Meeting of the
Pharmacy and Therapeutics Committee
October 23, 2008
Draft Minutes

Members Present:	**Guests:**
Randy Axelrod, M.D., Chair	88 representatives from pharmaceutical companies, providers,
Mark Oley, R.Ph., Vice Chair	advocates, associations, etc
Roy Beveridge, M.D.	Aryana Kahlid from Secretary of Health and Human Resources Office
Gill Abernathy, M.S., R.Ph.	**DMAS Staff:**
James Reinhard, M.D.	Patrick Finnerty, Agency Director
Rachel M. Selby-Penczak, M.D.	Cheryl Roberts, Deputy Director of Programs and Operations
Renita Driver, Pharm.D.	Bryan Tomlinson, Director, Division of Health Care Services
Reuben Varghese, M.D.	Usha Koduru, Counsel to the Board, Office of the Attorney General
Tim Jennings, Pharm.D.	Phillip Amiss, Pharmacy Program Manager
	Keith Hayashi, RPh., Clinical Pharmacist
Absent:	Maryanne Paccione Information Management Consultant
Avtar Dhillon, M.D.	Meredith Lee, Policy Analyst
Mariann Johnson, M.D.	Patricia Bryant, Pharmacy Administrative Assistant
	First Health Staff:
	Debbie Moody, R.Ph, Clinical Manager Virginia
	Doug Brown, R.Ph, MBA Director Rebate Contracting Management
A quorum was present	Sandy Kapur, Pharm.D, Rebate Support
	Donna Johnson, R.Ph, Clinical Manager Virginia

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

Patrick Finnerty welcomed the Committee to the fall P&T meeting. He informed the group that Dr. Axelrod, the Chair was on his way and would be joining the meeting soon. Mr. Finnerty noted that some of the Committee members had to attend to other business later today and that the meeting was on a tight time schedule. He informed the group that Dr. Beveridge would open the meeting until Dr. Axelrod arrived.

ACCEPTANCE OF MINUTES FROM APRIL 22, 2008 MEETING

Dr. Beveridge asked if there were any corrections, additions or deletions to the minutes from the April 22, 2008, meeting. With no comments, the minutes were accepted as written.

Mr. Finnerty called the first speaker to address the Committee with clinical data. Mr. Finnerty also reviewed the 3-minute clock rule and reiterated that it was especially important to adhere to the 3-minute rule today since several of the committee members need to leave early to attend other commitments. We need to make sure there will be a quorum at the end of the day when the Committee will vote on the PDL classes.

New Drug PDL Phase II- Serotonin Receptor Agonists (Triptans)-TREXIMET®

Jonathan Bekenstein, MD, Associate Professor Neurology, VCU, discussed Triptans/NSAID combination - Treximet®

Dr. Axelrod arrived during the presentation. At the conclusion of the presentation, Dr. Axelrod asked Dr. Bekenstein to declare any affiliations or conflicts of interest. Dr. Bekenstein replied that he is on the speakers' board for GlaxoSmithKline**.**

COMMENTS AND WELCOME FROM DR. RANDY AXELROD, CHAIRMAN

Dr. Axelrod asked that each practicing physician and pharmacist declare any affiliations or conflicts of interest at the start of their presentations. He also thanked the Committee for all their time and continued support. He also reiterated the rules and importance of the three-minute clock. He assured the speakers time for questions from the Committee was not included in the three-minute limit. Dr. Axelrod noted that there were 19 speakers.

Melinda Wilson, Pharm D, Regional Medical Scientist, GlaxoSmithKline, discussed Triptans/NSAID COMBO - Treximet®

Dr. Axelrod asked if the mechanism of action was different or if it was the pharmacokinetics? Dr. Wilson replied that yes, it is both; with the two products they have a dual action.

MARK OLEY REVIEWED SEROTONIN RECEPTOR AGONISTS (TRIPTANS) TREXIMET®

The FDA approved an oral, fixed-dose combination of Imitrex and naproxen sodium; it is called Treximet. A generic for Imitrex tablets is expected to be available in December. At first there will be only one generic, but when the patent expires in February 2009, it is expected that many different generics will be available.

Mark Oley motioned that new Serotonin Receptor Agonists (Triptans) Treximet be PDL eligible. The motion was seconded. The Committee voted unanimously to consider Serotonin Receptor Agonists (Triptans) Treximet as PDL eligible.

CONTINUATION OF COMMENTS AND WELCOME FROM DR. RANDY AXELROD, CHAIRMAN

Ranbaxy, one of the largest foreign suppliers of generics to the U.S., recently announced that the U.S. Food and Drug Administration (FDA) issued warning letters suspending importation of approximately 30 products manufactured in two plants in India. Although these products will no longer be imported into the U.S., the FDA said this action does not involve removing these products from the market or from the supply chain. The impact from this is that a few popular products will either not be available as a brand or generically, such as Amoxicillin Chewable Tablets. Ranbaxy was the exclusive supplier for this product. In addition, other products will be available by only one generic supplier, for example, drugs like Ofloxacin tablets and Cefaclor capsules. With Ranbaxy exiting the market for this product, there are expected to be supply and price disruptions– particularly during the cough and cold season.

Dr. Axelrod reminded the Committee that at the last meeting, the Committee discussed in detail the Oral Hypoglycemic class and considered the need for step therapy. He reminded the group the discussion revolved around the DPPIV inhibitors class. Dr. Axelrod spoke with several Endocrinologists and conducted an extensive review of the current diabetic guidelines, including both the 2008 ADA as well as what the American Academy of Clinical Endocrinologists has published in the past 18 months. The consensus was that if the Committee wanted to place a step therapy around Sulfonylureas and Metformin as a first step this was acceptable. However, multiple steps are not consistent with current clinical pathways that are published today. In consideration, with what our market share for this class is in Virginia, it is consistent with other states that have step edits in place. With all of these points noted above. Dr. Axelrod recommended not implementing a step therapy for the Oral Hypoglycemic class at this time; a motion to accept Dr. Axelrod's recommendation was seconded and accepted unanimously by the Committee.

Nathan T. Howard, Pharm.D, Senior Medical Information Scientist, Proctor &Gamble, discussed Actonel® (risedronate)
There were no questions or comments from the Committee.

To allow practicing physicians to return to their practices, Dr. Axelrod called speakers and reviewed classes in a different order from noted on the agenda.

Dr. Domenic Sica, Head of Clinical Pharmacology & Hypertension Nephrology, Department of Medicine, Virginia Commonwealth University, discussed Direct Renin Inhibitor ~ Tekturna® (aliskerin)
Dr. Axelrod asked if all of the hypertensive individuals in the world were combined what percentage would need to be on Tekturna.

Dr. Sica replied that this was a tough question. Physicians struggle to get to goal and need everything in the arsenal to get there. Typically, a person requires one, two or more products to get them to target. In the Richmond market, 45% of individuals have hypertension. Tekturna does not have a place as single therapy; however, it does as an add-on therapy. This area has a high incidence of hypertension and the hypertension is tenacious. It is not just this area where this is occurring; it is a national trend for people to be on more than three agents to treat to goal.

Dr Axelrod noted that the Joint National Committee (JNC) guidelines appear to be several years behind what is occurring in practice.

Dr. Sica replied that a JNC has convened; an initiative from the National Heart and Lung Institute is to collect guidelines on cholesterol, glycemic control and blood pressure to develop a universal set of guidelines that are more global and will be applicable to clinicians. This will be JNC-8 (eight). It will not focus just on hypertension.

Steven M. Koenig, MD, FCCP; Pulmonary, Critical Care & Sleep Medicine in Charlottesville, VA, UVA, discussed COPD Anticholinergics ~ Spiriva®
Dr. Jennings asked how the recent cardiac toxicity findings influence the speaker's practice.

Dr. Koenig replied that these findings came from a meta-analysis in JAMA, and meta-analyses are just hypothesis generating. Dr. Koenig said that if you looked at the details of the meta-analysis, there were many problems with it. Results of the UPLIFT (Understanding Potential Long-term Impacts on Function with Tiotropium) trial were just published in the New England Journal of Medicine. This was the right kind of study. It was a four-year, multicenter, multinational, randomized, double-blind, placebo-controlled, parallel-group prospective trial of 5993 male and female COPD patients. UPLIFT results showed no increased risk in mortality, including cardiac toxicity. Dr. Koenig added that when the UPLIFT data are included in the meta-analysis, you do not see the increased cardiac toxicity either, therefore, he was comfortable when he looks at the right kinds of data.

Debby Ham, M.D., National Medical Scientist for Respiratory; Boehringer Ingelheim, discussed COPD Anticholinergics ~ Spiriva®
There were no questions or comments from the Committee

New Drug In PDL Phase II -Cephalosporins - Cefuroxime Axetil Suspension

MARK OLEY REVIEWED CEPHALOSPORINS - CEFUROXIME AXETIL SUSPENSION
There is a new first time Generic for the brand suspension Ceftin.

Mark Oley motioned that the first time generic Cephalosporin cefuroxime axetil suspension be PDL eligible.. With the motion seconded, the Committee voted unanimously that the first time generic Cephalosporin cefuroxime axetil suspension be PDL eligible.

***New Drugs in PDL Phase II- Diabetes Oral Hypoglycemics-P*randimet® and New First Time Generic Acarbose**

MARK OLEY REVIEWED DIABETES ORAL HYPOGLYCEMICS - PRANDIMET® AND NEW FIRST TIME GENERIC ACARBOSE

PrandiMet® is a combination of two agents Prandin® and metformin. It is made by Novo Nordisk and received FDA approval on June 23, 2008. It is not on shelves yet, but will be very soon. It is for the treatment of Type 2 Diabetes Mellitus. There is a new first time generic acarbose for Precose®; it is an Alpha-Glucosidase Inhibitor.

Mark Oley motioned that the new Diabetes Oral Hypoglycemic agents PrandiMet® and new first time generic acarbose be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the new Diabetes Oral Hypoglycemic agents PrandiMet® and new first time generic acarbose PDL eligible.

MARK OLEY REVIEWED STIMULANTS/ADHD MEDICATIONS - LIQUADD® (NEW DOSAGE FORM OF CURRENT DRUGS)

Liquadd® was FDA approved as a new dosage formulation for Dextroamphetamine sulfate on March 10, 2008. It is an oral solution available as 5mg/5 ml. It is for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Mark Oley motioned that the new Stimulants/ADHD Medications, LiquADD®, be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the new Stimulants/ADHD Medications, LiquADD®, as PDL eligible.

MARK OLEY REVIEWED BISPHOSPHONATES FOR OSTEOPOROSIS - ACTONEL® 150MG

Actonel 150mg is a new once per month dosage of the oral bisphosphonate from Procter & Gamble that was released April 22, 2008.

Mark Oley motioned that the new Bisphosphonate for Osteoporosis, Actonel 150mg, be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the new Bisphosphonate for osteoporosis Actonel 150mg as PDL eligible.

Phase I PDL Annual Review-Asthma and Allergy- Antihistamines –2nd Generation

MARK OLEY REVIEWED ASTHMA AND ALLERGY- ANTIHISTAMINES –2ND GENERATION

The Over-The-Counter (OTC) choices continue to grow with the addition of Cetirizine OTC (Zyrtec®). It is the next 2nd-generation H1- antihistamine to become available over the counter. The antihistamine decongestant combination product cetirizine/pseudoephedrine (Zyrtec-D®) is also available.

Mark Oley motioned that asthma and allergy-Antihistamines – 2nd generation (includes combination products) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider asthma and allergy-Antihistamines – 2nd generation (includes combination products) as PDL eligible.

Phase I PDL Annual Review-Gastrointestinal - Proton Pump Inhibitors (PPIS)

DR. JENNINGS REVIEWED GASTROINTESTINAL - PROTON PUMP INHIBITORS (PPIS)

Omeprazole- RX delayed-release capsule has been generically available in strengths of 10mg and 20mg and is now available generically in 40mg strength. Aciphex® is now approved for short-term (up to eight weeks) treatment of gastroesophageal reflux disease (GERD) in adolescents twelve years of age and older. Nexium® is now approved for short-term use in children, ages one to eleven years of age, for treatment of gastroesophageal reflux disease (GERD). Both the delayed-release capsule and the liquid formulation are approved for this age and indication.

Dr. Jennings motioned that Gastrointestinal - Proton Pump Inhibitors (PPIs) Agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Gastrointestinal - Proton Pump Inhibitors (PPIs) Agents as PDL eligible.

Phase I PDL Annual Review-Gastrointestinal Histamine 2 Receptor Antagonists (H-2RA)

DR. JENNINGS REVIEWED GASTROINTESTINAL - HISTAMINE 2 RECEPTOR ANTAGONISTS (H-2RA)

No change in this class.

Dr. Jennings motioned that Gastrointestinal - Histamine 2 Receptor Antagonist (H-2RA) Agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Gastrointestinal - 2 Receptor Antagonist (H-2RA) Agents as PDL eligible.

Phase I PDL Annual Review-Electrolyte Depleters

DR. JENNINGS REVIEWED ELECTROLYTE DEPLETERS

No change in this class.

Dr. Jennings motioned that Electrolyte Depleter Agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Electrolyte Depleter Agents as PDL eligible.

Phase I PDL Annual Review-Topical Immunomodulators

DR. JENNINGS REVIEWED TOPICAL IMMUNOMODULATORS

No change in this class.

Dr. Jennings motioned that Topical Immunomodulator Agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Topical Immunomodulator Agents as PDL eligible.

Phase I PDL Annual Review-Growth Hormones

Dr. Jennings reviewed Growth Hormone Agents

No change in this class.

Dr. Jennings motioned that Growth Hormone Agents be PDL eligible. With the motion seconded, the Committee voted unanimously to consider Growth Hormone Agents as PDL eligible.

Phase I PDL Annual Review-Phosphodiesterase 5 Inhibitor for Pulmonary Arterial Hypertension (PAH)

GILL ABERNATHY REVIEWED CARDIAC MEDICATIONS-PHOSPHODIESTERASE 5 INHIBITOR FOR PULMONARY ARTERIAL HYPERTENSION
No change in this class.

Gill Abernathy motioned that Phosphodiesterase 5 Inhibitor be PDL eligible. With the motion seconded, the Committee voted unanimously to consider Phosphodiesterase 5 Inhibitor as PDL eligible.

Phase I PDL Annual Review-Hepatitis C Treatment Agents

Robert Cortes, Medical Science Specialist, Virology Schering-Plough Corporation, discussed Antivirals: Hepatitis C ~ PegIntron®
No questions or comments from the Committee.

DR. JENNINGS REVIEWED HEPATITIS C TREATMENT AGENTS
No real change in this class.

Dr. Jennings motioned that Hepatitis C Treatment Agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider Hepatitis C Treatment Agents as PDL eligible.

Phase I PDL Annual Review-Urinary Antispasmodics

Michelle Mattox, PharmD, Director, Urology/Sexual Medicine, Pfizer, discussed Urinary Antispasmodics-Detrol LA®
Dr. Axelrod asked when Detrol LA would lose its patent.
Dr. Mattox replied she believed in 2012.

DR. JENNINGS REVIEWED URINARY ANTISPASMODICS
No change in this class.

Dr. Jennings motioned that the Urinary Antispasmodics class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the Urinary Antispasmodics class as PDL eligible.

Phase I PDL Annual Review-Central Nervous System Benzodiazepine and Other Sedative Hypnotics

Jeffrey Harless, PhD, Internal Medicine-General Therapeutics, US Medical Affairs Sanofi-Aventis, discussed Sedative Hypnotics (Non-Benzodiazepine) - Ambien® CR
No questions or comments from the Committee.

GILL ABERNATHY REVIEWED CENTRAL NERVOUS SYSTEM- BENZODIAZEPINE AND NON-BENZODIAZEPINE SEDATIVE HYPNOTICS
No real change in these classes.

Gill Abernathy motioned that Central Nervous System- Benzodiazepine and Other Sedative Hypnotics continue to be PDL eligible. With the motion seconded, the Committee voted unanimously

to continue to consider Central Nervous System- Benzodiazepine and Other Sedative Hypnotics as PDL eligible

***Phase I PDL Annual Review-Asthma and* Allergy Classes: Nasal Steroids**

Jeffrey Harless, PhD, Internal Medicine-General Therapeutics, US Medical Affairs Sanofi-Aventis, discussed Nasal Steroids-Nasacort® AQ
No questions or comments from the Committee.

Tameka Lucas, PharmD, GlaxoSmithKline Regional Medical Scientist, Respiratory/Bone Health, discussed Nasal Steroids-Veramyst®
No questions or comments from the Committee.

MARK OLEY REVIEWED NASAL STEROIDS
Nasacort AQ® Nasal Spray is now approved for use in children two to five years of age. Previously, it had been approved for use in pediatric patients six years of age and older.

Mark Oley motioned that Nasal Steroids be PDL eligible. With the motion seconded, the Committee voted unanimously to consider Nasal Steroids as PDL eligible.

Phase I PDL Annual Review-Beta-2 Adrenergics

S Ronald Williams, MD, Assistant Professor Pediatric Pulmonology, VCU, discussed Beta-2 Adrenergic Agents-Xopenex®
Gill Abernathy asked about the studies that show decreased hospital stays and that it is more cost effective.
Dr. Williams replied that he is not sure if it is more cost effective, but the frequency of treatment is less often with Xopenex® than with albuterol.
Gill Abernathy asked if you dose them differently.
Dr. Williams replied yes.
Dr. Axelrod asked what the length of stay was.
Dr. Williams replied that one discharge criteria is that the patient must go 4 hours without a rescue treatment. In his opinion the Xopenex® helps get to that end point sooner.

Tameka Lucas, PharmD, GlaxoSmithKline Regional Medical Scientist, Respiratory/Bone Health, discussed Inhaled Corticosteroids Combination Products (Glucocorticoid and Beta Adrenergic)-Advair®
No questions or comments from the committee

Dr. Axelrod commented on Dr. Williams' discussion concerning the Xopenex® study discussed earlier. Dr. Axelrod noted that he did see the financial information but did not see anything with length of stay. It was noted that the length of stay difference between the two products was 5 hours. Dr. Williams agreed that no financial information was included in the study.

MARK OLEY REVIEWED BETA-2 ADRENERGICS
The CFC-propelled inhalers for albuterol will not be available in the United States after December 31, 2008. Recipients need to be switched to an HFA propelled inhaler for albuterol. The standard three available as an HFA version include -Proair® HFA, Proventil® HFA and Ventolin® HFA. Additionally, Xopenex® HFA is now available.

Mark Oley motioned that beta-2 agonist be PDL eligible. With the motion seconded, the Committee voted unanimously to consider beta-2 agonist as PDL eligible.

Phase I PDL Annual Review- COPD Anticholinergics

MARK OLEY REVIEWED COPD ANTICHOLINERGICS
Mark Oley mentioned that the UPLIFT trial had been discussed. He said that if the Committee had other questions, he would answer them.

Mark Oley motioned that COPD Anticholinergics be PDL eligible. With the motion seconded, the Committee voted unanimously to consider COPD Anticholinergics as PDL eligible.

Phase I PDL Annual Review- Inhaled Corticosteroids

MARK OLEY REVIEWED INHALED CORTICOSTEROIDS
No real change in this class.

Mark Oley motioned that Inhaled Corticosteroids continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Inhaled Corticosteroids as PDL eligible.

Phase I PDL Annual Review-Cardiac Medications: Calcium Channel Blockers

Sarah Karish Marshall, PharmD, National Medical Scientist, Boehringer Ingelheim Pharmaceuticals, Inc., discussed Angiotensin Receptor Blockers (ARB) + ARB Diuretic Combo -Micardis/Micardis HCT
Dr. Axelrod commented that he is troubled that the JNC specific guidelines for hypertension have been rolled-up into other disease states; he believes this is a valuable tool lost to physicians.

Michael R. DeLucia, RPh, Senior Managed Care Clinical Specialist, Forest, discussed Beta-Blocker-Bystolic
No questions or comments from the Committee.

GILL ABERNATHY REVIEWED CALCIUM CHANNEL BLOCKERS
No real change in this class.

Gill Abernathy motioned that all Calcium Channel Blocker Agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Calcium Channel Blocker Agents as PDL eligible.

Phase I PDL Annual Review-Beta Blockers

GILL ABERNATHY REVIEWED BETA BLOCKERS,
Bystolic is a new drug that has a different mechanism of action and has been approved by FDA for the treatment of hypertension. The American College of Cardiology recommends Bystolic for the non-approved indication of Congestive Heart Failure (CHF) though there are no outcome studies for anything other than hypertension.

Gill Abernathy motioned that all Beta Blocker Agents be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Beta Blocker Agents as PDL eligible.

Phase I PDL Annual Review-Angiotensin Receptor Blockers (ARBS)

GILL ABERNATHY REVIEWED CARDIAC MEDICATIONS- ANGIOTENSIN RECEPTOR BLOCKERS (ARBS)
There have been some interesting studies concerning ACE Inhibitors being similar to Angiotensin Receptor Blockers. They should not be used together, but they can be used in similar conditions. However, no real change in this class.

Gill Abernathy motioned that Cardiac Medications- all ARBS be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Cardiac Medications- all ARBS as PDL eligible.

Phase I PDL Annual Review- ACE Inhibitors Including Rennin Inhibitors

GILL ABERNATHY REVIEWED CARDIAC MEDICATIONS-ACE INHIBITORS, INCLUDING RENNIN INHIBITORS
No real change in this class.

Gill Abernathy motioned that all Cardiac Medications (all ACE Inhibitors, ARBs including combinations, all Calcium Channel Blockers, all Beta Blockers and their combinations) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider all Cardiac Medications (all ACE Inhibitors including Rennin inhibitors, all Calcium Channel Blockers, and all Beta Blockers) as PDL eligible.

Phase I PDL Annual Review-HMG COA Reductase Inhibitors (Statins); Lipotropics Non-Statins: Fibric Acid; Omega3; Niacin Derivatives and Others

Margaret Savage, MD, MPH, Account Manager, MerckScheringPlough, discussed Lipotropics – HMG CoA Reductase Inhibitors and Combinations (Statins) -Vytorin® and Zetia®
Dr. Axelrod commented that he believes that IMS DATA reveals that some physicians have followed the media information around potential Zetia and cancer reports.
Dr. Savage commented that she believes that there has been some response from the medical community after the lay press reports came out. There is a need for medical data to be reported to the medical committee first.

Pam Sardow, PharmD, Government Regional Clinical Executive, Public Health Policy and Strategy, Abbott discussed Lipotropics – Niacin Derivatives & HMG CoA Reductase Inhibitors (Statins) Combination ~ Simcor
No questions or comments from the Committee.

Ahmad Nessar, RPh, PharmD, Regional Scientific Manager, AstraZeneca, discussed Crestor ® (HMG CoA Reductase Inhibitors (Statins))
No questions or comments from the Committee

GILL ABERNATHY REVIEWED HMG COA REDUCTASE INHIBITORS (STATINS)
No real change in this class. There is the new Simvastatin and niacin combination that we have discussed before and will await Crestor® outcomes studies.

Gill Abernathy motioned that Cardiac Medications HMG CoA Reductase Inhibitors and their combinations (Statins) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Cardiac Medications HMG CoA Reductase Inhibitors (Statins) as PDL eligible.

GILL ABERNATHY REVIEWED LIPOTROPICS NON-STATINS: FIBRIC ACID
No real change in this class.

Gill Abernathy motioned that Cardiac Medications Lipotropics Non-Statins: Fibric Acid continue to be PDL eligible. With the motion seconded, the Committee voted unanimously that Cardiac Medications Lipotropics Non-Statins; Fibric Acid continue to be PDL eligible.

GILL ABERNATHY REVIEWED CARDIAC MEDICATIONS LIPOTROPICS NON-STATINS: NIACIN DERIVATIVES AND OTHER
No real change in this class.

Gill Abernathy motioned that Cardiac Medications Lipotropics Non-Statins Niacin Derivatives and other continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider Cardiac Lipotropics Non-Statins Niacin Derivatives as PDL eligible.

GILL ABERNATHY REVIEWED CARDIAC MEDICATIONS LIPOTROPICS NON-STATINS: OMEGA3
No real change in this class.

Gill Abernathy motioned that Cardiac Medications Lipotropics Non-Statins Omega3 continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider Cardiac Medications Lipotropics Non-Statins Omega3 as PDL eligible.

GILL ABERNATHY REVIEWED CAI AGENTS
Gill Abernathy reviewed data from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial of a possible association between the use of Vytorin and a potentially increased incidence of cancer. Preliminary results from the SEAS trial were released in July 2008. The clinical trial tested whether lowering LDL with Vytorin would reduce the risk of cardiovascular (CV) events in individuals with aortic stenosis. A lower overall CV risk was not found with Vytorin. However, there was an additional observation that a larger percentage of subjects treated with Vytorin were diagnosed with and died from all types of cancer combined when compared to placebo during the 5-year study.

The committee discussed the ENHANCE and the SEAS trials and agreed that more information is needed before any change in therapy is warranted.

Gill Abernathy motioned that Cardiac Medications Lipotropics Non-Statins CAI continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to consider Cardiac Medications Lipotropics Non-Statins CAI as PDL eligible.

CALL FOR CONFIDENTIAL SESSION
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 drug classes discussed at this P&T Committee meeting. 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.

COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL

Ms. Usha Koduru 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.

This motion was seconded and unanimously approved by the Committee.

The meeting adjourned to an executive session.

The committee returned from the executive session, Dr. Axelrod made the following comments.

Dr. Axelrod confirmed that to the best of each of the Committee member's knowledge the only information discussed at the confidential meeting was information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. As authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

The motion was made to continue the meeting
This motion was seconded and unanimously approved by the Committee

CRITERIA DISCUSSION OF PHASE I AND PHASE II

The Committee reviewed the current PDL criteria and the following motions were made:

Gill Abernathy motioned that recipients on Amiodarone who require a dose of greater than Simvastatin 20mg be automatically granted a PA when the physician or pharmacy calls. With the motion seconded, the Committee voted unanimously to make this change to the criteria.

No other changes to the criteria were identified.

GENERIC WATCH AND NEW DRUGS IN PHASE II REVIEW

Mark Oley made a motion to accept the change that occurred to the Bisphosphonates class on 9/9/08 per Generic policy, where generic alendronate tablets became preferred and the brand Fosamax® non-preferred. With the motion seconded, the Committee voted unanimously to maintain the current Bisphosphonates class with generic alendronate tablets preferred and the brand Fosamax® non-preferred.

Mark Oley made a motion to maintain the current PDL Antiviral Famvir® as brand preferred over the generic equivalent with no change. With the motion seconded, the Committee voted unanimously to maintain the current Antiviral Famvir® as brand preferred over the generic equivalent with no change

Mark Oley made a motion to maintain the current PDL Long acting Narcotic- Duragesic® as brand preferred over the generic equivalent with no change. With the motion seconded, the Committee

voted unanimously to maintain the current Long acting Narcotic- Duragesic® as brand preferred over the generic equivalent with no change.

Mark Oley made a motion to make the following change to the Calcium Channel Blocker class, both the generic nisoldipine and brand Sular® will be non-preferred starting 10/24/2008. With the motion seconded, the Committee voted unanimously to change the Calcium Channel Blocker class, both generic nisoldipine and brand Sular® will be non-preferred starting 10/24/2008.

Mark Oley made a motion to maintain the current PDL PPI Prilosec® OTC and Protonix® as brands preferred over the generic equivalent with no change. With the motion seconded, the Committee voted unanimously to maintain the current PPI Prilosec OTC and Protonix as brands preferred over the generic equivalent with no change.

Mark Oley made a motion to make the following change to the CCB/ACEI combinations class both brand Lotrel® and generic amlodipine/ benazepril will be preferred starting 10/24/08. With the motion seconded, the Committee voted unanimously to change the CCB/ACEI combinations class both brand Lotrel® and generic amlodipine/ benazepril being preferred starting 10/24/08.

Mark Oley made a motion to maintain the current PDL Oral Hypoglycemics –Alpha/Glycoside inhibitors Precose® as brands preferred over the generic equivalent with no change to the class. With the motion seconded, the Committee voted unanimously to maintain the current Oral Hypoglycemics –Alpha/Glycoside inhibitors Precose® as brands preferred over the generic equivalent with no change to the class. Dr. Axelrod clarified that there were no changes in the Oral Hypoglycemics-Meglitinides class as well. Mark Oley agreed.

Mark Oley made a motion to make the following change to the Short Acting Nebulizers class, to move the brand Accuneb® to non-preferred on 10/24/08. With the motion seconded, the Committee voted unanimously to change the Short Acting Nebulizers class, to move the brand Accuneb® to non-preferred on 10/24/08.

Mark Oley made a motion to maintain the current PDL Central Nervous System Stimulants/ADHD Focalin® brands preferred over the generic equivalent with no change to the class. With the motion seconded, the Committee voted unanimously to maintain the current Central Nervous System Stimulants/ADHD Focalin® brands preferred over the generic equivalent with no change to the class.

Mark Oley made a motion to maintain the current PDL Second Generation Cephalosporins class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Second Generation Cephalosporins class with no change.

Mark Oley made a motion to maintain the current PDL Triptans class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Triptans class with no change.

Mark Oley made a motion to maintain the current PDL Fibric Acid Derivatives class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Fibric Acid Derivatives class with no change.

Phase I PDL Annual Review~PDL Status Changes Effective January 1, 2009 Unless Otherwise Noted

PDL PHASE I ANNUAL REVIEW AND BISPHOSPHONATES RE-REVIEW TO START JANUARY 1, 2009

Mark Oley made a motion to maintain the current PDL Asthma and Allergy Beta Adrenergic Agents Short Acting Nebulizers class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy Beta Adrenergic Agents Short Acting Nebulizers class with no change.

Mark Oley made a motion to maintain the current PDL Urinary Antispasmodics class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Urinary Antispasmodics class with no change.

Mark Oley made a motion to make the following change to the Beta Adrenergic Agents Short Acting and Combination Metered Dose Inhalers or Devices class; to move Proair® HFA to preferred and Alupent® MDI to non-preferred. With the motion seconded, the Committee voted unanimously to change the Beta Adrenergic Agents Short Acting and Combination Metered Dose Inhalers or Devices class as stated.

Mark Oley made a motion to maintain the current PDL Growth Hormones class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Growth Hormones class with no change.

Mark Oley made a motion to make the following change to the Bisphosphonates class, to move Actonel® to non-preferred. With the motion seconded, the Committee voted unanimously to make the following change to the Bisphosphonates class, move Actonel® to non-preferred. ***(The Bisphosphonates class financials were re-reviewed- see spring 2008 meeting minutes.)***

Mark Oley made a motion to make the following change to the Lipotropics – HMG CoA Reductase Inhibitors (Statins) class- Advicor®, Altoprev® Lescol® and Lescol XL® to be moved to non-preferred. With the motion seconded, the Committee voted unanimously to make the change as stated.

Mark Oley made a motion to maintain the current PDL Antivirals: Hepatitis C class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Antivirals: Hepatitis C class with no change.

Mark Oley made a motion to make the following change to the Dihydropyridine Calcium Channel Blockers- Plendil® and Sular® be moved to non-preferred. With the motion seconded, the Committee voted unanimously to change the Dihydropyridine Calcium Channel Blockers- Plendil® and Sular® to non-preferred.

Mark Oley made a motion to maintain the current PDL Direct Renin Inhibitors class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Direct Renin Inhibitors class with no change.

Mark Oley made a motion to maintain the current PDL Angiotensin Receptor Blockers + Calcium Channel Blocker Combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Angiotensin Receptor Blockers + Calcium Channel Blocker Combinations class with no change.

Mark Oley made a motion to maintain the current PDL Asthma and Allergy Inhaled Corticosteroids (includes Metered Dose Inhalers, Nebulizer Solution and Combination Products) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy Inhaled Corticosteroids (includes Metered Dose Inhalers, Nebulizer Solution and Combination Products) class with no change.

Mark Oley made a motion to maintain the current PDL Asthma and Allergy Beta Adrenergics class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy Beta Adrenergics class with no change.

Mark Oley made a motion to maintain the current PDL Asthma and Allergy Nasal Steroids class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy Nasal Steroids class with no change.

Mark Oley made a motion to maintain the current PDL Asthma and Allergy COPD Anticholinergics class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy COPD Anticholinergics class with no change.

Mark Oley made a motion to maintain the current PDL Asthma and Allergy Second Generation Antihistamines (LSAs) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy Second Generation Antihistamines (LSAs) class with no change.

Mark Oley made a motion to maintain the current PDL Asthma and Allergy Second Generation Antihistamines and Combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Asthma and Allergy Second Generation Antihistamines and Combinations class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors) with no changes.

Mark Oley made a motion to maintain the current PDL Cardiac Medications ACE Inhibitors + Diuretic Combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications ACE Inhibitors + Diuretic Combinations with no changes.

Mark Oley made a motion to maintain the current PDL Cardiac Medications ACE Inhibitors + Calcium Channel Blocker Combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications ACE Inhibitors + Calcium Channel Blocker Combinations with no changes.

Mark Oley made a motion to maintain the current PDL Cardiac Medications Angiotensin Receptor Blockers (ARBs) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Angiotensin Receptor Blockers (ARBs) class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications Angiotensin Receptor Blockers + Diuretic Combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Angiotensin Receptor Blockers + Diuretic Combinations class with no change

Mark Oley made a motion to maintain the current PDL Cardiac Medications Beta Blockers class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Beta Blockers class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications Alpha/Beta Blockers class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Alpha/Beta Blockers class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Beta Blockers + Diuretic Combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Beta Blockers + Diuretic Combinations class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications Non-Dihydropyridine Calcium Channel Blockers class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Cardiac Medications Non-Dihydropyridine Calcium Channel Blockers class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications, Lipotropics Non-Statins: Fibric Acid class with no change. This included the CAI and Omega 3 products. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications, Lipotropics Non-Statins: Fibric Acid class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications, Lipotropics HMG CoA Reductase Inhibitors and Combinations (High Potency Statins) with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications, Lipotropics HMG CoA Reductase Inhibitors and Combinations (High Potency Statins) class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications, Lipotropics – Niacin Derivatives & HMG CoA Reductase Inhibitors (Statins) Combination with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications, Lipotropics – Niacin Derivatives & HMG CoA Reductase Inhibitors (Statins) Combination class with no change.

Mark Oley made a motion to maintain the current PDL Cardiac Medications Phosphodiesterase 5 Inhibitor for Pulmonary Arterial Hypertension class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Cardiac Medications Phosphodiesterase 5 Inhibitor for Pulmonary Arterial Hypertension class with no change.

Mark Oley made a motion to maintain the current PDL Sedative Hypnotics (Benzodiazepine) And Sedative Hypnotics (Non-Benzodiazepine) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Sedative Hypnotics (Benzodiazepine) And Sedative Hypnotics (Non-Benzodiazepine) class with no change.

Mark Oley made a motion to maintain the current PDL Gastrointestinal Histamine 2 Receptor Antagonists (H-2RA) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Gastrointestinal Histamine 2 Receptor Antagonists (H-2RA) class with no change.

Mark Oley made a motion to maintain the current PDL Gastrointestinal Proton Pump Inhibitors (PPIs) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Gastrointestinal Proton Pump Inhibitors (PPIs) class with no change.

Mark Oley made a motion to maintain the current PDL Electrolyte Depleters class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Electrolyte Depleters class with no change.

Mark Oley made a motion to maintain the current PDL Topical Immunomodulators class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Topical Immunomodulators class with no change.

Dr. Axelrod noted that the next meeting will be in the Spring of 2009. The meeting was adjourned.

Patrick Finnerty introduced Phillip Amiss as the new DMAS Pharmacy Program Manager, to the Committee.