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STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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PHARMACY AND THERAPEUTICS COMMITTEE

**Washoe County Administration Complex
Commission Chambers (Building A)
1001 E. 9th Street
Reno, Nevada 89512**

Meeting Minutes
July 27, 2006
1:00 p.m.

Committee Members Present:

Steven Phillips, MD, Chairman
Diana Bond, R.Ph.
Judy Britt, Pharm.D.
Carl Heard, MD
Linda Flynn, R.Ph.
Larry Pinson, Pharm.D.
Susan Pintar, MD
Robert Horne, MD (called-in)

Others Present:

Darrell Faircloth DAG, Coleen Lawrence DHCFP, Debbie Meyers DHCFP, Jeff Monaghan FHSC, Shirley Hunting FHSC, Dawn Daly FHSC, Jay Jennings Sanofi-Aventis, Maria Kootsikis Sanofi-Aventis, Randy Dossat Roche, Edward McKenna Roche, Penny Atwood Boehringer-Ingelheim, Kevin Carson KOS, Stephen Landis KOS, Eric Byrnes ALC, Oscar Johnson 3M, Sedrick Spencer Roche, Catherine Sterk Roche, Bonnie Kolor Roche, Allen Christie GSK, Garry Dawson Takeda, Shawna Blasing Takeda, Bert Jones GSK, Kathy Hollingsworth Takeda, Jennifer Stoll Sepracor, Lori Howarth Berlex, Patti Vassar Merck, Nancy Cherry GSK, Tamara Brown Sepracor, Steve Millanes Sepracor, Christy Lemons Sepracor, Kara Smir Cephalon, Doug Ethel GSK, Tom O'Connor Novartis, Michelle Harris Novartis, Jerome Catalino Novartis, Craig Nakamura MD, Daniel Yi Sepracor, B Wall Sepracor, John Ostezan Sepracor, Karen Theesen Glaxo Smith Kline, Mike Schilk King, Kirk Huffaker S-P, Danika Rambert Sade Pharma, Libby Mesker J&J Pharma, Judi Profant McNeil, Kele Griffiths Ortho McNeil, Traci Soltan Valeant, Meria Loskin Takeda, Brian Hueston TPNA, Tom Nicosia TPNA, Sandy Siekawski Pfizer, Ed Lewis Pfizer, John Stockton Genentech, Eric Rouse Eli Lilly, Alex Lapasaran Digestive Health Assoc., Joann Phillips, Mike Jensen University of Utah/Allergan, Steve Schaerrer Astra Zeneca, Tracey Green, Chris Lepore J&J, Charles Price Psychiatry Physician, Debbie Winters Wyeth, Roland Baldwin Wyeth, Juan Thomas Wyeth, Barbara Wheeler Merck, Johanna Fricke MD UNSOM, Susan Fisher AZ.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1:04 p.m.

II. Review and Approval of April 27, 2006 Minutes

MOTION: Larry Pinson motioned to accept the minutes as written.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

III. Overview of Preferred Drug List Review Process by Chairperson

Dr. Phillips stated that the review process followed last year will be repeated this year. Items V through XVI on the agenda are classes that will be fully reviewed with recommended changes to the Preferred Drug List. Item XVII, Drug Classes without Proposed Changes, will be presented last. Only new information is to be presented.

He said that DHCFP will be making an opening comment under Public Comment.

IV. Public Comment

The Committee was informed that included in their meeting packets are letters of written public testimony for various drugs being reviewed today.

Coleen Lawrence stated that First Health on behalf of DHCFP generates an annual report for CMS, the Nevada Medicaid Drug Utilization Review Report. The report is a summarization of drug utilization review as well as cost savings and expenditures. In comparing FFY '05 versus FFY '04, there was an overall increase in total drug costs of 2.5%, which was a substantial decrease from 22% the prior year. The national increase is 10%. She stated the 2.5% reduction is an astronomical effort and commended the DUR Board and P&T Committee. She thanked the committee members for their time and commitment by serving on the committee.

Dr. Phillips stated that hopefully the trend line will continue for the Nevada Medicaid program to be flatter than the Kaiser Family Foundation projects it to be which is an annual increase in drug expenditures of 10.7% for state Medicaid programs over the next ten years. He thanked First Health for their efforts.

No public comment.

V. Antibiotics: Cephalosporins 2nd Generation

Public Comment

No comment.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that the drugs in this class were determined to be therapeutic equivalents in April 2004 and reaffirmed in 2005. There is no significant clinical information to be presented at this time and recommended the drugs in this class be considered therapeutic equivalents.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Larry Pinson motioned that the agents in this class be considered therapeutically equivalent.
SECOND: Carl Heard
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dr. Monaghan stated that it is the recommendation of DHCFP and First Health to add the generic Cefaclor agents (Cefaclor, Cefaclor ER and Cefaclor suspension) to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Heard asked what the advantage of adding these to the PDL is; does it add to the therapeutic spectrum? Dr. Monaghan replied that it provides more choices without necessarily being a better product. Though the committee cannot discuss price, it is in the State's best interest to have these products available should a prescriber choose to use them.

Dr. Pinson agreed that it is good to have more choices particularly since these products are available generically.

MOTION: Larry Pinson motioned to move the three forms of generic cefaclor to the Preferred Drug List as recommended by First Health.

SECOND: Judy Britt

AYES: Unanimous

MOTION CARRIED

VI. Antibiotics: Macrolides

Public Comment

No comment.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that the drugs in this class have been determined to be therapeutically equivalent. There is one new generic product in this class, Clarithromycin XL, which is equivalent to Biaxin® XL. There is no significant or new clinical information to present and he recommended that the drugs in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Diana Bond motioned that the drugs in this class be considered therapeutic equivalents.

SECOND: Larry Pinson

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dr. Monaghan stated that it is the recommendation of DHCFP and First Health to:

- move Biaxin®, Biaxin XL®, Clarithromycin XL and Zithromax® tablets to non-preferred status.
- maintain Azithromycin suspension on the preferred list. The brand name product is currently on the PDL and it is anticipated that the generic will be available soon. When it does become available, it is recommended the generic suspension be placed on the PDL.

Dr. Heard asked what the clinical rationale is. Dr. Monaghan replied that per the bylaws, once drugs are considered therapeutic equivalents, cost can be considered. When making recommendations and assuming we're leaving an adequate therapeutic armamentarium on the list, it is in the State's best interest to move some of these items to non-preferred. There is no strong clinical rationale for the move. Dr. Heard stated that he personally feels these medications are over-utilized and most often not necessary and is in favor of moving them to non-preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Judy Britt motioned to move the Zithromax® agents to non-preferred with the exception of the suspension. When the suspension is generically available, Azithromycin generic suspension will be preferred. Move Biaxin, Biaxin XL and Clarithromycin XL to non-preferred.

SECOND: Diana Bond

AYES: Unanimous

MOTION CARRIED

VII. Antiemetics: Oral, 5-HT3s

Public Comment

Edward McKenna, Roche, spoke in support of Granisetron. He presented a handout to the Committee of key points regarding safety, metabolism and efficacy of Granisetron.

Dr. Heard asked what the overall incidence of torsades is in the other drugs. Mr. McKenna replied that there is no reported incidence in this class. He referenced his handout stating that as Roden points out in his article (Roden DM: Drug-induced prolongation of the QTc interval, New Engl J Med 2004; 350: 1013-21), there are two camps of thought. If you cause QTc prolongation, the risk for torsades is there and because of the multi-factorial etiology as well as the patient population these drugs are used in particularly the cancer population, it makes it very hard to detect sudden death. Most of patients being treated with chemotherapy are terminally ill or have a terminal diagnosis. The index of suspicion is not very high if someone has chemotherapy with metastatic disease and dies a sudden death or dies in their sleep. Also, in this area, terfenadine is the archetypical example. In this study, terfenadine produce a six millisecond increase in QTc prolongation. Cardiac arrhythmias have been reported as noted in the First Health report. Cardiac dysrhythmias are rare but have been noticed with both ondansetron and dolasetron. The Canadian Health Organization has recently placed additional restrictions on dolasetron in terms of where it can be used and the populations it can be used in, primarily around the question of QTc prolongation.

Nancy Cherry, Glaxo SmithKline, spoke in support of Zofran®.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that in past actions by this committee, this class has been considered therapeutic alternatives. Zofran® (ondansetron) was included on the PDL for children under the age of 18. The American Society of Clinical Oncology has developed evidence-based recommendations for the drugs in this class and their conclusion is that they are equivalent in safety and efficacy and can be used interchangeably. There are some differences in indications particularly with use in children. It is the recommendation of DHCFP and First Health that the drugs in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Phillips asked if Dr. Heard had any concerns with the QTc. Dr. Heard said that it seems that granisetron and ondansetron both have no QTc effect so there are two options there. The only thing that seemed to distinguish them was monitoring liver disease in ondansetron and he felt that was something that anyone in this circumstance would be having. He expressed no concerns with the recommendation.

MOTION: Larry Pinson motioned that the drugs in this class be considered therapeutic alternatives.

SECOND: Linda Flynn

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dr. Monaghan said that it is the recommendation of DHCFP and First Health to retain Kytril® on the PDL and expand the drug list to include all Zofran® products including the oral dissolving tablet, the solution and the regular tablet.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Britt asked if there would continue to be a prior authorization (PA) requirement for Zofran® for individuals over the age of 18 and Dr. Monaghan replied, no, that the age restriction would be lifted.

MOTION: Larry Pinson motioned to move all Zofran® products to the Preferred Drug List and to delete the PA requirement for age and maintain Kytril® on the preferred list.

SECOND: Diana Bond

AYES: Unanimous

MOTION CARRIED

VIII. Antifungals: Onychomycosis Agents

Public Comment

No Comment.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that there are no proposed changes to this category, at this time, and it is the recommendation of DHCFP and First Health to add this class under agenda item XVII, Drug Classes without Proposed Changes. She reminded the committee that there currently is a PA requirement for the agents in this class.

Dr. Pinson asked if a motion is required to move this agenda item and Mr. Faircloth stated a motion is not needed. It can be done at the discretion of the chairman.

Dr. Phillips stated that he accepts the recommendation to move agenda item VIII to agenda item XVII, Drug Classes without Proposed Changes. He called for public comment; no comment was offered.

IX. Anti-Migraine Agents: Triptans

Public Comment

Patti Vassar, Merck, spoke in support of Maxalt®.

Karen Theesen, Glaxo SmithKline, spoke in support of Imitrex®.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that the triptans were reviewed in April 2005. The motion was to accept these agents as therapeutic alternatives with consideration given to dosage forms. Patients were grandfathered on a non-preferred agent if there was a paid claim in the last 90 days. There is no new information since the last review. It is the recommendation of DHCFP and First Health that these agents be considered therapeutic alternatives with consideration given to dosage forms.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Diana Bond motioned to accept the agents in this class as therapeutic alternatives with consideration given to dosage forms.

SECOND: Larry Pinson

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Ms. Daly stated that it is the recommendation of DHCFP and First Health to have all dosage forms of Imitrex® and all dosage forms of Maxalt® available on the preferred list and to move all dosage forms of Zomig® to non-preferred. Any recipient who has a paid claim for Zomig® in the last 90 days will be grandfathered.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Heard asked how long the grandfathering would be and Ms. Daly replied one year.

Dr. Britt asked if the paid claim for Zomig® is an electronic search and Ms. Daly replied that it is an electronic search and that the system looks back 90 days for a paid claim. Dr. Phillips asked Dr. Britt if she is comfortable with the look back and electronic search and she stated yes that it is preferred because it saves the provider from calling in and Dr. Pinson agreed.

MOTION: Diana Bond motioned to accept First Health's recommendation to include all dosage forms of Imitrex® and include all dosage forms of Maxalt® to the Preferred Drug List and to move all dosage forms of Zomig® to non-preferred.

SECOND: Judy Britt

AYES: Unanimous

MOTION CARRIED

X. Central Nervous System: Sedative Hypnotics

Public Comment

Gary Dawson, Takeda, spoke in support of Rozerem®. He presented a fact sheet and letters of public testimony to the committee.

Dr. Heard asked if there is any effect on sleep architecture and Mr. Dawson replied that there is no effect.

Dr. Pinson asked if it is safe in pregnancy and Mr. Dawson replied it is categorized as pregnancy category C by the FDA. It has not been specifically studied in pregnancy.

Dr. Monaghan stated that based on the literature, this drug has been associated with an effect on the reproductive hormones reducing testosterone in males and also has an effect on prolactin levels and asked for Mr. Dawson's comment. Mr. Dawson stated that there is an extensive study that was just published and presented that addressed that specific issue. It was noted that in the first 90 days of the study, the levels of prolactin increase did not go outside of the normal ranges established by the central laboratory that did the testing and within 3-6 months, the levels normalized back to baseline. There were no symptoms associated with the isolated increase which did not go outside of the normal laboratory ranges for prolactin. Testosterone in elderly males at doses that are higher than the recommended dose, there was a slight decrease in testosterone that did not go outside of the established blood level ranges for males of those ages and returned to

baseline by 6 months. The FDA has not recommended or required any monitoring and that language is included in the package insert.

Dr. Heard referred to the drug interaction profile stating that it seems this is the only class of drugs that consistently interacts with the antifungals and asked if there is a liver effect. Mr. Dawson replied that Rozerem® is metabolized by the cytochrome P450-12A (CYP1A2) isoenzyme. Drugs that interact with that can cause the levels of Rozerem® to go up. The only contraindication is with fluoxamine (Luvox) which should not be given with Rozerem®. There are other interactions that are not clinically significant or associated with any adverse effects.

Dr. Heard said that it's categorized as a sedative hypnotic but does not have the same chemical action of a sedative. He asked is it appropriately classified as a sedative without actually having all the other effects of the other sedatives. Mr. Dawson replied that it is not a sedative in the classic sense but it is the only category it fit into and that hopefully that will be changing in the future.

Dr. Phillips clarified that the others have GABA whether it's a benzodiazepine derivative or not. Rozerem® does not fit the classic description of a sedative; it is not a GABA receptor. Dr. Monaghan stated that Rozerem® does have a sedating effect.

Dr. Heard asked that when a drug tests the limits of the definition we are using, would we recommend a different class? Dr. Monaghan stated that is the committee's call if they felt it couldn't cleanly be considered a therapeutic alternative. He stated that the definition of therapeutic alternative is that there can be chemical differences but what we're really looking at is what it does therapeutically.

Dr. Monaghan stated as long as the therapeutics make sense, it is in the State's best interest to have as many drugs in a category as possible.

Nancy Fairchild, Sepracor, spoke in support of Lunesta®.

Dr. William Torch, Washoe Sleep Disorders Center, presented his letter as a handout and read the letter in support of two new agents, Lunesta® and Rozerem®. In addition to Ambien® and Sonata®, he has prescribed these two medications to innumerable patients of all ages with sleep disorders. He stated they are very effective in inducing sleep by different mechanisms and have excellent safety profiles and a low incidence of side effects without any significant potential for abuse, tolerance, dependence or withdrawal.

Dr. Pinter asked if Dr. Torch has equal confidence in both Lunesta® and Rozerem® in the pediatric population. Dr. Torch replied that none of these drugs has been approved for use in children but he does use them in sleep labs off label. He stated he has lots of experience with use of Sonata®, Ambien® and Lunesta®, and beginning to experience more background information on Rozerem®, which is relatively new, with children. He's using sleep hygiene and use of these medications to induce sleep for temporary use in children with ADD who he believes to a very large extent are losing sleep not due to biological disturbance, but due to sleep deprivation, inadequate sleep and in many cases, sleep apnea that has not been diagnosed. The recommendation now is with children with ADD, if sleep disorder is suspected, a sleep study overnight should be done and he uses these sedatives to induce sleep in children. He's using Rozerem® more in adults but will be more in children particularly because Rozerem® does not have daytime cognitive-performance effects.

Dr. Heard asked if Dr. Torch has any affiliation with drug companies. Dr. Torch replied, no, but he has done studies with Cephalon as part of a multi-national study on the use of Modafinil. Dr. Heard stated that the biggest challenge is the concept of withdrawal and tolerance. He asked for Dr. Torch's thoughts on senior and/or adult use of sleep hypnotics and the relative benefit to this particular non-benzodiazepine class. Dr. Torch replied that with all of the medications, he tries to

use the very lowest dose especially with the elderly population. Everything needs to be adjusted to age. Because the metabolism can be affected, he looks at what other medications the patient is on as well as any hepatic issues.

Charles Price, MD, clinical associate professor of psychiatry for the University of Nevada and has an adult private practice in Washoe County, stated that he is on the speaker's bureau for all CNS medications including Ambien® CR, Lunesta® and Rozerem® and he referred to a letter he submitted to First Health in support of Rozerem®. Regarding child issues with Rozerem®, he said if you have a child with sleep problems and you have a non-scheduled agent, the parents are more likely to allow the child to take it. He has found that sometimes Ambien® will work for a patient, sometimes Lunesta® works, sometimes Rozerem®. As a clinician, he would like to have all of these agents available for this problem.

For clarification, Dr. Phillips stated that the point of the PDL is there are preferred drugs and if they fail, there is a process to go to a non-preferred agent. We need to get away from molecular pharmacology and look at it as a class causing hypnosis and sedation.

Dr. Heard added that all medications are theoretically available and administratively there are extra steps to go through in order to get the medications for a patient. His position has always been to minimize the administrative intrusion on the patient-provider relationship; on the other hand, we have to have a certain sanity that is brought to such a broad category of drugs.

Maria Kootsikis, Sanofi-Aventis, spoke in support of Ambien® CR.

Dr. Britt asked regarding recent new reports of psychomotor impairment involved with Ambien®. If it's causing psychomotor impairment with the 10mg regular release, what could be the potential with the 12.5mg controlled release? Ms. Kootsikis replied that she looked at the cases referenced by the newspaper and in each case that was reported, super-therapeutic levels of antidepressants were being used sometimes seven times the level of where it should be. There are a number of factors involved including multiple drugs, high doses and alcohol making it difficult to pinpoint. She stated that her company is looking at this.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this class was originally considered therapeutically equivalent with Sonta® and Ambien® available for female recipients due to the pregnancy category rating of X for benzodiazepines. Last year, zolpidem (Ambien®) was added to the PDL without restriction. At this time, there are two new agents to be reviewed, Ambien® CR and Rozerem® (remelteon).

Ambien® CR is an extended release version of Ambien®. It is a modified dosage form that releases drug in a biphasic manner and is available as a 6.25mg and 12.5mg tablet versus 5mg and 10mg for Ambien®. It offers an alternative to the immediate release version for patients who require a longer acting agent for sleep maintenance. Even with the subtle difference in the labeling of Ambien® CR like Lunesta®, both remain controlled substances, are CNS depressants and require close monitoring by the prescriber. This labeling nuance should not imply that these agents are free from side effects when taken for prolonged periods of time. All of these agents' product literature states that all other reasons for insomnia should be ruled out.

The other new agent is Rozerem® which works on the MT1 and MT2 melatonin receptors versus the GABA receptors. It's indicated for the treatment of insomnia characterized by difficulty of sleep onset. This drug seems to be effective in putting people to sleep; i.e., decreasing sleep latency but there is a question regarding its effectiveness in keeping patients asleep. It is not a controlled substance and has not been associated with tolerance, dependence or rebound. There are no trials comparing this drug to the newer sedative hypnotics or the benzodiazepines. As pointed out by the Drug Effectiveness Review Project, evidence about long term safety is limited and there is no comparative long-term efficacy or safety data.

Dr. Monaghan stated that the ideal hypnotic should induce sleep within 30 minutes, maintain sleep for 6-8 hours, no residual effects in the morning, no tolerance, no abuse, no dependence; no chance for overdose. While some of the newer agents approach this ideal, there is no perfect agent to offer today.

With the understanding that a selection of agents should exist on the PDL, it is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Heard stated that at last year's meeting, there was a referral to the DUR Board that non-benzodiazepines be considered for inclusion. Ambien® was included as a non-benzo hypnotic. He felt the commitment to a non-benzo alternative was not codified but a recommendation by the DUR Board.

MOTION: Dr. Heard motioned that the agents in this class be considered therapeutic alternatives with the request that a non-benzodiazepine agent be included.

Dr. Phillips suggested another option would be to accept them as therapeutic alternatives. If a non-benzo is not included in the recommendation for PDL addition from First Health and the State, we can move to not accept.

Dr. Heard withdrew his motion.

MOTION: Dr. Heard motioned to accept the agents in this class as therapeutic alternatives.

SECOND: Diana Bond

Prior to the vote, Dr. Britt commented that she would like for there to be sensitivity to the differences in tolerance and physical dependence among the different agents. The benzodiazepines, and to some extent Ambien®, tend to have more potential for drug dependence, abuse and physical dependence whereas the newer agents do not.

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that Ambien® CR be added to the PDL and Rozerem® be considered non-preferred.

Coleen Lawrence clarified that these two drugs came out during the year following the last review cycle. When a drug comes out during the year, it is automatically considered non-preferred until it is reviewed. Dr. Monaghan added that non-preferred drugs are not on a published list; the only published list is the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Horne asked that since Rozerem® has no addiction potential and is the only one that is not a Class IV, what would be the indication to get prior authorization. If a patient has an addiction history and the physician is concerned about giving a Class IV drug, do they have to fail a Class IV drug or the fact that the patient has an addiction history will be sufficient to obtain a prior authorization? Dr. Monaghan stated for patients with a history of drug abuse, you could make a case and the Clinical Call Center would agree that the PDL exception criteria of "history of unacceptable side effects" would apply.

Dr. Heard stated based on the literature, there is no difference between withdrawal and tolerance which are the two major indicators of addictive potential between Rozerem®, Ambien® or Sonata®. Those are therapeutic alternatives given their relative effect on addiction.

Dr. Horne stated the reason the FDA gave Ambien®, Ambien® CR and Sonata® a Class IV, is the patients that were studied either had withdrawal syndrome when they stopped taking it suddenly or when offered, patients wanted it because they felt “high” on it. These are the criteria the FDA uses.

Dr. Pinson also felt that the criterion for PA is met in PDL exception criteria 3. “History of unacceptable/toxic side effects to all preferred medications within the same class.”

Dr. Britt expressed concerns about the recent information regarding psychomotor impairment the next day and felt there is not sufficient information about Ambien® CR on the impact of this problem. She stated that if it placed on the PDL without restriction, it would be used first versus the regular release and suggested referral to the DUR Board.

Dr. Pinta stated that she would like to add Rozerem® as an alternative for the adolescent population. She felt it may be a safer alternative because of the side effect profile and schedule issue. Dr. Monaghan asked if Dr. Pinta agreed that there is no indication for use in children and she replied yes and stated but that there is usefulness for these medications in the adolescent population.

Dr. Phillips stated that the committee cannot specify Rozerem® for children and based on the recommendations, there is not enough reason to make it available for adults.

Dr. Monaghan stated that the Call Center receives many requests for off-label use of drugs which are referred to him. There is a review process in place for these types of cases.

Coleen Lawrence stated that according to policy, the PDL is for covered outpatient drugs. Covered outpatient drugs are drugs with an approved FDA indication. Experimental or non-peer reviewed indications are not covered. There are other avenues. The EPSDT program is available for children under the age of 21 to look at what is medically necessary based on best practice standards. Another example is Viagra® for pulmonary hypertension. Before the peer-review material was released with actual indications, we granted administrative exception.

MOTION: Judy Britt motioned for no changes to the PDL for this drug class.

SECOND: Larry Pinson

Darrell Faircloth asked if this motion meant that the new agent Rozerem® will be a non-preferred drug and Dr. Britt replied yes and Ambien® CR will be non-preferred.

AYES: Heard, Phillips, Pinson, Flynn, Britt

NAYES: Horne, Pinta, Bond

Dr. Phillips stated that although there is a majority vote of the eight sitting members, a majority of ten (including the two vacant positions) is required.

MOTION NOT CARRIED

MOTION: Dr. Horne motioned to add Ambien® CR to the preferred list and Rozerem® will be non-preferred.

SECOND: Diana Bond

Dr. Heard expressed concerned with Ambien® CR whether it’s going to have some delayed effect because there is some hangover effect with Ambien®. Will we be adding to the problem by making it more readily available. He asked what the rationale of adding it to the PDL is.

Dr. Horne replied that it’s no longer in terms of its half-life or effectiveness as a lot of the other medications that are on the list. His understanding from a cost point of view, First Health said the Ambien® CR is no more expensive than the Ambien®. The differences of the two medications in terms of half-life are not very long at all.

Dr. Phillips asked Dr. Horne if there is a potential problem with Ambien®, did he think it would be any greater with CR when you add other agents (alcohol, antidepressants).

Dr. Horne replied correct. Many patients complain that Ambien® is like Sonata® in that it doesn’t last long and does not give them even six hours of sleep.

Dr. Phillips said that the other consideration is if the literature comes out and supports that Ambien® does have these issues for us to be concerned about, there are mechanisms for First Health and the State to take action with the drug.

Diana Bond said that the intent of the PDL is to provide as broad a range as we can responsibly do to treat the patients and the educated group here who is attempting to treat these patients is asking for some expansion. Out of respect for their knowledge base in treating these groups of patients and since there really isn't hard evidence that this effect of the long acting or even Ambien® is the culprit and what the problem is. If you mix any of these drugs with alcohol or antidepressants, we'll see other issues. She felt a benzodiazepine is the only option for longer sleep induction.

AYES: Horne, Bond, Heard, Phillips, Flynn

NAYES: Pintar, Pinson, Britt

MOTION NOT CARRIED

No other motion was offered. Dr. Phillips tabled this item until the October meeting.

XI. Hepatitis C Agents

Public Comment

Alex Lapasatran, nurse practitioner, Digestive Health Associates, stated that he does not represent any drug companies and is not representing Digestive Health. He stated the most effective treatment for Hepatitis C is combination therapy with Pegasys® and PEG-Intron®. The Nevada Medicaid PDL only has Pegasys®. In clinical practice, he has used both agents, both with good effectiveness. There are specific conditions where he would choose PEG-Intron® over Pegasys® because Pegasys® has more bone marrow suppression over PEG-Intron®. He requested the committee consider adding PEG-Intron® to the PDL providing equal access in treating Hepatitis C.

Catherine Sterk, Roche, spoke in support of Pegasys®.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that pegylated interferons were considered therapeutic alternatives when last reviewed by the committee. The NIH consensus development conferences Management of Hepatitis C 2002 and the American Association for the Study of Liver Diseases 2004 practice guideline on the Diagnosis, Management and Treatment of Hepatitis C have not stated one pegylated interferon to be more efficacious than the other. It is the recommendation of DHCFF and First Health that the agents in this class are therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and to Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Phillips asked regarding indications for Hepatitis B. Ms. Daly stated pegylated interferon is not first line for Hepatitis B.

MOTION: Larry Pinson motioned that the agents in this class are therapeutic alternatives.

SECOND: Carl Heard

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Ms. Daly stated that it is the recommendation of DHCFF and First Health to add PEG-Intron® to the PDL. In addition, add the ribavirins which are now available generically to the preferred list and all others be non-preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Phillips asked if the ribavirin recommendation is outside of the agenda. Dr. Monaghan replied that the drugs under the Hepatitis C category include Copegus® (ribavirin). The issue now is that we are specifying Copegus® and what we want the PDL to reflect is ribavirin. He suggested that at the October meeting, an item be agendized that states when a drug becomes available generically, we can convert the brand names to the generic names since we're in a generic-mandatory state.

Dr. Phillips stated the only information presented in this category was for the pegylated agents and he would prefer to address Copegus® at the October meeting.

MOTION: Larry Pinson motioned to add PEG-Intron® to the Preferred Drug List and agendize the ribavirins for the October meeting.

SECOND: Carl Heard

AYES: Unanimous

MOTION CARRIED

XII. Herpetic Antiviral Agents

Public Comment

Allen Christie, Glaxo Smith Kline, spoke in support of Valtrex®.

Tracy Green, MD, Medical Director, Nevada State Health Division, Family Planning Services for the rural areas of Nevada, and practicing family physician, stated her opinion is based solely on her practice. She stated that in her public and private practice she has noticed an increase in herpes both in new outbreaks as well as recurrences. In regard to transmission, she felt the first problem is asymptomatic viral shedding and the second is compliance. Some of the data suggests that with one-time dosing, there is 90% compliance and with four a day dosing, 30% compliance. She felt Valtrex® represents the best agent to improve herpes, reduce the cost, and reduce incidence in our state for not only transmission but also appropriate dosing that people will be compliant with.

Michelle Harris, Novartis, spoke in support of Famvir®.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that it is the recommendation of DHCFP and First Health to consider the agents in this class as therapeutic alternatives with the availability of either famciclovir or valacyclovir.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Carl Heard motioned to accept the agents in this class as therapeutic alternatives with the mandatory inclusion of famciclovir or valacyclovir.

SECOND: Diana Bond

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Ms. Daly stated that it is the recommendation of DHCFP and First Health to add valacyclovir (Valtrex®) to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Phillips asked if the PDL would include acyclovir, Famvir® and Valtrex® and Ms. Daly stated that is correct.

MOTION: Carl Heard motioned to accept acyclovir, Famvir® and Valtrex® on the PDL.
SECOND: Judy Britt
AYES: Unanimous
MOTION CARRIED

XIII. Ophthalmic Antihistamines

Public Comment

Michael Jensen, clinical pharmacist, University of Utah, spoke on behalf of Allergan Pharmaceuticals in support of Elestat® for continued inclusion to the PDL.

Jerome Catalino, Novartis, spoke in support of Zaditor®.

Eric Byrnes, Alcon Labs, spoke in support of Patanol®.

Drug Class Review Presentation – First Health Services

Ms. Daly stated that this class was reviewed in January 2006, and the agents in this class were determined to be therapeutic alternatives at that time. It is the recommendation of DHCFP and First Health that the agents in this class continue to be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Larry Pinson motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Linda Flynn
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Ms. Daly stated that it is the recommendation of DHCFP and First Health to add Patanol® to the Preferred Drug List and move Elestat® to non-preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Diana Bond motioned to accept First Health's recommendation to add Patanol® to the Preferred Drug List and move Elestat® to non-preferred.
SECOND: Larry Pinson
AYES: Unanimous
MOTION CARRIED

3:40 p.m. - Dr. Phillips announced a five minute break.

XIV. Respiratory: Beta-Adrenergic Agents, Short-Acting Inhaled

Public Comment

Doug Ethel, Glaxo Smith Kline, spoke in support of Ventolin® HFA.

Craig Nakamura, MD, pediatric pulmonologist, stated that he is here on his own accord and does not represent any drug companies. He said that 30% of his patients are Medicaid patients and his concern is restricting access to medications. He presented pictures of some of his patients who did

not respond well to albuterol but did show improvement with Xopenex®, which he was able to obtain with a prior authorization. His concerns are the shortage of the CFC products and the ability to obtain a prior authorization on a Friday.

Dr. Phillips clarified that several months ago, the point was raised regarding the shortage and referred to the complaints that were brought to the State by representatives of Xopenex®. Once identified, it was immediately corrected. As chairman of the P&T Committee, working with First Health and the State, if there were any kind of shortage of an agent in either the CFC's or HFA's, Xopenex® would be made available. There is a mechanism in place for these types of situations and exists for any drug class.

Coleen Lawrence added a policy clarification stating that Nevada law requires prior authorization requests must be responded to within twenty-four hours. If an emergency situation exists, the pharmacist does have the authority to provide a 72-hour supply.

Dr. Heard thanked the physicians who attended this meeting and took the time from their practice to help with this process. He said that it's nice to know that there are professionals who are advocating for their patients at this level and looks forward to hearing from those professionals.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that there are two issues for the committee to consider today; a new product, levalbuterol inhaler, Xopenex® HFA, as well as the current availability of albuterol CFC multi-dose inhalers (MDI's). The CFC refers to the propellant vehicle, chlorofluorocarbon.

Dr. Monaghan stated that the FDA has communicated a final ruling regarding ozone depleting substances (ODS). All CFC-containing albuterol products are to be discontinued by December 31, 2008. The vehicle being substituted for CFC is HFA (hydrofluoroalkane). The current PDL lists only CFC albuterol products. He said that there have been some spot-shortages and that he has done intermittent surveys that have included the rural pharmacies as well as urban pharmacies, and there does not appear to be an acute problem today. As Dr. Phillips stated earlier, should there have been a problem, First Health and the State were poised to act. He suggested to the committee consideration be given to whether the issue of product shortages be added to the PDL exception criteria list as a PDL exception in general or handled on a product-by-product basis.

Dr. Monaghan addressed the new product, Xopenex® HFA. It's indicated for the prevention or treatment of bronchospasm in patients with reversible airway disease. It is approved for adults, adolescents and children four years and older. The inhalation solution has been reviewed by the committee and is currently non-preferred. The pharmacology, contraindications, major adverse effects and warning are similar for all agents in this class including Xopenex® HFA. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternates.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

Larry Pinson addressed the shortage issue stating that the Board of Pharmacy has investigated and prosecuted secondary source wholesalers. Very often the source of these inhalers is through the secondary source or the "gray market" which is where most of the counterfeit is moved.

MOTION: Diana Bond motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Dr. Horne

AYES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dr. Monaghan said based on the impending conversion and the potential for shortage in this marketplace and the potential negative impact on the recipients, it is the recommendation of DHCFP and First Health to expand the Preferred Drug List to include HFA products and one additional CFC product. The products recommended for addition to the PDL are Ventolin® HFA, Proventil® HFA, Xopenex® HFA, and Maxair Autohaler®. Dr. Monaghan added the recommendations are based on market availability that is difficult to predict at this time.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Phillips asked if the recommendations are also based on reasonable bids received from these companies and Dr. Monaghan replied that it is in the State's best interest to include these products.

Dr. Pinson asked the reason why generic albuterol HFA was not included and Dr. Monaghan replied that it's in the State's best interest.

Dr. Pintar said that she is advocating for Xopenex® nebulizer solution to be added to the PDL. She has found in her experience as a general pediatrician that Xopenex®, especially in the very young pediatric population, is superior to albuterol and less is used for better efficacy.

Dr. Phillips stated for clarification, that the MDI is not appropriate in some cases in children and the importance of having nebulized available for that group as well as the elderly in nebulization and Dr. Pintar agreed.

MOTION: Susan Pintar motioned to move Xopenex® HFA, Xopenex® solution, Ventolin® HFA, Proventil® HFA, and Maxair Autohaler® to the Preferred Drug List.

SECOND: Linda Flynn

Dr. Pinson asked if Dr. Pintar would consider prior authorization for the pediatric population for Xopenex® solution and she stated no. Dr. Monaghan asked what age break Dr. Pintar would consider. She requested input from Dr. Craig Nakamura and the recommendation was up to twelve years old. Dr. Phillips clarified that the recommendation is that the solution would be available up to the age of twelve years old without a prior authorization.

At committee request, Dr. Phillips clarified the motion:

Xopenex® solution (available without prior authorization for children twelve years old and under) Xopenex® HFA, Ventolin® HFA, Proventil® HFA, and Maxair Autohaler® be moved to the Preferred Drug List.

AYES: Unanimous

MOTION CARRIED

XV. Respiratory: Glucocorticoids, Inhalers

Public Comment

Doug Ethel, Glaxo Smith Kline, spoke in support of Advair®.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that at the August 2005, meeting, the committee determined that the agents in this class are therapeutic alternatives in the adult population with the exception of beclomethasone. The combination product, Advair®, was not included at that time. Advair® is a combination of long acting beta agonist salmeterol and the corticosteroid fluticasone. Though Advair® is technically not a therapeutic alternative, the two separate entities of this product are considered therapeutic alternatives within the agents in this class. She stated that DHCFP and First Health agree with the August, 2005, motion that the agents presented at that time are therapeutic alternatives and asked the committee if it would be their preference to include Advair® in this class or add a new class, beta-agonist/corticosteroid combinations.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Phillips stated that in reviewing past minutes, this was an issue with ace inhibitors and aces and diuretics. He stated that there was some “lumping” at that time and consideration could be given to doing the same with this class.

Dr. Heard said that in pediatric literature last year, there was information regarding greater therapeutic advantage in combined treatments in respiratory management.

Dr. Pinter stated that as a committee, we haven’t defined whether classifications are made based on use or chemistry. Dr. Phillips felt that use is a more appropriate way of looking at it.

Dr. Heard said that the definition of therapeutic alternatives is drug products with different chemical structures but which are of the same pharmacological or therapeutic class with similar effects and adverse reactions. It’s a good question as to whether we should consider an additional class.

Dr. Phillips said that one option is to address this class and defer Advair® to the next meeting.

Dr. Monaghan asked for clarification. If postponed, is the direction to create a separate class for the drug Advair® as opposed to including it in this class and calling it inhaled corticosteroids and combinations.

Dr. Heard stated that he would like to offer that they are therapeutic equivalents now with a recommendation that at the October meeting, there is discussion about additional classes with recommendations by First Health where there are similar considerations with other drugs.

MOTION: Carl Heard motioned that the agents in this class, including Advair®, are considered therapeutic alternatives with the recommendation at the October meeting, recommendations for additional classes are discussed.
SECOND: Larry Pinson
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Ms. Daly stated that it is the recommendation of DHCFP and First Health to add Advair® to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Britt expressed concern regarding adding Advair® without DUR Board evaluation due to the recent new warnings on the long-acting beta-agonists. Some of the literature is indicating that there is a subgroup of individuals that actually do much worse on a long-acting beta-agonist and therefore the new recommendation is not to use it first-line for mild or moderate asthma. Dr. Pinson added that there is a black box warning for sudden death syndrome.

MOTION: Judy Britt motioned that Advair® be added to the Preferred Drug List with DUR Board evaluation for possible restrictions.
SECOND: Linda Flynn
AYES: Unanimous
MOTION CARRIED

XVI. Respiratory: Glucocorticoids, Nasal

Drug Class Review Presentation – First Health Services

Dr. Monaghan stated that there are no proposed changes to this category, at this time, and it is the recommendation of DHCFP and First Health to add this class under agenda item XVII, Drug Classes without Proposed Changes.

Dr. Phillips stated that this item, including public comment, be moved to Item VXII.

XVII. Drug Classes without Proposed Changes

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy without Changes

1. Analgesics: Long Acting Narcotics
2. Antibiotics: Cephalosporins 3rd Generation
3. Antibiotics: Quinolones 2nd Generation
4. Antibiotics: Quinolones 3rd Generation
5. Antidepressants: Novel
6. Antidepressants: SSRIs
7. Antihistamines: 2nd Generation
8. Bone Ossification Agents: Biphosphonates
9. Cardiovascular: Ace Inhibitors & Diuretic Combinations
10. Cardiovascular: Angiotensins II Receptor Blockers & Diuretic Combination
11. Cardiovascular: Beta Blockers
12. Cardiovascular: Calcium Channel Blockers & ACEI Combinations
13. Cardiovascular: Lipotropics
14. Central Nervous System: ADHD/Stimulants/Non-Stimulants
15. Gastrointestinal Agents: H2RAs
16. Gastrointestinal Agents: PPIs
17. Immunomodulators – Injectable
18. Leukotriene Modifiers
19. Nasal Calcitonins
20. Ophthalmic Glaucoma Agents
21. Ophthalmic Quinolones
22. Respiratory: Anticholinergic Agents, Inhaled
23. Respiratory Agents: Beta-Adrenergic Agents, Long-Acting Inhaled
24. Antifungals: Onychomycosis Agents
25. Respiratory: Glucocorticoids, Nasal

Committee Discussion and Approval of Drug Classes without changes for the PDL

Dr. Horne stated that sertraline is now available generically and asked if consideration can be given today or the next meeting to consider it for inclusion to the PDL not just for OCD in children. Dr. Monaghan asked for clarification that Dr. Horne wanted to remove the age and OCD restrictions on Zoloft® and Dr. Horne replied correct since it's now available generically as of July 1st.

Dr. Pintar stated and Dr. Monaghan agreed that the age restriction did not change. Dr. Horne agreed and stated that he is suggesting that it be available as a preferred drug for adults.

Dr. Phillips clarified that it is currently available as a preferred drug for children between the ages of 6-17 with the ICD-9 code of 300.3 for OCD. Dr. Horne is requesting that we reevaluate this

based on the knowledge that it's now a generically available drug for the entire population as an antidepressant and not just for this subgroup.

MOTION: **Dr. Horne motioned that number 6. Antidepressants: SSRIs, be removed from item XVII. Drug Classes without Proposed Changes, and placed on the agenda for discussion at the October meeting.**

SECOND: **Diana Bond**

Dr. Heard asked if there is a reason why we cannot isolate any of these recommendations from First Health and make a recommendation to change the PDL at this time. Dr. Monaghan agreed stating that is the purpose of the meeting to get feedback from the committee and to get public input. Dr. Horne stated that if it's procedurally possible, he would like to make a motion today but if not, would like to act on it in October.

Darrell Faircloth, DAG, stated that it would be more appropriate to give notice to the public that the intention is to change the drug class in some fashion or add or change the selected preferred agents on the Preferred Drug List. Dr. Phillips stated that he favors Mr. Faircloth's recommendation that it be agendaized for October.

AYES: **Unanimous**

MOTION CARRIED

Dr. Phillips stated that Dr. Johanna Fricke, behavioral pediatric specialist, is attending the meeting as a clinician to request that item 14 of those without proposed changes, Central Nervous System: ADHD/Stimulants/Non-Stimulants, be agendaized for October as a drug class for discussion. (Dr. Fricke had stepped out of the meeting and Dr. Phillips wanted to ensure that her request was announced before the meeting closed.) Dr. Monaghan stated even without Dr. Fricke's request, a review of the class was scheduled to occur in October as a new drug has been added to that class.

Dr. Monaghan informed the committee that a new long acting narcotic product has recently been released and numbers 1, 6 and 14 under "Drug Classes without Proposed Changes", as well as any other classes the committee would direct for review at this point will be agendaized for the October meeting.

Dr. Phillips removed items 1, 6 and 14 to be agendaized at the October meeting and he entertained public comment for the remaining classes under "Drug Classes without Proposed Changes".

Mr. Faircloth suggested obtaining input from First Health as to whether they have researched any recent changes or literature on these drug classes. Dr. Monaghan clarified that the understanding based on the process, that between now and October, if any new drugs are released within these categories, it will be agendaized. Dr. Phillips and Mr. Faircloth agreed.

Dr. Britt requested that the long-acting beta-agonists (number 23 under item XVII) be reviewed at the October meeting.

Dr. Phillips stated that numbers 1, 6, 14 and 23 under item XVII will be agendaized for the October meeting.

Public Comment

No comment.

MOTION: **Diana Bond motioned to accept the recommendation from First Health that there are no changes to the drug classes listed under item XVII on the agenda, excluding numbers 1, 6, 14 and 23 from this motion.**

SECOND: **Susan Pintar**

VOTES: **Unanimous**

MOTION CARRIED

XVIII. Review of Next Meeting Location, Date, and Time

The next meeting is scheduled for October 26, 2006, in Las Vegas; location to be announced.

XIX. Public Comment

Libby Meske, Ortho McNeil Janssen, requested 3rd generation flourquinolones, specifically, Levaquin®, be reviewed in October. Dr. Phillips suggested she submit information to First Health.

Maria Kootsikis, Sanofi, thanked the committee for the re-review of the hypnotic class in October and mentioned that at that time, she would like to reintroduce a study that looked at 8 hours post-dose Ambien® CR testing.

Johanna Fricke, MD, specialist in developmental and behavioral pediatrics, asked that because something new comes out every few months in this field, if the psycho-stimulant medications can be an agenda item in October. Dr. Phillips stated that it is being agendaized for October.

XX. Adjournment

MOTION: Larry Pinson motioned for adjournment.

SECOND: Susan Pintar

AYES: Unanimous

MOTION CARRIED

Meeting adjourned at 4:43 p.m.