MINUTES OF THE SEPTEMBER 14, 2004 PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Myrna Alexander, M.D., Todd Barrett, R. Ph., Larry Calvert, R. Ph., Betsy Cummings, C.F.N.P., Jennifer Gholson, M.D., David Hudson, R. Ph., Jeff Jones, R. Ph., Pearl Wales, Pharm. D., Gary Davis, M.D., Michael O'Dell, M.D.

Members Absent: Raymond Wynn, M.D., Craig Dawkins, M.D.

Also Present: Warren A. Jones, M.D., Phillip Meredith, M.D., J.D., Sharon Barnett-Myers, Judith Clark, R. Ph., Terri Kirby, R. Ph., Phyllis Williams, Staff Officer II, Gay Gipson, R.N., Lauretta Cameron - DOM; Rob DiBenedetto, Sam Warman R. Ph., Lew Anne Snow, R.N., Joe Paradis, Pharm. D., Pam DeRuiter, R. Ph.- HID

Guests Present: Rob Reedy, ACS Account Manager, Nicole Stofer, Governor's Office

Old Business

Approve minutes of last meeting (February 14, 2004). Jeff Jones moved that the minutes be accepted as read. Jennifer Gholson seconded. All voted in favor of approval.

New Business

Dr. Myrna Alexander opened the meeting by introducing each P&T committee member. Judy Clark gave general rules and welcome. Dr. Warren Jones expressed his gratitude to the committee members for their willingness to serve. He also stated that Medicaid beneficiaries will have 90 days to secure a PA for items not on the PDL.

Dr. Alexander expressed concern that the committee has already spent 2 years on the current PDL and inquired if they may use it as a guide. Dr. Jones instructed the members to focus primarily on safety and clinical efficacy, independently of cost, in their PDL deliberations.

Jeff Jones questioned why UMC Pharmacy School was replaced by HID in reviewing therapeutic categories. Sharon Barnett-Myers responded that HID was contracted for these services.

Judith Clark stated that the process for choosing preferred drugs for PDL status will be by paper ballot. Mr. Calvert questioned this procedure. Ms. Clark explained that voting by paper ballot would assure privacy and members would be more prone to express their honest opinion on paper.

Jeff Jones made a motion to do away with the paper ballots. Larry Calvert seconded. Motion failed. Judith Clark stated that paper ballots would be cast after each class had been reviewed.

Therapeutic Category Reviews

Pam DeRuiter, R. Ph., with Health Information Designs (HID) moderated the therapeutic class reviews.

ANTIDEPRESSANTS

SSRIs: HID recommended generic Fluoxetine and Paroxetine as preferred agents and no brand name agents. Dr. Alexander was concerned about psychiatric patients who are already stabilized on non-PDL drugs being changed to preferred agents. Larry Calvert was concerned about how many PAs are approved. Sharon Barnett-Myers gave more clarification on the PA process and stated that the PA process is currently being defined. Pam DeRuiter suggested trying a PDL drug first and then a PA may be obtained for a non-PDL drug if needed. Larry Calvert asked about the duration of the PAs. Judy Clark explained the majority of the PAs are effective for six to twelve months. Dr. Gholson stated that Zoloft and Paxil are the safest antidepressants for breastfeeding women. Jeff Jones motioned to add Zoloft and Lexapro to the PDL in addition to HID's recommendation. Larry Calvert seconded the motion.

Mr. Calvert requested that board members have a workshop on the PA process. Ms. Clark referred this question to Sharon Barnett-Myers. Sharon Barnett-Myers said it would be possible to have a training workshop for the board members.

Tricyclics: HID recommendation: Include only generic formulations of Amitriptyline, Imipramine, Desipramine, Nortriptyline and Doxepin on the PDL. Dr. Meredith offered his insight on this class of drugs. Dr. Alexander voiced concerns that patients maintained on stable therapy should not be forced to change to a PDL drug. Todd Barrett made a motion to accept HID's recommendation. Jeff Jones seconded the motion.

Tricyclic-like agents (**Amoxapine**): HID recommended that no name brand or generics be on the drug list. Jeff Jones made a motion to accept HID's recommendation. Pearl Wales seconded the motion.

Triazolopyride: HID recommended that only generic Trazodone be included on the PDL. Jeff Jones motioned to accept HID recommendation. Larry Calvert seconded the motion.

SNRIs -Venlafaxine/Nefazodone: HID recommended that generic Nefazodone not be included on PDL due to its black box warning and the brand name is no longer in production. Venlafaxine is not recommended for inclusion. Ms. DeRuiter stated that if patients are intolerant to PDL drugs they may obtain a PA for Venlafaxine. Todd Barrett motioned to amend HID's recommendation and add Effexor and Effexor XR to the PDL because they are often first-line therapy in the geriatric population. Jennifer Gholson seconded the motion.

Aminoketones- HID recommended that only generic versions of Bupropion be

included. Todd Barrett motioned to accept HID's recommendation. Betsy Cummings seconded the motion.

Tetracyclics: HID proposed that no version of Mirtazapine be included on the PDL. Jeff Jones motioned to include all generic forms of Mirtazapine on the PDL. Pearl Wales seconded the motion.

Maproptiline: HID recommended that Maprotiline not be included on the PDL Jeff Jones motioned to accept HID's recommendation. David Hudson seconded the motion.

Monoamine Oxidase Inhibitors (MAOI): HID proposed that no MAOIs be included on the PDL. Larry Calvert motioned to exclude MAOIs from the PDL. Jeff Jones seconded the motion.

ANTIHYPERTENSIVES

Ace Inhibitors: HID proposed that only generic versions of Captopril, Enalapril, Fosinopril, Lisinopril and Moexipril as well as their respective multi-source diuretic combinations be included on the PDL. No brand name products are recommended for inclusion. Todd Barrett motioned to amend HID's recommendation by including Altace due to studies which have shown that it decreases cardiac death and extends patient longevity. Jeff Jones seconded the motion.

Discussion ensued concerning the difference between a formulary and a PDL. Dr. O'Dell stated that he considers the PA process an obstacle in the real world practice setting. Sharon Myers stated that the Division of Medicaid is attempting to streamline the PA process by 12-1-04. Dr. O'Dell expressed concern that HID is processing PAs as well as recommending drugs for PDL status and stated that it may be perceived as a conflict of interest. Sharon Myers stated that the Division of Medicaid will dictate criteria as well as the PA process and that HID is simply an extension of the Division of Medicaid. Jeff Jones stated that the University of Mississippi School of Pharmacy should reconsidered for performing the PDL reviews. Sharon Myers stated that the School of Pharmacy continues to be a partner with the Division of Medicaid and their expertise is invaluable.

Angiotensin II Receptor Blockers (**ARBs**): HID recommended no ARBs for inclusion on the PDL, the reason being that if no agent were preferred, DOM would have more negotiating leverage. Todd Barrett motioned to include at least 2 ARBs on the PDL. He then amended the motion to include Avapro and Diovan. Motion seconded by Larry Calvert.

Calcium Channel Blockers: HID recommended the PDL include generic Diltiazem, Nifedipine and Verapamil immediate and extended release formulations. Jeff Jones motioned to accept HID's recommendation and add Norvasc and Lotrel. Motion seconded by Todd Barrett. Dr. O'Dell voiced concern on including immediate release Nifedipine on the "hypertension list" as it is not approved or safe for this

indication. Dr. Alexander moved to amend the motion to accept HID's recommendation, add Norvasc and Lotrel but exclude the immediate release dihydropyridines (Nifedipine). Dr. O'Dell seconded the motion.

Beta Blockers: HID recommended including all generic agents on the PDL and brand Toprol XL due to its indication for CHF. Mr. Jones motioned to accept HID's recommendation and add Coreg. Mr. Calvert seconded the motion.

ANTIHYPERLIPIDEMICS

Statins: HID recommendation: Include Lipitor, Pravachol and generic Lovastatin as preferred agents. Mr. Barrett moved to accept HID's recommendation and add Zocor and Vytorin. Mr. Calvert seconded the motion.

Discussion ensued as to why Crestor was not included in HID's recommendation. Ms. DeRuiter stated that it doesn't have the FDA approved indication for primary prevention of cardiovascular events. Members also questioned why Vytorin was not included in the review. Ms. DeRuiter stated that Vytorin was approved in July 04 after HID had begun formulating their drug class reviews. Dr. Alexander stated that an agent has to be on the market 6 months before it is reviewed for PDL inclusion. It was agreed by other members that since both agents in Vytorin (Ezetimibe & Simvastatin) have been on the market longer than 6 months that it does qualify for PDL inclusion.

Niacin: HID recommended only OTC Niacin agents. Dr. Alexander stated that the OTC products are known for causing a high incidence of flushing. Mr. Barrett motioned to accept HID's recommendation and add brand Niaspan as a preferred agent. Jeff Jones seconded the motion.

Niacin combinations (Advicor): HID recommends not to include Advicor on the PDL. (Ms.DeRuiter stated that Advicor is now called Altoprev. This is incorrect. Altocor is now Altoprev. Altoprev is extended-release Lovastatin as correctly reflected in HID's packet). Mr. Calvert motioned to accept HID's recommendation. Mr. Jones seconded the motion. Dr. O'Dell motioned to amend the motion by adding Advicor to the PDL until DOM implements the unlimited generic policy. Dr. Gholson seconded the motion.

Fibric Acid Deriviatives: HID recommended generic Gemfibrozil. Mr. Calvert commented that Tricor is very useful in lowering TG levels and moved to include it on the PDL as well. Jeff Jones seconded the motion.

Bile Acid Sequestrants: HID recommended that only generic Cholestyramine be preferred. Dr. Odell moved to accept HID's recommendation. Todd Barrett seconded the motion.

Selective Cholesterol Absorption Inhibitor (Zetia): HID recommended that Zetia not be given preferred status. Betsy Cummings moved to accept HID's recommendation. Mr. Barrett seconded the motion.

RESPIRATORY AGENTS

Inhaled Corticosteroids: HID recommend ALL Brand agents as preferred. Larry Calvert motioned to accept the recommendation. Jeff Jones seconded the motion.

Antimuscarinic/Antispasmodic Respiratory Agents: HID recommended Atrovent Metered Dose Inhaler and generic Ipratropium for nebulization as preferred agents. Jeff Jones motioned to accept HID's recommendation and add Spiriva. David Hudson seconded the motion.

Leukotriene Modifiers: HID recommends that Singulair be the preferred agent. Jeff Jones motioned to accept this recommendation. Todd Barrett seconded the motion.

Mast Cell Stabilizers: HID recommended that Intal Inhaler and generic Cromolyn Sodium for nebulization be included on the preferred drug list. Todd Barrett motioned to accept the recommendation. Pearl Wales seconded the motion.

Smooth Muscle Relaxants: HID recommended only generic smooth muscle relaxants as preferred agents. Jeff Jones motioned to accept this recommendation. Todd Barrett seconded the motion.

Smooth Muscle Relaxant Combinations: HID recommended only the generic combinations be included on the PDL. Larry Calvert motioned to accept this recommendation. Jeff Jones seconded the motion.

Single Entity Sympathomimetic Agents: HID recommended that only the generic short-acting inhaled beta-2 agonists be included as preferred agents. Jeff Jones motioned to add Serevent because a long-acting agent is needed. David Hudson seconded the motion. vote.

Sympathomimetic Combination Agents: HID recommended that no brand agent be preferred. Jeff Jones motioned to add Combivent and Advair to the PDL. Dr. O'Dell seconded the motion.

Other Business

Judy Clark announced that the next P&T Committee meeting will be held September 28th, 2004 and another on October 12th, 2004. The floor was opened for nominations for Chairman and Vice Chairman of the Committee. Jeff Jones nominated Larry Calvert as Chairman. Jennifer Gholson seconded the motion. Dr. Alexander nominated Dr. O'Dell as Vice Chairman. Mr. Jones seconded the motion. Vote was decided by acclamation.

There being no further business, the meeting was adjourned at 4:30 PM.

Ballot Results – Ten Members Present

A. Antidepressants

1. SSRIs - Accept HID Recommendation: No Brands, Generic Paroxetine & Fluoxetine - No Votes

Amended to Include Zoloft and Lexapro - 7 Votes -

Alexander, Barrett, Calvert, Cummings, Gholson, Jones, O'Dell

Zoloft only - 3 Votes - Davis, Hudson (only age 18 & under), Wales

2. Tricyclics - Accept HID Recommendation: Generic Amitriptyline, Desipramine, Doxepin, Imipramine & Nortriptyline All voted in favor.

- 3. Tricyclic-Like- Accept HID Recommendation NOT to include Amoxapine. All voted in favor.
- 4. Triazolopyride- Accept HID Recommendation of only generic Trazodone: All voted in favor
- 5. SNRIs- Accept HID Recommendation-No Nefazodone/No Effexor 1 Vote-Wales

Add Effexor and Effexor XR - 8 Votes -

Alexander, Barrett, Calvert, Cummings, Davis, Gholson, Jones, O'Dell Add Effexor XR – 1 Vote- Hudson

- 6. Aminoketones- Accept HID Recommendation of Only generic Bupropion All voted in favor
- 7. Tetracyclics- Accept HID Recommendation of no Brand or Generic Mirtazapine and no Maprotiline: No Votes Amend to include all forms of generic Mirtazapine: All voted in favor.
- 8.MAOIs- Accept HID Recommendation of NO MAOIs on PDL: All voted in favor.

B. Antihypertensives

- 1.ACE Inhibitors- Accept HID Recommendation of generic Captopril, Enalapril, Fosinopril, Moexipril along with their respective diuretic Combinations 3 Votes Cummings, Davis, Hudson Amend recommendation to include Altace 7 Votes Alexander, Barrett, Calvert, Gholson, Jones, O'Dell, Wales
- 2. ARBs- Accept HID Recommendation of No ARBs as preferred 0 Votes Amend to include at least 2 ARBS: 10 Votes Alexander (Benicar preferred), Barrett (Avapro,Diovan), Calvert (Avapro,Diovan), Cummings (Avapro, Diovan), Davis (Atacand, Cozaar, Diovan), Gholson (Avapro,Diovan), Hudson (Avapro,Diovan), Jones (Avalide, Diovan, DiovanHCT), O'Dell (Avapro,Diovan), Wales (Avapro, Avalide, Diovan)
- 3. Calcium Channel Blockers- Accept HID recommendation of NO Brands and include all generic forms of immediate and

extended release Diltiazem, Nifedipine & Verapamil - 0 Votes
Amend to include Norvasc & Lotrel and exclude Immediate release Dihydropyridines (Nifedipine) - 6 Votes- Alexander, Calvert, Cummings, Hudson, Jones, O'Dell
Amend to include Norvasc, Lotrel, and generic

CCBs as recommended - 1 Vote- Barrett

4. Beta Blockers- Accept HID recommendation to include only generic agents and brand Toprol XL - 1 Vote- Hudson
Amend to also include Coreg - 9 Votes

C. Antihyperlipidemics

1. Statins- Accept HID recommendation to include Lipitor, Pravachol and generic Lovastatin - 1 Vote- Davis

Amend to also include Zocor- 2 Votes-Hudson, Alexander

Amend to also include Zocor and Vytorin- 7 Votes- Barrett, Calvert, Cummings, Gholson, Jones, O'Dell, Wales

- Niacin- Accept HID recommendation to include only OTC Niacin agents-2 Votes- Calvert, Hudson Amend to also include brand Niaspan: 8 Votes- Alexander, Barrett, Cummings, Davis, Gholson, Jones, O'Dell, Wales
- 3. Niacin Combinations Accept HID recommendation to exclude Advicor From PDL- 5 Votes- Barrett, Calvert, Davis, Hudson, Wales Include Advicor on PDL- 5 Votes- Alexander, Cummings, Gholson, Jones, O'Dell
- 4. Fibric Acid Derivatives- Accept HID recommendation to include generic Gemfibrozil only- 2 Votes- Davis, Wales
 Amend to also include Tricor- 8 Votes- Alexander, Barrett, Calvert, Cummings, Gholson, Hudson, Jones, O'Dell
- 5 Bile Acid Sequestrants- Accept HID recommendation to include generic Cholestyramine- All voted in favor.
- 6. Selective Cholesterol Absorption Inhibitor (Zetia)- Accept HID recommendation to exclude Zetia All voted in favor

D. Respiratory Agents

- 1.Inhaled Corticosteroids- Accept HID recommendation to consider ALL brands as preferred agents- All voted in favor.
- 2.Antimuscarinic/Antispasmodic- Accept HID recommendation to include brand Atrovent MDI and generic Ipratropium for nebulization: 0 Votes Amend to also include Spiriva- All voted in favor
- 3. Leukotriene Modifiers: Accept HID recommendation to include Singulair-All voted in favor.
- 4. Mast Cell Stabilizers: Accept HID recommendation to include Intal Inhaler and generic Cromolyn Sodium for nebulization All voted in favor.

- 5. Smooth Muscle Relaxants (Xanthines): Accept HID recommendation of all generic agents All voted in favor
- 6. Smooth Muscle Relaxant Combinations: Accept HID recommendation of all generic agents All voted in favor.
- 7. Sympathomimetics- Accept HID recommendation to include only short-acting Beta-2 agonists- 1 Vote- Davis

Amend to also include Serevent- 8 Votes- Alexander, Barrett, Calvert, Cummings, Hudson, Jones, O'Dell, Wales

Amend to also include Servent and Xopenex- Gholson

8. Sympathomimetic Combinations- Accept HID recommendation of no brand agents as preferred- 0 Votes

Amend to include Advair and Combivent - 7 Votes- Barrett, Cummings, Davis, Gholson, Jones, O'Dell, Wales

Amend to include Combivent only- 2 Votes- Alexander, Calvert Amend to include Advair or Combivent- 1 Vote- Hudson