Meeting of the
Pharmacy and Therapeutics Committee
September 20, 2004
Minutes
Final

Members Present:
Randy Axelrod, M.D., Chair
Gill Abernathy, M.S., R.Ph.

Avtar Dhillon, M.D.
Mariann Johnson, M.D.
Mark Oley, R.Ph.
James Reinhard, M.D.
Roy Beveridge, M.D
Tim Garson, M.D.
Renita Warren, Pharm.D.

Via phone:
Mark Szalwinski, Pharm.D.

Absent:
Christine Tully, M.D.
Sue Cantrell, M.D.
A quorum was present

Guests:

81 representatives from pharmaceutical companies, providers, advocates, associations, etc.
Manikoth Kurup, MD, Member, Board of Medical Assistance Services
Cindy Kirkwood, Pharm.D, Associate Professor of Pharmacy, VCU

DMAS Staff:
Patrick Finnerty, Agency Director
Cynthia Jones, Chief Deputy Director
Cheryl Roberts, Deputy Director of Programs and Operations
Emily Wingfield, Counsel to the Board, Office of the Attorney General
Adrienne Fegans, Program Operations Administrator
Javier Menendez, Pharmacy Manager
Bryan Tomlinson, Director Division of Health Care Services
Katina Goodwyn, Pharmacy Contract Manager

First Health Staff:
David Adams Rebate Support
Debbie Moody, R.Ph, Clinical Manager
Donna Johnson, R.Ph, Clinical Manager
Carol Perkins, Pharm.D, Clinical Manager
Rita Marcoux Director, Pharmacy Accounts
Doug Brown, R.Ph. Rebate Support
Doug Lipton

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

Patrick W. Finnerty welcomed those in attendance. He thanked the Committee for their expertise and their willingness to share their knowledge and experience. The success of the program has reaffirmed that at every step of the process, clinical efficacy came first and price is always the last consideration. The clinical decision will always override the financial.

Mr. Finnerty introduced of Cindy Kirkwood, Pharm.D., BCPP, Associate Professor of Pharmacy, Vice Chair for Education, Virginia Commonwealth University. Dr. Kirkwood's responsibilities are to work with the Committee as an expert in mental health and consult the Committee to ensure that patients will receive proper care and consideration.

The next meeting on October 6, 2004 will involve a discussion of anti-depressants and antianxiety medications. Language in the 2004 Appropriations Act directs the Department to review antidepressants and antianxiety drug classes for potential inclusion on the preferred drug list (PDL). Once the decision is made by the P&T Committee on PDL eligibility, a report must be submitted to Governor, Chairmen of the House Appropriations and Senate Finance Committees and the Joint Commission on Health Care by January 2005 to demonstrate that patients will be properly cared for and considered. If recommended for inclusion, the effective date would be no earlier than July 1, 2005.

COMMENTS FROM RANDY AXELROD, COMMITTEE CHAIR

Dr. Axelrod thanked everyone for their attendance and called the meeting to order. Nine P&T Committee members were in attendance. A quorum was present. Dr. Mark Szalwinski participated via conference call.

OPEN ISSUES

Proposed PDL Multi-source and Product Availability Policy

Patrick Finnerty noted that the Department has experienced circumstances in which pricing for multiple source drugs and product availability within PDL drug classes have become a concern. As these circumstances arise, multiple source drugs need to be reviewed to determine preferred or non-preferred status. This becomes an issue for the Department when the P&T Committee is not scheduled to convene to address these concerns. Given that the Committee is now only scheduled to meet twice a year, the Department has concerns about the potential impact on cost savings with a delayed decision.

Javier Menendez, R.Ph., DMAS Pharmacy Manager, reviewed the following proposed Preferred Drug List Generic (multi-source) Policy to address this issue:

In cases where generic (multi-source) drugs are designated as non-preferred and the generic market trends result in a less-expensive alternative (in terms of net-cost) to the preferred products(s), the Director of the Department of Medical Assistance Services may change the status of the non-preferred product to preferred. The Department of Medical Assistance Services may also do this in cases where market conditions limit dosage form availability to one product. These changes will be updated on the DMAS and First Health Services websites and the ePocrates download. The P&T committee will also be updated as they occur. They will also be communicated in the next regularly scheduled memo release. In cases where the changes are significant a special memo will be distributed.

Dr. Axelrod asked for comments or questions. None were voiced.

A motion was made to approve the policy as it is written. This motion was seconded and unanimously approved by the Committee.

Long acting Narcotics

Dr. Axelrod reviewed the issue of Long Acting Narcotics for the Committee, both discussions that occurred during the meeting on April 21, 2004 and since that meeting. It was noted that Long Acting Narcotics were reviewed and accepted for inclusion in phase three of the PDL class at the April P&T and this class met with a great deal of debate. The class was thoroughly discussed during the April meeting. Dr. Beveridge offered excellent insight to the Committee of his involvement with outside coalitions in this area. Also in preparation for the April class discussion, the Committee received some guidance from the Virginia Board of Pharmacy. Following that meeting, Dr. Axelrod consulted with two independent pain specialists, Dr. John C. Rowlingson and Dr. Steve Long, to receive additional guidance. Based on information provided by these specialists, draft long acting narcotics step therapy criteria was developed and reviewed by the Department, Dr. Rowlingson and Dr. Long. Due to prior commitments, both specialists were invited but could not attend the meeting in person. Dr. Rowlingson, who is Professor of Anesthesiology and Director of Acute Pain Management Services, University of Virginia Health

System, did submit a written statement that was read by Dr. Axelrod to the Committee and attendees. The statement read as follows:

I am sorry that I can't clear my schedule here to make the meeting of 9/20/04. But, thank you for the opportunity to review the Step Therapy Model for the use of short- and long-acting opioids in the Commonwealth's Medicaid program. I endorse the concept that the patient must have been trialed on one or two short-acting opioids to establish the clinical benefits of their use (decreased pain, improved quality of life, increased function) without drug-related side effects. The patient would then move to a long-acting opioid preparation with the intent of providing those benefits on a consistent basis. Another process by which the patient would move to the use of designated long-acting opioids would be evaluation by a pain medicine specialist/practice. Upon his/her/their documentation of the evaluation protocol utilized and declaration of the recommendation for opioid use and documentation of the planned follow-up, the long-acting opioids should be approved for use.

Dr. Axelrod noted that Dr. Rowlingson has been an active participant in CAM-related research during the past three years. The proposed step therapy was reviewed by the Committee in detail. The Long Acting Narcotic class was then opened for discussion. Mark Szalwinski, Pharm.D. stated that he and the physicians who worked on the step therapy criteria had the intention to manage these high risk drugs, while also allowing access to the medication in as patient-, pharmacy- and physician- friendly manner as possible. At the same time, building into the program a system to ensure that decisions made around pain management are made in as rational and safe a manner as possible.

Dr. Beveridge requested that the reference to methadone in the step therapy criteria, which states "the use of methadone for pain should ideally be used in a pain clinic", be changed to include appropriate use in a hospice setting or offices of pain management experts. Dr. Axelrod noted the change.

A motion was made to accept the Long Acting Narcotics step therapy criteria with the addition of hospice as an appropriate setting for methadone administration. This motion was seconded and unanimously approved by the Committee.

Clarification: This class will be included in the PDL, effective January 1, 2005, with Phase I PDL implementation to allow time for provider notification.

ACCEPTANCE OF MINUTES FROM APRIL 20, 2004 MEETING

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the April 21st meeting. None were noted and upon request of the Chairman, the Committee voted on a motion and a second to approve the minutes of the April 21st meeting as written. The Committee voted unanimously to approve the minutes as drafted.

DRUG CLASS REVIEW

Dr. Axelrod noted that there several drug class presentation today. He reminded the group that these classes have been reviewed by the Committee within the past 15 months and requested that comments be limited to new clinical information published in 2004. Each speaker was limited by a time clock to three minutes. Dr. Axelrod recognizes the importance of this clinical information to the decision making of the Committee and appreciates the time of the presenters.

HMG-CoA Reductase Inhibitors (Statins)

Dr. John Daniel, Virginia Physician, Kos Pharmaceuticals

Dr. Daniel stated that new information has come out in the past few months regarding lipid management. The American Heart Association, the American Pharmacist Association and the American Society of Health System Pharmacists have all come out against dietary supplements as being a way to treat hypercholesterolemia and increase HDL. There are no OTC supplements that will treat the condition safely and effectively. It should be a pharmaceutical grade Niaspan® given to patients. He referred to handouts and summary of study. Dr. Daniel cited the benefit of a drug like Advicor® is that it combines lovastatin and Niaspan®, targeting all four metabolic parameters involved in metabolic syndrome.

Sheryl Ashton, MD, Regional Medical Research Specialist, Pfizer INC.

Discussed Lipitor® and five recent outcome trials – two involving atorvastatin have lead to changes in ATPIII guidelines recommending lower LDL goals in some patients. Dr. Ashton cited and discussed results of various trials including ASCOT, which resulted in a label change for Lipitor® this summer. The new label reads in adult patients without clinically evident heart disease but with multiple risk factors for heart disease. Discussed CARDS trial.

John Kross, Pharm.D, Medical Information Scientist, AstraZeneca

Reviewed the renal protective paper published this year. It was noted they saw no changes or saw an improvement in GFR with Rosuvastatin.

Domenic A. Sica, M.D., Professor of Medicine and Pharmacology, Chairman, Section of Clinical Pharmacology and Hypertension, Division of Nephrology, Medical College of Virginia

Caduet® is a combination of amlodipine besylate and atorvaststin (a Calcium Channel Blocker and a HMG-CoA Reductase Inhibitor). This is the first product that goes across disease states. Dr. Sica discussed the attributes of this drug in his practice.

Dr. Axelrod expressed concern about drug cost when two drugs are combined that are to go generic soon. Response by Dr. Sica was that both drugs do have a fair amount of time left on patent one “07” the other “11”. MCV is adding to their formulary but will have to re-evaluate once the generic is released.

Robert Hilkert, MD, Cardiologist, Regional Medical Research Specialist, Pfizer Pharmaceuticals

Dr. Hilkert reviewed the combo product Caduet. He discussed the idea that adherence is increased with the combination products. He cited and reviewed two studies - the Avalon study and the Gemini study.

Dr. Axelrod asked if this data was a real world study or a Medicaid population. Dr. Hilkert stated that it was real world. Dr. Axelrod noted that real world is usually less that 10% Medicaid and could not always be meaningful to our population.

Margaret Savage, MD, MPH, Medical Science Specialist, Schering-Plough Corporation

Vytorin, a combination of medications Esetimibe and Simvastatin, was reviewed by the speaker. She stated that having two different mechanisms to lower lipids was an advantage. She reviewed three recent studies and claimed that the combination drug lowered LDL better and raised HDL.

Wally R. Smith, MD, Associate Professor and Chairman, Division of Quality Health Care, Virginia Commonwealth University
Dr. Smith's presentation was entitled -- a "statin" is not a "statin". He stated the lower the better when it comes to LDL and it does matter how you get lower. He referred to the A TO Z trial. He stressed the importance of the reversal trial with high potency statins. Discussed the clinical difference between high potency verses lower potency statins. He sees a place for atorvastatin.

Emmanuel Mahlis, MD Medical Director, Merck& Company
The Heart protection study has been developed. No further information.

Dr. Steve Van Elkton, Piedmont Family Practice, (Affiliations with AstraZeneca, Bristol Myers Squibb, and Pfizer Pharmaceuticals)
Reviewed MIRACLE, and PROVEIT trials. Concluded that Lipitor is superior to other "statin."

Elaine Warner, Critical Care Nurse, Attorney
Discussed the Lips trial and Lescol® trial. Mark Oley commented that changes to the class were the addition of combination products Vytorin (combination of Zetia® and Zocor®),

Mark Szalwinski urged the Committee to use caution in the role of combination products.

A motion was made for the HMG-CoA Reductase Inhibitors (Statins) class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Selective Cox-2 Inhibitors and NSAIDS
Daniel Montero, M.D., Volvo Medical Associates, Chesapeake, Virginia
Dr. Montero urged the committee to review the increased risk of Vioxx® as compared to Celebrex®. He stated that these red flags similar to Hurricane warning; Hurricane Vioxx® has hit Tennessee Medicaid as shown in the race study in The Lancet 2002 and recently hit California in this recent study looking at Kaiser Permanente patients. He asked the Committee to offer a safe choice, sort of shelter especially in today's medical legal society and the choice to use Celebrex® and Bextra®.
Dr. Axelrod asked Dr. Montero to comment on the August 22nd article from The Lancet where two studies were published and then an editorial by two representatives of the Cleveland clinic about COX2's in general. (This article was presented for the Committee near the end of the meeting for review)
Dr. Montero was not familiar with the noted articles.
Dr. Axelrod reviewed the articles for the Committee. The cover to The Lancet article was a quote from the Cleveland clinic editorial. The editorial questioned the compelling reasons for the extraordinary adoption of these drugs being used at the level that they are in light of marginal efficacy and the increased risk; which they all have to some degree over a NSAID. Some it looks like worse than others and the cost component. Dr. Axelrod went on to say that it was a very compelling piece in which the latest target studies being published were reviewed.

Dr. Axelrod asked Dr. Montero if he could comment on the dosage, did he think that this was a dose-related event? Dr. Montero responded he thought it was, most of the studies show that this is a dose related event with the 50 mg Vioxx®.

Mark Oley asked if it was true that as yet, no prospective, randomized head-to-head comparison trials including all of the available COX2 agents have been completed. Dr. Montero said that this

is true that to date no head to head studies have been completed; however, he believed that comparison trials are in progress.

Mark Oley asked where the current data came from, if it were observational.

Dr. Montero replied that all of the data coming out now is retrospective.

Emmanuel Mahlis, MD Medical Director, Merck& Company
Dr. Mahlis discussed the indications of Vioxx® with the March 2004 FDA expansion that includes acute treatment of migraine headache with and without aura in adults and the additional indication approved two weeks ago for juvenile rheumatoid arthritis (indicated for children 2 years and older and 22 lbs or more.) Vioxx® is the only COX with these indications. He reviewed the studies that were done to receive these new indications.

Gill Abernathy asked what is Merck's official response to the recent Kaiser Permanente study.

Dr. Mahalis noted the study in question related to an off label use. The official response is that observational studies have significant weaknesses associated with them as compared with randomized, controlled trials. It is important to know that over 10,000 patients are listed in the Vioxx® label that has been studied in randomized controlled studies for safety - the VIGOR trial with over 8,000 patients with RA and CV 2142. Negative conclusions do tend to get a lot more publicity and it is important to be aware that in the same meeting (the European meeting where the negative information was presented) two other abstracts were also presented with much more favorable results for Vioxx®. The FDA had the opportunity to review Vioxx® with the recent label expansions and no changes were made.

Dr. Axelrod noted that the literature is really beginning to speak out in this class of drugs, more than any other class. It is important that the Committee be cognitive of what it looks like and what's going on; however, not to be overly reactive and like a ping-pong ball go back and forth on the class.

Mark Oley commented that the Committee should continue to include the COX2s as PDL eligible and that they were anxiously awaiting the comparison trials that he hoped are in progress.

Gill Abernathy commented she agreed that the Committee needs to listen to the recent literature and think it through. This may reaffirm that need to use NSAIDs first and the COX2s second in patients who are not a risk for GI bleed.

Dr. Beveridge suggested cautioned when interpreting data that was not done prospectively. Retrospective studies are very difficult to interrupt and at times in medicine, incorrect decisions have been made based on retrospective data.

A motion was made for the COX2 class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Proton Pump Inhibitors (PPIs)
Monique Morehead, Ph.D, Health Sciences Executive, TAP Pharmaceuticals
Discussed Previcid® and the three new indications that have been received; June of 2004 gained indication for adolescent patients 12 to 17 years of age. Second a solutab, a fast dissolve tablet just

received two new indications. The tablet may be dispersed in water and may be administered orally via an oral syringe or down a gastric tube as small as an 8 French tube.

Kristen Mack, Pharm.D., Assistant Director, Regional Medical Services, Janssen Medical Affairs, L.L.C.
Discussed Rabeprazole and reviewed the ADASHI article, a comparative study where erosive esophogitis was reviewed. It was relayed that a higher healing rates with lower probability of reoccurrence occurred with Rabeprazole. Discussed study that evaluated 7-day therapy and its impact on H-Pylori.

Douglas S. Levine, MD, FACG, Executive Director, Strategic Development, NEXIUM Development Brand Leader, AstraZeneca Pharmaceuticals
Dr. Levin noted that a lot of data has come out in the last year. Concerning acid inhibitory effects, he reviewed a study that was a 5-way crossover study, published by AstraZeneca, which went head to head with all PPIs. This was consistent with other similar studies published. Reflux disease and clinical efficacy using healing of erosive esophogitis as a marker of acid related disease Resistant GERD.
New information on alternative modes of administration granted labeling for NG-tube administration via suspension. Received an approval letter from FDA for an IV formulation that is expected to be approved next year. In all of these studies, there was no new information on safety and tolerability.
On demand use was looked at in a European study and on demand did not fair well. Just presented data for treating patients on nonselective NSAIDs or COX2s and demonstrated efficacy across the entire class in healing ulcers and ulcer prevention.

A motion was made for the Proton Pump Inhibitors (PPIs) class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Angiotensin II Receptor Blocking Agents (ARBs)

Dr. Ray Lancaster, Novartis Pharmaceuticals Corp.
Dr. Lancaster represents Diovan®. Discussed the VALUE trial that was published in Lancet in 2004, which consisted of 1500 patients. Follow was conducted up of 4.2 years with no difference between mortality and morbidity. The most interesting part of this study to the Medicaid population and the diabetic population was a 23% reduction of new onset Diabetes with in this particular trial. Compliance information from 2003 was presented, which compared an ARB, an ACE, and CCB. This was a retrospective data base analyses.

Funmi Odulolowu, Pharm.D D, Medical Science Manager, Bristol Myers Squibb
Reviewed the two land make studies involving Avapro.

John Kross, Pharm.D, Medical Information Scientist, AstraZeneca
Dr. Kross discussed Atacand® and presented a summary of the CHARM trial.

Emmanuel Mahlis, MD Medical Director, Merck& Company
Discussed Hyzaar® and its new indications for the treatment of hypertension. The fixed dose combination is not indicted for the initial therapy of hypertension, except when the hypertension is sever enough that the value of achieving prompt BP control exceeds the risk of indicating combination

A motion was made for the Angiotensin II Receptor Blocking Agents (ARBs) class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Angiotensin Converting Enzyme Inhibitors (ACE inhibitors)

Arlene R. Price, Pharm.D, National Clinical Executive, Abbott Laboratories

Mavik® and Tarka® were presented together. Dr. Price stated that Mavik® is cost competitive with all ACES even generic. They have a flat pricing across all doses so there is no increase cost with an increase in dose. Reviewed a cost effective study presented in May. The PEACE study will be presented at AHA in November, sponsored by NIH. The PEACE study will show the impact of trandolapril in terms of reducing cardiovascular morbidity and mortality. A subset of diabetic patients was reviewed in this study.

Tarka® is a combination product of Trandolapril and Terapamil - it provides additive reductions of blood pressure and proteinuria in hypertensive diabetics. This is an area that patients need to be aggressively managed. Dr. Price reviewed two new studies presented this year. One was a subset analysis of invest trial that was published in April 2004 in JAMA, in the diabetic population.

Edgar Gonzalez Pharm.D., Dean of College Pharmacy at Appalachian College in Grundy, Virginia

Dr. Gonzalez stated that he represented the underserved citizens of Southwest Virginia. He quoted a recent report presented to the Virginia legislature in the spring session of 2004. Citizens in Southwest, Virginia have a 26% greater mortality rate from MI and stroke and a 28% greater mortality rate from diabetes than the rest of Virginia. Dr. Gonzalez reviewed a recent study published in the July issue of Annuls of Internal Medicine, a retrospective study sponsored by the Canadian institute of health conducted at Miguel University. The study looked at 18,000 patients with a median age 75. Sample of 7,500 patients were derived and followed for 2 years. Dr. Gonzalez reviewed the positive impact of Ramipril (Altace®) as noted in this study. He asked that we look at outcomes data and explore the prospective value of this study.

A motion was made for the ACE inhibitors class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Beta Blockers

Phillip Duncan, MD, Virginia Heart Group, Richmond, Virginia

Dr. Duncan spoke about carvedilol and reviewed the metoprolol European COMMON trial that compared a head to head comparison of carvedilol to immediate release metoprolol. Dr. Duncan stated that he sees carvedilol as a unique molecule among the beta blockers. He calls it a sympathetic nervous system blocker because of its ability to block beta 1 and improve insulin sensitivity in patients.

Gill Abernathy noted that there is some question in the COMMON trial concerning the dose of metoprolol as the comparator - it is not equivalent to some of the doses used in the US. Dr. Duncan agreed with the comment, he views the importance of the trial as looking at the difference of the parasympathetic nervous system blockade verses beta 1 selective blockade.

John Kross, Pharm.D, Medical Information Scientist, AstraZeneca

Dr. Kross reviewed the metabolism of metoprolol XL.

Elaine Warner, Reliant Pharmaceuticals
Presenting Innopran XL- reviewed one study that was done by NUTALLIN and will be published this year. This study looked at ambulatory blood pressure monitoring; median age was 53 years old. The studied pulled out the top 25% responders to find a difference.

A motion was made for the Beta Blockers class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Inhaled Corticosteroids

Daria Brown, PharmD, BCPS, Medical Information Scientist, Respiratory, AstraZeneca Pharmaceuticals
Pulmicort Respule® was reviewed including the indication and new safety data that was released this year. Dr. Brown reviewed the study by Stan Suffler. Most important is that Pulmicort Respule®, is the most studied of all ICSS in reference to growth data. Pulmicort Respule® is an important first line in pediatrics.

Richard Thompson, Pharm.D, Regional Medical Scientist, GlaxoSmithKline
Dr. Thompson reviewed Advair Disc® and cited three studies. The first study reviewed cost effectiveness, the second study expanded COPD as a new indication this year for Advair Disc®, and refill persistence was evaluated in the third study.
A motion was made for the Inhaled Corticosteroids class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Nasal Steroids

Richard Thompson, Pharm.D, Regional Medical Scientist, GlaxoSmithKline
Dr. Thompson reviewed a recent efficacy study of fluticasone and two safety studies of fluticasone.

Dr. Janice Riga, Shering-Plough
Dr. Riga reviewed the onset of action and safety of Nasonex®.

Daria Brown, PharmD, BCPS, Medical Information Scientist, Respiratory, AstraZeneca Pharmaceuticals
Dr. Brown stated that Rhinocort Aqua® was upgraded to a Category B for Pregnancy in 8/2004. Is the only in its class that is a Category B

A motion was made for the Nasal Steroids class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Inhaled Beta Adrenergics

Peter Hatala, Pharm.D, Sepracor, Inc.
Xopenex® is the single S isomer of albuterol. All other albuterols are 50% R AND S isomer. Reviewed articles that will be released this fall

A motion was made for the Inhaled Beta Adrenergics class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Calcium Channel Blockers

Sheryl Ashton, MD, Regional Medical Research Specialist, Pfizer INC.

Dr. Ashton reviewed Norvasc® and recent study, the Value trial. Commented that CCB are recommended for stage I and II hypertension

Elaine Warner
Reviewed a study completed this year concerning Dynacirc CR®

A motion was made for the Calcium Channel Blockers class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

H2 Antagonists

Mark Oley commented that changes to H2 Antagonists – new Axid® formulation approved – an oral solution. This is not available generically.

A motion was made for the H2 Antagonists class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Second Generation Antihistamines (LSAs)

Mark Oley commented that the Clarinex® solution was approved and indicated down to children 6 months of age for perennial allergic rhinitis and chronic idiopathic urticaria. Previously only Zyrtec® was approved for children this age. There is tentative FDA approval for a Zyrtec generic.

A motion was made for the Second Generation Antihistamines (LSAs) class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Sedative Hypnotics

Cecelia N. King, MPH, PhD, National Medical Manager, Sanofi~Synthelabo
Discussed two new studies concerning Ambian®. In one study, they reviewed falls in the geriatric population in relationship to use of Benzos. There is also a recommendation that the dose of Ambian be 5mg in the elderly population.

A motion was made for the Sedative Hypnotics class to remain PDL eligible. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod introduced Emily Wingfield from the Attorney General office.

COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL

Ms. Wingfield from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 33 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 33 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42 U.S.C. 1396r-8(b)(3)(D) requires such pricing information to be kept confidential. On this point federal law supersedes the Virginia FOIA. Since the P&T Committee must discuss

this pricing information as part of its duties, pursuant to federal law a confidential meeting must occur for the consideration of this pricing information She cautioned only this confidential information should be discussed.

Mark Oley, made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drugs previously discussed in today's meetings. This confidential meeting is authorized by Federal Law at 42 U.S.C. § 1396r-8(b)(3)(D) that requires this information to be kept confidential.

This motion was seconded and unanimously approved by the Committee.
The meeting adjourned to an executive session.

DISCUSSIONS FOR ROUND 1 ANNUAL REVIEW

HMG-CoA Reductase Inhibitors ("Statins")

Dr. Axelrod relayed that some questions came up during the confidential session concerning the contracting for HMG-CoA Reductase Inhibitors ("Statins"). First Health will follow up on the clarifications of these financial questions. Responses will be reviewed and discussed during a confidential session at the October 6th meeting. A final decision on this class will be made during the October 6th meeting.

Selective Cox-2 Inhibitors and NSAIDS

Dr. Axelrod opened discussion on this class. Gill Abernathy expressed a need for the Committee to further review some of the cardiac events recently noted with Vioxx. The Committee reviewed different ways to ensure that they make the most informed decision on COX-2. It was determined that a subcommittee would be developed. Dr. Roy Beveridge and Mark Oley were identified as the subcommittee to work with DMAS and First Health to identify some experts and bring information back to the Committee as soon as possible on retrospective as well as any prospective data. Dr. Axelrod reminded the group that, while the information was wanted quickly, the real priority is for the data to be of good quality and complete. No time line was developed. The class will continue to be reviewed for safety but this will not delay the PDL decision.

Mark Oley motioned to keep the Cox-2 Inhibitors as they appear on the PDL today. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod noted that the rest of the classes from today's discussion would be taken in mass. He read the classes in question.

Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors), Inhaled Beta Adrenergics. Beta Blockers, Calcium Channel Blockers, H2 Antagonists, Inhaled Corticosteroids, Nasal Steroids, Proton Pump Inhibitors (PPIs), Second Generation Antihistamines (LSAs), Sedative Hypnotics.

Mark Oley motioned to keep all of the mentioned classes as they appear on the PDL today. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod noted that concerning Angiotensin II Receptor Blocking Agents (ARBs)the proposed preferred drugs in this class were: Diovan, Benicar, Micardis, Cozaar

Mark Oley motioned to accept these drugs as preferred for the PDL. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod noted that concerning Angiotensin II Receptor Blocking Agents (ARBs) with diuretics the proposed preferred drugs in this class were Diovan HCT, Benicar HCT, Micardis HCT, and Hyzaar

Mark Oley motioned to accept these drugs as preferred for the PDL. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod relayed that this was a very hard meeting and thanked everyone for their time and patience. He thanked the speakers for their contributions. He commented that this was a lot of information to go through. The process has been very successful and that during the economic discussion market shares are reviewed as well. He stated that the Committee has heard positive comments concerning how Mr. Patrick Finnerty, the DMAS staff, and First Health have handled the process and driven the program in a clinical orientation first and a financial second. He believes this point is big advantage when the PDL is discussed with legislators and the medical staff with their peers. He thanked the group for sticking to this process. He reminded the group that this is an imperfect science and the need to have a fluid process that may be continually reviewed as needed. He informed the group that if anyone had any concerns that they should e-mail him in private so that they can be addressed.

Next meeting October 6th 2004 at 1:00 pm. DMAS Board meeting

Chairman Axelrod adjourned the meeting.