals have a process in place to review polypharmacy. These include review by the clinical director, a second opinion obtained from a colleague or reporting to the Pharmacy and Therapeutics Committee. The State Schools either report polypharmacy on drug regimen reviews, to the Medical Director or to the Pharmacy and Therapeutics Committee or similar Committee.

Dr. Hemlock reported that a conference on polypharmacy is being provided to the Medical Directors on May 19<sup>th</sup>. The Committee recommended that the Clinical Directors for the State Hospitals be invited as well.

## **Proposed Drug Deletion List -**

**Analgesic Agents**  
**Antiemetic/Antivertigo Agents**  
**Sedative/Hypnotic Agents**  
**Anticonvulsant Agents**

The Committee did not receive any comments from the field about the proposed deletions for the analgesic, antiemetic/antivertigo, sedative/hypnotic and anticonvulsant agents. On a motion of Ms. Chadwick, seconded by Dr. Ward, the motion to delete these agents was approved.

## **DSHS Drug Formulary Sectional Review-**

**Muscle Relaxant Agents**  
**Antiparkinson Agents**  
**Migraine Agents**  
**Miscellaneous CNS Agents**  
**Endocrine Agents**

Dr. Tramonte provided the review of the muscle relaxant agents with her recommendation. Attachment D. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment D).

Dr. Tramonte recommended that cyclobenzaprine (Flexeril®) be added to the Formulary.

Cyclobenzaprine relieves skeletal muscle spasm of local origin without interfering with muscle function by acting at the brain stem as oppose to the spinal cord level. It is ineffective in muscle spasm due to central nervous system (CNS) disease. Evidence suggests that the net effect of cyclobenzaprine is a reduction of tonic somatic motor activity, influencing both gamma ( $\gamma$ ) and alpha ( $\alpha$ ) motor systems. Pharmacological studies in animals showed a similarity between the effects of cyclobenzaprine and the structurally related tricyclic antidepressants, including reserpine antagonism, norepinephrine potentiation, potent peripheral and central anticholinergic effects and sedation. Cyclobenzaprine is indicated as a short-term (up to 2 or 3 weeks) adjunct to rest and physical therapy for relief of muscle

spasm associated with acute, painful musculoskeletal conditions. Cyclobenzaprine can be confused with cyproheptadine and Flexeril® can be confused with Floxin®. See Attachment E.

On a motion by Ms. Chadwick, seconded by Dr. Heidel, the recommendation to add cyclobenzaprine (Flexeril®) to the formulary was approved. The Formulary CheckList was completed.

Dr. Tramonte provided the review of the antiparkinson agents with her recommendations. Attachment F. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment F).

Dr. Tramonte recommended that entacapone (Comtan®), pergolide (Permax®) and pramipexole (Mirapex®) be added to the Formulary.

Entacapone is a selective and reversible inhibitor of catechol – O – methyltransferase (COMT). The mechanism of action of entacapone is believed to be through its ability to inhibit COMT and alter the plasma pharmacokinetics of levodopa. When entacapone is given in conjunction with levodopa and an aromatic amino acid decarboxylase inhibitor, such as carbidopa, plasma levels of levodopa are greater and more sustained than after administration of levodopa and an aromatic amino acid decarboxylase inhibitor alone. It is believed that at a given frequency of levodopa administration, these more sustained plasma levels of levodopa result in more constant dopaminergic stimulation in the brain, leading to greater effects on the signs and symptoms of Parkinson's disease. Entacapone is indicated as an adjunct to carbidopa/levodopa to treat patients with idiopathic Parkinson's Disease who experience the signs and symptoms of end – of dose “wearing- off.” See Attachment G.

On a motion by Ms. Chadwick, seconded by Dr. Ward, the recommendation to add entacapone (Comtan®) to the formulary was approved. The Formulary CheckList was completed.

Pergolide is a potent dopamine receptor agonist. Pergolide is 10 – 1,000 times more potent than bromocriptine on a milligram per milligram basis in various in vitro and in vivo test systems. In Parkinson's disease, pergolide is believed to exert its therapeutic effect by directly stimulating postsynaptic dopamine receptors in the nigrostriatal system mimicking the endogenous neurotransmitter. Pergolide is indicated as adjunctive treatment to levodopa/carbidopa in the management of the signs and symptoms of Parkinson's disease. Permax® may be confused with Bumex®, Pentrax® or Pernox®. See Attachment H.

On a motion by Dr. McCoy, seconded by Dr. Still, the recommendation to add pergolide (Permax®) to the formulary was approved. The Formulary CheckList was completed.

Pramipexole is a non-ergot dopamine agonist with high relative in vitro specificity and full intrinsic activity at the D<sub>2</sub> subfamily of dopamine receptors, binding with higher affinity to D<sub>3</sub> than to D<sub>2</sub> or D<sub>4</sub> receptor subtypes. By binding to these receptors it is thought that pramipexole can stimulate dopamine activity on the nerves of the striatum and substantia nigra. Mirapex® may be confused with Mifeprex® or MiraLax®. See Attachment I.

On a motion by Dr. McCoy, seconded by Dr. Still, the recommendation to add pramipexole (Mirapex®) to the formulary was approved. The Formulary CheckList was completed.

Dr. Tramonte recommended the deletion of the following dosage strengths/formulations.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Dosage forms to be deleted</b>	<b>Dosage forms still available</b>
biperiden	Akineton®	Injection: 5 mg/ml	Tablet: 2 mg
levodopa	Larodopa®	Capsule: 100 mg, 250 mg, 500 mg Tablet: 100 mg, 250 mg, 500 mg	None

trihexyphenidyl	Artane®	Capsule, sustained release: 5 mg	Elixir: 2 mg/5 ml Tablet: 2 mg, 5 mg
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On a motion of Ms. Chadwick, seconded by Dr. McCoy, the motion to delete these products was approved. Feedback will be obtained from the field.

Dr. Tramonte provided the review of the agents for migraines with her recommendations. Attachment J. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment J).

Dr. Tramonte recommended the following:

- The addition of metoprolol 25 mg to the Formulary
- The addition of timolol (Blocadren®) and fluoxetine (Prozac®) to this section.

On a motion of Dr. Ward, seconded by Dr. McCoy these recommendations were approved.

Dr. Tramonte recommended the deletion of the following dosage strength/formulation:

Generic Name	Brand Name	Dosage forms to be deleted	Dosage forms still available
propranolol	Inderal®	Tablet: 90 mg	Capsule, sustained release: 60 mg, 80 mg, 120 mg, 160 mg Injection: 1 mg/ml Solution, oral: 4 mg/ml, 8 mg/ml, 80 mg/ml Tablet: 10 mg, 20 mg, 40 mg, 60 mg, 80 mg

On a motion of Dr. Ward, seconded by Dr. McCoy, the motion to delete these products was approved. Feedback will be obtained from the field.

Dr. Tramonte provided the review for the miscellaneous CNS agents with her recommendations. Attachment K. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment K).

It was recommended that the name of this section be changed to Dementia Agents since all the drugs listed are used for the treatment of dementia. In addition, it was recommended that the reserve category for these drugs be reviewed at the next meeting. On a motion of Dr. Ward, seconded by Dr. Heidel, the recommendations were approved.

Dr. Tramonte provided the review of the endocrine agents with her recommendations. Attachment L. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment L).

Dr. Tramonte recommended that risedronate (Actonel®) be added to the Formulary.

Risedronate is a pyridinyl bisphosphonate that inhibits osteoclast-mediated bone resorption and modulates bone metabolism. Risedronate has an affinity for hydroxyapatite crystals in bone and acts as an antiresorptive agent. At the cellular level, risedronate inhibits osteoclasts. The osteoclasts adhere normally to the bone surface, but show evidence of reduced active resorption. Animal studies show that risedronate reduces bone turnover (activation frequency, i.e., the rate at which bone remodeling sites are activated) and bone resorption at remodeling sites. Risedronate is indicated for the treatment and prevention of osteoporosis in postmenopausal women, glucocorticoid-induced osteoporosis in men and women and the treatment of Paget's disease of bone. Non-FDA approved indications include

treatment of hypercalcemia of malignancy, breast cancer or multiple myeloma associated osteolytic bone disease. See Attachment M.

On a motion by Dr. McCoy, seconded by Ms. Chadwick, the recommendation to add risedronate (Actonel®) to the formulary was approved. The Formulary CheckList was completed.

Dr. Tramonte recommended the following:

- Addition of alendronate (Fosamax®) oral solution 70 mg/75 ml
- Addition of estradiol (Vagifem®) vaginal tablet 25 mcg
- Addition of Depo-Medrol® as a trade name for methylprednisolone
- Addition of Levoxyl® as a trade name for levothyroxine

On a motion of Dr. McCoy, seconded by Ms. Chadwick, the recommendations were approved.

Dr. Tramonte recommended the deletion of the following dosage strengths/formulations.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Dosage forms to be deleted</b>	<b>Dosage forms still available</b>
corticotropin	ACTH®	Injection, repository: 40 units/ml, 80 units/ml Powder for injection: 25 units, 40 units	None
cortisone		Injection: 50 mg/ml Tablet: 5 mg, 10 mg, 25 mg	None
liotrix	Thyrolar® Euthroid®	Tablet: 15 mg, 30 mg, 60 mg, 120 mg, 180 mg (thyroid equivalent)	None
methyltestosterone	Android® Oreton®	Capsule: 10 mg Tablet: 10 mg, 25 mg Tablet, buccal: 5 mg, 10 mg	None
prednisolone	Delta-Cortef®	Injection, as sodium phosphate: 20 mg/ml Liquid, oral: 5 mg/ml	Syrup: 15 mg/5 ml Tablet: 5 mg
prednisone	Meticorten® Deltasone®	Solution, oral, concentrate: 5 mg/ml with 30% alcohol	Syrup: 5 mg/5 ml Tablet: 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg
probenecid	Benemid®	Tablet: 500 mg	None
testosterone	Androlin®	Injection, in oil, as enanthate: 100 mg/m, 200 mg/ml	Injection, in oil, as cypionate: 100 mg/m, 200 mg/ml

On a motion of Dr. McCoy, seconded by Ms. Chadwick, the motion to delete these products was approved. Feedback will be obtained from the field.

### **Sectional Review for July 2005**

The infectious agents will be reviewed at the next meeting.

### **Other Issues**

At the last meeting, it was suggested that the use of amoxicillin (Amoxil®) in combination with amoxicillin/clavulenic acid (Augmentin®) was cheaper at the higher doses of Augmentin®. The availability of generic Augmentin® is more cost effective than the combination of amoxicillin and Augmentin®.

The Committee discussed the possibility of implementing a therapeutic interchange with the proton pump inhibitors. Over the years, the Committee has discussed therapeutic substitution. At this time, the Committee recommended that the basic information regarding therapeutic substitution be discussed with the clinical/medical directors prior to any further discussions. Dr. Richards will make arrangements to complete this task.

The FDA issued a public health advisory on deaths with antipsychotics in elderly patients with behavioral disturbances. The following is the advisory that was released:

The Food and Drug Administration has determined that the treatment of behavioral disorders in elderly patients with dementia with atypical (second-generation) antipsychotic medications is associated with increased mortality. Of a total of seventeen placebo controlled trials performed with olanzapine (Zyprexa®), aripiprazole (Abilify), risperidone (Risperdal®), or quetiapine (Seroquel®) in elderly demented patients with behavioral disorders, fifteen showed numerical increases in mortality in the drug-treated group compared to the placebo-treated patients. These studies enrolled a total of 5106 patients, and several analyses have demonstrated an approximately 1.6-1.7 fold increase in mortality in these studies. Examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).

The atypical antipsychotics fall into three drug classes based on their chemical structure. Because the increase in mortality was seen with atypical antipsychotic medications in all three chemical classes, the Agency has concluded that the effect is probably related to the common pharmacologic effects of all atypical antipsychotic medications, including those that have not been systematically studied in the dementia population. In addition to the drugs that were studied, the atypical antipsychotic medications include clozapine (Clozaril®) and ziprasidone (Geodon®). All of the atypical antipsychotics are approved for the treatment of schizophrenia. None, however, are approved for the treatment of behavioral disorders in patients with dementia. Because of these findings, the Agency will ask the manufacturers of these drugs to include a Boxed Warning in their labeling describing this risk and noting that these drugs are not approved for this indication. Symbyax®, a combination product containing olanzapine and fluoxetine, approved for the treatment of depressive episodes associated with bipolar disorder, will also be included in the request.

The Agency is also considering adding a similar warning to the labeling for older antipsychotic medications because the limited data available suggest a similar increase in mortality for these drugs.

This information will be distributed to the field.

The Food and Drug Administration is advising health care professionals about a new warning for atomoxetine (Strattera®). The labeling is being updated with a bolded warning about the potential for severe liver injury following two reports (a teenager and an adult) in patients who had been treated with atomoxetine for several months, both of whom recovered. The labeling warns that severe liver injury may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients. The labeling also notes that the number of actual cases of severe liver injury is unknown because of under-reporting of post-marketing adverse events. The bolded warning indicates that the medication should be discontinued in patients who developed jaundice (yellowing of the skin or whites of the eyes) or laboratory evidence of liver injury. This information will be distributed to the field.

Novartis Pharmaceuticals Corporation has issued a Dear Health Care Provider letter for oxcarbazepine (Trileptal®). The updated warning section call attention to serious dermatological reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis that have been reported in both children and adults in associated with oxcarbazepine use. The precaution section has been updated to include language regarding multi-organ hypersensitivity reactions that have been reported in association with oxcarbazepine use. This information will be distributed to the field.

The name of galantamine is changing from Reminyl® to Razadyne™ in order to prevent confusion with Amaryl®.

The Committee discussed whether or not computerized prescriber order entry (CPOE) increases medication errors and whether or not our system has reviewed pre- and post- CPOE medication errors. It was noted that any change in the medication use system will change the type and number of medication errors, however, it isn't fair to compare medication errors immediately after a change in process since there is a learning curve associated with the process.

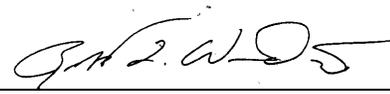
### **Next Meeting Date**

The next meeting was scheduled for July 22, 2005.

### **Adjourn**

There being no further business, the meeting was adjourned at 2:23 p.m.

Approved: \_\_\_\_\_



Robert Ward, D.O., Interim Chairman

### **Attachments**

- Attachment A: Antipsychotic Audit Criteria
- Attachment B: Consent List for Psychoactive Medication
- Attachment C: New Drug Application Monographs
- Attachment D: Muscle Relaxant Agents Class Review & Cost Review and Alphabetical Listing
- Attachment E: Cyclobenzaprine (Flexeril®) Monograph
- Attachment F: Antiparkinson Agents Class Review & Cost Review and Alphabetical Listing
- Attachment G: Entacapone (Comtan®) Monograph
- Attachment H: Pergolide (Permax®) Monograph
- Attachment I: Pramipexole (Mirapex®) Monograph
- Attachment J: Migraine Agents Class Review & Cost Review and Alphabetical Listing
- Attachment K: Miscellaneous CNS Agents Class Review & Cost Review and Alphabetical Listing
- Attachment L: Endocrine Agents Class Review & Cost Review and Alphabetical Listing
- Attachment M: Risedronate (Actonel®) Monograph

Minutes Prepared by:

Ann L. Richards, Pharm.D.

Rosha Chadwick