



JIM GIBBONS  
Governor

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

MICHAEL J. WILLDEN  
Director

CHARLES DUARTE  
Administrator

**Pharmacy & Therapeutics Committee**

Las Vegas Chamber of Commerce  
3720 Howard Hughes Parkway  
Las Vegas, NV

December 13, 2007  
1:00 p.m.

**Committee Members Present:**

Robert Horne, MD, Chairman  
David Chan, R.Ph.  
Linda Flynn, R.Ph.  
Justin Holt, Pharm.D.  
Michael Karagiozis, DO  
John Lee, MD  
Chad Luebke, Pharm.D.  
Rudy Manthei, DO  
Chris Shea, Pharm.D.

**Absent:**

R.D. Prabhu, MD

**Others Present:**

Coleen Lawrence-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Gabriel Lither, DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Bert Jones-GSK, Doug Ethel-GSK, Tae Hwang-GSK, John Stockton-Genentech, Chad Michna-ACL, Craig Boody-Lilly, Sandy Sierawski-Pfizer, Teev Heinaufon-Schering Plough, Kirk Huffaker-Schering Plough, Jim Goddard-Shire, Lee Boyle-Shire, Ann Childress, MD-Private Practice, Roland Baldwin-Wyeth, Kara Smith-Cephalon, Helen Kale-Takeda, Dan Bay-Abbott, Tava Golden-Bristol-Myers, Doug Powell-Forest, Chris Almeida-Purdue.

**I. Call to Order and Roll Call – Chairperson**

Dr. Robert Lynn Horne called the meeting to order at 1:04 p.m. He introduced himself as the newly appointed chairperson for the P&T Committee and thanked the Governor and those involved in his appointment.

Dr. Horne stated that most of the committee members are newly appointed and asked the members to introduce themselves:

- Linda Flynn, R.Ph., pharmacist, Las Vegas, reappointed member.
- David Chan, R.Ph., pharmacist, Reno, new member.
- Michael Karagiozis, DO, family practice and HIV specialist, Las Vegas, new member.
- John Lee, MD, cardiologist, Nevada Heart and Vascular Center, Las Vegas, new member.
- Darrell Faircloth, Deputy Attorney General, northern Nevada, advisor to the Committee.
- Robert Lynn Horne, MD, psychiatrist, professor at Nevada's School of Medicine, teaching psychopharmacology to the residents.
- Chris Shea, Pharm.D., clinical pharmacist specializing in geriatric care, Reno, reappointed member.
- Rudy Manthei, DO, ophthalmologist, Nevada Eye and Ear, served on the Board of Medical Examiners for twelve years, Las Vegas, new member.
- Justin Holt, Pharm.D., pharmacist, Las Vegas, new member.
- Chad Luebke, Pharm.D., CVS Pharmacy, Las Vegas, recently appointed to the Nevada State Board of Pharmacy, new member.

**II. Review and Approval of June 21, 2007, Meeting Minutes**

At Dr. Horne's request, Jeff Monaghan, FHSC, gave an update on the Drug Use Review (DUR) Board's discussion related to the stimulants from the October 18, 2007 meeting. The P&T Committee had requested that the DUR Board consider relaxing the current prior authorization (PA) criteria for ADHD. There was testimony and discussion, however, no action was taken. The DUR Board agreed to consider the use of ICD-9 codes versus prior authorization. The Board also asked the State to develop an audit procedure to validate that ICD-9 codes are being applied. The proposed audit plan is to be presented at the next DUR Board meeting.

**MOTION: Linda Flynn motioned to approve the minutes as presented.**

**SECOND: Chris Shea**

**AYES: Unanimous**

**MOTION CARRIED**

**III. Welcome and Introductions – Coleen Lawrence, DHCFP**

Coleen Lawrence, DHCFP, Chief of Program Services, stated for the record, that all committee members are present with the exception of Dr. Prabhu. There is a quorum present for this meeting.

On behalf of the Division of Health Care Financing and Policy, she thanked the members for participating and volunteering their time to serve on this committee.

Ms. Lawrence introduced Mary Griffith, RN, Program Services, DHCFP. Ms. Griffith is the contact at the State for the pharmacy program. Any questions regarding process or policy should be referred to Ms. Griffith.

Legislation passed in 2003, required the development of a list of preferred drugs to be used for the Medicaid Program. First Health Services (FHSC) was awarded the contract to assist the State in the development and maintenance of a Preferred Drug List (PDL). Clinical information distributed at the meetings is provided by First Health. She introduced the FHSC pharmacy staff:

- Jeff Monaghan, Pharm.D., Clinical Account Manager
- Dave Wuest, R.Ph., Clinical Pharmacist
- Shirley Hunting, Pharmacy Provider Relations Coordinator

**IV. Committee Background, Purpose, and Operational Overview – Coleen Lawrence, DHCFP**

Ms. Lawrence gave an overview of the P&T process. She stated that DHCFP has a rigorous process for implementing and maintaining the PDL. Several drug manufacturer representatives present at this meeting today have been involved with this process since the beginning. In some states, there is a contentious relationship between the state, manufacturers and the committees but that does not exist in this state. Everyone understands the boundaries; what the roles and responsibilities are.

In Washoe and Clark Counties is the Temporary Assistance for Needy Families (TANF) and Child Health Assurance Programs (CHAP). Participants in these counties are covered by a Medicaid managed care organization (MCO). Decisions made by this committee affect participants in the Nevada Medicaid fee-for-service population and not MCO participants. The fee-for-service population comprises the rural areas (including TANF and CHAP) and state-wide for the aged, blind and disabled. Fee-for-service are typically the high-cost, high-utilizers, the sicker recipients in this population that the P&T is helping DHCFP to manage.

DHCFP is here to assist the P&T Committee to ensure the policy is in order and transparent. All decisions affecting the PDL are conducted in an open meeting. New drugs in classes that have been reviewed are automatically considered non-preferred until the next review of that class.

The goal of DHCFP is to ensure quality care in the most cost-effective manner. The P&T Committee is prohibited by statute to consider cost when determining drugs for the PDL. This committee provides the clinical expertise and the experience of what is seen in day-to-day life of what works, what the exceptions are whether age, gender or disease-specific exceptions.

Drug manufacturers are respectful and know they are not to solicit committee members outside of the meetings on behalf of the committee. Meetings are conducted in an open forum with public comment. To ensure there is no conflict of interest, committee members cannot have any financial affiliation with any drug manufacturers.

By federal regulation, Nevada Medicaid does not reimburse for weight loss drugs, drugs for cosmetic purposes, infertility agents, Yohimbine, DESI (less than effective drugs), drugs considered experimental or agents for impotence/erectile dysfunction.

The PDL is not a closed formulary. Drugs selected to the PDL shift market share from non-PDL drugs to PDL drugs and there is a process in place to access non-PDL agents. Use of drugs in classes that have been reviewed and not included on the PDL will require a call by the prescriber to the FHSC Clinical Call Center for prior authorization (PA). PDL exception criteria (included in reference binder) must be met to grant approval of a non-PDL drug. There is a fair hearing process in place through DHCFP for recipients to appeal a denied PA. The Call Center is required by policy to respond to PA requests within twenty-four hours of receipt.

Other state Medicaid programs, including Nevada Medicaid, have pooled together to increase purchasing power by participating in the National Medicaid Pooling Initiative. Overall, there are approximately three million in this pool with less than 100,000 being Nevada Medicaid recipients. In order for pharmaceutical manufacturers to participate in Nevada Medicaid, they must participate in the pooling initiative. Different levels of drug rebates are offered to the State through this initiative. Rebate negotiations occur between the FHSC corporate office and the drug manufacturers. The State does not participate in the negotiation process.

Ms. Lawrence provided an overview of the drug class review process. FHSC determines the classes to be reviewed and posts to their website the drug class reviews to be discussed at each meeting forty-five days in advance of the meeting. Drug manufacturers have the opportunity to submit to FHSC product information for classes being reviewed prior to the meeting by the date specified. FHSC provides meeting materials to committee members in advance of the meeting. The State is required by statute to post notification of the meeting a minimum of three days in advance. FHSC on behalf of DHCFP provides 1) an overview of the drug class to include a recommendation of therapeutic alternative and 2) recommendation for addition and/or removal of drugs to the PDL. The committee acts upon these recommendations in two separate actions and can amend or accept the recommendations. The committee also has the option of applying restrictions when adding agents to the PDL; e.g., use of ICD-9 code(s), age restriction, etc. If the P&T Committee recommends that an agent may be added to the PDL with PA criteria, that recommendation is referred to the Drug Use Review Board (DUR). DUR is charged with establishing clinical criteria. Providers are notified of changes to the PDL and the effective date.

Ms. Lawrence stated that during the review process, the cost of medications is not discussed or considered by the committee. FHSC recommendations are in the best interest of the State and may include consideration of cost. Public comment is limited to five minutes per entity and any affiliation with drug manufacturers must be disclosed prior to speaking.

Dr. Manthei asked why cost cannot be discussed. Ms. Lawrence replied that during negotiations with the State Legislature and PHARMA, it was decided that decisions by the committee should be based on clinical evidence and not cost. The State can consider cost when considering recommendations.

**V. Discussion of Open Meeting Law – Darrell Faircloth, DAG**

Prior to discussion of the Open Meeting Law, Mr. Faircloth introduced Gabriel Lither, DAG, who may attend meetings in place of Mr. Faircloth should circumstances not allow Mr. Faircloth's attendance.

Mr. Faircloth stated that the purpose of the Open Meeting Law is to provide access to the public to the processes of government. It's accomplished by providing notice to the public and that notice is the agenda as provided today of what is intended for discussion, deliberation, and action (vote) and allows the public the opportunity to comment and make their views known through the public comment portions of the meeting as noted on the agenda. General public comment is also offered at the end of the meeting and comment should be related to matters of the committee's authority.

An open meeting is a gathering of the majority of the members of the committee. There may be circumstances that may not be considered a meeting due to administrative reasons for discussion. These situations would not include deliberation and decision-making related to the P&T's authority; e.g., availability for a P&T meeting, consultations on subjects outside of the committee's business. There are ten appointed members of this committee. Six members present, whether in person or telephonically, constitute a quorum. Situations may arise whereby a quorum of committee members is present in a social setting. Though not an open meeting, this circumstance should not be used as a subterfuge to create serial discussions to try and arrive at decisions pertaining to P&T business.

Agendas are subject to the three day open meeting law requirement; however, the staff attempts to publish the agenda far in advance of those deadlines in the interest of openness and cooperation with the industry. Referring to today's agenda, Mr. Faircloth noted that it provides statutory mandated requirements; time, location, etc., and a detailed listing of items to be discussed and actions which may be taken. Action (voting) may be taken on agenda items noted with an asterisk. In enforcing the Open Meeting Law, items requiring action (voting) must be so noted on the agenda or the action may be considered to be invalid. Action taken on an item that knowingly was not properly agendized or not agendized can result in misdemeanor penalties.

The open meeting law is found in Chapter 241 of the Nevada Revised Statutes. Another resource is the open meeting manual located on the Office of the Attorney General's website. Mr. Faircloth offered to provide the web address to interested parties following the meeting. He stated that if there are questions regarding the open meeting law or the authority of the committee, contact Mary Griffith or him.

Mr. Faircloth stated that his role is to provide advice to the committee during the meetings and when special situations arise; e.g., emergency meeting, closed sessions. Ms. Griffith or Mr. Faircloth should be contacted prior to meeting under special circumstances to ensure it is appropriate and legally sound.

#### **VI. Discussion of Confidentiality and Conflict of Interest – Darrell Faircloth, DAG**

Mr. Faircloth welcomed the new members and thanked the committee for their service to the State. He said that he assumed but was unsure if the new members had been apprised prior to the meeting of their position as public officers and how they are subject to the jurisdiction of the Ethics Commission and the statutes that govern ethics in government. Committee members should not have a financial relationship with pharmaceutical manufacturers. The rules that the Ethics Commission apply and enforce to public officers are found in NRS 281A. The rules apply to members of the P&T Committee. Should there be a question regarding a member's particular relationship with a pharmaceutical manufacturer or related entity that may create a conflict, an advisory opinion of the Ethics Commission will be requested.

Mr. Faircloth stated since the new members may not have received prior to this meeting the ethics rules and acknowledgement to sign a document indicating the ethics rules had been received and reviewed, the documents will be sent prior to the next meeting.

In addition to the ethics rules, there are other rules located in the statute that created this committee (NRS 422.403). It states that a person must not be appointed to the committee if he's employed by, compensated in any manner by, has a financial interest in or is otherwise affiliated with a business or corporation that manufactures prescription drugs.

Mr. Faircloth said if members have questions regarding the ethics rules to contact Ms. Griffith or him.

#### **VII. Anticoagulants, Injectable**

##### **Public Comment**

Tae Hwang, GlaxoSmithKline, spoke in support of Arixtra®. Arixtra® is a synthetic, non-heparin injectable anticoagulant although it is often included in the low molecular heparin class. He stated that in GSK orthopedic trials when Arixtra® was given as least six hours after surgery as indicated in the package insert, the major bleed risk was identical to enoxaparin. Timing of administration after surgery as recommended in the package insert is stressed to health care providers. Arixtra®

is available in four dosage forms and only available in pre-filled syringes. One dose (2.5mg in .5ml pre-filled syringe) will cover all prophylactic doses or prophylaxis for all surgical and medical patients. For the treatment of pulmonary embolism or deep vein thrombosis, it's available in 5mg, 7.5mg and 10mg pre-filled syringes. Other agents in this class are available in both pre-filled syringes and multi-dose vials. He felt that Arixtra® pre-filled syringes are a safer method of administration for patients versus drawing from a multi-dose vial. Because Arixtra® is a synthetic agent, patients with heparin or pork allergies or patients who cannot take an animal product due to religious reasons, are able to take Arixtra® in a safe manner.

Dr. Lee asked if the dosage of Arixtra® is independent of the patient's weight. Mr. Hwang replied that for prophylaxis, it's 2.5mg for every patient greater than 50kg. Arixtra® is contraindicated in patients that weight less than 50kg or have a creatinine clearance of less than 30. For treatment of DVT or PE, dosing is based on a sliding scale (weight less than 50kg = 5mg; 50 to 100kg = 7.5; greater than 100kg = 10mg).

### **Drug Class Review Presentation – First Health Services**

Jeff Monaghan welcomed and congratulated the new members on their appointment to this committee. He stated that it's been four years since the development of the PDL and there are now forty-five drug classes covered within the PDL.

Dr. Monaghan said that the anticoagulant injectable class being reviewed today is a new class that has not been reviewed for the PDL prior to this meeting. The next two drug classes are for review of new drugs within existing classes. Drug class reviews are provided by Provider Synergies which is a sister company of First Health both owned by Coventry Health Care Company. Provider Synergies and First Health are currently involved in PDLs in twenty states. He read the definition of therapeutic alternative as defined by the AMA. The definition is also located in the meeting materials and reference binders.

He stated that his review will focus on the therapeutic equivalency of the low molecular weight heparin products. Unfractionated heparin will not be considered in this PDL class. As indicated in the drug review, there are four products being considered: dalteparin (Fragmin®), enoxaparin (Lovenox®), fondaparinux (Arixtra®) and tinzaparin (Innohep®). Unfractionated heparin acts primarily by inactivating thrombin. The low molecular weight heparins primarily inhibit factor Xa rather than thrombin. Arixtra® is considered a direct thrombin inhibitor due to its higher selectivity for factor Xa. The low molecular weight heparins have very little effect on PTT therefore eliminating the need for laboratory monitoring, can also be given by the subcutaneous route eliminating the need for an infusion pump and have the advantage of less frequent dosing. The kinetics of the different agents is on page three of the drug review. All agents in this class carry a black box warning regarding bleeding specifically spinal and epidural hematomas with either epidural or spinal anesthesia. All are contraindicated in patients that are hypersensitive to any low molecular weight heparin, unfractionated heparin or pork products. In general, all products have various degrees of warning regarding the risk of bleeding complications. All of these agents should be used cautiously in patients with severe renal insufficiency. Arixtra® carries the unique contraindication in surgical patients weighing less than 50kg due to the occurrence of major bleeding observed in the trials in this patient group. Drug interactions are all similar for these products and adverse effects primarily involve bleeding risks. Safety and effectiveness in the pediatric population has not been established. All four agents are Pregnancy Category B and all are recommended by the American College of Chest Physicians for therapy and prophylaxis of DVT and PE in pregnant women. Dosage guidelines and forms are included on page seven of the drug review. In terms of clinical efficacy, on page eight of the drug review, Dr. Monaghan said not every study dealing with low molecular weight heparins is referenced. There are ninety-nine pieces of literature that are referenced. FHSC does filter studies to ensure they meet criteria and look for randomized controlled trials if available. Comparative trials are best; if not available, placebo controlled trials are considered. Studies included in the review under the clinical trial are felt to have merit. When used in equal potent dosages, all of the low molecular weight heparins can provide a therapeutic anticoagulant effect. In orthopedic surgery, Arixtra® appears to be more effective; however, there is a higher incidence of increased bleeding. Although each product has different FDA-approved indications, the evidenced-based guidelines from the American College of Chest Physicians at their seventh conference on Antithrombotic and Thrombolytic Therapy held in 2004, made no distinction between the agents for orthopedic surgery, prophylaxis or treatment of VTE. The document further states that although these agents

have subtle differences in pharmacokinetics and anti-Xa activity, the clinical characteristics of these agents are very similar. It is the recommendation of DHCFP and FHSC that the agents 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:** Linda Flynn motioned that the agents in this class be considered therapeutic alternatives.  
**SECOND:** Chris Shea  
**AYES:** Lubke, Holt, Manthei, Shea, Horne, Lee, Karagiozis, Chan, Flynn  
**NAYES:** None  
**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 is the recommendation of DHCFP and FHSC that this drug class be added to the PDL and the agents, Lovenox®, Fragmin® and Arixtra® be added to this class on the PDL.

**MOTION:** Chris Shea motioned to accept FHSC's recommendation to add this drug class to the PDL and to include in this class the agents Lovenox®, Fragmin® and Arixtra® to the PDL.  
**SECOND:** Michael Karagiozis  
**AYES:** Flynn, Chan, Karagiozis, Lee, Horne, Shea, Manthei, Holt, Lubke  
Dr. Manthei asked why a list is created first and then an alternative is added after there is a list.  
Dr. Horne stated that the law that created this committee specified that the committee is to determine what the alternatives within a drug class are and then consider FHSC's recommendation. FHSC cannot provide a PDL recommendation until therapeutic alternatives within the drug class have been determined by the committee.  
Dr. Manthei asked alternative to what?  
Dr. Horne replied agents that are alternative agents within the drug class and Dr. Monaghan added alternative agents within the drug class being considered for addition to the PDL, in this case, the low molecular weight drug class.  
Dr. Manthei stated this class is not on the PDL.  
Dr. Horne said that is a new class being considered to the PDL. There are certain classes that by law cannot be considered; e.g., antipsychotics, anticonvulsants, antidiabetic agents, HIV agents, transplant medications. All other agents within the remaining classes can be considered for the PDL.  
Dr. Manthei asked why create the preferred list first and then have alternatives to it.  
Dr. Monaghan asked if Dr. Manthei felt there should there be agreement or a motion that the committee wants to create a new drug class within the PDL first. It's not been done that way in the past, although the committee has the ability to suggest the addition of any drug class. The drug classes being addressed are classes that DHCFP and FHSC feel have a reasonable chance of being accepted by the committee and considered therapeutic alternatives. If there are enough drugs in the class and market share is moved to the preferred agents, it would be to the State's benefit. The reason all drug classes are not addressed is because some drug classes do not fit well into the therapeutic alternative discussion. In addition to what is brought before the committee by DHCFP and FHSC, the committee can request review of any drug category.  
**NAYES:** None  
**MOTION CARRIED**

**VIII. Intranasal Steroids-New Drug Review-Fluticasone furoate (Veramyst®)**

**Public Comment**

Doug Ethel, GlaxoSmithKline, spoke in support of Veramyst®. He stated that fluticasone fuorate (Veramyst®) is not another soft form of fluticasone propionate (Flonase®). The furoate molecule is a five sided furan ring with two double bonds. If the bonding on the side chain is increased, lipophilicity is increased. Lipophilicity increased in a steroid means it sits on the receptor longer.

Pediatricians complained that the spike on the Flonase® bottle was too long and fat for children's noses and can initiate a rhinitic response in patients that are hypersensitive to smell due to the preservative phenylethyl alcohol. Veramyst® has a spike which is much thinner and shorter and the preservative in Veramyst® has been changed to benzyl sodium chloride which has no smell. Flonase® and Nasonex® have a spray volume of 100 micro liters per spray. Veramyst® is 50 micro liters per spray with less run off problems. Veramyst® is indicated down to age two; Flonase® down to age four. Veramyst® is the only intranasal steroid that can provide relief of ocular symptoms in adult patients twelve years and above and for seasonal allergic rhinitis.

Dr. Horne asked what the ICD-9 code is for the ocular indication that the other agents in this class do not have. Mr. Ethel replied that there is not a different ICD-9 code for the ophthalmic indication. It all falls under rhinitis. He stated that he does not have the data to support that Veramyst® works as well as or better than an intranasal steroid and a non-sedating antihistamine. GSK is in the process of conducting a clinical trial.

Dr. Shea asked what's different about Veramyst® that it covers the ocular problem where the others don't. Mr. Ethel stated that GSK and other manufacturers have been unsuccessful in obtaining an ocular indication for intranasal steroids. GSK has been able through clinical trials to get a "claim" for relief of ocular symptoms. For an indication, a verified mechanism of action is required. It's thought that Veramyst® relieves ocular symptoms by modulation of a nasal ocular neurogenic reflex.

Dr. Monaghan asked what patient population experienced relief of ocular symptoms. It seemed specific to adults. Mr. Ethel stated relief was shown in adults and adults with seasonal rhinitis. A statistical difference in the relief of ocular symptoms in pediatric patients and in patients with perennial allergic rhinitis was not shown.

Teev Heinaufon, Schering Plough, spoke in support of Nasonex®. He stated that Nasonex® was introduced into the market in 1999 and is the most commonly prescribed nasal steroid. It's indicated down to the age of two in seasonal allergic rhinitis and perennial allergic rhinitis. It is indicated in patients twelve years of age and older for prophylaxis of seasonal allergic rhinitis and in the treatment of nasal polyps in patients eighteen and older. Bioavailability is less than 1% with no HPA axis suppression. The product did not show any gross depression in the pediatric population. In one preference trial versus Flonase®, Nasonex® was preferred two to one. Nasonex® does not have a smell or taste, the nozzle was preferred in the study and the product has the stamp of approval from the Arthritis Foundation. There are no significant reports of run off associated with Nasonex®. Nasonex® has a proven track record, efficacy and safety.

### **Drug Class Review Presentation – First Health Services**

Jeff Monaghan stated that traditionally in reviewing new products within an existing drug class, all of the detail for each drug within the class is not reviewed. The focus is generally on the new drug product within that drug class.

Dr. Monaghan introduced Dave Wuest who recently joined FHSC in the role of clinical pharmacist. Dave's experience includes experience in home infusion, retail and hospital settings and he is the former president of the Nevada State Board of Pharmacy. Mr. Wuest will be presenting this class.

Dave Wuest stated that the Intranasal Steroids class was last reviewed in June 2007, during the annual review process. At that time, the committee voted not to make any changes to the PDL within this class. Testimony was received during that meeting concerning the release of a new product, fluticasone fuorate (Veramyst®). Since there was not time to incorporate the product in the review for that meeting, the Committee decided to review it at the next scheduled meeting. Currently, flunisolide (Nasarel®) and mometasone (Nasonex®) are on the PDL. Veramyst® is now available for seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in patients age two years and older. Veramyst® is similar to Flonase® which is now available generically. The clinical studies have shown that the drugs in this class have comparable efficacy. Veramyst® was shown to be superior to placebo in the treatment of SAR and PAR. No studies have been published comparing Veramyst® to any of the other intranasal corticosteroids. Studies in adults with SAR taking Veramyst® demonstrated an improvement from baseline in the mean ocular symptoms of itching, burning, tearing and redness compared to placebo. There was no effect in

these symptoms in adults with PAR or children with SAR. According to *The Medical Letter*, other agents in this class may also relieve ocular symptoms. Adverse effects are similar within the class. Flonase® and Veramyst® are substrates of cytochrome P450 3A4 and have a potential for increased plasma fluticasone levels. It is recommended that patients taking Veramyst® be monitored for adverse events on the nasal mucosa. The differences between the drugs in this class are primarily found in the number of sprays needed per day and dosing frequency. Though Veramyst® claims to offer a significant advantage over existing products on the market, this claim is not supported in the literature. It is the recommendation of DHCFP and FHSC that the products in this class be considered therapeutic alternatives.

Mr. Wuest referred the Committee to page 2 and 3 of the drug review clarifying that the agents (Atrovent® and Astelin®) on page 3 are not steroids and not considered in this class.

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

Dr. Karagiozis asked if intranasal rhinitis agents are being considered or intranasal steroids. Mr. Wuest replied steroids.

**MOTION:** Michael Karagiozis motioned that the agents in this class be considered therapeutic alternatives.

**SECOND:** Linda Flynn

Dr. Horne clarified that on the PDL, this class is listed as respiratory nasal corticosteroids.

Dr. Manthei stated that the initial medication (Flonase®) is exceptional and clinically the new product (Veramyst®) he felt cannot out perform that medication as far as day in/day out usage.

Ms. Lawrence stated that in deeming therapeutic alternative, it is finding the “universe.” If the new drug is not deemed as a therapeutic alternative, it will continue to be available to recipients. It will not be affected by PDL decisions within this drug class. The next motion is to determine the addition of the new drug to the PDL or leave the existing two drugs.

**AYES:** Flynn, Chan, Karagiozis, Lee, Horne, Shea, Holt, Lubke

**NAYES:** Manthei

**MOTION CARRIED**

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

Mr. Wuest stated that it is the recommendation of DHCFP and FHSC that Veramyst® not be added to the PDL at this time and there be no changes to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion in the PDL**

Chad Luebke asked for clarification regarding the ocular indication with Veramyst®. Is there evidence with the other available products? Mr. Wuest referenced the November 5, 2007, *Medical Letter* which states that other agents *may* treat the same symptoms.

**MOTION:** Linda Flynn motioned to accept FHSC’s recommendation for no changes to this drug class and maintaining flunisolide and Nasonex® as the preferred nasal corticosteroids.

**SECOND:** Chad Lubke

**AYES:** Flynn, Chan, Horne, Shea, Manthei, Holt, Lubke

**NAYES:** Lee, Karagiozis

**MOTION CARRIED**

Dr. Horne requested clarification that in order to get Veramyst® approved with a prior authorization, the patient would have to fail or be allergic to both agents in this class or meet the other criteria and Dr. Monaghan stated that is correct.

## **IX. Stimulants and Related Agents-New Drug Review-Lisdexamfetamine Dimesylate (Vyvanse®)**

### **Public Comment**

Ann Childress, MD, child and adolescent psychiatrist, in private practice, disclosed that she is on the speaker's bureau and a consultant for Shire Pharmaceuticals which makes Vyvanse® and Norvartis. She receives research support to do clinical trials from Shire, Novartis, Abbott, Astra-Zeneca, Bristol Myers Squibb, Somerset Pharmaceuticals, Sanofi Aventis, Johnson and Johnson and Lily. She stated that she has clinical trial experience with Vyvanse® and has conducted six studies with children and adults (sixty-seven patients). Vyvanse® is a prodrug which means it's a drug that's not active outside of the body. A L-lysine molecule is attached to d-amphetamine so when swallowed, enzymes break it apart and d-amphetamine goes to work. It's not dependent on gastric pH or emptying making it more consistent. In a classroom study of children comparing Adderall® XR and Vyvanse® to placebo, there was a variability in peak time of three to twelve hours. With Vyvanse®, peak time was between four hours and thirty minutes and six hours. Her patients taking Adderall® XR or methylphenidate twice per day are now taking one dose of Vyvanse® per day and doing well due to the peak time. In one study, parents rated their children's behavior after taking Vyvanse® between 7:30 a.m. and 8:00 a.m. and through 6:00 p.m. Some parents noted that the children's behavior and attention were 50% improved. Because it's a prodrug, there is a low abuse potential with Vyvanse®.

Dr. Horne asked what the PK was after C<sub>max</sub>. From the peak at twelve hours, some patients may do better on Adderall® XR in terms of having it last longer for them and be more likely to take only one. If four hour and thirty minutes to six hours is the C<sub>max</sub> for Vyvanse®, it's shorter. Dr. Childress stated that in the classroom study, children were doing significantly more math with Vyvanse® at twelve hours out then with Adderall® XR.

Lee Boyle, Shire Pharmaceuticals, spoke in support of Vyvanse®. She stated that in the classroom trial Dr. Childress referred to, it was a double-blind crossover study, which means each of those patients were their own control. All were on Vyvanse®, Adderall® XR and placebo at one time. Results were within their own behaviors and how they were reacting to each of the different medications. Vyvanse® was originally designed to limit the abuseability. In likeability studies, substance users were tested with IR amphetamine and Vyvanse® as well as placebo as a negative control. At therapeutic doses, they did not like Vyvanse® statistically more than placebo whereas they did like the immediate release statistically more than placebo. Vyvanse® 150mg or more had to be reached before likeability scores were closer to the immediate release. Due to the enzymatic process which slowly leads the molecule into the system, it creates an inherently extended release molecule without having to create an additional mechanism like the other orals and a smoother profile is maintained. Another advantage of not having two separate systems is variation in patients in the pH of their GI tract or in how fast things pass through the GI tract that will effect how the second part of the mechanical formulation is going to be taken up. That may be why some people reach their C<sub>max</sub> at three hours versus some at ten hours because of the variability in a mechanical release system that is not seen with Vyvanse®.

Ms. Boyle stated that the PERMP math test looks at how well the children can sit still and write down their responses. Vyvanse® maintained a statistically significant improvement in the PERMP scores versus Adderall®. The PERMP at the twelve hour time point, children on Adderall® were declining versus Vyvanse®. Dr. Karagiozis asked how statistically different. Dr. Childress responded .05.

Dr. Lee asked if lower abuse risk is unique to this drug. Ms. Boyle replied a survey conducted by Bright et al in 2006 looked at 335 people that responded to the survey. 20% of those that responded stated that they had abused stimulants. Within the 20%, 80% had abused immediate release stimulants; 16% abused the long-acting. The current orals can be crushed or soaked to get to the amphetamine medication. Vyvanse® has been created with a chemically bonded molecule (mimics an amino acid bond) so it can't be left in a glass of water to get the amphetamine out of it.

### **Drug Class Review Presentation – First Health Services**

Jeff Monaghan stated that this drug class was reviewed at the June 21, 2007, meeting during the annual review process. By statute, the committee is required to review each drug class at least annually. At that time, the Committee voted to add Concerta® and delete methamphetamine from

this drug class. The PDL currently includes seventeen drugs within the ADHD/Stimulant medication category. At the June meeting, a committee member inquired about Vyvanse®. At that time, there was not time to incorporate this product in the drug class review due to its recent release date and it was agreed that it would be reviewed at the next meeting.

Vyvanse®, lisdexamfetamine dimesylate, is a prodrug in which dextroamphetamine has been covalently bonded to L-lysine. This bond is resistant to hydrolysis in vitro but is broken down upon oral administration. It is thought that this may limit its abuse potential if used IV or intranasally but there is not enough data or experience to support that but theoretically, it makes sense. The manufacturer had wanted a C-III designation but the FDA has classified it as a C-II controlled substance as are all the other amphetamine products. Limited studies have demonstrated a lower preference or liking score with patients but this appears to be dose related. At therapeutic doses, patients seem to prefer the other amphetamine salts versus Vyvanse®. There is some evidence that this prodrug formulation results in a more consistent peak and a slightly longer duration of action. Evidence of this has been seen in the number of dosage units per prescription. In terms of effectiveness, adverse events and drug interactions, Vyvanse® is comparable to the other amphetamine salts. It is the recommendation of DHCFP and FHSC that Vyvanse® be considered a therapeutic alternate within the stimulant/ADHD drug class.

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

**MOTION:** Michael Karagiozis motioned that the agents in this class be considered therapeutic alternatives.

**SECOND:** David Chan

**Dr. Karagiozis stated that diversion is an important issue, but if there is clinical superiority, there is an ethical obligation to the patients to ensure the drug is available to patients that are very severe.**

**AYES:** Flynn, Chan, Karagiozis, Lee, Horne, Shea, Manthei, Holt, Lubke

**NAYES:** None

**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 FHSC to add Vyvanse® to the PDL.

#### **Committee Discussion and Approval of Drugs for Inclusion in the PDL**

**MOTION:** Linda Flynn motioned to add Vyvanse® to the Preferred Drug List.

**SECOND:** Michael Karagiozis

**AYES:** Flynn, Chan, Karagiozis, Lee, Horne, Shea, Manthei, Holt, Lubke

**NAYES:** None

**MOTION CARRIED**

Dr. Monaghan stated that the Pharmacy Web-PA system is now available which allows providers to request PAs online and receive real-time responses. FHSC staff is available to provide onsite training.

#### **X. Report by FHSC on Brand Name Preferred Drugs Converted to Generic Status and Line Extensions**

Jeff Monaghan provided background for the new members. Nevada is a generic-mandatory state. When a brand name drug on the PDL becomes available generically and it's in the best interest of the State financially, the brand name drug is converted to the generic product. A report of any changes will be reported to the committee quarterly. He presented a report of changes which were put in place since the last meeting.

Dr. Shea stated that use of Coreg® requires the ICD-9 code for congestive heart failure. Now that it's available generically, can it be used for a diabetic with resistant hypertension and bad lipids without going through the PA process? Dr. Monaghan replied a PA is required for that indication and the prescriber will need to contact the Clinical Call Center.

Ms. Lawrence stated that the purpose of this report is to present the conversion of brand name drugs to the generic on the PDL and not change any restrictions that the P&T may have established since the class was last reviewed. Consideration for changes would need to be agendized and presented at a future meeting.

Dr. Horne requested the ICD-9 code requirement for carvedilol be reviewed at the March meeting.

Dr. Horne asked if Wellbutrin® 150mg is available generically and Dr. Monaghan stated not at this time. As agreed at the last meeting, review of the 150mg will be presented to the committee when available. Bert Jones, GlaxoSmithKline, stated that due to legal implications, it has not been released generically. He offered to follow-up with his legal staff and report back to the committee.

#### **XI. Review and Approval of Meeting Schedule for CY 2008**

Dates and locations for 2008 were presented. In the past, meeting locations alternated between northern and southern Nevada. Due to the majority of committee members residing in southern Nevada as well as State budget considerations, Dr. Horne suggested that all the meetings could be conducted in Las Vegas.

Dr. Manthei stated that the Osteopathic Board of Medical Examiners traditionally alternated back and forth but when the majority of board members were from southern Nevada, the decision was made to have all meetings in southern Nevada basically due to the cost.

Ms. Lawrence requested that the committee members lock in the dates of the meetings and the location will be discussed offline and the members notified via email within the next two weeks.

#### **XII. Public Comment**

Ms. Lawrence encouraged the committee members to review Chapter 1200 of the Medicaid Services Manual which contains the policy for the pharmacy program. She stated that when PDL exceptions are being considered, they must be based on FDA-approved indications. In addition, some drugs on the PDL may require clinical prior authorization and are so noted on the PDL.

Bert Jones, GlaxoSmithKline, asked if the intent for 2008 is to conduct the annual review in June and would the product categories that were reviewed in 2007 be reviewed within the next annual review.

Dr. Monaghan replied that the annual review is currently scheduled for June, 2008, and categories reviewed in 2007 will be included. Dr. Horne added that what occurs procedurally is the classes are grouped into two categories: drug classes with recommended changes and drug classes without recommended changes.

Dr. Manthei asked regarding the class of agents for macular degeneration. Dr. Monaghan stated that there currently is no drug review available for this class but will report back at the next meeting.

At Dr. Shea's request, Ms. Lawrence clarified the PDL for the new members. Drug categories not listed on the PDL are not subject to the requirement of the PDL and market share is not considered for those categories. Drugs within drug categories not on the PDL are available without prior authorization although clinical criteria may apply.

Ms. Lawrence stated that members can contact her or Ms. Griffith with questions regarding the PDL or the process. Contact information is included in the P&T reference binder.

#### **XIII. Adjournment**

**MOTION: Linda Flynn motioned to adjourn the meeting.**

**SECOND: John Lee**

**AYES: Unanimous**

**MOTION CARRIED**

The meeting was adjourned at 3:17 p.m.