

**Meeting of the  
Pharmacy and Therapeutics Committee  
April 17, 2007  
Minutes**

**Members Present:**

Randy Axelrod, M.D., Chair  
Mark Oley, R. Ph., Vice Chair  
Gill Abernathy, M.S., R.Ph.  
Avtar Dhillon, M.D.  
Rachel M. Selby-Penczak, M.D.  
Renita Driver, Pharm.D.  
Tim Jennings, R.Ph.  
Arthur Garson, M.D.  
Katherine Nichols, M.D.

**Absent:**

James Reinhard, M.D.  
Mariann Johnson, M.D.  
Roy Beveridge, M.D.

**A quorum was present**

**Guests:**

Manikoth Kurup, MD, Member Board of Medical Assistance Services  
75 representatives from pharmaceutical companies, providers,  
advocates, associations, etc.

**DMAS Staff:**

Patrick Finnerty, Agency Director  
Cheryl Roberts, Deputy Director of Programs and Operations  
Bryan Tomlinson, Director, Division of Health Care Services  
Reatha Kay, Counsel to the Board, Office of the Attorney General  
Keith Hayashi, R.Ph., Clinical Pharmacist  
Katina Goodwyn, Pharmacy Contract Manager  
Rachel Cain, Pharm.D, Clinical Pharmacist  
Maryanne Paccione, Information Management Consultant

**First Health Staff:**

Debbie Moody, R.Ph, Clinical Manager Virginia  
Doug Brown, R.Ph, Director of Rebate Contracting Management  
Sandy Kapur, Pharm.D, Rebate Support  
Justin Lester, Pharm.D, M.B.A., Clinical Manager DC

**WELCOME FROM DR. RANDY AXELROD, CHAIRMAN**

Dr. Axelrod welcomed the Committee and thanked them for their attendance and continued support. He stated that the Committee was invaluable to managing the program. Dr. Axelrod reviewed the meeting agenda. Dr. Axelrod called the meeting to order.

**WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR**

Patrick Finnerty welcomed the Committee to the meeting. He thanked the Committee members for their contributions. Mr. Finnerty commented that the PDL program continues to work very well and that the success is largely due to the Committee's efforts.

Mr. Finnerty reviewed with the Committee recent General Assembly activity related to Virginia Medicaid's pharmacy program. The Deficit Reduction Act (DRA) of 2005 mandated a change in the Medicaid reimbursement method for generic drugs. Reimbursement in the future will be based on the average manufacturer price (AMP). CMS is in the process of completing the rule making for this program. Once the rules are established, there is language in the Appropriations Act that directs DMAS to determine how this new program will affect its pharmacy program as well as retail pharmacies and report this information to the General Assembly.

In 2006, language was added to the Appropriations Act that directed Medicaid to develop a specialty drug program; some small changes to this program were made during this past General Assembly session. DMAS has planned a phased in approach to the specialty drug program with several different components that will be developed in the coming year. A review of the P&T Committee's role with this program would be reviewed during the meeting. Mr. Finnerty closed by thanking the Committee for their time and energy and stated that they are a great resource for the program.

**COMMENTS FROM DR. RANDY AXELROD, CHAIRMAN**

Dr. Axelrod expanded on Mr. Finnerty's comments concerning the Committee's role in the development of a specialty pharmacy program and reminded them of the presentation on specialty drugs during their

August 2005 meeting. Dr. Axelrod mentioned a number of specialty drug categories that lend themselves to management with the PDL approach as well as a care management component. He views this as an important step forward in the management of Medicaid pharmacotherapeutics. Specialty drug classes will be reviewed in more detail at the next P&T meeting. The Committee and other stakeholders will receive information concerning this meeting well in advance. He reviewed the guidance for presentations during the meeting.

**ACCEPTANCE OF MINUTES FROM October 23, 2006 MEETING**

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the October 23, 2006 meeting. Katherine Nichols, M.D. noted that she is currently associated with the Virginia Department of Health, full-time, and was formerly with Advocates for Children. Dr Axelrod noted the correction to her introduction at the last meeting for the minutes. He requested any other comments. With no other comments, the minutes were accepted with the noted correction.

**REVIEW OF PROTON PUMP INHIBITORS (PPI) DRUG CLASS**

At the last P&T Committee meeting during the PPI criteria review, the Committee requested that DMAS solicit feedback from a practicing gastroenterologist to ensure the PDL criteria are consistent with current medical practice standards of care. Tim Jennings reviewed the current criteria, which he had shared with a practicing gastroenterologist, Dr. Taylor Wooten for comment. Dr. Wooten noted that the current criteria are consistent with current medical practice standards of care and supported this approach. In addition, a review of other Medicaid programs' and Virginia health insurance plans' PPI criteria was conducted for comparison. This comparison found that the Virginia PPI criteria are similar to other plans across the Commonwealth (88% of the plans were consistent with Virginia Medicaid). On May 1<sup>st</sup>, the 120-day "automatic" prior authorizations, granted in January 2007 with the introduction of the new criteria, will be terminated. At this time, physicians will be required to ensure recipients meet criteria or receive prior authorization.

**Review of New Drugs in PDL Phase I**

**MARK OLEY REVIEWED A NEW DOSAGE FORMULATION COREG CR<sup>®</sup> (BETA BLOCKERS)**

GlaxoSmithKline added a new formulation of Coreg CR<sup>®</sup> to the market in March 2007. Coreg CR<sup>®</sup> is an extended release formulation of the Alpha/Beta-adrenergic blocker now approved, but in a once daily extended-release capsule for the treatment of hypertension, post-myocardial infarction, left ventricular dysfunction, and mild to severe heart failure. The drug is available in doses of 10, 20, 40 & 80 mgs. There were no other significant changes to this class.

Mark Oley motioned that Coreg CR<sup>®</sup> be PDL eligible.

The motion was seconded.

The Committee voted unanimously to consider Coreg CR<sup>®</sup> as PDL eligible.

**MARK OLEY REVIEWED THE NEW GENERIC OXYBUTYNIN CHLORIDE ER (URINARY TRACT ANTISPASMODICS)**

Oxybutynin chloride ER (Brand: Ditropan XL<sup>®</sup>) is a new first time generic, and is available in strengths of 5mg, 10mg, and 15mg. There were no other significant changes to this class.

Mark Oley motioned that Generic Oxybutynin Chloride ER be PDL eligible.

The motion was seconded.

The Committee voted unanimously to consider generic Oxybutynin Chloride ER as PDL eligible.

## **PHASE II PDL ANNUAL REVIEW**

### **Vanessa I. Land, Pharm.D., Senior Regional Medical Scientist, Clinical Development & Medical Affairs, Metabolic Division, GlaxoSmithKline Pharmaceuticals, discussed Avandamet®, Avandia® and Avandaryl™ (Biguanide Combination)**

ADOPT (A Diabetes Outcome and Progression Trial) was recently completed and published in the New England Journal of Medicine (Kahn et al., 2006. N Engl J Med, Vol. 355, No. 23:2427-2443). ADOPT is the largest head-to-head study to date. This was a randomized, double blind, parallel group study of patients with recently diagnosed type 2 diabetes mellitus with progression of diabetes. The study's primary goal was to compare glycemic control with rosiglitazone (Avandia®) relative to metformin and to glyburide monotherapies in over 4,400 randomized patients. There was a 32% risk reduction in time of monofailure with Avandia® compared with metformin and a 65% risk reduction in time of monofailure when compared with glyburide.

Since last year, both Avandamet® and Avandia® have received indications from the FDA for initial therapy in drug-naïve patients. These indications are unique to the GSK products.

One of two studies that achieved this indication was a 32-week, randomized, double-blind clinical trial. Drug-naïve patients with type 2 diabetes mellitus were randomized to Avandamet®, rosiglitazone, or metformin. Statistically significant improvements in FPG and HbA1c were observed in patients treated with Avandamet® compared to either rosiglitazone or metformin alone. No overall weight change was seen in this study. The pattern of LDL and HDL changes following therapy with rosiglitazone in combination with sulfonylureas were generally similar to those seen with rosiglitazone in monotherapy. Rosiglitazone as monotherapy was associated with increases in total cholesterol, LDL, and HDL and decreases in free fatty acids. The changes in triglycerides during therapy with rosiglitazone were variable and were generally not statistically different from placebo or glyburide controls. In a 28-week, randomized, double-blind clinical trial, 901 drug-naïve patients with type 2 diabetes were started on Avandia®, rosiglitazone, or glimepiride. Improvements in FPG and HbA1c were observed in patients treated with Avandia® compared to either rosiglitazone or glimepiride.

Dr. Garson asked why there was not a weight change seen during the studies. He suggested that GSK should consider a combined approach of control for type two diabetics.

The speaker agreed with the comment.

### **Dr. Charlie Kelly, Regional Scientific Manager, Takeda Pharmaceuticals America, Inc., discussed Actos®, Actosplusmet® and Duetact® (Thiazolidinediones)**

Dr. Kelly Reviewed a study entitled Chicago, A Study Evaluating Carotid Intima-Media Thickness in Atherosclerosis Using Pioglitazone published in JAMA (2006; 296: 2572-2581). It randomized 460 patients to Actos or the beneficial effect of Actos (Thiazolidinediones) in Carotid Intima-Media Thickness. This study is consistent with the Proactive trial, published in Lancet, showing the reduction of MI and stroke in type two diabetic patients by 16%.

### **Stephen George, MS, RPh, Vice President, Healthcare Consulting, Conexus Health, LLC. discussed Glumetza™ (Biguanides)**

Mr. George reviewed the current American Diabetes Association (ADA) standards of medical care for diabetes (Diabetes Care 2006; 29: Suppl (1):S4-42). ADA recommends Metformin as the drug of choice for diabetes, which should be titrated to its maximum effective dose within one to two months. Mr. George reviewed a study entitled Efficacy, tolerability, and safety of a novel once-daily extended-release Metformin in patients with type 2 diabetes (Schwartz S, Fonseca V, Berner B, Cramer M, Chiang Y-K, Lewin A. Diabetes Care 2006; 29(4):759-764). This study showed 60.04% of patients on two grams a day of Glumetza™ achieved A1C target goals of less than 7g/d. This was maintained over a period of 48 weeks. This difference from other products in this trial is statistically significant.

Glumetza™ has a unique delivery system that uses AcuForm™ technology. It is a three dimensional product and is different from other dosage forms of metformin including both the immediate release (IR) and extended release (ER) formulations. This difference reduces dose dumping and decreases side effects. There is approximately a 60% compliance rate with diabetics so tolerability drives compliance and adherence.

**GILL ABERNATHY REVIEWED ORAL HYPOGLYCEMICS: SECOND GENERATION SULFONYLUREAS**

There have been no significant changes in this class over the past year.

**GILL ABERNATHY REVIEWED ORAL HYPOGLYCEMICS: ALPHA-GLUCOSIDASE INHIBITORS**

There have been no significant changes in this class over the past year.

**GILL ABERNATHY REVIEWED ORAL HYPOGLYCEMICS: BIGUANIDES AND COMBINATIONS**

There have been no significant changes in this class over the past year.

**GILL ABERNATHY REVIEWED ORAL HYPOGLYCEMICS: MEGLITINIDES**

There have been no significant changes in this class over the past year.

**GILL ABERNATHY REVIEWED ORAL HYPOGLYCEMICS: THIAZOLIDINEDIONES**

Results of the ADOPT (A Diabetes Outcome and Progression Trial) were recently completed and published in the New England Journal of Medicine (Kahn et al., 2006. N Engl J Med, Vol. 355, No. 23:2427-2443). This study as well as the analysis showed the risk of fractures with rosiglitazone (Avandia®) was increased. It is believed that there may be a doubling of the fracture risk with rosiglitazone compared to placebo. The actual numbers appear to be 4.9 fractures per 100 patient years' verses 1.1 fractures per 100 patient years with patients on placebo. This number is low and the benefits of this drug should be considered. This risk of fracture is limited for women.

There is a new combination drug called Duetact® now available containing a Thiazolidinediones and a Sulfonylurea. It is a combination product of pioglitazone and glimepiride. The Manufacturer is Takeda and Duetact® is available in strengths of 30mg / 2mg and 30mg / 4mg.

Gill Abernathy motioned that reviewed Diabetic classes continue to be PDL eligible

The motion was seconded

The Committee voted unanimously that reviewed Diabetic classes would continue as PDL eligible.

**Danny Icenhour, Pharm.D, King Pharmaceuticals, Professional Information Services, discussed Avinza® (Long acting narcotics)**

Dr. Icenhour reviewed the Avinza® Comparator Trials in Opioid Naïve (ACTION) study published in the Journal of Opioid Management (Volume 2 Number 3 2006). In this study, Avinza® was compared to Oxycontin® in Opiate naive patients with a median age of fifty years and a 6 to 7 year history of chronic moderate to sever low back pain. Avinza® showed a significant improvement in pain scores, better pain control, a significant reduction in breakthrough pain, a significant improvement in quality of sleep, a lower total dose of opioid than the Oxycontin® group, and an overall comparable safety and tolerability.

Dr. Icenhour then reviewed the Avinza® Chronic Clinical Pain Trial (ACCPT) study published in Pain Practice (Volume 6, Issue 4, 2006). This study of Avinza® lasted over three months. This consisted of Opioid naïve subjects as well as those who had failed other opioids. This study showed a significant improvement in pain scores, significant improvement in quality of sleep, and significant improvement of physical function for activities requiring moderate activity such as climbing a flight of stairs.

In closing, Dr. Icenhour stated that Avinza® with its unique sustained release technology has been shown to provide consistent once daily around the clock pain control.

**Maged S. Hamza, MD, Associate Professor/ Associate Director, Pain Fellowship Program, VCU Departments of Anesthesiology and Physical Medicine and Rehabilitation reviewed NSAIDs**

Dr. Hamza discussed his evaluation of recently published articles concerning Celecoxib, the only Cox II inhibitor currently available. He stated to the Committee that pain management needs to have a multimodal approach and Celecoxib has its place as a product with proven success in managing pain and has increased gastrointestinal safety compared to other traditional NSAIDs. He noted the concern with using a Cox II is the reported possible cardiovascular side effects. He believes that cardiovascular safety of NSAIDs, including COX II inhibitors has been documented and referred to an article "Risk of Cardiovascular Events in Patients Receiving Celecoxib: A Meta-analysis of Randomized Clinical Trials" (William White, MD; American Journal of Cardiology 2007; 99: 91-98).

Dr. Hamza closed stating that in his opinion Celecoxib should be available without requiring failure of traditional NSAIDs because GI side effects can occur with traditional NSAIDs in high doses after a few weeks.

Dr. Axelrod asked to review the current criteria. The Committee reviewed the COX II inhibitors, Long Acting Narcotic step edits and NSAIDs criteria together.

Gill Abernathy noted the Long Acting Narcotic step therapy edit is important because it limits these drugs to appropriate use and makes sure these drugs are not used for immediate postoperative pain or PRN. This advocates responsible prescribing.

Tim Jennings commented that he also found the current criteria and step edits to be appropriate especially with the current FDA black box warning concerning COX II inhibitors.

**MARK OLEY REVIEWED ANALGESICS: NSAID WITH COX-2 INHIBITORS NSAIDS**

A new trial referred to as Gut (12/06) compared the risk of upper GI bleeding with COX-2 selective inhibitors and nonselective NSAIDs. This study supports the notion that COX-2 inhibitors reduce the risk of upper GIB to the same extent as adding a PPI to a nonselective NSAID. It also provides more evidence that any benefit of COX-2 inhibitors concerning GIB is negated with the addition of low dose ASA.

The FDA approved a new indication. Celebrex® (Celecoxib), a COX-2 selective non-steroidal anti-inflammatory drug (NSAID), is now approved for the relief of the signs and symptoms of Juvenile Rheumatoid Arthritis (JRA) in patients two years of age and older. In addition, Ponstel has a first time generic available, Mefenamic Acid. Flector® (Diclofenac Topical Patch, 1.3%) is a new formulation of a non-steroidal anti-inflammatory drug now approved in a topical formulation for treatment of acute pain due to minor strains, sprains and contusions.

**MARK OLEY REVIEWED ANALGESICS: LONG ACTING NARCOTICS**

A new oral product, Opana ER®, has been approved by the FDA for oral administration as an immediate-release (IR) tablet. Opana® is used for treatment of moderate to severe acute pain, and as an extended-release tablet (Opana ER®) for the treatment of moderate to severe pain in patients requiring continuous opioid treatment.

It has a potential for abuse, as it is a Schedule II controlled substance. By injection, oxymorphone is 10 times as potent as morphine. A 10-mg tablet crushed, dissolved and injected delivers the equivalent of 100 mg of morphine, a potentially lethal dose. If abused, the new ER formulation with tablets of up to 40 mg could be even more dangerous.

In conclusion, for patients who require opioids for analgesia, oral oxymorphone (Opana ER®) offers an additional option. The drug must be dosed between meals, however, and its potency (10 times that of

morphine by injection) makes the possibility of abuse especially worrisome. Abstinence from alcohol is required with Opana ER. Older, less potent oral opioids should be attempted first.

Mark Oley motioned that NSAIDS (with COX-2 Inhibitors) and Long Acting Narcotics classes continue to be PDL eligible.

The motion was seconded.

The Committee voted unanimously that NSAIDs (with COX-2 inhibitors) and Long Acting Narcotics classes would continue as PDL eligible.

**E. John Kuhnley, MD, Child & Adolescent Psychiatrist, Central Virginia Community Services Board, Child & Family Division (Lynchburg) discussed Adderall XR® and Daytrana® (Antihyperkinesis/CNS Stimulants)**

Dr. Kuhnley noted that he is a speaker for Shire Pharmaceuticals. Dr. Kuhnley reviewed a randomized, double Blind, placebo-controlled, laboratory classroom assessment of Methylphenidate Transdermal System (MTS) in Children with ADHD by James J. McGough, et al. published in the Journal of Attention Disorders (J. of Att. Dis. 2006; 9(3)476-485). This study evaluated the efficacy, duration of action, and tolerability of methylphenidate transdermal system in children with ADHD. Results showed the MTS was tolerated well and displayed significant improvement compared with placebo. Improvements were seen at the first postdose time point measured and continued through 12 hours. In conclusion, the treatment with MTS resulted in statistically significant improvements on all efficacy measures. Time course and therapeutic effects of MTS suggest that this novel methylphenidate delivery system is an efficacious once-daily treatment for ADHD. Dr. Kuhnley noted the benefits of the new MTS – it is a skin patch so no first pass problems and less total exposure to active drug. He also noted that confirmation to adherence could occur, there are reduced swallowing issues, and the drug has a flexible wear time and if side effects occur, the patch can be removed where an oral formulation cannot be reversed. The patch has less abuse potential. In Dr. Kuhnley's experience, he can replace doses that are more complex.

Dr. Garson asked if Dr. Kuhnley had information on how many children removed the patch.

Dr. Kuhnley said that he did not have the data available.

**Eileen Wall, Medical Science Liaison, McNeil Pediatrics, discussed Concerta® (Antihyperkinesis/CNS Stimulants)**

Ms. Wall discussed recent key literature data for the use of Concerta® in the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The safety and efficacy of Concerta® has been demonstrated in three double blind, placebo-controlled studies in 416 children and an additional open-label long-term usage study. The efficacy results were consistent across settings, raters and instruments among these trials. The safety and efficacy of Concerta® has demonstrated in the adolescent population. Concerta® produced a statistically significant improvement in core ADHD symptoms compared to placebo in 177 adolescents (13-17 years of age). Long-term efficacy with Concerta® has been demonstrated showing effectiveness maintained for up to 2 years with adverse events similar to short-acting stimulant medications. The use of methylphenidate has demonstrated marked decrease in the incidence and severity of traumatic injury in children with ADHD. In addition, there was no evidence of clinically significant changes in growth in patients taking Concerta® for up to 2 years. Dr. Daniel Cox, of the Psychiatric Department of the University of Virginia substantiated the impact of ADHD to society. In three studies by Cox et al, demonstrated that Concerta® significantly improved driving scores and improved driving performance in both simulated and on-road settings. The American Academy of Child and Adolescent Psychiatry's Practice Parameter for the Use of Stimulant Medications in the Treatment of Children, Adolescents, and Adults identifies Concerta® as being less prone to abuse and diversion than IR MPH. IR tablets necessitate the need for multiple doses during the day where Concerta® is administered once a day in the morning and does not lend it self to be given away or sold.

Tim Jennings asked how often patients had to add a short acting product to supplement Concerta®  
Ms. Wall did not have this information.

Mr. Jennings noted that approximately 30% of people receiving Concerta® also had a short acting as well. The once a day claim is not necessarily only once a day dosing.

**Amy D. Kemner, M.P.H., Neuroscience Outcomes Liaison, Eli Lilly and Company, reviewed Atomoxetine/ Strattera (Antihyperkineses/ CNS Stimulants)**

Results from the National Comorbidity Survey Replication published in the American Journal Psychiatry (2006; 163:716-723) found that a high rate of adults in the ADHD population have comorbidities. Approximately 38 % suffer from a comorbidity mood disorder such as depression at a rate three times higher than adults without ADHD. In addition, the study showed that 47 % suffer from anxiety disorders, 16.5% suffer from a substance abuse problems or dependence. These differences suggest different therapies are needed to treat these patients.

Not all ADHD Patients are the same. Recommendations on use of atomoxetine in AACP Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder state that at times Atomoxetine may be considered as the recommended first line agent for ADHD. When use patterns were evaluated, it was confirmed that physicians are following these guidelines. Stimulants and Atomoxetine are not being used interchangeably. There are different populations that benefit from each product. It is important to have the option of either product. With the increased problem and burden of stimulant diversion, it was reported in data published in 2006 from the 2002 National Survey on Drug Use and Health that 30% of persons 12 to 14 years of age report misuse of a stimulant at some time. This is issue is increasing.

**MARK OLEY REVIEWED CNS: ANTIHYPERKINESIS/STIMULANTS (MEDICATIONS FOR ADD/ADHD)**

The Food and Drug Administration (FDA) will now require that manufacturers of all drug products approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) provide patient medication guides with these medications. The purpose is to alert patients to possible cardiovascular risks as well as risks of adverse psychiatric symptoms associated with these drugs and to alert them to precautions that should be taken. A careful history and evaluation of current health status, especially related to cardiovascular and psychiatric problems, including family history, should be done prior to starting patients on these medications.

Mark Oley motioned that Antihyperkineses/Stimulants (Medications for ADD/ADHD) classes continue to be PDL eligible.

The motion was seconded

The Committee voted unanimously that Antihyperkineses/Stimulants (Medications for ADD/ADHD) classes would continue as PDL eligible.

Dr. Garson asked for data on patch removal. Dr. Axelrod confirmed that this information would be provided by First Health Services Corporation as follow-up at the next meeting.

**Peter Blakey, M.D., Practicing Physician in the Richmond area discussed Omnicef (Cephalosporin)**

Dr. Blake reviewed two articles by Dr. Itzhak Brook from Georgetown: 1) The Role of B-Lactamase Producing Bacteria and Bacterial Interference in Streptococcal Tonsillitis (published in the International Journal of Antimicrobial Agents 2001) and 2) Long-Term affects on the Nasopharyngeal Flora of Children Following Antimicrobial therapy of Acute Otitis Media with Cefdinir or Amoxicillin/Clavulanate (Dr Itzhak Brook and Dr Alan Gober published in the Journal of Medical Microbiology 2005). Both studies reviewed the frequency and recovery of pathogens in both adults and children. They looked at the outcomes at pre-release and post-release of the pneumococcal conjugate vaccine PCV7 (Prevnar). In the prerelease, the primary microorganism was Streptococcus pneumoniae.

In the post release, the primary microorganism was Haemophilus Influenzae. This should be considered with the choices concerning antibiotics. Both articles show this pathogen shift with pre- and post- release of Prevnar. The next set of articles had similar findings and the outcomes were comparable for all products evaluated. The difference was a preference for Cefdinir due to its ease of use, better taste, better adherence, and less diarrhea.

**Russell C. Bowes III, PhD., Scientific Affairs Liaison, Ortho-McNeil Janssen Scientific Affairs, LLC discussed Levaquin (Third Generation Quinolones)**

Dr. Bowes discussed recent studies that evaluated short course high dose therapy with Levaquin compared with conventional course therapy in Acute Bacterial Sinusitis, respiratory infections like community-acquired pneumonia (CAP). In each study, the eradication rates, side effects, outcome rates and reoccurrence rates were comparable.

He also reviewed current updated IDSA/ATS Guidelines for CAP in adults (Mandell 2007). Levaquin was the only Fluoroquinolone that was recommended for empirical use for outpatients with comorbidities, non-ICU and ICU patients.

**Susan E. Malenbaum, PhD., Medical Science Liaison/ Global Medical Affairs, Schering-Plough discussed Avelox (Third Generation Quinolones)**

Avelox® is indicated for use in the treatment of adult respiratory tract infections (RTIs), including acute bacterial exacerbation of chronic bronchitis (ABECB), acute bacterial sinusitis (ABS), and community-acquired pneumonia (CAP). Avelox also treats uncomplicated skin and skin structure infections.

Avelox's newest indication is for complicated intra-abdominal infections. A study, known as Community-Acquired Pneumonia Recovery in the Elderly, or CAPRIE showed Avelox® (moxifloxacin HCl) was highly successful and safe in elderly patients with community-acquired pneumonia (CAP) compared to the antibiotic Levaquin (levofloxacin). Dr. Malenbaum also reviewed current updated IDSA/ATS Guidelines for recommended empirical antibiotics for community-acquired pneumonia. Moxifloxacin is indicated in outpatient treatment with the presence of comorbidities such as chronic heart, lung, liver or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions; or use of immunosuppressing drugs.

Dr. Selby-Penczak asked the age range of the patients in the study.

Dr. Malenbaum responded that they were 65 years of age to 90 with a median age of 75.

**GILL ABERNATHY REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: 2<sup>ND</sup> & 3<sup>RD</sup> GENERATION CEPHALOSPORINS**

There have been no significant changes in this class over the past year.

**GILL ABERNATHY REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: 2<sup>ND</sup> & 3<sup>RD</sup> GENERATION QUINOLONES**

There have been no significant changes in this class over the past year.

**GILL ABERNATHY REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: MACROLIDES ADULT AND PEDIATRIC**

With Ketek® (Telithromycin), the labeling for this ketolide antibiotic, the only antibiotic in this class, will be revised to remove two of the three previously approved indications. The benefits of the drug can no longer be supported for treatment of acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis based on the existing risks of the drug. Product labeling will strengthen warnings for hepatotoxicity, loss of consciousness and visual disturbances and will be updated with a "boxed warning" that states the drug is contraindicated in patients with myasthenia gravis. Ketek® will remain available for treatment of mild to moderate community-acquired pneumonia and must be distributed with a new Patient Medication Guide with information on risks of the drug and how it can be used safely.

The Committee discussed whether Ketek® should remain PDL eligible or if the guidelines for the criteria should be tightened due to the serious side effects. Currently Ketek® is non-preferred and use is minimal. It was determined that the PA criteria for Ketek® will be changed.

Gill Abernathy motioned that all Cephalosporins, Quinolones, and Macrolides classes continue to be PDL eligible.

The motion was seconded

The Committee voted unanimously that all Cephalosporins, Quinolones, and Macrolides classes would continue as PDL eligible.

A motion was made to change the PA criteria for Ketek® to FDA indication (allergies). In addition, the PA request should state that the physician is aware of the side effects/risks and still wants to proceed with authorization.

**Charlie Howe, Pharm.D., Senior Regional Medical Scientist/ Medical Information, GlaxoSmithKline Pharmaceuticals, discussed Valtrex (Antivirals for Herpes)**

Study published in 2006 that centered around 119 newly diagnosed patients, this group of patients is at a higher risk for transmission and recurrence. The study showed a significant reduction in the reoccurrence rate and in the medium time to remission. He reviewed the CDC guidelines for genital herpes.

In summary, the most important new information for Valtrex is the new indication for the reduction in the risk of transmission of genital herpes.

**GILL ABERNATHY REVIEWED ANTIVIRALS: HERPES AND INFLUENZA**

There have been no significant changes in this class over the past year.

Gill Abernathy motioned that all Antivirals classes continue to be PDL eligible.

The motion was seconded.

The Committee voted unanimously that all Antivirals classes would continue as PDL eligible.

**Rachel Preston, Pharm.D., Scientific Manager, Managed Markets, Professional & Scientific Relations, Procter & Gamble Pharmaceuticals, discussed Actonel (Bisphosphonates)**

Actonel has a new indication to increase bone mineral density in men with osteoporosis.

New outcomes data published in January 2007 demonstrate that Actonel works quickly to reduce non-vertebral and hip fractures. This reinforces non-vertebral and fracture efficacy demonstrated in Phase III pivotal trials. The Risedronate, Alendronate (REAL) cohort study (Silverman et al. OI 2007; 18:25-34) was a retrospective analysis of a health service utilization database. The REAL study utilized a U.S database of insured participants. Recipients aged 65 years and older were identified who were new users of weekly bisphosphonate therapy, either risedronate or alendronate. In the study, patients on risedronate had 46% and 43% lower incidence of hip fracture than patients taking alendronate at 6 and 12 months, respectively. With respect to nonvertebral fracture, patients on risedronate had 19% and 18% lower incidence of nonvertebral fracture than patients on alendronate at 6 and 12 months, respectively.

**Min Tsuboi, Pharm.D., Medical Liaison, Scientific Field Operations, Roche, discussed Boniva (Bisphosphonates)**

The efficacy of oral Boniva® at improving bone mineral density (BMD) in postmenopausal osteoporosis observed in the 1-year analyses of the MOBILE study was maintained at 2 years. BMD gains were consistently higher for the monthly compared with the daily dosing. After 1 year on once-monthly Boniva®, BMD improvements were at least as great as those seen after 2 years of daily Boniva®. Both doses of Boniva® brought a bone-turnover marker, serum C-telopeptide crosslinks of type I collagen (sCTX) values within the normal premenopausal range at all time points measured. The safety of both Boniva® regimens was comparable and acceptable. The efficacy and safety of oral Boniva® in the

treatment of postmenopausal osteoporosis observed in the 1-year analyses of the MOBILE study was maintained at 2 years.

In summary, the PERSIST study demonstrated that persistence on treatment was increased in patients receiving once-monthly Boniva® plus patient support compared with once-weekly alendronate. Increased persistence on bisphosphonate treatment in patients with postmenopausal osteoporosis is expected to improve patient outcomes and decrease the social and economic burden of this debilitating condition. The majority of women in BALTO II preferred once-monthly oral Boniva® to weekly oral alendronate for convenience and ease of use. Consistent with results from the US BALTO I study, once-monthly bisphosphonate dosing shows a strong potential to increase adherence.

### **MARK OLEY REVIEWED OSTEOPOROSIS: BISPSPHONATES**

On August 11, 2006, the FDA approved a new indication for once-weekly risedronate 35 mg tablets (Actonel®) for treatment of osteoporosis in men.

Mark Oley motioned that Bisphosphonates for osteoporosis class continue to be PDL eligible.

The motion was seconded.

The Committee voted unanimously that Bisphosphonates for osteoporosis class would continue as PDL eligible.

### **Teresa I. Brevetti, M.D., Glaucoma Specialist/Director, Research and Medical Specialist, Pfizer, reviewed Ophthalmics Prostaglandin Inhibitors**

Multiple independently conducted studies reveal all the prostaglandin analogs in this category, Xalatan, Lumigan, and Travatan, are equivalent in efficacy. However, Xalatan has demonstrated superiority to Lumigan and Travatan when it comes to patients staying on the medication long enough to get the clinical benefit. In a study by Nordstrom et al., Xalatan was associated with greater persistence, a larger number of refills and a higher prevalence of refills in hand than either Lumigan or Travatan. A meta-analysis of randomized controlled trials was performed (Li et al.) comparing travoprost with other prostaglandin analogues or timolol in patients with primary open angle glaucoma or ocular hypertension. The combined results showed that travoprost 0.004% (Travatan) was less effective than Lumigan or Xalatan. Travoprost caused a higher percentage of hyperemia than timolol, or latanoprost. There was an increased incidence of pigmentation with travoprost than timolol. Travoprost caused a higher percentage of eyelash changes than timolol, or latanoprost.

In another study by Lewis et al, travoprost preserved with SOFZIA (Travatan Z) was compared to marketed formulation of travoprost preserved with BAK (Travatan) in patients with primary open angle glaucoma or ocular hypertension. No statistically or clinically significant difference between BAK-preserved Travatan and Sofzia- preserved Travatan Z in regards to IOP lowering or ocular adverse events.

### **Richard Fiscella, RPh, MPH, Clinical Professor, University of Illinois at Chicago, discussed Zymar (Ophthalmic Quinolones)**

ZYMAR™ (gatifloxacin ophthalmic solution) is a 4th-generation (FQ) topical ophthalmic fluoroquinolone that meets ophthalmologists' needs for powerful protection from key 3rd-generation resistant pathogens and provides good patient outcomes. Ophthalmic preparations are used to treat nonvision-threatening infections such as bacterial conjunctivitis as well as vision threatening conditions such as bacterial keratitis, corneal ulceration and surgical prophylactic. While there are approved fluoroquinolones for use for bacterial conjunctivitis, a 4th-generation ophthalmic fluoroquinolone is often inappropriate. The 4th-generation ophthalmic fluoroquinolone should be reserved for treatment of vision threatening conditions such as bacterial keratitis. In a study published in 2006, significantly more of the moxifloxacin-treated eyes healed faster than the gatifloxacin-treated eyes. In all cases, gatifloxacin-treated eyes showed a larger epithelial defect than the moxifloxacin-treated eyes. Moxifloxacin had more corneal toxicity and slowed corneal wound healing both in the epithelium and in the stroma, compared with gatifloxacin. They found that on days three through six, a greater percentage

of patients in the gatifloxacin and BAK group were completely healed compared with the moxifloxacin group. Zymar is prescribed by eyecare practioners (94%) vs. primary, care practioners and pediatricians (6%). Eye care physicians (55%) prescribe Vigamox vs. PCPs & Peds (45%). PCP's and Pediatricians prescribe FQ's for conjunctivitis 86% of the time.

**Richard Fiscella, RPh, MPH, Clinical Professor, University of Illinois at Chicago discussed Elestat (Ophthalmic Antihistamines)**

Approximately 90% of allergy patients suffer from ocular allergy. Ideal therapy should include: H<sub>1</sub> and H<sub>2</sub> Antihistamine activity; mast cell stabilization; anti-inflammatory properties; and multi-action therapy is optimal. Antihistamines with MCS activity are used clinically because they are the most complete therapy in regards to patient response and they are extremely safe medications in young children. In a study called "Efficacy of epinastine ophthalmic solution for post exposure treatment of signs and symptoms of allergic conjunctivitis in cat-sensitive subjects." (Monson, B., ACAAI, published in November 2004), there were no significant differences between epinastine and olopatadine in itching, burning, tearing, hyperemia and chemosis.

Elestat<sup>TM</sup> multi-action and comprehensive treatment has proven MCS; prevents histamine release; potent H<sub>1</sub>-antagonist; fast relief of itching & control of vascular leakage; H<sub>2</sub>-receptor antagonist; and sustained ↓ in pro-inflammatory mediators (Bielory L et al. Efficacy and tolerability of newer AH's in treatment of allergic conjunctivitis. Drugs 2005; 65: 215-228). It is the only product to be identified to block H<sub>2</sub>-receptor affinity (possible benefit in reducing hyperemia and eyelid swelling). In addition, the drug has Neutral pH (pH 7.0) with soothing upon instillation, less ocular dryness (Trattler), rapid action with relief in 3 minutes and sustained duration for up to 12 hours. All AH's/MCS are safe in children 3 years of age or older.

**MARK OLEY REVIEWED OPHTHALMIC: GLAUCOMA AGENTS**

This class consists of Ophthalmic Alpha-2 Adrenergic, Beta-blockers, Carbonic Anhydrase Inhibitors and Prostaglandin Inhibitors.

There have been no significant changes in this class over the past year.

**MARK OLEY REVIEWED OPHTHALMIC: ANTI-INFLAMMATORY**

There have been no significant changes in this class over the past year.

**MARK OLEY REVIEWED OPHTHALMIC: QUINOLONES**

There have been no significant changes in this class over the past year.

**MARK OLEY REVIEWED OPHTHALMIC: ANTIHISTAMINES & MAST CELL STABILIZERS**

Zaditor<sup>®</sup> RX is being replaced with OTC products Alaway and Zaditor OTC (Ketotifen fumarate Ophthalmic Solution, 0.025%).

Mark Oley motioned that all current ophthalmic class continue to be PDL eligible.

The motion was seconded.

The Committee voted unanimously that all current ophthalmic class would continue as PDL eligible.

**Melinda Wilson Mitton, Pharm.D, Regional Medical Scientist, GlaxoSmithKline Medical Affairs – Neurology discussed Imitrex® (Serotonin Receptor Agonists -- Triptans)**

Imitrex<sup>®</sup> offers proven efficacy and tolerability with vast clinical experience of treating more than 764 million attacks worldwide. The news for Imitrex today is the availability of the 4mg stat dose system. This new strength offers an easy to use low dose system that maintains the sharps with ease. It is an easy to use low dose option. The lower dose shows similar effectiveness with a trend towards fewer side effects. The 6mg is still the recommended starting dose; the 4mg is an option. The multiple formulations

of Imitrex® offer the flexibility to tailor treatment to the patient without the concern for the contraindication of co-administering two different triptans in a headache. Imitrex® is approved for the acute treatment of migraine with or without aura in adults, is the most widely studied migraine medication and is available in three formulations: injection, nasal spray, and tablets. Some migraine patients need different formulations to treat their multiple types of migraine attacks.

**MARK OLEY REVIEWED SEROTONIN RECEPTOR AGONISTS (TRIPTANS)**

On July 19, 2006, the FDA released a Public Health Advisory related to new safety information regarding the use of triptan medications with selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs). A life-threatening condition called “serotonin syndrome” may occur.

Mark Oley motioned that all serotonin receptor agonists (triptans) class continue to be PDL eligible. The motion was seconded.

The Committee voted unanimously that the serotonin receptor agonists (triptans) class would continue as PDL eligible.

**GILL ABERNATHY REVIEWED ANTIBIOTICS/ANTI-INFECTIVES: ORAL ANTIFUNGALS FOR ONYCHOMYCOSIS**

There have been no significant changes in this class over the past year.

**MARK OLEY REVIEWED ASTHMA/ALLERGY: LEUKOTRIENE MODIFIERS**

There have been no significant changes in this class over the past year.

Mark Oley motioned that the Leukotriene modifiers class continue to be PDL eligible. The motion was seconded.

The Committee voted unanimously that the Leukotriene modifiers class would continue as PDL eligible.

**COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL**

Ms. Reatha Kay 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 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.

This motion was seconded and unanimously approved by the Committee.

The meeting adjourned to an executive session.  
The Committee returned to the room.

Mark Oley 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.

Mark Oley made a motion for the Committee to resume the meeting to discuss the PDL.  
With the motion seconded, the Committee voted unanimously to resume the meeting to discuss the PDL.

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

Mark Oley motioned to add generic Oxybutynin Chloride ER as preferred to the PDL Urinary Tract Antispasmodics class. With the motion seconded, the Committee voted unanimously to add generic oxybutynin chloride ER as preferred to the PDL urinary tract antispasmodics class

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

Mark Oley made a motion to maintain the current PDL Non-Steroidal Anti-Inflammatory Drugs (NSAID) including the COX II Inhibitors with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Non-Steroidal Anti-Inflammatory Drugs (NSAID) including the COX II Inhibitors with no change.

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

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

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

Mark Oley made a motion to maintain the current PDL Oral Hypoglycemics Thiazolidinediones-Sulfonylurea combinations class with no change. With the motion seconded, the Committee voted unanimously to maintain the current Oral Hypoglycemics Thiazolidinediones-Sulfonylurea combinations class with no change.

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

Mark Oley made a motion to make the following change to the current PDL Macrolides-pediatrics/adults

class: the brand products Biaxin suspension, Biaxin tablet, Biaxin XL, Zithromax packet, Zithromax suspension, Zithromax tablet would move to non-preferred; the rest of the class to remain preferred. Dr. Axelrod reminded the Committee that generic equivalents of these drugs would remain preferred. With the motion seconded, the Committee voted unanimously to accept the recommended change.

Mark Oley made a motion to make the following change to the current PDL Second Generation Cephalosporins class: the brand products Cefzil suspension and Cefzil tablets to move to non-preferred; the rest of the class to remain preferred. Dr. Axelrod reminded the Committee that there would be generic availability. With the motion seconded, the Committee voted unanimously to accept the recommended change.

Mark Oley made a motion to make the following change to the current PDL Ophthalmic Antihistamines class: to remove the drug Zaditor RX from the PDL because is no longer on the market and add as preferred Zaditor OTC, Alaway OTC, Pataday; the rest of the class to remain preferred. With the motion seconded, the Committee voted unanimously to accept the recommended change.

Mark Oley made a motion to maintain the current PDL Antihyperkinesis (CNS- ADHD) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Antihyperkinesis (CNS- ADHD) class with no change.

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

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

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

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

Mark Oley made a motion to maintain the current PDL Systemic Quinolones class with one change to move the generic Ciprofloxacin XR tablet to non-preferred. With the motion seconded, the Committee voted unanimously to maintain the current PDL Systemic Quinolones class with no change.

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

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

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

Mark Oley made a motion to maintain the current PDL oral Hypoglycemics Thiazolidinediones-Metformin Combination class with no change. With the motion seconded, the Committee voted unanimously to maintain the current oral Hypoglycemics Thiazolidinediones-Metformin Combination class with no change.

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

Mark Oley made a motion to maintain the current PDL Carbonic Anhydrase Inhibitors for glaucoma with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Carbonic Anhydrase Inhibitors for glaucoma with no change.

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

Mark Oley made a motion to maintain the current PDL Alpha-2 Ophthalmic Adrenergic for glaucoma class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Ophthalmic Alpha-2 Adrenergic for glaucoma class with no change.

Mark Oley made a motion to maintain the current PDL Ophthalmic Anti-Inflammatory (NSAIDS) class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Ophthalmic Anti-Inflammatory (NSAIDS) class with no change.

Mark Oley made a motion to maintain the current PDL Ophthalmic Beta-blockers for glaucoma class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Ophthalmic Beta-blockers for glaucoma class with no change.

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

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

Mark Oley made a motion to maintain the current PDL Oral Hypoglycemics Biguanide Combination Products class with no change. With the motion seconded, the Committee voted unanimously to maintain the current PDL Oral Hypoglycemics Biguanide Combination Products class with no change.

### **Criteria Discussion of Phase I and Phase II**

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

Tim Jennings motioned to change the PA criteria for Ketek® to reflect FDA indication, allergies, and require physician signature on PA stating the physician is aware of the side effects and still desires a PA for Ketek®. Information would be included on the form to educate the physicians about the adverse affect profile of Ketek. With the motion seconded, the Committee voted unanimously to make the criteria changes.

Tim Jennings expressed an interest in making change to the Oxymorphone criteria. Dr. Axelrod noted that this class will require a thorough discussion by the Committee and that today a vital P&T member

was absent from the meeting. He asked that this conversation occur at the next meeting to include Dr. Beveridge who will be instrumental in the discussion regarding oncology use. No other motions to change criteria were made by the Committee. Dr. Beveridge will be consulted prior to the next meeting.

The Committee discussed a need for a generic drug policy, in particular a decision regarding when a generic drug is adopted as preferred on the PDL. They discussed different possible options to determine the appropriate price point and circumstances for adopting generics as preferred. Mark Oley motioned that a Guidance Document be created to outline a proposed policy addressing when a generic product is adopted as preferred with an automatic substitution of a generic for the preferred brand, e.g., when there is a cost savings of 75% or greater compared to the brand.

Mr. Finnerty and DMAS staff clarified the request for the Guidance Document and proposed process for generic recognition on the PDL. The Committee agreed unanimously to request the Guidance Document to address management of this issue.

Dr. Axelrod reviewed plans for the next meetings, including the review of specialty drug classes. **The meeting was adjourned.**