KENNY C. GUINN
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

Location of Meeting
Legislative Building - Room 2135
401 South Carson Street
Carson City, Nevada

Meeting Minutes
July 28, 2005 and October 27, 2005
Time: 1:00 p.m.

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

Absent:
Susan Pintar, MD

Others Present:
Darrell Faircloth DAG, Coleen Lawrence DHCFP, Vickie Langdon DHCFP, Nancy Davis DHCFP, Jeff Monaghan FHSC, Shirley Hunting FHSC, Dawn Daly FHSC, Karen Campbell P&GP, Jennifer Brown Sepracor, Nancy Fairchild Sepracor, Melissa Longstreet-Kay Sepracor, Victor Torrence Alpharma, Ellen McCormick Astra Zeneca, Bruce Martz Boehringer Ingelheim, Michelle Shuffett Boehringer Ingelheim, Susan Fisher Astra Zeneca, Bob Kling Alcon, Braden Lynch Pfizer, Debbie Winter Wyeth, Mike Gastafson Wyeth, Dennis Ryan Pfizer, Debbie Kavanaugh Pfizer, Lisa Wilson J&J, Ann Speiser J&J, Scott Cullins Wyeth, Nicole Materne Pfizer, Jim Seaboldt GSK, Tom Wood Wyeth, Steve Cooper Pfizer, Mylan Hawkins Nevada Diabetes Association, Alan Sloan Purdue, Diane Buckley National Patient Advocate Foundation, Irene Camerino Forest, Brian Carlson Forest, Doug Power Forest, Jay Jennings Sanofi-Aventis, Muein Kootsikas Sanofi-Aventis, Joe Duarte Cephalon, Ron Wilkes Genzyme, Sedrick Spencer Roche, Lucy Maa Roche, Jim Goddard Shire, David Abrahamson Merck, Joann Phillips, Greg Hollen Teamm Pharmaceuticals, Susan Corazzi Merck, Bob Ulmer P&GP, Johnna Nelson Eli Lilly, Laurie Squartsoff Eli Lilly, Kirk Huffaker Schering-Plough, Steve Schaerrer Astra-Zeneca, John Ostezan Lilly, Beck Marsen Eli Lilly, Steve Hill Organon, B. Landrum Reliant, Gil Preston Watson Pharmaceuticals, Bert Jones GSK, Doug Ethel GSK, Dick Knosder Abbott, John Schaeffer, Oscar Johnson 3M, Gerri Steinagel MD, Michael Lucia MD Sierra Pulmonary, Mark Doubraun MD, William Torch MD Washoe Sleep Disorder Center, Katherine Hollingsworth Takeda.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1:03 p.m.

II. Review and Approval of April 28, 2005 meeting Minutes

MOTION: Diana Bond motioned to accept the minutes as written.
SECOND: Larry Pinson
AYES: Bond, Phillips, Britt, Flynn, Pinson, Horne
ABSTAINED: Heard
MOTION CARRIED

III. Public Comment

Tom Wood, Wyeth, asked if this public comment pertained to the next agenda item, "Drug Classes without Proposed Changes".

Dr. Phillips stated that this public comment is informational and does not include comment about any drug classes.

Dr. Phillips requested that Dr. Monaghan give a brief update of the past year's development of the Preferred Drug List (PDL).

Dr. Monaghan stated that the P&T Committee convened in February 2004 to select a PDL for the state of Nevada. This was accomplished in seven meetings with the review of thirty-two drug classes. Relative to other First Health PDL's, the Nevada PDL has been very successful and Dr. Monaghan credited and commended the committee for their efforts.

He reported that in the past six months, the PDL compliance rate was 92%. There are an estimated 2,000 claims for PDL drugs per day generating approximately 18 calls (less than 1%) to the Call Center requesting an exception. After discussion with the Clinical Call Center, 50% of the callers requesting an exception to the PDL agreed to use a drug on the PDL. He stated that this is excellent compared to other states which average 20-30%. He referred to the Nevada Clinical Call Center Report (attached) which details which drug classes are generating the calls.

IV. Drug Classes without Proposed Changes

Dr. Phillips announced that he is changing the order in which the agenda items will be presented. Item IV, "Drug Classes without Proposed Changes", will be moved to the last item of discussion.

V. Analgesics: Long Acting Narcotics

Public Comment

Don Young, Organon, spoke in support of Avinza® to the PDL.

Dr. Phillips clarified that only new information is to be presented.

Drug Class Review Presentation – First Health Services
Dr. Monaghan stated that this drug class was originally scheduled for review due to a new drug being released in this category as well as changes in the National Medicaid Pooling Initiative (NMPI). The new drug, Palladone®, has since been withdrawn from the market and there is no new significant clinical information to present in this class. He recommended the drugs in this class be considered therapeutic alternatives.

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

MOTION: Diana Bond motioned that the agents in this category be considered therapeutic alternatives.
SECOND: Dr. Horne
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Jeff Monaghan stated that DHCFP in conjunction with FHSC is recommending:

1) Avinza® and Oxycontin® be moved to non-preferred status
2) Duragesic® be added to preferred status while applying the clinical edits (attached) proposed by the DUR Board (will not be authorized if oral on long-acting narcotics)

He recommended no more than a 60-day look back to determine previous use if grandfathering is considered.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Heard asked if there are other clinical recommendations for Duragesic®. The National Association of Anesthesiologists made a recommendation for use in only terminal cancer.

Dr. Monaghan stated that the labeling for Duragesic® has been recently strengthened and states use only for persistent pain in people that are opioid-tolerant.

Ms. Bond asked for clarification of the proposed PA criteria, if Duragesic® is moved to preferred, will a PA be required. Dr. Monaghan replied yes, even though preferred, clinical criteria will have to be met.

Dr. Heard asked in order to shorten the process, can criteria be supplied on the prescription or some other means eliminating the need to call for authorization.

Dr. Monaghan stated there are drugs on the preferred list which require the ICD-9 code thereby avoiding a call to the Call Center, but that is not currently in place for Duragesic®.

Dr. Heard asked for clarification between PDL and non-PDL. He felt adding additional administrative requirements for a non-PDL drug helped refine performance on the clinician side and inclusion on the PDL gave relatively easy access to that medication.

Dr. Monaghan stated that there are two components. In most cases, there is ease of access if the drug is on the preferred side. In addition, the State receives a supplemental rebate for preferred drugs.

Dr. Britt stated that the requirements for fentanyl are a trial of a long-acting and not to be combined with a long-acting. She asked if a step-edit would capture that.

Dr. Monaghan replied that the previous criteria included the requirement of a trial of a long-acting but the proposed criteria do not include that condition. The proposed PA requirements are that the patient cannot be managed by lesser means and requires continuous opioid administration.

Ms. Bond asked if it is only for Duragesic® or are fentanyl patches included. He replied both, but the PDL will only include the brand name because of lower net cost to the State.

MOTION: Diana Bond made a motion to approve the recommendations as presented by First Health with Avinza® and Oxycontin® moved to non-preferred status and Duragesic® (fentanyl transdermal patches) be added to the preferred drug list with a notation on the list that prior authorization is required. A 60-day grandfathering will apply for patients currently undergoing therapy.

SECOND: Larry Pinson

Dr. Horne asked if there is any drug on the list that does not require a prior authorization. Dr. Phillips replied that the extended release morphine, Oramorph SR®, and Kadian® do not require a prior authorization.

Dr. Heard felt a cover letter should be included with the next release of the PDL explaining to the clinician that the asterisked items require a prior authorization.

Dr. Horne asked what the advantage is to placing a drug on the preferred list. Dr. Phillips replied that as Dr. Monaghan explained, it helps the State in recognition by the manufacturer of Duragesic® for an enhanced rebate.

Dr. Heard added that it seems that preferred does not exclusively relate to the clinician's perspective. It also relates to administrative function. Preferred is preferred by the purchaser and does not necessarily mean anything administratively for the clinician. That is why we are requesting the asterisk with a footnote to explain that prior authorization is required.

Dr. Monaghan referred the Committee to the Preferred Drug List (attached) which currently includes notations for those drugs that require prior authorization and stated that if this is insufficient, other ways can be considered to highlight it. Dr. Phillips replied that is a technicality for First Health and the State and he is comfortable with that.

AYES: Unanimous
MOTION CARRIED

Dr. Monaghan asked for clarification regarding the grandfathering. Is the expectation that patients are to be converted to a preferred product within 60 days?

Dr. Phillips replied yes, it is a 60 day grandfathering and Ms. Bond added that is the case as long as there is no other justification to authorize them differently.

VI. Antibiotics: Quinolones 2nd Generation

Public Comment
No Comment

Drug Class Review Presentation – First Health Services
Dr. Monaghan stated that there is no new significant clinical information to present in this class and recommended drugs within this class be considered therapeutic alternatives.

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

MOTION: Diana Bond motioned that the drugs in this class be considered therapeutic alternatives.
SECOND: Linda Flynn
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and FHSC that Cipro XR® be moved to non-preferred status based on the NMPI and net cost to the State.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Ms. Bond asked if the ciprofloxacin on the PDL is the generic and he replied yes.

MOTION: Larry Pinson motioned to move Cipro XRÒ to non-preferred status with no other PDL changes to this class of drugs.
SECOND: Judy Britt
AYES: Unanimous
MOTION CARRIED

VII. Antidepressants: Novel

Public Comment

Johnna Nelson, Eli Lilly, spoke in support of Cymbalta®.

Brian Strang, Glaxo SmithKline, spoke in support of Wellbutrin XL®.

John Schaeffer, neurologist, spoke in support of Cymbalta® in the treatment of neuropathic pain. He stated that traditionally, neuropathic pain has been treated with medications not approved for that purpose because there was not one available. He would like to have Cymbalta® available for use in patients with neuropathic pain.

Geri Steingel, MD, spoke in support of Cymbalta®. She stated that in experience with her patients, the medication is easily tolerated, easy to titrate, no withdrawal side-effects, and pulls them out of depression within a couple of weeks. There was also significant improvement in pain for those patients who experienced both pain and depression.

Dr. Heard asked Dr. Steingel if she is sponsored or affiliated with any manufacturer and if that is why she is here today. She responded that she is affiliated with several manufacturers but is not being paid to be here today.

He asked if she is on the speakers' bureau for Cymbalta®. She stated that she is and is also on the speakers' bureau for Glaxo SmithKline, Forrest Pharmaceuticals and Wyeth.

Dr. Heard asked how this is such a unique drug and what are the benefits.

Dr. Steingel replied what is unique about this medication is the pain and depression part. Being a psychiatrist, most of the patients seen have pain and are on other medications. Patients on this drug do not need as much pain medication and sometimes get off pain medication and from a cost standpoint she felt that was huge.

Dr. Heard recognized that she is speaking from anecdotal experience and asked if there is good, substantial literature to support that.

Dr. Steingal replied that what it's approved for from a pain standpoint is for diabetic peripheral neuropathy. Research is now being done for the indication of fibromyalgia and back pain, and anecdotally, her patients have done much better on this medication.

Dr. Horne stated that Cymbalta® has some excellent properties for pain and that other medications which are grouped as novel antidepressants don't have that pain indication or effectiveness.

Tom Wood, Wyeth and Pharma, stated that last year there was a grandfathering issue and therapeutic failure in which you could go to another drug. He asked the Committee to consider reauthorizing that as well as the 90-day look back for Effexor XR®.

Drug Class Review Presentation – First Health Services
Dawn Daly informed the Committee that within the meeting packet are letters of written public testimony for various drugs being reviewed today.

Ms. Daly stated that this class is being reviewed due to the release of the new drug, duloxetine (Cymbalta®). At the 6/17/04 meeting, the motion was made that all drugs in this class were considered therapeutic alternatives with nefazodone and maprotiline being non-preferred.

Ms. Daly presented an overview and comparison of the drugs within this class (attached) and stated that is the recommendation of DHCFP and First Health that duloxetine be considered a therapeutic alternative within the Novel Antidepressant class.

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

MOTION: Dr. Horne motioned that the drugs in this class be considered therapeutic alternatives.
Drs. Pinson and Heard asked Dr. Horne if this motion included CymbaltaÒ and Dr. Horne replied yes.
SECOND: Larry Pinson
Dr. Heard stated that we are looking for unique drugs with unique indications that need to be included otherwise we run the risk of upsetting a sustainable balance. Should we include an addendum that states since Cymbalta® is the only drug in the novel class with neuropathic pain indication or that this is an early research finding and that every one in this class is going to have it. This is a discussion for the Committee more than trying to guess what the science literature will bring out in the future.
Dr. Horne replied that this is the newest one out. The ones that have been tested are gabapentin and pregablin which is about to be approved. None of the others, the Remeron®, Serzone® or Wellbutrin® have the same usefulness.
Dr. Phillips clarified with Dr. Horne that within the class of novel antidepressants that have been reviewed, Cymbalta® is the only one that has shown any pain management for peripheral neuropathy within the field of research.
Dr. Horne replied yes that the other drugs have been around for a relatively long period of time (1985 – 2002).
Dr. Heard asked, if in Dr. Horne's opinion, it's likely there is no literature available that all the drugs in this class have the same benefit for neuropathic pain, so this would constitute a unique characteristic in this drug. Dr. Horne replied yes and asked regarding the ICD-9 code for peripheral neuropathy.

Dr. Phillips stated that the ICD-9 code, 356.9, is a range for peripheral neuropathy not specific to diabetes.
Dr. Heard stated that, at this point, he will not offer an amendment to the motion.
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dawn Daly stated that it is the recommendation of DHCFP and FHSC to maintain the PDL for this class of drugs as it currently is and have Cymbalta® be non-preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Britt expressed concern should the Committee not approve a drug which is approved for a very important indication especially in a disease like diabetes.

Ms. Daly suggested requiring the ICD-9 code and Dr. Britt stated that she would be comfortable with that.

MOTION: Dr. Horne made a motion that the current medications on the preferred list remain on the preferred list, and the current medications on the non-preferred list remain on the non-preferred list. Cymbalta® will be non-preferred, but will be authorized for ICD-9 code, 356.9.
SECOND: Dr. Heard
Following the second, Dr. Horne continued with the motion adding: to extend the grandfathering for one year for patients who have been on an antidepressant for the past year and responding well.
Dr. Heard stated that he is fine with the first part of the motion but the grandfathering for a year was of concern to him.
Ms. Daly stated that the grandfathering for the antidepressants will end September 22nd. At that point, the prescriber will be required to call in for a prior authorization for continued use of a non-preferred drug for another year. If the patient has been responding well on that drug for the past year, they will not be asked to change.
Dr. Heard asked how this will affect the overall call rate and volume of work in the Call Center.
Dr. Monaghan stated that considering the number of patients on those drugs and the number of calls, it's relatively small, and felt the call rate would remain the same.
Dr. Britt asked if First Health has looked at the possibility of doing step-therapy with an electronic edit so calls would not have to be made.
Dr. Monaghan replied that there is a 90-day look back with Effexor® XR and added that 50% of calls for that drug class have resulted in a change to a preferred drug.
Ms. Bond stated that the motion did not include any continuation of the status of Effexor® XR after one failure. Dr. Monaghan suggested that be addressed in a separate motion as it affects all drugs in the class. Dr. Horne accepted this as a

friendly amendment which he withdrew upon Dr. Phillips' clarification that this would be addressed in a separate motion, if necessary.
Ms. Bond asked for clarification of the motion. Did it include grandfathering of all patients who were previously grandfathered for another year.
Dr. Horne replied, yes, that if the patient had been grandfathered for the previous year, they be grandfathered for another year.
Dr. Monaghan stated a look-back in the computer system could be an issue and restated that if they are currently on a non-preferred agent and doing well, approval for another year would require only one phone call to the Call Center.
Dr. Heard asked for clarification on the grandfathering. He felt it would be impractical if not impossible on the administrative side. Grandfathering does not imply how long they've been on the drug but how long we're going to allow the grandfathering of the drug.
Dr. Horne said he would like for those that have been grandfathered for the past year without requiring a prior authorization be allowed to continue without having to get a prior authorization. He did not want any disruption to the patient being maintained on their antidepressant because the pharmacy could not fill the prescription.
Dr. Phillips asked if Dr. Horne would be willing to remove the grandfathering statement from the motion and address it as a separate motion.
Dr. Horne requested a vote be called before he considered removing the grandfathering from the motion.
Darrell Faircloth asked Dr. Heard to clarify his second to the motion as it appeared when made, the second was not inclusive of the grandfathering.
Dr. Heard said that further clarification of what the grandfathering meant relative to what is administratively possible and what has traditionally been the way of grandfathering in drugs, was not the same, and suggested rewording the motion.
Dr. Horne asked First Health if it would be possible administratively to grant another year of grandfathering for the same medication without first requiring the patient to switch and fail on a preferred medication within the class. He also expressed concern that the provider would have no advance notice that the grandfathering has ended and there will be a lapse in the patient receiving the medication they've been receiving.
Ms. Bond said that there is concern about not forcing people in this category to switch medications if they've been well managed and the PDL exception criteria does not apply to this scenario.
Dr. Monaghan stated that criteria can be added stating that at the end of the one year of grandfathering, if the patient is doing well, a change in therapy will not be required. A call to the Call Center will still be necessary at the end of the one year of grandfathering requesting prior authorization for another year. He offered to provide notification to the providers informing them that the one year of grandfathering will be expiring and that authorization to continue therapy will require prior authorization.
Dr. Phillips called for a vote of the motion.
Nayes: Bond, Heard, Phillips, Britt, Flynn, Pinson
AYES: Horne
MOTION NOT CARRIED

MOTION: Dr. Horne motioned to exclude the grandfathering.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

MOTION: Dr. Horne motioned that criteria be added stating that patients who have responded well on an antidepressant for at least a year, will be extended authorization and that providers will be notified that a call for prior authorization is required before the patient is permitted the refill.

Dr. Horne asked Dr. Monaghan to clarify if that is what he stated First Health could do.

Dr. Monaghan responded that a general mailing can be sent announcing that the end of the one year grandfathering period for patients that were on the non-preferred agents when that edit went into effect is upcoming. The medical community can be notified and high prescribers can be identified, but patient-specific information cannot be guaranteed due to the use of the provider "dummy identification number".

Dr. Heard suggested to Dr. Horne that in lieu of a motion and a formal vote, clarification of grandfathering be provided and discussed at the next meeting.

Dr. Monaghan offered to provide the written direction which will be given to the Call Center regarding how to address the requests for grandfathering extension calls and added that the hard edit date for those patients grandfathered is September 22nd.

Dr. Phillips confirmed that this information will be provided to all Committee members and that no second was offered for this motion. The previous approved motion will stand.

VIII. Antidepressants: SSRIs

Public Comment

Brian Carlson, Forrest Pharmaceuticals, spoke in support of Lexapro®.

Brian Strang, Glaxo SmithKline, spoke in support of Paxil® CR.

Dr. Heard asked if there are any changes within this class for pediatric indications. Mr. Strang replied they are not indicated in the pediatric realm.

Dr. Pinson asked Mr. Strang to address the lack of availability of Paxil® CR. Mr. Strang replied that toward the end of April, the consent decree was made between GSK and the FDA and it was determined that there was no safety risk to the public; it was re-launched on June 27th and back on the market.

Braden Lynch, Pfizer, spoke in support of the grandfathering clause and stated that any other restriction in the antidepressant class is probably not the best approach given the fact that the Medicare Modernization Act is going to effect in February and CMS is indicating they want a breadth of antidepressants available in the future.

Dr. Phillips asked if Mr. Lynch is familiar with the Omnicare Formulary and suggested that he familiarize himself with it as it will probably be the template for Part D.

Drug Class Review Presentation – First Health Service
Ms. Daly stated that there is no new significant clinical information to present in this class and it is being presented due to revisions in the NMPI. One of the agents, Celexa®, is now available as a generic. She reminded the Committee that the 7/14/04, motion from the Committee was the agents in this class are therapeutic alternatives and that a pediatric choice be available.

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

MOTION: Dr. Horne motioned that fluoxetine, sertraline, paroxetine, citalopam and escitalopram are therapeutically equivalent and that a pediatric choice be available.
SECOND: Judy Britt
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dawn Daly stated that it is the recommendation of DHCFP and FHSC to move Lexapro® to non-preferred status with grandfathering for one year from the date of the hard edit and move citalopram (Celexa®, now available generically) and Pexeva® to preferred status.

Dr. Heard requested that for the future, drugs be referred to by the generic name.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Dr. Horne motioned that the current medications in this class remain on the preferred list with the exception of Lexapro® to be moved to non-preferred, paroxetine mesalate (PaxilÒ) and citalopram (CelexaÒ) be added to the preferred list.
SECOND: Larry Pinson
AYES: Unanimous
MOTION CARRIED

IX. Antihistamines: 2nd Generation

Public Comment
Kirk Huffaker, Schering-Plough Pharmaceuticals, spoke in support of, Clarinex®. He stated that Clarinex® syrup is now available in the 0.5mg/ml strength and is

the only non-sedating antihistamine with approved dosing down to 6 months of age. Clarinex® Reditabs are now available in the 2.5mg strength.

Drug Class Review Presentation – First Health Services
Dr. Monaghan stated that there is no new significant clinical information to present in this class and recommended drugs within this class be considered therapeutic alternatives. He added that, as Mr. Huffaker stated, Clarinex® syrup is now available in the pediatric strength.

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

MOTION: Diana Bond motioned that the drugs in this class be considered therapeutically equivalent.
SECOND: Larry Pinson
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that at the July, 2004, meeting, Dr. Heard offered a friendly amendment asking that more than one second generation antihistamine be on the preferred drug list. This was a reasonable request at that time, but the result has been a significant financial impact on the State. He stated that it is the recommendation of DHCFP and FHSC to move Allegra® and AllegraD® to non-preferred, and the generic loratadine products be the only preferred second generation antihistamines on the Preferred Drug List. The only exception is Zyrtec® and/or Clarinex® liquid for pediatrics. In terms of a step-edit, he suggested that if there is documented payment history for loratadine in the past 90 days, the PA process could be avoided with the claim processing without a call to the Call Center.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Heard asked if the step-edit would be apparent to the clinician. Dr. Monaghan replied providers can be notified, but it becomes apparent when the pharmacy processes the claim and it pays as opposed to denying for PA required.

Dr. Britt asked if there is a message on the pharmacy side that states if the step-edit isn't met, try loratadine. Dr. Monaghan replied that he did not think the system currently provides those types of messages but will followup.

Ms. Bond asked that if patients have been on the other drugs for the last five or ten years and have failed loratadine, will they be required to try loratadine. Dr. Monaghan replied only if there is no payment history in the past 90 days for loratadine.

MOTION: Diana Bond motioned to accept First Health's recommendations to only include loratadine products on the preferred drug list with a step-edit in place, and have the pediatric formulations of cetirizine (ZyrtecÒ) and desloratadine (ClarinexÒ) available for pediatric use.
SECOND: Judy Britt
AYES: Unanimous
MOTION CARRIED

X. Bone Ossification Agents: Biphosphonates

Public Comment
Karen Campbell, Proctor and Gamble, spoke in support of Actonel®.

David Abramson, Merck, spoke in support of Fosamax®.

Lucy Maa, Roche, spoke in support of Boniva®.

Drug Class Review Presentation – First Health Services
Ms. Daly stated that this class is being reviewed due to the release of the new agents, Boniva® and Fosamax D. She reminded the Committee that at the 2/26/04 meeting, the motion was made that all drugs in this class were considered therapeutic alternatives.

She stated that Fosamax® D is Fosamax 70 with 28 IU's of Vitamin D3 added as a once week tablet. She presented an overview (attached) of the drugs within this class stating that there are no head-to-head trials comparing lbandronate (Boniva®) to alendronate (Fosamax®) or risedronate (Actonel®). It is the recommendation of DHCFP and First Health that lbandronbate (Boniva®) be considered a therapeutic alternative.

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

MOTION: Diana Bond motioned that the class of bisphosphonates be considered therapeutic equivalents as presented.
SECOND: Carl Heard
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Ms. Daly stated that it is the recommendation of DHCFP and FHSC that Fosamax® and Fosamax® D be moved to the preferred list with Boniva® and Actonel® as non-preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Dr. Horne motioned to place Fosamax® and Fosamax® D on the preferred list and move Boniva® and Actonel® to non-preferred status.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

XI. Cardiovascular: Lipotropics

Public Comment
David Abramson, Merck, spoke in support of Vytorin®. Vytorin® is a combination drug combining ezetermibe, a cholesterol absorption inhibitor with a statin, simvastatin.

Dr. Heard asked if there is any reason why these two medications can't be taken separately or is it a combination pill unique in its effect. Mr. Abramson replied that the two medications can be taken separately but the cost would be higher even if using ezetermibe with generic lovastatin. The combination medication is cost-effective.

Debbie Kavanaugh, Pfizer, spoke in support of atorvastatin (Lipitor®).

Dr. Britt asked what the backgrounds were of the patients in the TNT trial. Were patients eliminated if they were over a certain age or had a certain medical burden, like multiple medication problems? Ms. Kavanaugh replied that the cut-off age was 75 and that there was no difference in side-effect profiles in patients over 65. The outcomes were similar in patients over 65 and less than 65. These were secondary prevention patients.

George Osataki, Astra-Zeneca, spoke in support of rosuvastatin (Crestor®).

Drug Class Review Presentation – First Health Services
Dr. Monaghan presented an overview of the new products added to this category. He stated that a new drug entity has been added to this class since the initial review, ezetemibe (Zetia®). When combined with a statin, further LDL reduction can be achieved versus a statin alone. Vytorin® is the combination of ezetemibe and simvastatin. It is the recommendation of DHCFP and FHSC that the previously reviewed products as well as Zetia® and Vytorin® be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in This Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Heard stated when cardiovascular agents were reviewed last year, combination agents were taken into separate consideration and asked if there is an

intention to do that here or is it the whole category regardless of their mechanism of action.

Dr. Monaghan replied that last year's review included Advicor®, which is a combination of lovastatin and niacin. The combinations were addressed last year. Because the combination was an existing agent which was reviewed plus a new agent, we are asking to have it considered.

Ms. Bond asked since it has not yet been reviewed, what is the status of Zetia today if a prescription was written.

Dr. Monaghan replied because it has not been reviewed, there are no restrictions on that drug today.

MOTION: Ms. Bond motioned that the agents in this class including combinations be considered therapeutic alternatives.
SECOND: Carl Heard
AYES: Unanimous
MOTION CARRIED

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

Dr. Monaghan stated that at the July, 2004, meeting, the Committee determined equivalency but they chose to include Lipitor® on the PDL, which was not recommended at that time by First Health. This was based on clinical preferences as well as testimony from respected members of the medical community. First Health and the State are again recommending that Lipitor® be non-preferred. With the availability of Zocor® on the PDL, patients have access to a very effective drug with an excellent safety profile and outcome. For those cases that do not respond to 80mg of Zocor®, Lipitor® in a 40mg or 80mg dose would be available via PA. He referred them to the copy of Dr. Lardinois' email which strongly supports this position. Dr. Lardinois is a Professor of Medicine and Director of Endocrinology at the University of Nevada School of Medicine and gave permission to use this email as public testimony.

DHCFP and First Health are recommending:
-Lipitor® be moved to non-preferred status. If a patient is now on Lipitor® 80mg, he recommended they be grandfathered.
-Crestor is currently on the PDL with a daily dosage limit of 20mg. The FDA has effectively addressed the safety concerns. The recommendation is to leave Crestor 20mg on the PDL.
-Zetia be considered non-preferred. It would be available via PA for patients intolerant of statins.
-Vytorin® be available as a preferred agent for those patients requiring Zetia plus a statin. He suggested deferring to the DUR Board to develop criteria.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Horne asked if the proposal is that those on less then 80mg of Lipitor® be switched.

Dr. Monaghan replied yes and Dr. Phillips added for grandfathering of those that are currently on it, that there will be a 90-day look back in paid claims history.

Dr. Horne asked how the FDA has adequately addressed the safety of Crestor®.

Dr. Britt stated there is overwhelming evidence that the FDA is comfortable with the 40mg and recommended the 40mg strength be added to the preferred list. She recommended step-therapy that there be a trial of the 20mg before moving to the 40mg.

MOTION: Larry Pinson motioned to move Lipitor® to non-preferred status, grandfather Lipitor® 80mg; Crestor remain on the preferred list with step therapy implemented requiring a trial of 20mg before moving to the 40mg strength; place Vytorin on the preferred list and refer to the DUR Board to determine criteria; place Zetia on the non-preferred list.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

XII. Central Nervous System: Sedative, Hypnotics

Public Comment
Dr. William Torch, Neurologist, Medical Director, Washoe Sleep Disorder Center, spoke in support of expanding the availability of non-benzodiazepine medications, primarily Lunesta, Ambien and Sonata. He stated in his experience, Lunesta has been effective in getting people to sleep, maintaining sleep without any psychomotor effects the following day, and no addictive potential has been demonstrated. His greatest experience in is his practice has been with Ambien which has been a very effective medication. He uses all these medications in children as well as adults.

Dr. Heard asked if there's a new indication for chronic use. Dr. Torch replied that there have been studies for use of Lunesta for up to one year without any signs of intolerance in chronic insomnia patients.

Dr. Horne stated that Lunesta is the only one indicated for long-term use.

Dr. Pinson asked is Lunesta use safe in pregnancy and breast milk. Dr. Torch replied that most of these medications like Ambien and Sonata have been approved for women during pregnancy.

Muein Kootsikas, Sanofi-Aventis, spoke in support of Ambien. She stated that the non-benzodiazepines do not have a long-term indication. They are all indicated for the treatment of insomnia.

Dr. Michael Lucia, pulmonary and sleep specialist stated that Lunesta is a novel drug in that it has the long term indication although he has used Ambien and Sonata long-term in many patients for chronic insomnia. Each of these drugs has a different half-life and duration of action which is helpful in a clinical setting. Having one drug fits all does not work in sleep medicine. He stated that he also treats patients for obstructive sleep apnea and they should not be receiving benzodiazepines in that it worsens apnea, increases the risk of arrhythmia as well as worsening hypoxia. These drugs provide a unique alternative to treatment. This class of drugs does not worsen apnea or distort the sleep architecture and improves the quality of sleep. Benzodiazepines make people sleep in a tranquilizer effect but do not restore normal sleep. There is a long safety record with Lunesta and the other two drugs in this class and having all three drugs available to choose from in the management of patients is important.

Dr. Heard asked Dr. Lucia if he could select one drug in the non-benzodiazepine class which he felt had the greatest safety profile, which he would select.

Dr. Lucia replied that all three have equivalent safety profiles in terms of not worsening or potentially causing worsening of obstructive sleep apnea and related disorders because they do not have any type of muscular effect in terms of being a muscle relaxant as with the benzodiazepines. In terms of usage, Ambien has been around for the longest time having been the first drug approved in this class. In terms of studying them specifically used in that population of sleep apnea patients, all three drugs have been looked at with comparable safety. The half-life and duration of action is variable with these drugs.

Melissa Longstreet, Sepracor, spoke in support of Lunesta. She stated that the indication for Lunesta versus the other non-benzodiazepines is that there is a lack of a short-term restriction as well as sleep maintenance listed within the indication.

Drug Class Review Presentation – First Health Services

Ms. Daly stated that this class is being reviewed due to the release of the new agent, Lunesta®. She referenced the *Medical Letter* which states that Lunesta, Ambien and Sonata all appear to be effective and relatively safe. Comparative data are lacking. The main difference between all of them, except for half-life, may be that the manufacturer of Lunesta sponsored a six month trial and submitted the results to the FDA while the other two manufacturers did not. It is the recommendation of DHCFP and First Health that these agents be considered therapeutic alternatives.

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

MOTION: Larry Pinson motioned that all agents in this class be considered therapeutic alternatives.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

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

It is the recommendation of DHCFP and First Health that Lunesta® be non-preferred and the preferred agents remain the same.

Dr. Horne asked how long-term use would be handled if Lunesta is the only one indicated for long-term usage.

Ms. Daly replied that all drugs in this class have been used long-term without that indication and the Lunesta package insert doesn't state long-term use, it states for treatment of insomnia. In addition, if the exception criteria are met, a prior authorization can be obtained for Lunesta.

Ms. Flynn asked if there are clinical edits in place for long-term use. Ms. Daly replied no, that there is a quantity limit of 30 per month in place.

Dr. Horned asked if two agents have to be failed before a non-preferred is authorized and Dr. Phillips replied yes. Dr. Horne asked if Lunesta is the only one indicated for long-term use, how criteria should be specified to get approval for the long-term use of a benzodiazepine.

Dr. Phillips stated that the confusion seems whether there is actually a written long-term indication, meaning 12 months.

Ms. Daly stated that Sepracor submitted Lunesta use to the FDA for the treatment of insomnia for at least six months and she has not seen anything indicating use for a year.

Dr. Phillips asked if Dr. Torch could respond to this and Dr. Torch stated that the PDR recommends shorter term use but it's generally left to the discretion of the physician.

Dr. Heard asked if consideration has been given to sleep apnea and having a non-benzodiazepine available with a diagnosis code on the prescription. He stated the current list does not include a non-benzodiazepine for males. The non-benzodiazepines are only approved for females on the PDL. He felt senior males may have as much falling problems with benzodiazepines as females but more importantly, sleep apnea is seen more in men than in females.

Ms. Daly stated that Ambien and Sonata were added to the PDL for use in pregnancy because all of the benzodiazepines are a category X.

Dr. Phillips said that specific diagnostic groups like obstructive sleep apnea should be taken into consideration.

Dr. Heard pointed out that the PDL is as much to try and encourage appropriate behavior in clinical patient relationships. To have a non-benzodiazepine on the PDL would be important.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Dr. Heard motioned to have a recommendation brought to the Committee which has a non-benzodiazepine available for men and women and will also allow for an exception for obstructive sleep apnea accessed through the PDL.

DHCFP and First Health requested a three minute period to consult.
Ms. Daly requested clarification on the motion for males.
Dr. Heard stated that he would like to see a non-benzodiazepine on the PDL for men and women with no restrictions.
Ms. Daly stated that it is the recommendation of DHCFP and First Health to add Ambien with no restrictions to the Preferred Drug List with the list to otherwise remain the same.
Dr. Heard asked regarding the diagnosis code on the prescription for sleep apnea and Dr. Phillips asked that be referred to the DUR Board for review.

Dr. Heard modified his motion. Ambien will be added to the preferred list with no restrictions and no other changes to the current PDL. Consideration for including a non-benzodiazepine on the PDL with a diagnosis code of obstructive sleep apnea included on the prescription will be referred to the DUR Board for guidance.

SECOND: Dr. Horne
AYES: Unanimous
MOTION CARRIED

Ms. Lawrence requested clarification on what the Committee is asking the DUR Board to review.

Dr. Heard stated that formularies are around for two reasons. One is to manage cost; the other is to encourage proper behavior. At this point, there's nothing to indicate that we are doing anything to encourage proper behavior. We are asking the DUR Board for administrative guidance as to how we are going to encourage proper behavior when it comes to benzodiazepines and non-benzodiazepines in sleep apnea.

Due to the time limitation, Dr. Phillips entertained a continuance of the meeting to address the remaining items on the agenda.

MOTION: Dr. Horne motioned for a continuance of the meeting.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

Dr. Phillips asked the State what the status is on the two open positions on the P&T Committee.

Ms. Lawrence stated that during the last meeting, solicitations were going to be sent for the committee nominations. At the same time, the Governor's office approved and reappointed members. The State will now be soliciting for two positions, a physician and a pharmacist. Letters will be sent to the same associations as before.

Next Meeting
October 27, 2005
12:00 p.m.
Las Vegas

Public Comment
Tom Wood, Wyeth, asked if the continuance will include agenda items XIII, XIV, XV, and IV.

Dr. Phillips stated that is correct.

CONTINUANCE OF JULY 28, 2005 MEETING

Location of Meeting
Las Vegas Library – Multipurpose Room
833 Las Vegas Blvd., North
Las Vegas, NV

October 27, 2005
12:00 p.m.

Committee Members Present:
Steven Phillips, MD, Chairman
Judy Britt, Pharm.D.
Linda Flynn, R.Ph.
Robert Horne, MD
Diana Bond (12:10 p.m.)
Larry Pinson, Pharm.D. (1:05 p.m.)
Carl Heard, MD (called-in)
Susan Pintar, MD (called-in)

Others Present:
Vickie Langdon DHCFP, Carla Sloan Advisory Committee, Gabriel Lither DAG, Jeff Monaghan FHSC, Shirley Hunting FHSC, Dawn Daly FHSC, Roland Baldwin Wyeth, Floyd Schiffer Pfizer, Megan Schroeder Wyeth, Mark Doubrava, MD Eye Care of Nevada, John Vasquez Pfizer, Harry Hewlett King Pharmaceuticals, Doug Ether GSK, Bert Jones GSK, Marv Orrock GSK, Nancy Fairchild Sepracor, Steve Schaerrer Astra Zeneca, Johnna Nelson Eli Lilly, Laurie Squartsoff Eli Lilly, Eric Rowe Eli Lilly, Alan Sloan Purdue, Helga Pizo, MD ECAN, Eric Byrnes Alcon, Chad Clatterbaugh Alcon, Chad Wolf Boehringer, Napesh Singh, MD Pulmonary Associates, Edward Lewis Pfizer, Bruce Martz Boehringer, Kara Smith Cephalon, Sedrick Spencer Roche, Doug Power Forest, Jennifer Brown Sepracor

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 12:05 p.m. He stated that this is a continuance of the meeting held on July 28, 2005, in Carson City.

Dr. Phillips announced at the July meeting that agenda item "Drug Classes without Proposed Changes" was moved to the last item of discussion and this meeting will begin with agenda item III, "Glaucoma Agents-Prostaglandins."

II. Drug Classes without Proposed Changes

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

1. Antibiotics: Cephalosporins 2nd Generation
2. Antibiotics: Cephalosporins 3rd Generation
3. Antibiotics: Macrolides
4. Antibiotics: Quinolones 3rd Generation
5. Antiemetics: Oral, 5-HT3s
6. Antifungals: Onychomycosis Agents
7. Cardiovascular: Ace Inhibitors & Diuretic Combinations
8. Cardiovascular: Angiotensins II Receptor Blockers & Diuretic Combination
9. Cardiovascular: Beta Blockers
10. Cardiovascular: Calcium Channel Blockers & ACEI Combinations
11. Central Nervous System: ADHD/Stimulants/Non-Stimulants
12. Erectile Dysfunction Agents
13. Gastrointestinal Agents: H2RAs
14. Gastrointestinal Agents: PPIs
15. Glaucoma Agents: Beta-Blockers, Alpha adrenergics, Carbonic Anhydrase Inhibitors
16. Hepatitis C Agents
17. Herpetic Antiviral Agents
18 Leukotriene Modifiers
19. Respiratory: Glucocorticoids, Inhalers
20. Respiratory: Glucocorticoids, Nasal
21. Glaucoma Agents-Prostaglandins

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

Dr. Phillips stated that public comment for items 1-22 will all be taken at one time.

Public Comment

Jennifer Brown, Sepracor, spoke in support of Xopenex® nebulizer solution. She stated that in the short-acting bronchodilator class, new strategies that other states are employing provide access to bronchodilators without restrictions. This is due to recent publicized deaths which are controversial due to restrictions in this class. Patients are being discharged from the hospital many times with a prescription. The two viable options in this class are albuterol and levalbuterol (Xopenex®). Emergency room physicians don't know what is on the Nevada Medicaid PDL. The physician writes for Xopenex®, the patient goes to a pharmacy on a Friday night, and they get a denial. There are options in place to provide access: prior authorization, step-therapy, grandfathering and the 72-hour clause. In each of these cases, prior authorization is not a viable option in this class due to the fact that there are potentially severe health consequences if the patient doesn't get access. Nevada provides a 24-hour response time to a PA, but many times the physician is not there to accept the phone call or approve a prior authorization. The 72-hour supply does not work in Nevada. Typically, the pharmacy tech gets the call and does not know the 72-hour clause and denies the prescription or pharmacists are cynical of the 72-hour fill because they think they will not get paid. Xopenex® comes in sleeves of 12 and many times pharmacists won't break that sleeve to provide the 72-hour clause. What states like Tennessee and Mississippi have done is provide access to Xopenex® through a 2-3 prescription fill per patient per year. By opening access, you're not going to be causing the patient or the state additional financial burden.

Dr. Heard stated that the major rationale being offered here is because of administrative non-performance by the pharmacy. He felt that modification of the PDL should not be based on inability of the pharmacist to perform according to standards and Dr. Phillips agreed.

Roland Baldwin, Wyeth, read written testimony on behalf of Raj Chanderraj, M.D., cardiologist, who was not able to attend. Dr. Raj supported the placement of Altace® to the PDL for patients who fit the HOPE criteria stating that: 1) the HOPE trial has shown proven evidence of a decrease in cardiovascular death, stroke and myocardial infarction for patients already at risk for a cardiovascular event; 2) Altace® appears to have unique properties that have proven outcomes and are not a shared "class effect" and is the only tissue ACE inhibitor that has proven results; 3) many patients are on multiple medications and/or at risk for additional cardiovascular events and requested consideration be given for having Altace® available with no prior authorization process.

Helga Pizio, MD, ophthalmologist stated that the PDL includes Travatan® and Lumigan® and currently that is working very well and believes there should be two choices of prostaglandins for patients. Typically with her glaucoma patients,

Travatan® or Xalatan® is started and if there is additional pressure lowering effect needed, she treats with Lumigan®. As a first line treatment, her patients have experienced additional side effects with Lumigan® such as hyperemia. A study by (study name not stated clearly) shows Travatan® can lower the pressure up to 84 hours post-dose and that is not seen in Xalatan® or Lumigan®. She feels it's important to have several choices of prostaglandins including Travatan®, Xalatan® and Lumigan®.

Dr. Britt asked how many patients were involved in the study and Dr. Pizio stated that she did not know.

Floyd Schiffer, Pfizer, read written testimony on behalf of Mark Doubrava, MD, ophthalmologist who was in attendance but had to leave. Dr. Doubrava states in his letter that he supports the inclusion of Xalatan® to the PDL, is not a paid consultant for Pfizer and does not receive any funds or monies from Pfizer. Dr. Doubrava feels the three prostaglandins are not equivalent and that Xalatan® is the only prostaglandin used to lower intraocular pressure that has FDA approval for first line therapy and is reported to have less hyperemia. Less hyperemia means fewer phone calls to his office and less costly office visits to evaluate "red eye". He states that all prostaglandins are equally efficacious in lowering intraocular pressure but are not therapeutically equivalent when looking at side effect profiles combined with patient compliance and long-term use and feels Xalatan® is more efficacious in a clinical setting.

Steven Schaerrer, Astra Zeneca, stated that since the Committee last met, there is a new indication for Atacand®. Atacand® is indicated in the treatment of heart failure in class II-IV in patients with left ventricular systolic dysfunction (ejection fraction <40%) to reduce cardiovascular death and to reduce heart failure hospitalizations. Atacand® has an added effect on these outcomes when used with an ACE inhibitor and it's the only once-a-day agent within this class that can be used for heart failure.

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

Dr. Horne referred to Dr. Doubrava's testimony for re-adding Xalatan® to the PDL and asked for Committee consideration.

Dr. Heard asked for a definition of therapeutic equivalence. He felt it did not include acceptable and commonly understood side effect of medication but only applied to medications when used as prescribed which will have roughly the same therapeutic outcome.

Dr. Monaghan stated that he does not have a copy of the definition with him, but the Committee agreed to use the AMA's definition which states that drugs when used for a certain diagnosis or condition, and that when used in equipotent doses can be considered therapeutic alternatives. The definition assumes there is not a significant side effect which would preclude a drug's use.

Dr. Heard said as he recalls, the definition does not define a specific variation of an accepted margin of side effect and felt that Xalatan® could be accepted as a therapeutic equivalent in its class because the only distinction offered thus far is one side effect. The letter from Dr. Doubrava indicates the therapeutic outcome of those medications was equivalent; it was simply a matter of side effect and imposition on his staff that he was requesting the inclusion.

MOTION: Dr. Horne motioned that drug classes without proposed changes be maintained as presented.
SECOND: Bond
VOTES: Unanimous
MOTION CARRIED

III. Glaucoma Agents-Prostaglandins

Drug Class Review Presentation – First Health Services
Jeff Monaghan stated that since the posting of this item as a proposed change, First Health, at this time, is not recommending any changes. There are currently two prostaglandin agents in this category on the PDL, Lumigan® and Travatan®.

Dr. Phillips stated that since there is no recommended change, this item will be added to Item II.A. as number 21. Public comment will be taken when Item II is open for discussion.

IV. Respiratory: Anticholinergic Agents, Inhaled

Public Comment
Chad Wolfe, Boehringer-Ingelheim, spoke is support of Spiriva®. He stated that Spiriva® is the only once daily inhaled anticholinergic indicated for long term maintenance treatment in bronchospasms associated with COPD, provides greater improvement than either ipratropium or albuterol (which was verified in a head-to-head trial using Spiriva® once daily versus albuterol twice daily), and improves lung function, exercise tolerance and decreases hospitalization secondary to exacerbation.

Napesh Singh, MD, pulmonologist spoke in support of Spiriva®. He stated that it is his opinion that this is a superior product and not an equivalent product because there is a residual affect that none of the other bronchodilators have. As a result, there is less dyspnea and better quality of life. Patients who have been given samples and empiric doses have a 70-80% success rate and favorable response rate as compared to the older product, ipratropium.

Dr. Phillips asked if Dr. Singh is on the speakers' bureau for Boehringer-Ingleheim or Pfizer and if he does funded research for them. He replied that he is on the speakers' bureau but does no research for these companies.

Dr. Britt asked Dr. Singh if from his experience with his patients using Spiriva®, are they using less of the short-acting beta-adrenergics throughout the day as

compared to when they use ipratropium throughout the day. He replied yes that they are using less short-acting bronchodilators of both the anticholingeric and the beta-adrenergic.

Drug Class Review Presentation – First Health Services
Dawn Daly noted that on the handout, ipratropium nebs was inadvertently omitted and should be listed under the Preferred Drugs column. She said at the 10/28/04, meeting, the motion was made that agents in this category were considered therapeutically equivalent. At that time, Spiriva® was a new product and the Committee requested the drug be revisited during the annual review when more studies may be available. She stated that there are no significant changes and recommended the drugs in this class be considered therapeutically equivalent.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in This Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Horne felt the drugs in this class are not equivalent but are alternatives.

Dr. Britt stated that the literature she has read comparing titropium (Spiriva®) to short-acting ipratropium and long-acting salmeterol, showed favorable outcomes not necessarily in the progression of the disease but in symptom management. She stated that patients in her clinic on Spiriva® do better.

MOTION: Diana Bond motioned that as a class of anticholinergics, there is an equivalency though SpirivaÒ has a documented enhancement in overall symptom management with the noted reduction in use of some rescue therapies.
SECOND: Linda Flynn
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Ms. Daly stated that it is the recommendation of DHCFP and First Health to add Spiriva® to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Dr. Horne made a motion that SpirivaÒ be added to the PDL.
SECOND: Diana Bond
VOTES: Unanimous
MOTION CARRIED

V. Respiratory Agents: Beta-Adrenergic Agents, Long-Acting Inhaled

Public Comment
Bert Jones, GlaxoSmith Kline, spoke in support of the Serevent Diskus® stating that asthma continues to be a problem and that data from the Asthma and America Study confirms that. He introduced Doug Ether, GlaxoSmithKline, to address adherence issues. Dr. Ether provided a demonstration on the Foradil® aerolizer inhaler. He stated the Foradil® aerolizer requires removing the capsule from a foil pack and placing it in the chamber to pierce for inhalation and felt it could be of concern considering the age and population of COPD patients. He demonstrated the Serevent Diskus® (open it, click, inhale, close the diskus).

Drug Class Review Presentation – First Health Services
Dr. Monaghan stated that, at this time, there is no new clinical information to present.

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

MOTION: Diana Bond motioned to maintain the equivalency status of the products in this class.
SECOND: Dr. Horne
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that Serevent Diskus® remain on the PDL and Foradil® be added to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Diana Bond motioned to add Foradil® to the Preferred Drug List and that Serevent® remains on the PDL.
SECOND: Judy Britt
VOTES: Unanimous
MOTION CARRIED

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

Drug Class Review Presentation – First Health Services
Dr. Monaghan stated that the new product anticipated to be released was not therefore First Health is currently not recommending any changes to this category.

Dr. Phillips stated that since there is no recommended change, this item will be added to Item II.A. as number 22. Public comment will be taken when Item II is open for discussion.

VII. Presentation on the Continuation of the Grandfathering Policy for Antidepressants by First Health Services

Jeff Monaghan stated that at the July 28, 2005, meeting, the Committee requested clarification of the grandfathering process be presented at this meeting (attached). He reminded the Committee that grandfathering has been applied to antidepressants, ADHD agents, Hepatitis C agents and Coreg® (beta-blocker). Antidepressant grandfathering was scheduled to expire on September 22, 2005. DHCFP, in conjunction with First Health, is proposing that this date be extended to January 17, 2006, to coincide with the implementation of the annual PDL revisions which were enacted upon in July as well as this meeting. On that date, clinicians will be required to contact the Clinical Call Center to request prior authorization on the non-preferred antidepressants. If a patient is well maintained, authorization for a year will be given for the non-preferred agent.

Dr. Horne asked how many patients are affected that a physician would have to make a call by January 17th. Dr. Monaghan replied that the system does not allow for that type of patient-specific information, but in August, for instance, there were approximately 1,000 claims for non-preferred antidepressants. He felt the number of patients grandfathered is not that large and Dr. Horne agreed. Dr. Horne asked if the number is fairly small, why we would ask those physicians to call in if we agree that the patient is doing well and the grandfathering is going to be extended for another year. Why don't we just extend it?

Dr. Phillips asked if First Health has the ability to determine which are on PA's because of failures and Ms. Daly replied that the system cannot. Dr. Phillips stated that grandfathering is not meant to be forever and agreed with Dr. Monaghan that it has to have a beginning and an end.

Dr. Horne suggested that what needs to be looked at is the number of patients whose authorizations expire on 9/22/05, and extend it to January. Can't this be determined in the system by the date the authorization is to end? After a patient has received a prior authorization for a year, what are the criteria under which it will be extended? This is not addressed in what is being presented here.

Dr. Phillips stated that after conferring with Mr. Lither, DAG, what needs to be acted upon today, after public comment, is what is being proposed by First Health. If that fails, the item will be brought back at another time.

Public Comment

Johnna Nelson, Eli Lilly, spoke in support of Cymbalta®. She stated that despite a number of treatment options available for depression, research continues to bear out that patients still do not get the adequate therapy based on duration and that's where grandfathering can help. Some recommendations state that the duration depends on the number of episodes. Because depression is not an acute disorder, and the recommendations for maintenance treatment can go into a year or more,

grandfathering for patients on Cymbalta® for a year would be ideal and crucial in providing continuity of care for those patients.

Committee Discussion and Action on Continuation of Grandfathering for Antidepressant Medications

Dr. Heard stated that his encountering of this term in other environments such as grandfathering for family physicians relative to their board status or grandfathering of a house previously constructed that has a waiver to a certain regulation are not limited in their length of time that they are approved. The concept of putting a deadline on grandfathering is counter intuitive to the previous things he's encountered. Dr. Horne agreed.

Dr. Monaghan stated that this is a program policy decision. In conferring with Vickie Langdon, DHCFP, the State's direction is that grandfathering has a beginning and an end date.

Dr. Britt stated that in the pharmaceutical industry there is definitely a beginning and an end date. Rebates are driven by the amount of time they are grandfathered and it's usually a 60 day grandfathering.

Dr. Phillips stated that his preference is to have the DUR Board resolve this issue.

Dr. Heard said that it seems that we are not giving a grandfathering exclusion but saying there's an automatic exception to the PDL and saying that the automatic exception expires at a certain time. He felt this isn't a DUR Board consideration since the P&T Committee is to consider the clinical effects of these decisions. He suggested that there may be two categories to consider from a clinical perspective. One is the patient is dependent on a medication; has been through a variety of attempts to prove that and now has a life-long need for a medication (certain bipolar or antidepressant medications could be considered in this category). We are grandfathering for them long enough to complete their current course of therapy so we can do a trial off the medications, and if there's a need to go back on them, they are required to go back through the PDL and other exceptions as we set up them up. Maybe we can use the pharmaceutical term, grand fathering, for the time-limited exceptions, but there may be need for a non-time limited exception.

Dr. Phillips disagreed stating that there is PDL exception criteria which the Committee agreed to on all five points. First Health has proposed and their process clearly states that on an annual basis, if someone continues to need that PDL exception or prior authorization, it will be granted. Ms. Bond added that the PA process is a consistent process and a process used in the industry and the Committee is better off following the standard.

Dr. Heard suggested that the definition for grandfathering as proposed by First Health be approved and ask First Health to consider and bring back to the next meeting, a possible permanent waiver to the medication exception process for certain life-long key cases. He asked if there is interest among any other members to pursue this as a matter of comparison. One is grandfathering in the

pharmaceutical sense that has a start and end date and the other is considering patients that may need a life-long grandfathering.

Dr. Phillips requested that Dr. Heard offer his suggestion as two separate motions and Dr. Heard stated he is not offering a motion but asking for other thoughts or suggestions.

MOTION: Dr. Horne motioned that if a patient has been maintained on a non-preferred agent, either due to grandfathering or having obtained a PA due to failure, the physician can call and request an extension of the PA.

SECOND: Dr. Heard made a second to the motion and to bring back to the next meeting the second consideration for life-long grandfathering.

Dr. Phillips requested clarification on the motion stating that is what First Health is proposing and is Dr. Horne making the motion to accept First Health's proposal as presented? Dr. Horne stated his motion is to make it more general and delete the word "grandfather" and state "well maintained on the agent".

Dr. Heard stated that it was his understanding that the motion was to approve the document as presented and he withdrew his second.

Dr. Horne withdrew his motion and restated it.

MOTION: Dr. Horne motioned to accept First Health's proposal on grandfathering as presented.

SECOND: Dr. Heard

Dr. Pintar asked for clarification on the phrase "continuous payment history". Dr. Monaghan replied that it indicates that the patient has been receiving the medication continuously during the twelve month period.

VOTES: Unanimous

MOTION CARRIED

Dr. Heard requested First Health consider a life-long exception to the PDL for certain key cases in an effort to avoid building in an administrative hurdle that will have to be crossed in many years to come. Dr. Heard stated that he is available to discuss and help develop this idea with First Health staff prior to the next meeting.

Dr. Horne asked if a patient has obtained a prior authorization for an antidepressant because they failed a preferred agent, after one year they must be taken off of that drug. Dr. Monaghan replied no, there is no annual failure requirement.

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

Dr. Monaghan presented proposed dates and time for the 2006 meetings.

MOTION: Dr. Horne motioned to change the January meeting to Las Vegas because of possible inclement weather conditions in Reno and that due to his unavailability, the April 27th the meeting be moved to April 20th in northern Nevada.

SECOND: **No second was offered.**
MOTION: **Dr. Pinson motioned to accept the 2006 P&T meeting scheduled as presented.**
SECOND: **Dr. Britt**
AYES: **Pinson, Bond, Flynn, Britt, Phillips, Heard, Pintar**
ABSTAIN: **Horne**
MOTION CARRIED

Dr. Monaghan asked if the Committee preferred the start time of the meeting to be noon or 1:00 p.m. The Committee preferred a 1:00 p.m. start time and requested a Reno versus Carson City location be explored for the northern Nevada location because of flight arrangements.

IX. Public Comment

No public comment.

X. Adjournment

MOTION: **Judy Britt motioned for adjournment.**
SECOND: **Diana Bond**
Meeting adjourned at 1:25 pm.