MINUTES OF THE APRIL 10, 2007 PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Michael O'Dell, M.D., Vice Chair; Jeff Jones, R.Ph.; Steve Roark; Jennifer Gholson, M.D.; Pearl Wales, Pharm.D.; Garry McFerrin, R.Ph.; Deborah King, F.N.P.; Robert Lomenick, R.Ph.; John Cook, M.D.; Robert Smith, M.D.; Manisha Sethi, M.D.; Phyllis Williams, Deputy Administrator of Health Services, MS DOM; Judith Clark, Pharmacy Bureau Director, MS DOM; Terry Kirby, R.Ph., MS DOM; Paige Clayton, Pharm.D., MS DOM; Dennis Smith, R.Ph., HID.

Members Absent: Larry Calvert, R.Ph.

In Chairman Calvert's absence, Vice Chair Michael O'Dell called the meeting to order at 1:00pm.

Introductions: Judith Clark began by welcoming attendees to the meeting. Ms. Clark expressed appreciation to the committee members for their service. She briefly explained the purpose of the P & T Committee. Ms. Clark announced staffing changes at the Division of Medicaid. She introduced Phyllis Williams, new Deputy Director of Health Services and Paige Black Clayton, new pharmacist with the Pharmacy Bureau. Ms. Clark continued by introducing Pharmacy Bureau staff members, Vicky Donaho, Gay Gipson, Ella Holmes, and Terri Kirby. Ms. Clark invited Ms. Williams to make comments.

Ms. Williams thanked the committee for their participation and gave a brief outline of her service to the Division of Medicaid prior to her assuming her current role. She explained that there would be no changes in the pharmacy program due to the legislative session. She went on to explain that changes to the PDL would only take place in July and January. Everything reviewed in January and April will become effective July 1, and everything reviewed in July and October will become effective in January.

Administrative Business: Ms. Clark asked everyone to sign in if they had not previously done so. She reminded the committee and guests that the meeting room must be left clean and that no food or drinks are allowed. She asked that all cell phones, pagers and PDAs be silenced or turned off during the meeting. She also requested that guests leave the room only during breaks so as to minimize noise and distractions. Ms. Clark reviewed the safety exits for the meeting room and for the building. She explained that the meeting room is limited to a maximum capacity of 90 persons and that at no time would more than 90 be allowed to remain in the room due to state fire regulations. Ms. Clark called committee members' attention to the packet at their seats. She instructed members to fill out travel vouchers and return them before leaving the meeting. She also called attention to the ballots and reviewed some of the new formatting regarding price of drugs. Ms. Clark reminded members that the meeting was being audio taped to facilitate the

recording of the meeting minutes. Ms. Clark also added that information regarding the recall of Zelnorm was included in the meeting packets.

Approval of Minutes: Vice Chair, Dr. Michael O'Dell, asked if there were additions, changes or deletions to the minutes of the last meeting. None were brought to the attention of the committee. Mr. Lomenick made a motion to accept the minutes as presented. Mr. Jones offered a second to the motion. Dr. O'Dell asked for a voice vote to approve the minutes. A voice vote carried unanimously. Ms. Clark reminded the committee that the minutes of the meeting would be posted to the web within 30 days of the meeting, or on or before May 10. She stated that there is no requirement that the Executive Director act on the committee's recommendation within 30 days.

Administrative Business: Ms. Clark asked Paige Clayton to provide a DUR update. Ms. Clayton stated that at the last P & T meeting, the committee asked that the DUR board review Soma and make a recommendation. They recommended the first step be academic detailing using a prescribing update and tapering schedule. Ms. Clayton asked Dennis Smith, HID, to further explain the academic detailing program. Mr. Smith explained that the academic detailers are trained in Pharmacy Bureau policies and procedures. He stated that they call on physicians and recently have begun to call on pharmacies. He explained that the detailers are responsible for their own geographic territory.

Mr. Lomenick commented that he commends HID in including pharmacies in the detailing efforts. Ms. Clark added that another initiative recently put in place, was that ACS added a pharmacist, Lauren Wrighton. Ms. Wrighton calls on pharmacies to address claims issues.

Ms. Clark announced that starting at today's meeting, advocates would be given two minutes to speak. She stated that policies and procedures for those speakers and their comments should be in place for the July meeting.

Two advocate speakers addressed the committee: Dr. Ronnie Kent on behalf of the Center for Education Excellence, and Dr. Marshall Bouldin on behalf of Delta Diabetes Alliance.

Therapeutic Category Reviews: Dennis Smith, R.Ph., of Health Information Designs, Inc., (HID), moderated the therapeutic class reviews.

<u>NUCLEOSIDE AND NUCLEOTIDE ANTIVIRAL AGENTS (ORAL</u> <u>ANTIVIRALS) (ANNUAL REVIEW)</u>

Mr. Smith noted that the review of the oral antiviral agents is being revisited after the class was tabled at the January meeting. After directing the committee members to page 9 of the meeting packet, Mr. Smith began the review of the Oral Antiviral category by summarizing HID's recommendations as follows: HID recommends generic acyclovir, Hepsera, ganciclovir, Ribavirin, valacyclovir (Valtrex), and valganciclovir (Valcyte) for preferred status. Famvir is not recommended for preferred status. Mr. Smith stated that

this recommendation is consistent with HID's recommendation at the January P & T meeting.

One speaker addressed the committee: Richard Prejean, Famvir, Novartis.

Dr. O'Dell asked if there were any questions regarding the antivirals. There were none.

Dr. O'Dell asked for a motion regarding HID's recommendation. Mr. Jones made a motion to accept HID's recommendation as presented. Ms. King offered a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

ACE INHIBITORS (ANNUAL REVIEW)

Mr. Smith referred committee members to the recommendations portion of the ACE Inhibitor review on pages 18 and 19 of the meeting packet. He noted that the class is heavily generic and summarized HID's recommendations by stating that HID recommends all available generics and Altace for preferred status. HID does not recommend Aceon for preferred status.

There were no speakers for the ACE Inhibitor class of products.

Dr. O'Dell asked for questions or comments from committee members. There were none.

Dr. O'Dell asked for a motion on HID's recommendation. Dr. Smith made a motion to accept the recommendation as presented. The motion was seconded by Dr. Cook. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

ANGIOTENSIN II RECEPTOR ANTAGONISTS (ANNUAL REVIEW)

Mr. Smith directed the committee members' attention to the Angiotensin II Receptor Antagonists Review on page 28 of the meeting manual. He stated that this is an annual review. Mr. Smith summarized HID's recommendation as follows: HID recommends for preferred status: valsartan (Diovan and Diovan HCT) and irbesartan (Avapro and the combination product Avalide). HID recommends that the following products remain nonpreferred: Teveten, Cozaar, Benicar, Micardis and Atacand, along with all their corresponding HCTZ combination products. Several industry speakers were heard by the committee: Dr. Harish Madnani, Benicar, Forest Pharma/Sankyo; Julia Compton, Diovan, Novartis; Vicky Star, M.D., Cozaar, Merck; Tina Dancer, Avapro, BMS; Derek Terada, Micardis, Boehringer Ingelheim.

Dr. O'Dell asked the committee for any questions, comments or discussion regarding HID's recommendations. Discussion followed regarding the addition of telmisartan, losartan, olmesartan to the PDL There was also discussion regarding supplemental rebates for these products.

Dr. O'Dell asked for a motion from the committee. Dr. Smith made a motion to accept HID's recommendation with the addition of telmisartan, losartan, and olmesartan. Mr. Jones offered a second to that motion. Dr. O'Dell asked members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Cozaar/Hyzaar, Benicar/Benicar/HCT, Micardis/Micardis HCT: 11 votes

BETA-ADRENERGIC BLOCKING AGENTS/BETA BLOCKERS (ANNUAL <u>REVIEW)</u>

Mr. Smith referred the committee members to the beta blocker recommendations on page 38 of the meeting manual. He summarized HID's recommendations by stating that HID recommends all generically available beta blockers and beta blocker/diuretic combinations. HID also recommends Coreg, Coreg CR and Toprol XL.

Dr. O'Dell asked the committee for questions, comments or discussion regarding the Beta Blockers. There was no further discussion.

One industry speaker addressed the committee: Dr. Richard Galloway, Coreg, Hattiesburg Clinic PA.

Dr. O'Dell asked for a motion regarding HID's recommendation. Mr. Jones made a motion to accept the recommendation as presented. The motion was seconded by Dr. Wales. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

CALCIUM CHANNEL BLOCKERS (ANNUAL REVIEW)

Mr. Smith announced that HID's recommendation for the calcium channel blockers was quite straightforward. HID recommends no changes to the PDL for this class. The current preferred agents are Norvasc, diltiazem, nicardipine, nifedipine and verapamil.

A discussion followed regarding generics that are more expensive than their brand products.

One speaker was heard: Dr. John Edwards, Sular, Sciele Pharma, Inc..

Dr. O'Dell asked the committee for further questions and discussion.

Dr. O'Dell asked for a motion on HID's recommendation. Dr. Gholson made a motion to accept HID's recommendation as presented. Mr. Lomenick offered a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

DIURETICS (ANNUAL REVIEW)

Mr. Smith began the presentation of the diuretic class by stating that HID recommends no changes in this class. The current preferred products are amiloride, bumetanide, chlorothiazide, chlorothialidone, furosemide, hydrochlorothiazide, indapamide, methyclothiazide, metolazone, torsemide and triamterene.

Dr. O'Dell asked the committee for questions, comments or discussion regarding the diuretic recommendations. There was no discussion.

No speakers were present for the diuretic class of agents.

Dr. O'Dell asked for a motion to accept HID's recommendation as presented. Dr. Wales made a motion to accept HID's recommendation as presented. Dr. Cook gave a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

MINERALOCORTICOID (ALDOSTERONE) RECEPTOR ANTAGONISTS (ANNUAL REVIEW)

Mr. Smith began his presentation by stating that there are only two agents in the class. HID recommends spironolactone (generically available) for preferred status and Inspra (eplerenone) for non-preferred status.

There were no speakers for the aldosterone receptor antagonist class.

Dr. O'Dell asked the committee for questions, comments or discussion regarding HID's recommendation. There was no discussion.

Dr. O'Dell asked for a motion to accept HID's recommendation as presented. Mr. Roark made a motion to accept HID's recommendation as presented and Dr Sethi seconded the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

COMBINATION HYPERTENSION AGENTS/PRIMARY THERAPEUTIC CLASS A4K/ACE INHIBITORS/CALCIUM-CHANNEL BLOCKER COMBINATION (ANNUAL REVIEW)

Mr. Smith began the review of the combination hypertension agents by calling the members' attention to the recommendations on page 81 of the meeting packet. He noted that there are three brand products available in the class: Lexxel, Lotrel and Tarka. These agents are currently preferred and HID recommends that these products be made non-preferred. JNC 7 guidelines do not support first line use of these agents.

No speakers were present for this class of agents.

There was discussion of HID's recommendation and the desire to have combination agents readily available.

Dr. O'Dell asked for a motion on HID's recommendation. Mr. Jones made a motion to recommend Lotrel for preferred status. Ms. King offered a second to the motion. Dr. O'Dell asked committee member to mark ballots.

Committee vote: 11 votes cast Accept HID's recommendations with the addition of Lotrel: 11 votes

ALISKIREN – TEKTURNA

Mr. Smith presented HID's recommendation by stating the following: Tekturna is a novel agent in the antihypertensive class. It is the first agent that directly inhibits renin. Its properties provide effective inhibition of additional renin, angiotensin I, and angiotensin II production as a result of the negative feedback loop. These actions lead to effective lowering of blood pressure. Tekturna is effective as monotherapy and in combination with hydrochlorothiazide, ARBs and amlodipine. Currently, Tekturna is only indicated for hypertension. ACE inhibitors and ARBs, as well as other antihypertensive agents,

treat hypertension and have proven outcomes. Results from outcome studies involving Tekturna are still pending. Until these results are known, Tekturna is not recommended as a preferred agent.

One industry speaker was heard: Julia Compton, Tekturna, Novartis.

Dr. O'Dell asked the committee for questions, comments or discussion. Discussion followed pertaining to the length of time a drug needs to be on the market before it is placed on the PDL.

Dr. O'Dell asked the committee to make a motion regarding the recommendation. Mr. Roark made a motion to accept HID's recommendation as presented. Dr. Smith offered a second to the motion. Dr. O'Dell asked committee members to mark ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

AMLODIPINE/ATORVASTATIN-CADUET M4I PRIMARY THERAPEUTIC CLASS (ANNUAL REVIEW)

Mr. Smith began by stating that only one agent exists in this class, Caduet. He explained that Caduet is a very unique agent in that it combines a calcium channel blocker with a statin. This agent is currently on the PDL. Mr. Smith stated that HID recommends changing Caduet from preferred to non-preferred status. To further explain, Mr. Smith noted that a calcium channel blocker is not recommended as a first line agent in treatment according to JNC 7 guidelines.

No speakers for Caduet were present.

Dr. O'Dell asked for a motion regarding HID's recommendation. Mr. Lomenick made a motion to reject HID's recommendation, thereby keeping Caduet on the PDL as a preferred agent. Ms. King offered a second to the motion. Dr. O'Dell asked committee members to mark ballots.

Committee vote: 11 votes cast Accept HID's recommendations with the addition of Caduet: 11 votes

PLATELET AGGREGATION INHIBITORS (ANNUAL REVIEW)

Mr. Smith summarized the recommendations for the platelet aggregation inhibitors by stating the following: HID recommends aspirin as a preferred product and Aggrenox and Plavix as non-preferred products. He elaborated by explaining that aspirin/dipyridamole

combination product combines two generically available products although in different strengths that are not available individually. One study presented last year suggests that the combination is more effective than the component therapy. However, other products are available and considered preferred therapeutically for reducing the risk of stroke. Dipyridamole is not recommended by the Beers criteria due to safety concerns. Studies on the adverse reactions listed in the manufacturer labeling do not indicate that there is a benefit over aspirin with respect to safety. Regarding clopidogrel, or Plavix, outcomes are clear with this agent and its place in therapy. Questions on cost effectiveness remain conclusively unanswered. Utilization data shows that this is one of the most prescribed agents monthly, leading to questions of overutilization when compared to claims of aspirin. In addition, a recent report from the New England Journal of Medicine in 2006 concluded that the combination of aspirin and clopidogrel is not superior, significantly, to aspirin alone in reducing the rate of myocardial infarction, stroke or death from cardiovascular causes.

Two industry speakers addressed the committee: Tina Dancer, Plavix, BMS; Derek Terada, Aggrenox, Boehringer Ingelheim.

Dr. O'Dell asked the committee for questions, comments or discussion regarding HID's recommendations. There was no discussion.

Dr. O'Dell asked for a motion regarding the recommendation. Dr. Smith made a motion to accept HID's recommendation, with the addition of Plavix and Aggrenox. Jeff Jones offered a second to the motion. Dr. O'Dell asked the committee to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Plavix and Aggrenox: 11 votes

A brief recess was taken.

ANTIDIABETIC AGENTS (ANNUAL REVIEW)

Mr. Smith called the committee's attention to the recommendations page of the Antidiabetic Agents review on page 122 of the meeting manual. HID recommends the following products for preferred status: acetohexamide, chlorpropamide, glimepiride, glipizide, glipizide/metformin, glyburide, glyburide/metformin, metformin, pioglitazone (Actos), pioglitazone/metformin (Actoplus met), pioglitazone/glimepiride (Duetact), rosiglitazone (Avandia), rosiglitazone (Avandamet), tolazamide, tolbutamide and insulins (injectable). HID recommends the following products be non-preferred: acarbose (Precose), exenatide (Byetta), miglitol (Glyset), nateglinide (Starlix), pramlintide (Symlin), repaglinide (Prandin), sitagliptin (Januvia) and insulin for inhalation (Exubera). HID suggests that the Division of Medicaid be free to determine the appropriate preferred products within the insulin group on a financial basis. There was discussion regarding the advantages of beginning insulin therapy earlier in the treatment process and the need for multiple forms of insulin being available to prescribers. Mr. Smith reiterated the fact that products not on the PDL are still available to prescribers through the PA process.

Mr. Smith continued his presentation of the recommendations with a brief description of Exubera, a new product. He stated that HID is not recommending Exubera for inclusion on the PDL at this time. He stated that the product had been discussed by the DUR Board and that some of the concerns discussed included appropriate use, potential for waste, and difficulty with dose titration. He notes that while Exubera is an exciting new product, consideration for inclusion on the PDL should be taken with caution, from a Medicaid standpoint, to ensure appropriate utilization.

Several industry speakers addressed the committee: Lee Ann Griffin, PharmD., Exubera, Pfizer; Bryan Gallagher, Levamir, Novo Nordisk; Rick Szymalis, Humalog, Eli Lilly; Gustavus Aranda, Jr., Duetact and Actoplus met, Takeda; Vicky Star, M.D., Januvia, Merck; Deborah Epps, Pharm D., Lantus and Apidra, Sanofi-Aventis; Cindy Weakly, Byetta, Amylin.

Dr. O'Dell asked if there were any questions, comments or discussion from the committee. There was no further discussion.

Dr. O'Dell asked for a motion regarding HID's recommendation. A motion was made by Mr. Jones to accept HID's recommendation with the addition of Byetta. The motion was seconded by Mr. McFerrin. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Byetta: 10 votes Accept HID's recommendations: 1 vote-Roark

ELECTROLYTE DEPLETERS/PRIMARY THERAPEUTIC CLASS C1A (ANNUAL REVIEW)

Mr. Smith stated that because HID was recommending changes in three of four agents in the Electrolyte Depleter class, he would read through the recommendations for the class. The first agent, Magnebind, is a combination of calcium carbonate, magnesium carbonate and folic acid. He stated that very little information was found on this agent. It is not recommended for everyone due to the possible accumulation of magnesium, especially in patients with renal failure. This recommendation would result in a change in status for this agent from preferred to non-preferred status. The second product is PhosLo, or calcium acetate. The CARE study indicated that calcium acetate is very effective for reducing phosphorous levels and maintaining those levels in the recommended range with only transient hypercalcemia occurring in the studied patients. In addition, the

authors of the Medical Letter recommend that calcium acetate is a reasonable first choice. Detailed utilization data provided earlier in this annual review suggests that this may be a more economical choice as well despite the large average daily dose. We are recommending a change from non-preferred to preferred status for PhosLo. Mr. Smith stated that Fosrenol is non-preferred and HID recommends that it remain non-preferred. The only study found on this relatively new agent compared Fosrenol with calcium carbonate. The six-month study demonstrated that lanthanum is well tolerated and may be more effective than calcium carbonate with less incidence of hypercalcemia in hemodialysis patients. This product should be reserved for patients not controlled by other oral phosphate binders or where possible hypercalcemia is of a concern. The last product is Renagel. This oral phosphate binder has been shown to reduce serum phosphorous to levels similar to calcium acetate with a lower incidence of hypercalcemia. Studies with Renagel also show that reductions in LDL cholesterol are also possible. However, it may induce or exacerbate metabolic acidosis in patients on dialysis. This agent should be reserved for patients not reaching goal with calcium acetate or in those patients at risk for developing hypercalcemia. HID recommends a change from preferred status to non-preferred status for Renagel.

One industry speaker addressed the committee: J. Lanta, Fosrenol, Shire U.S.

Dr. O'Dell asked if there were questions or comments from the committee.

Dr. O'Dell asked for a motion on the recommendation. Mr. Jones made a motion to accept HID's recommendation with the addition of Magnebind, Fosrenol and Renagel. Dr. Smith seconded the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition_of Magnebind, Fosrenol, and Renagel: 11 votes

DIGESTIVE HEALTH (INFLAMMATORY BOWEL DISEASE) AGENTS (ANNUAL REVIEW)

Mr. Smith began the digestive health agents class by calling the committee's attention to the recommendations found on page 144 of the meeting manual. He introduced a new agent in this drug class, Lialda, a new form of mesalamine. It offers the convenience of once daily dosing, which makes it unique among the oral mesalamine products. HID recommends preferred status for this product. HID also recommends for preferred status the following: Asacol, Pentasa, mesalamine enema, Canasa, Dipentum, and Lialda. HID recommends Entocort EC and Colazal for non-preferred status.

No speakers addressed the committee for this class of agents.

Dr. O'Dell asked for a motion on HID's recommendation. Dr. Smith moved to accept the recommendation as presented. Mr. McFerrin offered a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

HISTAMINE 2 RECEPTOR ANTAGONISTS (ANNUAL REVIEW)

Mr. Smith summarized HID's recommendation in the histamine 2 receptor antagonist class. He stated that HID recommends no changes in PDL status for any of the agents in this class. Preferred products currently include cimetidine, famotidine, nizatidine, ranitidine, Axid solution and Zantac syrup.

No speakers addressed the committee for this class of agents.

Dr. O'Dell asked the committee for questions, comments or discussion.

Dr. O'Dell asked for a motion on HID's recommendation. Mr. Roark made a motion to accept the recommendation as presented. It was seconded by Dr. Cook. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

PROTON PUMP INHIBITOR (ANNUAL REVIEW)

Mr. Smith began the PPI review by stating that HID recommends no changes in the status of any of the products in this class. Currently the preferred products are Prevacid and Zegerid.

Two industry speakers addressed the committee: Dr. Sam Patel, Zegerid, Santarus; Michelle Mckee, Nexium, Astra Zeneca;

Discussion followed regarding the placement of Nexium on the PDL.

Dr. O'Dell asked if there were further questions or comments. There was no further discussion.

Dr. O'Dell asked for a motion regarding HID's recommendation. A motion was made by Ms. King to accept HID's recommendation with the addition of Nexium. The motion was seconded by Mr. Jones. Dr. O'Dell instructed the committee to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Nexium: 11 votes

<u>GU SMOOTH MUSCLE RELAXANTS/MISCELLANEOUS GI DRUGS</u> (ANNUAL REVIEW)

Mr. Smith noted that since the printing of the meeting materials, Zelnorm has been taken off the market. He instructed committee members to strike thorough Zelnorm on the ballot. Approval of HID's recommendation would result in one change in regard to Enablex (darifenacin). HID recommends non-preferred status for this agent. He went on to further explain that justification. This agent appears to be more selective, producing few anticholinergic side effects. It has a higher affinity for the M3 receptor, which mediate effects at the bladder. However, there is more potential for drug interactions with this agent. Although receptor selectivity may be enhanced, dry mouth seems to occur more frequently than with placebo. Additionally, a review in The Medical Letter concluded that there is no convincing evidence that darifenacin offers any advantage in efficacy and tolerability over other long acting anticholinergic agents. Results from a recent long-term study indicate that darifenacin is safe and effective during the long-term treatment of overactive bladder. Lastly, there are no comparative studies with the extended release preparations of tolterodine or oxybutynin. HID recommends flavoxate and oxybutynin for preferred status.

Dr. O'Dell asked the committee for questions, comments or discussion regarding the GU/GI drugs.

One industry speaker addressed the committee: Bennett Sosna, VESIcare, Astellas.

Dr. O'Dell asked for a motion regarding HID's recommendation. Ms. King made a motion to accept HID's recommendation with the addition of VESIcare, Detrol, Enablex and Sanctura. Mr. Jones offered a second to the motion. Dr. O'Dell asked the committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Detrol/Detrol LA, Enablex, Sanctura, Vesicare: 11 votes

LEGEND LAXATIVES (ANNUAL REVIEW)

Mr. Smith began the legend laxatives by calling the committee members' attention to page 198 of the meeting packet. He stated that there is one new product in the class, Moviprep, a PEG 3350 combination product for colonoscopy prep. HID's recommendation is that it not be a preferred product. There are several generic PEG 3350 products currently preferred. HID does not recommend any changes to the PDL. The

current preferred products are generic lactulose, PEG 3350/electrolyte solution and Glycolax powder.

Dr. O'Dell asked for questions, comments or discussion from the committee.

One industry speaker addressed the committee: David Bridgers, Amitiza, Takeda.

Dr. O'Dell asked for a motion on HID's recommendation. Dr. Sethi made a motion to accept HID's recommendation with the addition of Amitiza to the PDL. The motion was seconded by Mr. McFerrin. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Amitiza: 10 votes Accept HID's recommendations: 1 vote-O'Dell

NON-STEROIDAL ANTI-INFLAMMATORY AGENTS AND CYCLOOXYGENASE-2 INHIBITORS (ANNUAL REVIEW)

Mr. Smith called the members' attention to the recommendations page of the NSAIDS review found on page 211 of the meeting manual. HID's recommendation does not involve any changes to the preferred status for these agents. Generically available NSAIDs are currently on the PDL as preferred products. Arthotec, Ponstel and Celebrex are non-preferred. HID recommends continued status for these agents.

Dr. O'Dell asked the members for questions, comments or discussion. There was none.

One industry speaker was heard: John Huntwork, Celebrex, Pfizer.

Dr. O'Dell asked for a motion regarding HID's recommendation. Mr. Jones made a motion to accept HID's recommendation with the addition of Celebrex. Dr. Sethi offered a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Celebrex: 10 votes Accept HID's recommendations: 1 vote-O'Dell

OPIATE AGONISTS AND PARTIAL OPIATE AGONISTS

Mr. Smith began the opiate agonist and partial opiate agonist class by stating that he would break down the group by sustained release and immediate release. HID recommends no changes to the current PDL in this class. Currently preferred products in the sustained release category include transdermal fentanyl, morphine sulfate ER, Avinza and Kadian. In the immediate release category, currently only generics are preferred.

No industry speakers for the class addressed the committee.

Dr. O'Dell asked the committee for questions or discussion regarding the recommendations. There was no discussion.

Dr. O'Dell asked the committee for a motion from the committee. Mr. Jones made a motion to accept HID's recommendation as presented. Dr. Cook offered a second. Dr. O'Dell asked the committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

<u>SEROTONIN 5-HYDROXYTRYPTAMINE (5-HT_{1B/1D}) AGONISTS / TRIPTANS</u> (ANNUAL REVIEW)

Mr. Smith directed the committee members' attention to the recommendations page for the Triptans class review on page 256 of the meeting manual,. He stated that currently the preferred agents in the class are Maxalt and Imitrex. The non-preferred agents include Axert, Relpax, Frova, Amerge and Zomig. HID recommends no changes in this class.

Dr. O'Dell asked the committee for questions, comments and discussion regarding HID's recommendation.

One industry speaker addressed the committee: Ken Flynt, Maxalt, Merck.

Dr. O'Dell asked the committee for a motion on HID's recommendation. Dr. Sethi made a motion to accept HID's recommendation as presented. Mr. Roark offered a second to the motion Dr. O'Dell asked the committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

RESPIRATORY AGENTS (ANNUAL REVIEW)

Mr. Smith informed the committee that due to the fact that the respiratory agents are such a large class, he would summarize the recommendations in subcategories and only state those recommendations that would result in changes to the PDL and then answer questions. The first change recommended by HID is a change in status from nonpreferred to preferred for Flovent HFA. HID recommends that QVAR be changed from preferred to non-preferred status. For Oxtriphylline, HID recommended for a change from preferred to preferred status. Maxair Autohaler is recommended for a change from non-preferred to preferred status. Xopenex Inhalation Solution is recommended for a change from preferred to non-preferred status. HID recommends that Serevent be changed from preferred to non-preferred status. DuoNeb, currently non-preferred, is recommended for a change to preferred status. Advair, currently preferred, is recommended for non-preferred status. HID recommends the following agents remain preferred: aminophylline, dyphylline, theophylline, albuterol inhalation solution, albuterol CFC inhaler, albuterol oral, Xopenex HFA, metaproterenol, Maxair inhaler, terbutaline, Atrovent, Spiriva, Pulmicort Respules, Asmanex, Singulair, cromolyn sodium, and Combivent.

A discussion followed regarding asthma and asthma inhalers.

Several industry speakers addressed the committee: James Tislow, Asmanex, Schering Plough; Brad Warnock, Spiriva, Boehringer Ingelheim; Todd Adkins, Advair, MS Asthma and Allergy/GSK; Vicky Star, M.D., Singulair, Merck; Dr. Winn Walcott, Xopenex, Sepracor; Ben Everette, Symbicort, Astra Zeneca; James Tislow, Foradil/Proventil HFA, Schering Plough.

Dr. O'Dell asked the committee for questions comments and discussion. Further discussion regarding inhalers continued.

Dr. O'Dell asked for a motion regarding HID's recommendation. Dr. Cook made a motion to accept HID's recommendation with the addition of albuterol HFA, Advair and Xopenex solution. Mr. Jones offered a second to the motion. Dr. O'Dell asked the committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with addition of Albuterol HFA, Xopenex solution and Advair: 11 votes

INTRANASAL CORTICOSTEROIDS (ANNUAL REVIEW)

Mr. Smith began the review of the Intranasal Corticosteroids by calling the committee members' attention to the recommendations for the class on pages 298 and 299 of the meeting packet. He stated that currently the preferred products are Nasonex, flunisolide and fluticasone. The non-preferred products are Beconase AQ, Nasacort AQ, Nasarel, Rhinocort and Omnaris. HID recommends no changes in the status of these agents.

Two industry speakers addressed the committee: James Tislow, Nasonex, Schering Plough; Keith Campagna, Nasacort AQ, Sanofi-Aventis.

Dr. O'Dell asked if there were questions or comments regarding HID's recommendation. There were none.

Dr. O'Dell asked for a motion regarding HID's recommendation. Dr. Wales made a motion to accept HID's recommendation as presented. The motion was seconded by Mr. McFerrin. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

FIRST AND SECOND GENERATION ANTIHISTAMINES (ANNUAL REVIEW)

Mr. Smith directed the committee members to the recommendations portion of the Antihistamines review on page 313 of the meeting manual. Mr. Smith began by stating that HID recommends no changes to the current PDL. Currently, preferred products in this category include the generic legend antihistamines and antihistamine-decongestants *combination products*, Astelin nasal spray, Zyrtec product line, Clarinex product line, fexofenadine, over the counter loratadine products, Pediatex products, Vazol and Vazol D products. He noted that the Pediatex formulations on the PDL are no longer available.

Several industry speakers addressed the committee: Todd Beeler, Pediox-S and Sudal-12, Atley; James Tislow, Clarinex, Schering Plough; Keith Champion, Allegra Oral Suspension, Sanofi-Aventis; Dr. Winn Walcott, Astelin, Med Pointe; Selika Sweet, M.D., Palgic, PanLab.

Dr. O'Dell asked if there were any questions or further discussion on HID's recommendations. No discussion followed.

Dr. O'Dell asked for a motion from the committee. Dr. Sethi made a motion to accept HID's recommendation with the addition of Palgic. Dr. Wales offered a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with the addition of Palgic: 11 votes

ALZHEIMER'S AGENTS/PARASYMPATHOMIMETIC (CHOLINERGIC) AND MISCELLANEOUS CENTRAL NERVOUS SYSTEM AGENTS (ANNUAL <u>REVIEW)</u>

Mr. Smith called the members' attention to the recommendations for the Alzheimer's agents on page 325 of the meeting packet. He explained that currently Aricept, Namenda and Exelon are preferred agents. Razadyne and Cognex are non-preferred. HID recommends no changes to PDL status for these agents at this time.

No industry speakers addressed the committee for this class of agents.

Dr. O'Dell asked if there were questions regarding HID's recommendation. There was no discussion.

Dr. O'Dell asked for a motion on HID's recommendation. Mr. Roark made a motion to accept HID's recommendation as presented. Dr. Sethi offered a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

SEDATIVE/HYPNOTIC AGENTS (ANNUAL REVIEW)

Mr. Smith directed the committee members' attention to the recommendations for the Sedative Hypnotics class, found on pages 333 through 335 of the meeting manual. He stated that currently, the preferred products are estazolam, Lunesta, flurazepam, triazolam and Ambien CR. The non-preferred products are Sonata and Ambien. The only change recommended by HID is a change of status for Ambien CR from preferred to non-preferred. Mr. Smith explained HID's justification by stating that other products are available with longer safety and efficacy study periods.

Dr. O'Dell asked for questions or discussion from the committee.

Several industry speakers addressed the committee: Gustavur Aranda, Rozerem, Takeda; Joseph Kwentas, Lunesta, Sepracor; Keith Campagna, Ambien CR, Sanofi-Aventis.

Dr. O'Dell asked for a motion to accept HID's recommendation. Dr. Cook made a motion to accept HID's recommendation as presented. The motion was seconded by Mr. Roark. Dr. O'Dell asked the committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) AGENTS (ANNUAL REVIEW)

Mr. Smith directed the committee members' attention to the recommendations page for the ADHD agents, found on pages 348 through 349 of the meeting manual. Currently preferred products include amphetamine mixtures, Adderall, Strattera, Focalin XR, dextroamphetamine, generic methylphenidate formulations, Methylin, Metadate CD and Concerta. HID recommends continued preferred status for all these products except Metadate CD and Concerta. HID also recommends that Focalin immediate release be changed from non-preferred to preferred status, thus making the full Focalin line preferred. Two industry speakers addressed the committee: Rose Mullen, Strattera, Eli Lilly; Sileen Wall, Concerta, Janssen Ortho McNeil.

Dr. O'Dell asked the committee for discussion or questions regarding the recommendation.

Dr. O'Dell asked the committee for a motion regarding the recommendation presented. Dr. Sethi made a motion to accept HID's recommendation with the addition of Metadate CD and Concerta. Mr. Jones made a second to that motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations with the addition of Metadate CD and Concerta: 11 votes

OSTEOPOROSIS AGENTS (ANNUAL REVIEW)

Mr. Smith referred committee members to the recommendations for the Osteoporosis Agents review, on page 361 of the meeting packet. He stated that currently Fosamax, Evista, Boniva and Miacalcin are preferred agents. Fortical, Actonel and Forteo are currently non-preferred agents. HID recommends no changes in the PDL status of these agents at this time.

One industry speaker, representing two products, addressed the committee: Shonda Foster, Evista and Forteo, Eli Lilly.

Dr. O'Dell asked for discussion regarding the recommendation.

Dr. O'Dell asked the committee for a motion on HID's recommendation. Mr. Jones made a motion to accept HID's recommendation as presented. Dr. Wales gave a second to the motion. Dr. O'Dell asked committee members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

ANTIEMETIC/ANTIVERTIGO AGENTS

Mr. Smith directed the committee members' attention to the recommendations page for the antiemetic/antivertigo class of agents beginning on page 383 of the meeting manual. He summarized HID's recommendation by stating the following: Emend, meclizine, prochlorperazine, promethazine and scopolamine are recommended for preferred status. Dronabinol is not recommended for preferred status.

No industry speakers addressed the committee for this class of products.

Dr. O'Dell asked the committee for questions or discussion regarding HID's recommendation. There was no discussion.

Dr. O'Dell asked for a motion regarding HID's recommendation. Mr. Jones made a motion to accept HID's recommendation as presented. Dr. Gholson made a second to the motion. Dr. O'Dell asked members to mark their ballots.

Committee vote: 11 votes cast Accept HID's recommendations: 11 votes

Ms. Clark reminded committee members to complete travel vouchers and turn them in before leaving the meeting. She announced the next P& T meeting date as July 10, 2007. Ms. Clark thanked Dr. O'Dell for chairing the meeting in Mr. Calvert's absence.

Dr. O'Dell adjourned the meeting at 5:15pm.