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Governor

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

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PHARMACY & THERAPEUTICS COMMITTEE

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. , Suite 300
Las Vegas, NV

Meeting Minutes
June 25, 2009

Committee Members Present:
Linda Flynn, R.Ph., Chairman
Judy Britt, Pharm.D.
David Chan, R.Ph.
Justin Holt, Pharm.D.
Constance Kalinowski, MD
Michael Karagiozis, MD
Rudy Manthei, DO
R.D. Prabhu, MD

Absent:
John Lee, MD
Chad Luebke, Pharm.D.

Others Present:
Coleen Lawrence-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, David Abrahamson-Merck, Robert Spivock-Gilead, M. Shefehyk-NNI, Sarah Day-VCG & Associates, Randy Carpio-VCG & Associates, Felicia Fuller, Elson Kim-Forest Research, Doug Powell-Forest, Leigh Platte-Astellas, David Case-Astellas, Kirk Huffaker-Schering Plough, Doug Stogsdell-Astra Zeneca, Sandy Sierawski-Pfizer, Michael Steelman-Pfizer, Karen MacDonald-Astra Zeneca, Dan Hong-Astra Zeneca, Gary Comstock-Pfizer, Brad Evans-Allergan, Jane Stephen-Allergan, Chris Johnson-UCB, Clinton Wright-UCB, Joe Busby-Lilly, Chad Patel-Lilly, Chris Jensen-Lilly, Eric Eilers-Lilly, Gun Mee Lee-Pfizer, Erin Nremeyer-Pfizer, Trisha Williams-Teva, Isam Herndon-GSK, Roland Baldwin-Wyeth, Doug Ethel-GSK, Stuart Stolof, MD, Brian McManns-GSK, Teev Heimanson-SP, Ken Frisand-Sanofi Aventis, Lori Horwarth-Bayer, Dan Bay-Abbott Labs, Annie Ogostalick-Abbott, Deanne Calvert-Sanofi Aventis, Carlos Palasciano-Hawthorn, Gregg Polacek-Nephron, George Tu-Lung Center of Nevada, Jae Sady-Teva, Chase Freeca-Primary Care, Mike Pinocci-Primary Care, Steve Yurick-Pfizer, E.J. Milas-GSK, Firhaad Ismail-Endocrinology, Sedrick Spencer-Roche, Chris Almeida-Purdue, Dean Donato-Alcon.

I. Call to Order and Roll Call

Chairperson, Linda Flynn, called the meeting to order at 1:08 p.m.

II. Review and Approval of March 26, 2009, Meeting Minutes

MOTION: **R.D. Prabhu motioned to approve the March 26, 2009, minutes as presented.**
SECOND: **Michael Karagiozis**
VOTES: **Unanimous**
MOTION CARRIED

Coleen Lawrence introduced new member Judy Britt to the Committee. She stated that today's meeting is the term limit meeting for the majority of the current committee members. Members have the opportunity to be reappointed. Nominations for this committee can be submitted to the Governor's office. Ms. Lawrence requested that a copy of the applications be sent to DHCFP to ensure submission to the appropriate office. She thanked the committee members for their service on this committee.

Ms. Lawrence stated that an annual review of the Preferred Drug List (PDL) is required by statute. The annual review process consists of two categories, drugs that will be considered for change and drug classes without proposed changes. Public comment is limited to three minutes and only new clinical information will be permitted for comment per individual, organization or agency. Public offering comment is asked to disclose any affiliations with drug manufacturers.

Linda Flynn announced that item IX. Respiratory: Inhaled Corticosteroids/Nebs will be moved to the first order of business.

Ms. Flynn noted that Dr. Manthei joined the meeting at 1:11 p.m.

ANNUAL REVIEW- DRUG CLASSES WITH PROPOSED CHANGES

III. Antidepressants: Other

A. Public Comment

Clinton Wright, UCB, spoke in support of venlafaxine extended release tablets. The new drug application for venlafaxine ER tablets was approved last July. His company relied on the safety and efficacy data of Effexor® XR as well as the bioequivalency trials conducted to prove the bioequivalency between the two products. The formulation of a tablet allows for the single 225mg dose in one tablet versus a capsule which would be dosed at three 75mg capsules or a 75mg and 150mg capsule. Regarding the relative pill size across each of the strengths, the tablet is smaller in all cases, which may lead to simplified dosing at the 225mg strength and improve adherence. It is indicated for the treatment of Major Depressive Disorder and Seasonal Affective Disorder but is not indicated for Panic Disorder or Generalized Anxiety Disorder.

Judy Britt asked for clarification of the bioequivalency between the venlafaxine ER and Effexor® XR.

Mr. Wright responded that the FDA New Drug Application (NDA) process for the 505B2 bioequivalency studies is identical for what a generic would go through. The studies included the 37.5mg, 75mg and 225mg single dose. The 37.5mg and 75mg were under fed and fasted conditions. At 37.5mg, the venlafaxine single dose tablets were bioequivalent under both conditions to the Effexor XR® which was the reference product. The 75mg under fasted conditions did not meet the same level as the other three arms so bioequivalence could not be shown, however, the level was met under fed conditions. The 225mg was studied only under fed conditions and shown to be bioequivalent. A seven day multi-dose trial looked at kinetics at day seven and did show bioequivalence. It is not AB rated.

Elson Kim, Forest Pharmaceuticals, spoke in support of Citalopram®. Jeff Monaghan informed Mr. Kim that Citalopram® is an SSRI and not included in the category being reviewed today.

Chad Patel, Eli Lilly, spoke in support of Cymbalta®. Cymbalta® is an SNRI and has been on the market since August, 2004 for two psychiatric conditions, Major Depressive Disorder (MDD) and Generalized Anxiety Disorder (GAD), and two painful conditions, diabetic peripheral neuropathic pain and fibromyalgia. The recommended dose is 40-60mg for acute MDD and 60mg for the other indications. Two clinical studies have demonstrated efficacy at the 60mg once daily dose for fibromyalgia. Both studies included patients with MDD and without. Pain reduction was observed in both patients with or without co-morbid mood conditions. The most common adverse events in clinical studies compared to placebo are nausea, dry mouth, constipation and somnolence. He requested the Committee consider Cymbalta® as a therapeutic alternative for the treatment of fibromyalgia.

Dr. Karagiozis asked if there is a category for fibromyalgia. Jeff Monaghan replied that currently there is not a specific category for fibromyalgia, but the DUR Board has

addressed it and has placed criteria on Lyrica®. The DUR Board may address clinical criteria on Cymbalta® at a future meeting.

Dr. Karagiozis asked if the co-morbidity in fibromyalgia with depression is high. Mr. Patel replied that in population based studies, approximately two-thirds of patients with fibromyalgia have co-morbid conditions. In clinical studies, it's 25%.

Dr. Karagiozis said that a concern expressed by the medical director for the state psychiatric facility is the pain phenomenon in those patients and getting them off opioids. Due to the opioid overuse in that population, he felt it would be worthwhile to review as an antidepressant side effect for those drugs that reduce pain. Dave Wuest stated that will be addressed at a future DUR meeting.

B. Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this drug class was last reviewed during the annual review in June, 2008. At that time, Pristiq® was reviewed but not added to the PDL. Today, there are two new products to review. The drugs themselves are not new, but they have been brought to the market as either a different salt of an existing drug in the case of Aplenzin®, which is an extended release bupropion hydrobromide (versus hydrochloride) similar to Wellbutrin XL which is currently on the PDL. The other drug, venlafaxine hydrochloride ER (tablet form), is an existing drug similar to Effexor ER® (capsule form). Venlafaxine ER has a higher strength tablet available (225mg). The two products are bioequivalent at some doses but not interchangeable, therefore not AB rated at this time, so pharmacies cannot substitute between Effexor XR® and venlafaxine ER. The PDL for this class contains a full listing of drugs. In terms of effectiveness, all the second generation antidepressants are effective at reducing symptoms of depression, and no significant differences in efficacy have been borne out by clinical trials and systematic reviews. There can be a difference in their overall adverse event profile. All of the agents contain the black box warning regarding suicidality in children, adolescents and young adults. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

C. Committee Discussion and Action 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: **Connie Kalinowski**
VOTES: **Unanimous**
MOTION CARRIED

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

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that no changes be made to the PDL in this class at this time.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: **Michael Karagiozis motioned to accept First Health's recommendation that no changes be made to the PDL in this class.**
SECOND: **Connie Kalinowski**
VOTES: **Unanimous**
MOTION CARRIED

IV. Antiemetics: Oral, 5-HT3s

A. Public Comment

Sarah Day, VCG and Associates, stated that she is representing ProStrakan, Inc. ProStrakan has developed a transdermal delivery system for granisetron, an established antiemetic approved for the prevention of chemotherapy induced nausea and vomiting (CINV). Marketed under the brand name Sancuso®, the granisetron patch is designed to sustain delivery of granisetron 3.1mg per day over five days of chemotherapy. A single patch is applied 24 to 48 hours prior to the first chemotherapy dose to prevent CINV for up to five days. Patients who cannot or will not take medicines orally can benefit from transdermal treatment such as those who have tumors of the head and neck, the GI tract or cancers that can preclude the oral route of anti-nausea medicines. The primary comparative products to Sancuso® include granisetron hydrochloride (tablets, oral solution and IV forms). Oral granisetron 2mg daily was used as a primary comparative in clinical efficacy trials. In the pivotal trial, Sancuso® demonstrated efficacy equivalent to daily oral granisetron. The primary endpoint of that study was a proportion of patients with complete control; no vomiting and mild nausea. The most frequent adverse effect was constipation at 5% of patients and 99% of patients remained adhered during the entire study period. Sancuso® offers patients and prescribers an alternative treatment option for prevention of CINV for the duration of an entire chemotherapy cycle, similar to oral granisetron, but does not require multiple daily dosing.

B. Drug Class Review Presentation – First Health Services

Dave Wuest stated that this class was last reviewed at the annual review in June, 2008. He agreed with the presentation by Ms. Day and clarified that there is no study that states Sancuso® is more effective than the oral agents which are currently on the PDL. Sancuso® shows fewer side effects in a class of drugs that have very mild side effects. He stated that when this class was placed on the PDL, only oral agents were available and the class was categorized as "Antiemetics: Oral, 5-HT3s. With the release of the transdermal product, the recommendation is to remove "Oral" from the class name.

MOTION: Michael Karagiozis motioned to re-categorize the class as "Antiemetics: 5-HT3s".
SECOND: R.D. Prabhu
VOTES: Unanimous
MOTION CARRIED

Dave Wuest stated that it is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

MOTION: Justin Holt motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Judy Britt
VOTES: Unanimous
MOTION CARRIED

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

Dave Wuest stated that if a patient has a predisposed condition whereby they could not take an oral medication, a prior authorization will be approved for the transdermal patch. It is the recommendation of DHCFP and First Health that no changes be made to the PDL in this class.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Michael Karagiozis motioned to accept First Health's recommendation that no changes be made to the PDL in this class.
SECOND: Justin Holt
VOTES: Unanimous
MOTION CARRIED

V. Cardiovascular: Antihyperlipidemics: Triglyceride Lowering Agents

A. Public Comment

Annie Ogostazick, Abbott, spoke in support of Trilipix®. Trilipix® is indicated as an adjunct in combination with statins to reduce triglycerides and increase HDL in patients with mixed dyslipidemia and coronary heart disease or coronary disease risk equivalent that are on optimal statin therapy to achieve their LDL goal. It's also indicated as monotherapy to reduce triglycerides in patients with severe hypertriglyceridemia and to reduce elevated LDL-C, total cholesterol and Apo B and increase HDL-C in patients with primary hyperlipidemia or mixed dyslipidemia. No incremental benefit of Trilipix® on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established. Trilipix® is administered as a 135mg single daily dose in adult patients with mixed dyslipidemia or primary hyperlipidemia. The recommended dose ranges from 45mg to 135mg per day for adults with severe hypertriglyceridemia and should be adjusted based on patient response. An initial dose of 45mg per day is recommended for patients with dyslipidemia who have mild to moderate renal impairment and the dose should only be increased after evaluation of effects on renal function. Three trials were conducted testing safety and efficacy with one of three statins: simvastatin, atorvastatin and rosuvastatin. Significantly statistical differences were observed for all three primary efficacy comparisons with Trilipix® co-administered with both low and moderate dose statins. Trilipix® is the only fibric acid derivative extensively studied and FDA approved for combination use with statins. She requested consideration be given to adding Trilipix® to the PDL.

Dr. Firhaad Ismail, endocrinology, disclosed that he is a speaker for numerous drug companies including Glaxo Smith Kline and spoke in support of Lovaza®. The major focus is efficacy. It's efficacious in reducing triglycerides and also increases HDL cholesterol. Lovaza® goes through a five step refinement process making it 90% pure omega-3 fatty acids. The comparison is dietary supplements. Dietary supplements have 35% to 65% purity and do not require studies to treat disease therefore the data with dietary supplements is lacking. Scientifically, there is no comparison between omega-3 in the form of Lovaza® versus the dietary supplements because of lack of evidence. The next comparison is fibrics, gemfibrozil and fenofibric. The NCEP guidelines are clear that gemfibrozil and statins have a significant drug-drug interaction profile with regard to liver function and rhabdomyolysis. Fenofibrate has drug-drug interaction profile concerns with regard to statin combination therapy. There have been studies done with Lovaza® and high dose statins with wonderful efficacy in dropping triglycerides as well as lowering LDL and increasing HDL with good safety profile. He recommended Lovaza® be added to the PDL.

Dr. Karagiozis asked if Lovaza® raises HDL and Dr. Ismail replied correct.

Jeff Monaghan stated that this Committee had an extensive discussion about this a year ago. At that time, the representative from Glaxo Smith Kline said that there were no good outcome studies available and asked what has changed in the last year.

Dr. Ismail replied that the label now is for triglyceride above 500. The outcomes with Lovaza® are post MI. In Europe, Lovaza® has been available for fourteen years. The standard of care in Europe is using Lovaza® 1gm per day post MI. More than 10,000 post MI patients were given Lovaza® 1gm per day, and within 90 days there was a dramatic decrease in cardiovascular mortality; sudden death decreased 40-45%.

Dr. Prabhu asked regarding Dr. Ismail's experience with Lovaza® in patients with mixed dyslipidemia who are on statins but their triglyceride is below 500.

Dr. Ismail referred to the COMBOS Trail. Patients were on simvastatin 40mg per day whose triglycerides were in the range of 200-499. Lovaza® was added and triglycerides were lowered 25-30%; HDL was increased and non-HDL dropped. He added that this is off-label use.

Dr. Karagiozis asked the efficacy of Lovaza® in patients who have dyslipidemia secondary to a drug; e.g., atypical antipsychotics or protease inhibitors.

Dr. Ismail stated that he has used it in patients taking atypicals who have dyslipidemia but has not seen trials in that regard. He added that it is efficacious in drug-induced dyslipidemia and has used it in that setting as well.

David Chan stated that he is a proponent of omega-3 due to personal use. He has experienced a significant improvement in HDL since taking over-the-counter (OTC) omega-3. He asked what the advantage of Lovaza® is over the OTC product.

Dr. Ismail replied that the OTC dietary supplement may be called omega-3 but may contain omega-6 and other saturated fats which may have negative effects.

E.J. Milas, Glaxo Smith Kline, spoke in support of Lovaza®. He referred to Dr. Ismail's comments and clarified that combination therapy with a statin is not off-label, it's off indication. Lovaza® offers efficacy and safety. He requested the Committee consider adding Lovaza® to the PDL, and if a dietary supplement is to be included, select one or two that have been tested and consistent in their purity and contains a certain percentage of omega-3.

Jeff Monaghan referred to the minutes from the previous annual meeting whereby Mr. Milas stated that there were no definitive outcome studies with randomized, double-blind placebo controls. There was a large study in Italy which was open-label.

Mr. Milas stated that since that time, the GC Heart Failure has come out. The GC Heart Failure was a randomized, double-blind placebo controlled study which was a head-to-head study against rosuvastatin. There was an 8% reduction in all cause mortality and a 9% reduction in combined endpoint in all-cause mortality hospitalization. Rosuvastatin did not meet the primary endpoint in that study. He added this is off-label use and that the GC Heart Failure was not a U.S. based study.

B. Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this class was last reviewed in June, 2008, with no changes made at that time. There are currently seven different formulations of fenofibric acid on the market. The one currently preferred is Tricor®. Trilipix® is the new agent and is the active metabolite of Tricor®. There is no comparative data comparing the two products. What does distinguish Trilipix® is that it is the only fibrate FDA approved for use in combination with a statin. Fibrate and statin therapy has been associated with an increased risk of rhabdomyolysis and all the products carry that warning. In terms of Lovaza®, the issue is the question of evidence. We've heard about some reduced mortality, which is encouraging, and there has been personal testimonial. Statins are such valuable agents with good evidence. There is concern that a product such as Lovaza® would erode the use of statins as first-line agents. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

Dr. Prabhu stated that some patients on statins may continue to have dyslipidemia. Lovaza® seems to decrease the cardiovascular risks by increasing the HDL and would like to move that Lovaza® be added to the PDL.

Ms. Lawrence clarified that the recommendation at this time is to determine if the agents are therapeutic alternatives.

Dr. Karagiozis clarified that a statin is good for use when a statin is needed and any of the lipidic agents are good for lipids. He would not like to see Trilipix® or Lovaza® prescribed for people who have LDL elevations.

MOTION: Michael Karagiozis motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Rudy Manthei
VOTES: Unanimous
MOTION CARRIED

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

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that Trilipix® be added to the PDL.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: R.D. Prabhu motioned to add Trilipix® and Lovaza® to the PDL.
SECOND: Michael Karagiozis
AYES: Manthei, Karagiozis, Flynn, Prabhu, Kalinowski
NAYES: Britt, Chan, Holt
Darrell Faircloth stated that six affirmative votes are required to carry the motion.
MOTION FAILED
Coleen Lawrence requested a recount of the votes.
AYES: Manthei, Karagiozis, Flynn, Prabhu, Kalinowski
NAYES: Britt, Chan, Holt
Darrell Faircloth restated that six affirmative votes are required to carry the motion.
MOTION FAILED

MOTION: R.D. Prabhu motioned to include Lovaza® to the PDL.
Dr. Karagiozis asked for patients with triglycerides greater than 500 and Dr. Prabhu replied yes and also for patients that are on statins with triglycerides in excess of 200mg.
Ms. Lawrence stated that the pharmacy system is not able to differentiate the levels because lab values are not in the claims system and it could not be an ICD-9 driven code.
Ms. Lawrence asked Dr. Prabhu to clarify the motion.
Dr. Prabhu replied to include Lovaza® to the PDL for the treatment of dyslipidemia which includes hypertriglyceridemia.
Dr. Karagiozis said that three ICD-9 codes could be applied; 272.4, 272.2, 272.1.
Ms. Lawrence asked if the intent of the motion is that Lovaza® will be available if one of those three ICD-9s is on the prescription and the PA process would be bypassed and he replied yes.
SECOND: Michael Karagiozis
Dr. Manthei stated that Trilipix® was not debated and the current motion does not include it. The motion now only includes the Lovaza®.
Dr. Karagiozis understood the motion to include Trilipix® and Lovaza® with its FDA approved indication.
Dr. Karagiozis withdrew the second.

MOTION: **Michael Karagiozis motioned to include Trilipex® and Lovaza® to the PDL for dyslipedemia and its FDA approved guidelines, ICD-9 codes 272.4, 272.2, 272.1.**
Jeff Monaghan asked if the ICD-9 codes would apply only to Lovaza® or to both agents.
Dr. Karagiozis stated that the ICD-9 codes would apply only to Lovaza®.
SECOND: **R.D. Prabhu**
AYES: **Manthei, Karagiozis, Flynn, Prabhu, Kalinowski**
NAYES: **Britt, Chan, Holt**
MOTION FAILED

Jeff Monaghan restated the DHCFP and First Health's recommendation that Trilipix® be added to the PDL.

MOTION: **Rudy Manthei motioned to accept First Health's recommendation that Trilipix® be added to the PDL.**
SECOND: **Judy Britt**
VOTES: **Manthei, Karagiozis, Flynn, Prabhu, Britt, Chan, Holt, Kalinowski**
MOTION CARRIED

Ms. Lawrence reminded the public that public comment is limited to three minutes per individual organization or agency.

VI. Electrolyte Depleters

A. Public Comment

No comment.

B. Drug Class Review Presentation – First Health Services

Dave Wuest stated that this class was last reviewed in June, 2008. There is now a new agent in the class, Eliphos® (calcium acetate). PhosLo®, a preferred agent, is now available as a generic. Renagel® (sevelamer hydrochloride), a preferred agent, is expected to leave the market and be replaced with Renvela® (sevelamer carbonate). All the agents in this class share the same indication, similar dosing regimens, same side effects, and are used for the control of hyperphosphatemia in end stage renal disease patients. Eliphos® is the tablet form and strength of PhosLo®, calcium acetate. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

C. 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: **Justin Holt**
VOTES: **Unanimous**
MOTION CARRIED

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

Dave Wuest stated that it is the recommendation of DHCFP and First Health that the generic form of PhosLo®, calcium acetate, be preferred, the brand PhosLo® be non-preferred, Renagel® to remain on the PDL and to add Renvela® to the PDL.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Michael Karagiozis motioned to accept First Health's recommendation that calcium acetate be preferred, PhosLo® be non-preferred, Renagel® remains on the PDL and to add Renvela® to the PDL.
SECOND: David Chan
Judy Britt asked why Renagel® is leaving the market.
Dave Wuest replied that the same company manufacturers Renagel® and Renvela® and the compounds are similar. The literature indicates that Renagel® will leave the market in 2010, probably due to market factors.
Justin Holt asked if the literature indicated that a generic for Renagel® is being pursued or the product is just leaving the market.
Dave Wuest replied that the product is not widely used and will leave the market. Jeff Monaghan added that most of the market share is going to the generic calcium acetate which may also be a factor.
VOTES: Unanimous
MOTION CARRIED

VII. Gastrointestinal Agents: PPIs

A. Public Comment

Doug Stogsdill, Astra Zeneca, spoke in support of Nexium®. Nexium® is now approved for pediatric use in patients one to seventeen years of age. The recommended dosage in patients one to eleven years of age is 10mg once a day for up to eight weeks for symptomatic GERD, and for erosive esophagitis in this patient population, 10mg or 20mg once a day depending on the patient's weight. Patients twelve to seventeen, 20mg – 40mg once per day for up to eight weeks for the treatment of symptomatic GERD. A suspension is available in 10mg, 20mg and 40mg. The capsules can be opened and sprinkled on applesauce or suspended in water and there is also an IV formulation available. In clinical trials, Nexium® has been well tolerated in both short and long term studies with no new safety concerns identified in patient populations during these trials.

B. Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this class was last reviewed in June, 2008, and no changes were made to the class at that time. There are two new products for review, Kapidex® (dexlansoprazole) and Prilosec® Packets for oral suspension. Prilosec® Packets are simply a new strength and formulation of an existing product, Prilosec®. Prilosec® is currently non-preferred but omeprazole OTC and Prilosec® OTC are on the PDL. Kapidex® is the enantiomer of lansoprazole, Prevacid®, which is currently on the PDL, and both are made by the same company. Kapidex® does not have some of the indications that Prevacid® does. It is not FDA approved for the treatment of any type of GI ulcer or pathological hypersecretory conditions such as Zollinger-Ellison syndrome. The safety and efficacy of Kapidex® has not been established in pediatrics and there is no comparative data to support the use of Kapidex® over any other PPI. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

MOTION: R.D. Prabhu motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Michael Karagiozis
VOTES: Unanimous
MOTION CARRIED

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

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that no changes be made to the PDL in this category.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Michael Karagiozis motioned to accept First Health's recommendation that no changes be made to the PDL in this category.
SECOND: Judy Britt
VOTES: Unanimous
MOTION CARRIED

VIII. Intranasal Rhinitis Agents

A. Public Comment

Ken Frisard, Sanofi-Aventis, spoke in support of Nasacort AQ®. Nasacort AQ® has recently been approved by the FDA for use in children down to two years of age. There is limited intranasal corticosterioid (INS) safety and efficacy data in children less than six years of age. He stated that the efficacy of other agents is based on subjects across a range of three to eleven years old. His company has the first well known, well controlled study assessing the safety and efficacy of INS in children two to five years of age in allergic rhinitis. There were 474 subjects in a four week, double blind, placebo controlled study, extended out to six months open label. He recommended adding Nasacort AQ® for the safety and efficacy down to two years of age.

Doug Ethel, Glaxo Smith Kline, spoke in support of Veramyst®. Veramyst® is not a salt form of Flonase®; it's not a patent extension but an ester molecule. Veramyst® is dosed once per day down to the age of two. It's the only INS that has an ocular claim for efficacy for eye symptoms. Since the majority of rhinitis patients also have ocular symptoms, this is a drug that makes it possible to treat those patients with one drug rather than adding non-sedating antihistamines or antihistamine eye drops.

B. Drug Class Review Presentation – First Health Services

Dave Wuest stated that this drug class was last reviewed in September, 2008. There is a new drug, Astepro®, which contains the same chemical as the currently preferred drug, Astelin® which may be leaving the market. The claim is that Astepro® contains a slightly different but still unpleasant taste. Veramyst® has the ocular claim but there is no effect on ocular symptoms in adults with perennial allergic rhinitis or children with seasonal rhinitis. The other drugs are most likely to have a similar effect but have not been studied. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

C. 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: Rudy Manthei
VOTES: Unanimous
MOTION CARRIED

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

Dave Wuest clarified that mometasone (Nasonex®) is FDA approved down to the age of two and is currently on the PDL. It is the recommendation of DHCFP and First Health to add Astepro® to the PDL with the expectation that Astelin® may be leaving the market.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Prabhu stated that Veramyst® is better tolerated and is highly effective in allergies affecting the eyes and well tolerated in kids.

MOTION: R.D. Prabhu motioned to add Astepro® and Veramyst® to the PDL.
SECOND: Rudy Manthei
Dr. Karagiozis stated that there is an overwhelming community drive for this drug. He has not prescribed the drug but the physicians that he refers his patients to have been put on the drug.
Dr. Manthei agreed adding that in his practice, it's a preferred drug with good results.
Judy Britt asked if there is any comparative data with Veramyst® and other agents.
Jeff Monaghan replied there is none; there is data comparing to placebo. The Oregon Drug Effectiveness Project essentially has grouped all of these agents together. There is no good evidence of one over the other at this point.
Dave Wuest reminded the Committee that non-preferred drugs are available through the PA process, if there is failure on a preferred agent.
AYES: Kalinowski, Holt, Prabhu, Flynn, Karagiozis, Manthei
NAYES: Chan, Britt
MOTION CARRIED

IX. Respiratory: Inhaled Corticosteroids/Nebs

A. Public Comment

Dr. Stuart Stolof, family physician, Carson City, said that for the last fifteen years, he is one of sixteen people that have written guidelines for asthma for the United States for the National Heart, Lung and Blood Institute. He stated that he is not being paid by any drug company to speak here. For years, metered dose inhalers were used in children because the data is insufficient to clearly say that not increasing the dose of inhaled corticosteroids (ICS) in very young children is not effective versus using other delivery systems. The diskus is now approved in children. There is a 100 microgram diskus and a 250/50 but it's about ease of use for the young kids. With the diskus, he can now go up to an appropriate dose for the children. He requested the Committee review the prior authorization requirement for budesonide (Pulmicort®) adding that Pulmicort® has a great wealth of data and he is one of the people that wrote on pregnancy and asthma for the National Heart, Lung and Blood Institute. The foundation for asthma care is monotherapy and requested that the diskus be available.

Teev Heimanson, Schering Pharmaceuticals, spoke in support of Asmanex® dry powder inhaler. A year ago, Schering received approval from the FDA to market 110mcg of mometasone (Asmanex®) for children down to age four. It has been extensively studied comparing dosages of 110mcg to 220mcg. The 110mcg faired well in clinical trials and the FDA permitted Schering to launch the product as a single 110mcg dose. If the patient has been previously controlled on inhaled corticosteroids or on rescue medication, the only dose FDA approved is a 110mcg of mometasone given in the evening. The product has also been studied for growth suppression and effect and is similar to the information found with other corticosteroids. Asmanex® is the only inhaled corticosteroid in a dry powder formulation that's approved for once-a-day dosing.

Dr. George Tu, Lung Center of Nevada, spoke in support of Advair® Diskus for COPD. COPD affects approximately 22 million Americans with 10 million of those not being

diagnosed. The myth has been that COPD is an elderly disease in people in their 70s and 80s but it afflicts people in their 40s to 60s. He has recently treated two women in their 50s diagnosed with COPD due to a history of smoking. Data recently released for Advair® with combination therapy of 250/50 indicates that it helps to reduce the frequency of exacerbation. Seventy-five percent of the cost for treating COPD is attributed to COPD exacerbation. He feels that this is an important product and should continue to be available. In his personal experience, he has seen many patients with very severe COPD that end up in the hospital multiple times. Their physical health and quality of life continue to decline. His patients on Advair® feel much better and the frequency of exacerbation reduces. He stated that he is not being paid by any pharmaceutical company.

Dan Hong, Astra Zeneca, spoke in support of Symbicort®. Astra Zeneca does not recommend the use of Symbicort® in any other manner than is described in the full prescribing information. Symbicort® is a combination budesonide and formoterol available in two doses 80mcg/4.5mcg and 160mcg/4.5mcg of budesonide and formoterol respectively. Symbicort® 160mcg/4.5mcg is now approved for the maintenance treatment in patients with chronic obstructive pulmonary disease including chronic bronchitis and emphysema. The FDA approval is based on results from two clinical trials which included over 3,600 patients. These studies demonstrated that Symbicort® significantly improved lung function as early as day one and sustained up to twelve months. It's the only ICS combination maintenance medication for COPD with an onset of bronchodilation within five minutes of the first and subsequent doses. It reduces COPD symptoms by 35% versus formoterol over twelve months and total daily rescue medication by 56% versus formoterol over twelve months. The safety profile is comparable with placebo. Symbicort® is indicated for patients twelve years of age and older with uncontrolled moderate to severe persistent asthma who are not adequately controlled on other asthma medications or if the disease clearly indicates the use of two maintenance medications. Astra Zeneca's respiratory portfolio includes Pulmicort Respules® as well as Pulmicort Flexhaler® which are indicated for the maintenance treatment of asthma and prophylactic treatment in adults and pediatric patients six years of age and older. He requested Symbicort® be considered for addition to the PDL.

B. Drug Class Review Presentation – First Health Services

Dave Wuest stated that this class was last reviewed in June, 2008, at which time no changes were made to this PDL class. Since that time, two new agents have been released, ciclesonide (Alvesco®), which is not a new chemical to the Committee as it was previously reviewed as the nasal spray Omnaris®. It is now available as a multi-dose inhaler for the treatment of asthma. The second agent is Flovent Diskus®. The agents in this class are similar in action, side effect and effectiveness. There is speculation that Alvesco® may work better than other inhaled steroids due to its smaller particle size, but no studies have demonstrated that to be true. Data suggests that Alvesco® is less likely to cause thrush and hoarseness than other inhaled steroids. He noted that Symbicort® has the indication for maintenance treatment of airflow obstruction in COPD patients. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

C. 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: Justin Holt
VOTES: Unanimous
MOTION CARRIED

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

Dave Wuest stated that it is the recommendation of DHCFP and First Health that the current PDL agents in this class remain on the PDL and to add Flovent Diskus®.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: David Chan motioned to accept First Health's recommendation that that the current PDL agents in this class remain on the PDL and to add Flovent Diskus®.
SECOND: Judy Britt
VOTES: Unanimous
MOTION CARRIED

X. Urinary Tract Antispasmodics

A. Public Comment

Sandy Sierawski and Gary Comstock, Pfizer, spoke in support of Toviaz®. Mr. Comstock stated that Toviaz® is a new antimuscarinic agent for the treatment of over active bladder (OAB) approved by the FDA in October, 2008. Toviaz® has been approved for the treatment of OAB and the associated symptoms of urge urinary incontinence, urgency and frequency. It's a muscarinic receptor antagonist available in two doses, 4mg and 8mg, the dose titration to achieve optimum symptom control. After oral administration, Toviaz® is rapidly and extensively hydrolyzed by nonspecific esterases to its active metabolite, 5-hydroxymethyl tolterodine (5-HMT). The formation of 5-HMT does not occur via oxidation in the liver and does not require Cytochrome P450 system. Two phase three registration trials establish the efficacy and safety of both doses of Toviaz®. Urge urinary continence episodes were reduced by a median of 80% at 4mg and 87% at 8mg versus 50% placebo in the international study and reduction of 67% at 4mg and 82% at 8mg versus 40% placebo in the U.S. study. All values were statistically significant versus placebo. The two most common adverse events were dry mouth and constipation as is typical for this class of drugs. Discontinuation due to the most common adverse advent, dry mouth, was less than 1% at the highest dose of Toviaz®. Constipation rates were low; 2% for placebo, 4% for Toviaz® 4mg, and 6% for Toviaz® 8mg. CNS side effects were low and comparable to placebo. Toviaz® is the first antimuscarinic drug with safety data from a three year, open label extension study within its label. There were no unexpected adverse events and no clinically relevant changes in vital signs or laboratory parameters over the duration of the study. Toviaz® can be taken any time of day without regard to food intake. No dosing adjustments are required due to age, gender or in patients with mild or moderate renal impairment or mild or moderate hepatic impairment. Toviaz® comes with a comprehensive patient support plan called "Your Way".

Leigh Platte, Astellas, spoke in support of Vesicare®. The VENUS Study is a controlled trial of Vesicare® versus placebo to reduce episodes of urgency and urgent continence and improve warning time. Vesicare® was statistically significant in both endpoints and improved warning time by 31.5 seconds. The VECTOR Trial, a Canadian study, compared Vesicare® 5mg to oxybutynin immediate release 5mg in 132 patients. It was a multi-center, prospective, randomized, double blind, double dummy study in patients with overactive bladder. Dry mouth was lower in Vesicare® in which 75% reported cases were mild versus oxybutynin in which 30% were mild. Vesicare® was associated with fewer overall adverse events, lower severity of adverse events and few drop outs. Vesicare® and oxybutynin immediate release both significantly reduced related OAB symptoms and significantly improved patient reported outcomes from baseline to study endpoint. Vesicare® has the same side effects and precautions as other drugs in this class. In all studies of Vesicare®, over 50% of the patients that were incontinent upon entering the trial were continent by the end of the trial.

Dr. John Dudek, urologist, spoke in support of Toviaz®. He stated that his colleagues approve of Toviaz®. It's a safe and effective drug. All of these drugs are effective but the side effects can be bad. Pfizer has been a leader in these overactive bladder medications, especially, Detrol LA®, which is the number one drug used for overactive bladder. There is a new plan with Toviaz® that helps people with behavioral therapy which is important as far as what foods to take and how to manage the bladder. We encourage people to take an active behavioral approach by having this special plan. All of these drugs are equally effective but a good behavioral approach helps.

Dr. Karagiozis asked if the discontinuance rate for the various medications related to side effect in this class. Dr. Dudek replied undoubtedly, and this one has a very low rate of quitting. The biggest thing about these drugs is people quitting because of the side effects especially dry mouth and constipation. Toviaz® has been studied for three years with no serious events.

Ms. Flynn asked if Dr. Dudek has any affiliation with any pharmaceutical companies and he replied that he is not being paid by any drug company but was asked to attend and support their drug.

B. Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this class was last reviewed in September, 2008. At that time, Sanctura XR® was added to the PDL. There is currently a broad range of agents in this class available on the PDL. Five of the available six agents for overactive bladder are on the PDL and they are Detrol LA®, Enablex®, generic oxybutynin tablets and syrup, Vesicare® and Sanctura XR®. Today the class is being reviewed due to the release of the new agent, Toviaz® or fesoteridine. Fesoteridine is rapidly converted in the body to the same active metabolite of Detrol® and Detrol LA®. All of these agents have been shown to be up to 75% effective in reducing the symptoms of overactive bladder. The primary limitation of the class is the somewhat bothersome side effects which are listed on page six of the drug review. He noted that the percentages included in the drug review are taken from the package insert. Studies in the review have head-to-head comparisons. One of the studies that compare Toviaz® to Detrol LA® showed a higher percentage of dry mouth with Toviaz®. Generally, these agents are selected on tolerability. Toviaz® provides another option for over active bladder. It has not distinguished itself clinically over the other agents that are currently available on the PDL. No one particular agent in this class has distinguished itself as being superior to the other agents. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

MOTION: **David Chan motioned that the agents in this class be considered therapeutic alternatives.**
SECOND: **Judy Britt**
VOTES: **Unanimous**
MOTION CARRIED

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

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that no changes be made to the PDL in this class.

E. Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Karagiozis said that even though Toviaz® is the inline drug for Detrol® what about the discontinuance rate, adverse effects and behavioral therapy.

Jeff Monaghan stated that the active metabolite of Toviaz® is Detrol LA® and from the evidence seen, the data is not compelling to distinguish one from the other. The head-to-head study included in the drug review indicates a higher incidence of dry mouth with Toviaz®. In terms of the behavioral therapy, since Pfizer has both products, the question is why Pfizer couldn't offer the same program for Detrol LA®.

Ms. Flynn stated that the PDL exception criteria can be applied for a non-preferred agent if there is failure of two preferred agents or unacceptable side effects.

MOTION: Rudy Manthei motioned to accept First Health's recommendation that no changes be made to the PDL in this class.
SECOND: Michael Karagiozis
VOTES: Unanimous
MOTION CARRIED

XI. Annual Review - Drug Classes without Proposed Changes

A. 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. Alzheimer's Agents
2. Analgesics: Long Acting Narcotics
3. Antibiotics: Cephalosporins 2nd Generation
4. Antibiotics: Cephalosporins 3rd Generation
5. Antibiotics: Macrolides
6. Antibiotics: Quinolones 2nd Generation
7. Antibiotics: Quinolones 3rd Generation
8. Anticoagulants: Injectable
9. Antidepressants: SSRIs
10. Antifungals: Onychomycosis Agents
11. Antihistamines: 2nd Generation
12. Anti-Migraine Agents: Triptans
13. Antiparkinson's Agents: Non-ergot Dopamine Agonists
14. Benzoyl Peroxide and Clindamycin Combinations: Topical Agents
15. Bone Ossification Agents: Bisphosphonates
16. Cardiovascular: ACE Inhibitors & Diuretic Combinations
17. Cardiovascular: Angiotensin II Receptor Blockers & Diuretic Combinations
18. Cardiovascular: Antihyperlipidemics: Cholesterol Absorption Inhibitors
19. Cardiovascular: Antihyperlipidemics: Niacin Agents
20. Cardiovascular: Antihyperlipidemics: Statins & Statin Combinations
21. Cardiovascular: Beta Blockers
22. Cardiovascular: Calcium Channel Blockers & Combinations
23. Central Nervous System: ADHD/Stimulants
24. Central Nervous System: Sedative Hypnotics
25. Direct Renin Inhibitors
26. Erythropoiesis Stimulating Proteins
27. Gastrointestinal Agents: H2RAs
28. Growth Hormone Agents
29. Hepatitis C Agents
30. Herpetic Antiviral Agents
31. Immunomodulators: Injectable
32. Immunomodulators: Topical
33. Impetigo Agents: Topical
34. Leukotriene Modifiers
35. Multiple Sclerosis Agents
36. Nasal Calcitonins
37. Ophthalmic Antihistamines
38. Ophthalmic Glaucoma Agents
39. Ophthalmic Non-Steroidal Anti-Inflammatory Agents
40 Ophthalmic Quinolones
41. Otic Fluoroquinolones

42. Platelet Aggregation Inhibitors
43. Pulmonary Arterial Hypertension Agents - Endothelin Receptor Antagonists
44. Respiratory: Inhaled Anticholinergic Agents
45. Respiratory: Long Acting Beta Adrenergics
46. Respiratory: Short Acting Beta Adrenergic-Inhalers/Nebs
47. Skeletal Muscle Relaxants

Jeff Monaghan stated that there will be no presentation on the drug classes without proposed changes. There has been no new convincing or compelling information in these classes for recommended changes at this time.

Public Comment

Gregg Polacek, Nephron, requested that at the next P&T meeting, generic pediatric strength albuterol be reviewed.

Trisha Williams, Teva Pharmaceuticals, respectfully requested that the Committee re-review the growth hormone class and consider adding Tev-Tropin to the PDL due to new advances. Dr. Karagiozis requested that this class be placed on the agenda for the coming year.

Ms. Lawrence requested that if new information is available, the manufacturers submit to First Health the new clinical information in advance.

Jae Sady, Teva Respiratory, respectfully requested that the Committee re-review the short-acting beta adrenergic class and consider adding ProAir HFA to the PDL because many physicians in Nevada currently use ProAir HFA and it is a low cost alternative. Dr. Karagiozis requested that this class be placed on the agenda for a future meeting.

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

MOTION: Michael Karagiozis motioned to accept First Health's recommendation that there be no changes to the PDL in classes listed as 1 through 47.
SECOND: Justin Holt
VOTES: Unanimous
MOTION CARRIED

XII. Report by FHSC on Brand Name Preferred Drugs Converted to Generic Status and the Extension of Existing Product Lines

Jeff Monaghan referred to the report in the meeting packet and noted that new drugs released but not added to the PDL pending P&T review will be tentatively placed on the September, 2009, agenda.

XIII. Report by FHSC on Botulium Toxin Utilization

Dave Wuest stated that the Committee requested a review of pharmacy claims for Botulium Toxin Type A (Botox) utilization and referred to the report in the meeting binder. The reporting period is 6/1/08 through 5/31/09, and indicates low utilization (five claims for the reporting period). He noted that for the medical claims (physician administered drugs), only the NDCs for medical use (non-cosmetic) are covered.

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

The next meeting is tentatively scheduled for September in Reno.

Darrell Faircloth announced that between now and the next meeting, he will have additional job duties which may or may not change the number of times he participates in this Committee's

meetings adding that he enjoys working with this committee. Gabriel Lither will assist should Mr. Faircloth not be available.

Ms. Flynn stated that it has been a pleasure working with this committee, however, she will be resigning her position on the committee.

XV. Public Comment

Ms. Lawrence thanked the Committee and stated that DHCFP will respectfully acknowledge all nominations submitted for reappointment to this committee.

Ms. Lawrence stated that due to the recent economy changes, there have been increased requests for assistance for people that are not on Medicaid and have no insurance. She asked that if manufacturers offer programs for indigent care, to email her or submit their business card to her indicating indigent care is available and DHCFP will contact her. She will in turn supply contact information to other healthcare agencies throughout the state.

XVI. Adjournment

MOTION: R.D. Prabhu motioned to adjourn the meeting.
SECOND: Justin Holt
VOTES: Unanimous
MOTION CARRIED

Meeting adjourned at 3:07 p.m.