Meeting of the Pharmacy and Therapeutics Committee February 9, 2010

Members Present: DMAS Staff:

Randy Axelrod, M.D., Chair Cynthia B. Jones, Acting Agency Director

Mark Oley, R.Ph., Vice Chair
Gill Abernathy, M.S., R.Ph.
Tim Jennings, Pharm.D.

Cheryl Roberts, Deputy Director of Programs and Operations
Bryan Tomlinson, Director, Division of Health Care Services
Usha Koduru, Counsel to the Board, Office of the Attorney General

Rachel M. Selby-Penczak, M.D.

Donna Proffitt R.Ph., Pharmacy Manager
Keith Hayashi, RPh., Clinical Pharmacist
Rachel Cain, Pharm.D., Clinical Pharmacist

Sue Cantrell, M.D. Maryanne Paccione, Information Management Consultant

Renita Driver, Pharm.D. Scott Cannady, Senior Policy Analyst

James Stewart III, Interim
Commissioner and alternate

First Health Staff:

Michele Thomas, Pharm.D. Debbie Moody, R.Ph., Clinical Manager, Virginia

Doug Brown, R.Ph., MBA Director Rebate Contracting Management

Sandy Kapur, Pharm.D., Rebate Support

Absent: Donna Johnson, R.Ph., Clinical Manager, Virginia

Krishna Madiraju M.D. Guests:

61 representatives from pharmaceutical companies, providers,

A quorum was present advocates, associations, etc

Dr. Axelrod opened the meeting by introducing Cynthia B. Jones, DMAS Acting Director. Ms. Jones welcomed Committee members and attendees. She announced that Virginia's new Secretary of Human Health and Resources is Dr. Bill Hazel. She also stated that Provider Synergies (formerly known as First Health Services) was awarded the contract for Pharmacy Services Administrator effective July 1, 2010.

Dr. Axelrod acknowledged the service of Drs. Reuben Varghese and James Reinhard to the P&T Committee and welcomed Dr. Sue Cantrell back to the Committee.

Dr. Axelrod noted there are a number of speakers on today's agenda and requested that all speakers comply with the 3-minute time limit and that they present only information from the literature (no anecdotal reports). He also asked that physicians without formal affiliations with a drug company state if they have received any fees or grants from any pharmaceutical manufacturer within the past two (2) years.

Dr. Axelrod and the Committee discussed the need to tighten the criteria for Long Acting Narcotic (LAN) edits on the PDL. Dr. Jennings suggested that DMAS collect data on the utilization of LAN by requiring prescribers to include the diagnosis on the prescription. The point-of-sale dispensing program cannot capture patient diagnosis at this time, so it was suggested DMAS require prescribers to complete a form when prescribing LANs which captures diagnosis information. The Committee suggested that the use of LANs be restricted to chronic pain syndromes. The Committee asked Debbie Moody, Virginia's Clinical Manager, to draft a form for review at the April P&T meeting.

Acceptance of minutes from October 22, 2009 meeting: Dr. Axelrod asked if there were any corrections, additions or deletions to the draft meeting minutes. With no revisions or corrections from the Committee members, the minutes were approved as written. Dr. Axelrod noted that Dr. Cantrell abstained.

PDL Management (*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.*)

Potential New Therapeutic Classes (PDL Category)

1. Injectable Hypoglycemic Agents including amylin analogs (Diabetes)

Speakers:

- David Rhein, Pharm.D., Outcomes Liaison with Eli Lilly & Company (Lilly's Humalog, Humalog Mix, Humulin R)
- Dr. James Wigand, MD, Endocrinologist, (Humulin & Humalog)
 - o Dr. Axelrod requested that Dr. Wigand's support of insulin pens in diabetic patients be captured in the minutes.

<u>Injectable Hypoglycemic Agents</u>: Ms. Abernathy noted that this is a large class that includes short, intermediate and long acting insulins in various strengths as well as insulins in various delivery devices. She recommended that all products and delivery devices in the class be included on the PDL. After Committee discussion of the class, Ms. Abernathy motioned that the injectable hypoglycemic agents be included as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this class as PDL eligible.

<u>Injectable Amylin Analogs</u>: Ms. Abernathy discussed Symlin® (pramlintide) as adjunct therapy in type one and type two diabetic patients who use mealtime insulin therapy and have failed to achieve desired glucose control despite optimal insulin therapy. Symlin®, is a synthetic analog of amylin and affects the rate of glucose appearance by several mechanisms. Symlin® slows gastric emptying, suppresses glucagon secretion, and centrally modulates appetite. Hemoglobin A1c improvements with Symlin® are generally 0.3-0.6 percent with potential weight reduction of 0.5-1.5 kg. This reduction comes with a greater risk of hypoglycemia and nausea. Symlin® should only be considered in patients who have failed to achieve adequate glycemic control on insulin. Ms.Abernathy motioned that injectable amylin analog agents be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this class as PDL eligible.

Note that Ms. Abernathy also discussed Byetta®, which will be reviewed in the April meeting.

2. Platelet Inhibitors (Cardiac Medications)

Speakers:

- Dr. George Vetrovec, MD; VCU Health Systems cardiologist (Prasagrel)
- Kirk Dzenko, PhD; Regional Medical Scientist from Boehringer-Ingelheim (Aggrenox)
- David Rhein, PharmD; Outcomes Liaison with Eli Lilly & Company (Prasagrel)

Ms. Abernathy noted that this class of drugs is widely used and that there is an issue with genetic polymorphism and the metabolism of clopidrogel (Plavix®). She also discussed that Effient® (prasagrel), a new drug in this class, has been associated with bleeding complications that have been well documented in clinical trials. Ms. Abernathy posed the question as to if these complications will

be an issue in the real world. Ms. Abernathy expressed a need to maintain at least two products in this class with one being a thienopyridine.

Tim Jennings expressed concern that some physicians may use Effient® in the place of Plavix® and use it in the wrong patient population.

The committee discussed the class and expressed potential concerns with the use of Effient®. Discussion about requiring a PA for the drug resulted in concern about some patients that may need the drug not having access. Dr. Axelrod stated that VA Medicaid has an "emergency policy" that allows for a 72-hour supply of medication to allow the physician time to create the PA. Ms.Abernathy and the committee discussed in detail the need of placing a prior authorization on Effient®. Dr. Axelrod noted that a motion to make this class PDL eligible needed to be made prior to additional criteria discussion for the use of prasugrel (Effient).

Ms. Abernathy motioned for the Platelet Inhibitor class be included as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this class as PDL eligible.

Dr. Jennings motioned that a Prior Authorization be created for Effient® that requires an indication for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndrome who are to be managed with PCI as follows:

- Patients with unstable angina or, non-ST-elevation myocardial infarction
- Patients with ST-elevation myocardial infarction (STEMI) when managed with either primary or delayed PCI of acute coronary syndrome (ACS).

With the motion seconded, the Committee voted unanimously to add the motioned Prior Authorization to the criteria. (*Dr. Axelrod noted that the criteria were derived from the PI; a PA fax form will be developed and reviewed at the April meeting.*)

3. Androgenic Agents (Endocrine and Metabolic)

Ms. Abernathy stated that testosterone is currently available in many forms. She motioned that Androgenic Agents be considered PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider this class as PDL eligible.

PDL Phase II Annual Review

1. Analgesics

Speakers:

• Laurie Cooksey, PharmD; VCU Health Center (Celebrex®)

Non-Steroidal Anti-Inflammatory Drugs (NSAID) (includes Cox-2 Inhibitors): Dr. Jennings noted that several new products have recently been introduced to the market including Nexcede® - ketoprofen oral soluble film formulation; Zipsor® - diclofenac liquid-filled capsule and Cambia® - diclofenac potassium for oral solution.

<u>Topical Analgesics and Anesthetics:</u> Dr. Jennings stated that this category includes Flector® patches, Voltaren® Gel and now Lidoderm® patches are being included as a potential new drug. Lidoderm® is a topical lidocaine 5% patch. Recommended dosage is up to 3 patches to affected area once daily

for up to 12 hours within a 24-hour period. The patches are indicated for the relief of pain associated with post-herpetic neuralgia.

Long Acting Narcotics: Dr. Jennings noted there is a new product in this class, Embeda® (a long acting morphine sulfate and naltrexone hydrochloride combination) which is available in a granular formation.

Dr. Jennings motioned that NSAIDs including Cox-2 Inhibitors; Topical Analgesics, Anesthetics, and Long Acting Narcotics continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

2. Antibiotics/Anti-infectives

Speakers:

• Michaela Jones, PhD, MPH; Medical Science Liaison for Merck (Avelox®)

Second and 3rd Generation Cephalosporins, second and 3rd Generation Quinolones (systemic), Ketolides, Macrolides, Oral Antifungals for Onychomycosis, Otic Quinolones, Topical Antibiotics: Dr. Jennings noted that there were no significant changes in these classes since the last annual review and motioned that the listed antibiotic classes continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

3. Central Nervous System

Speakers:

- Dr. Edward John Kuhnley, MD; Child & Adolescent Psychiatrist, Lynchburg, VA (Vyvanse®)
- Dr. Ali Azez, MD; Child and Adolescent Psychiatrist, Richmond, VA (Intuniv®)
- David Rhein PharmD; Outcomes Liaison for Eli Lilly & Company (Strattera®)
- Michael West, Regional Medical Scientist for GSK (Requip XL®)

Antihyperkinesis/CNS Stimulants Agonists and Non-Ergot Dopamine Receptor Agonists: Dr. Jennings stated that a new product IntunivTM (guanfacine SR), a non-scheduled medication available in 1, 2, 3 and 4 mg oral extended release tablets, has been approved for use in Attention Deficit Hyperactivity Disorder (ADHD) in children between the ages of six and 17 years. IntunivTM is a non-stimulant, non-abusable alternative for the treatment of ADHD. He also noted that there have been not appropriate that the notation of the treatment of appropriate that there have been not appropriate that the notation of the treatment of appropriate that there have been not appropriate that the notation of the treatment of appropriate that the notation of the

Hyperactivity Disorder (ADHD) in children between the ages of six and 17 years. Intuniv TM is a non-stimulant, non-abusable alternative for the treatment of ADHD. He also noted that there have been no significant changes in the Non-Ergot Dopamine Receptor Agonist drug class since the last annual review.

Dr. Jennings motioned that Antihyperkinesis/CNS Stimulants Agonists and Non-Ergot Dopamine Receptor Agonists continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

4. Immunologic Agents

Speakers:

- Dr. Alfred Denio, MD; Director, Div. of Rheumatology, Eastern VA Medical School (SimponiTM) & Certolizumab (Cimzia®)
 - o Dr. Axelrod suggested to the Committee that he and a group of clinicians who are RA specialists form a subgroup to develop a treatment algorithm for RA to bring back to the committee to be discussed at the April meeting.

- Sherwanna Clarke, PharmD; Government Clinical Executive for Abbott (Humira®)
- Anne Davis, PharmD; Medical Science Liaison for Biogen Idec (Avonex®) Speakers (continued):
- Christian Lesuisse, PhD; Medical Science Liaison for Bayer Healthcare (Betaseron®)
- Arti Baig, PharmD; Medical Science Liaison for UBC (Cimzia®)
- Evan Gliptis, PharmD; Clinical Science Liaison for Centocor (Simponi®)

Self-Administered Drugs for Rheumatoid Arthritis (RA) and Multiple Sclerosis Agents: Ms.

Abernathy noted that the speakers had addressed the efficacy of these agents, especially TNF agents as compared with placebo; however, there are limited head-to-head clinical trials with these agents. Ms. Abernathy mentioned that the American College of Rheumatology does not distinguish between agents. She acknowledged that there are some differences seen with administration timeframes with the various agents—but with no specific differences in efficacy, she motioned that both self-administered drugs for RA and multiple sclerosis agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider both of these classes as PDL eligible.

Dr. Axelrod announced that Mr. James Stewart III, Interim Commissioner had to leave and that his alternate Michele Thomas, Pharm.D. would replace him.

5. Ophthalmics

Speakers:

- Dr. John Sheppard, MD; ophthalmologist, Virginia Eye Consultants (Besivance ®)
- Chris Pebbles, ISTA (Bepreve®)
- Vince Perotta, Senior Area Manager for Allergan (Lumigan®)

<u>Alpha-2 Adrenergics, Beta-blockers*, Carbonic Anhydrase Inhibitors, Prostaglandin Analogs and Sympathomimetics (all for the treatment of glaucoma)</u>: Mr. Oley stated that there have been no significant changes in these classes since the last annual review and motioned that the products for the treatment of glaucoma as listed above continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible. (*Note: Mr. Oley omitted beta-blockers in his motion; however, these drugs were included in the Phase II Annual Review.)

Antihistamines and Mast Cell Stabilizers for Conjunctivitis: Mr. Oley reported that there has been one new product in the antihistamine class since the last review. That product, Bepreve [®] (generic bepotastine), is indicated for people greater than 2 years of age for the treatment of ocular itching associated with allergic conjunctivitis. Mr. Oley motioned that these classes continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible.

Nonsteroidal Anti-Inflammatory (NSAID): Mr. Oley noted that the drug Acuvail® (ketorolac tromethamine 0.45% solution) indicated for Cataract surgery has been approved since the last annual review of this class. He motioned that the Nonsteroidal Anti-Inflammatory (NSAID) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible.

Quinolones and Macrolides: Mr. Oley stated that new fluoroquinolone antibiotic available on the market is Besivance [®] indication for bacterial conjunctivitis has entered the market since the last

annual review of this class. Mr. Oley motioned that the Quinolones and Macrolides continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible.

6. Oral Hypoglycemics

Speakers:

- Dr. James Mulinda, MD, endocrinologist, Southwest Virginia (Avandia®)
- Dr. Maurice Cuffee, MD; Medical Science Liaison for BMS (Onglyza®)

 2^{nd} Generation Sulfonylureas: Ms. Abernathy noted that there have been no significant changes in this class since the last review and recommended that they continue to be PDL eligible.

<u>Alpha-Glucosidase Inhibitors</u>: Ms. Abernathy noted that there have been no significant changes in this class since the last review recommended that they continue to be PDL eligible.

Biguanides including combination products: Ms. Abernathy noted that there have been no significant changes in this class since the last review and recommended that they continue to be PDL eligible.

<u>DPP-IV Inhibitors and combination products:</u> Ms. Abernathy noted that there have been some reports of serious hypersensitivity reactions including anaphylaxis, cutaneous vasculitis, exfoliative skin conditions such as Stevens-Johnson syndrome, elevations in hepatic enzymes, and pancreatitis with sitagliptin. However, she still recommended that they continue to be PDL eligible.

<u>Meglitinides:</u> Ms. Abernathy noted that there have been no significant changes in this class since the last review and recommended that they continue to be PDL eligible.

<u>Thiazolidinediones and combiniation produtes</u>: Ms. Abernathy noted that there have been no significant changes in this class since the last review and recommended that they continue to be PDL eligible.

Dr. Axelrod referred to Ms. Abernathy motions that all six classes of the hypoglycemic agents continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

7. Osteoporosis

<u>Bisphosphonates</u>: Mr. Oley noted that there have been no significant changes in this class since the last review and recommended that they continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible.

<u>Calcitonins:</u> Mr. Oley motioned that Osteoporosis agents Calcitonins continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible.

8. Dermatologic

Benzoyl Peroxide, **Benzoyl Peroxide** and **Clindamycin combinations**, **Clindamycin**: Mr. Oley stated that the Committee would like to include benzoyl peroxide and clindamycin as potential new products

in this class. He noted that there with no other significant changes to this class since the last review and motioned that Topical Agents for Acne continue to be PDL eligible.

Topical Agents for Psoriasis: Mr. Oley noted that there are no significant changes to this class since the last review and motioned that this class continue to be PDL eligible.

Topical Retinoids and combinations

With no significant changes to this class since the last review, Mr. Oley motioned that Topical retinoids and combination products continue to be PDL eligible.

Dr. Axelrod referred to Mr. Oley's motions that all of the Dermatologic agents including (Benzoyl Peroxide, Benzoyl Peroxide and Clindamycin combinations, Clindamycin), topical agents for psoriasis and topical retinoids and combinations agents continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

9. Antivirals

<u>Herpes Antivirals:</u> Dr. Jennings reviewed this class and noted that there have been no significant changes to class since last reviewed.

<u>Influenza</u>: This class was reviewed by Dr. Jennings who stated that there have been no significant changes to class since last reviewed.

<u>Topical Antivirals</u>: This class was reviewed by Dr. Jennings who stated that there is a new product, Lipsovir® (hydrocortisone and acyclovir) topical cream, for the treatment of cold sores in patients 12 years of age and older.

Dr. Jennings motioned that Antivirals (Herpes Antivirals, Influenza Antivirals, and Topical Antivirals) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

10. Asthma & Allergy

<u>Intranasal Antihistamines:</u> Dr. Jennings noted Astepro[®] nasal spray has been introduced to the market since the last review. Astepro[®] is used once daily.

<u>Leukotriene Formation Inhibitors and Leukotriene Modifiers:</u> Dr. Jennings noted that this class includes Singulair[®] (montelukast), Accolate[®] (zafirlukast), Zyflo[®]/Zyflo CR[®] (zileuton). He stated that the FDA requested in June 2009 that manufacturers include a precaution in the labeling for these products. The FDA precaution recommends that patients and healthcare professionals should be aware of the potential for neuropsychiatric events associated with these medications, patients should talk to their healthcare providers should these events occur, and discontinuing these medications should be considered if neuropsychiatric conditions develop.

Dr. Jennings motioned that Intranasal Antihistamine, Leukotriene Formation Inhibitors and Leukotriene Modifiers continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these classes as PDL eligible.

11. Miscellaneous

Speaker:

• Michael West, Regional Medical Scientist for GSK (Treximet®)

Serotonin Receptor Agonists (Triptans)

Mr. Oley noted that there is a new FDA approved formulation Sumavel DoseProTM (sumatriptan) Injection. Sumavel is a selective 5-HT1 serotonin receptor agonist indicated for the acute treatment of migraine (with or without aura) and cluster headache. In addition, the indications Axert® have been extended to use in adolescents 12-17 years of age whose attacks usually last four hours or more. The other products in this class have not been approved for use in pediatric populations (<18 years of age).

Mr. Oley motioned that Serotonin Receptor Agonists (Triptans) continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider these agents as PDL eligible.

12. Gout Suppressants

Gill Abernathy reported that Colcrys® (colchicine) is an anti-inflammatory and anti-gout agent used for the treatment of gout flairs and familial Mediterranean fever (FMF) in patients four years of age or older.

Ms. Abernathy motioned that Gout Suppressants continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to continue to consider this class as PDL eligible.

PDL Phase I - New Drugs

Twynsta® (Angiotension II Receptor Blockers and Calcium Channel Blocker Combination): Ms. Abernathy presented Twynsta® (Telmisartan/Amlodipine) as a new combination product consisting of an angiotensin receptor blocker (ARB) and a calcium-channel blocker (CCB) indicated for treatment of hypertension, alone or in combination with other antihypertensive agents, not significantly different from the other products in the class. She motioned that Twynsta® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

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 one of the 42 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 42 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 pricing information should be discussed.

Mr. 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.

Following the confidential session, the Committee members re-assembled in the 7th floor conference room. 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 resume the meeting. The motion was seconded and unanimously approved by the Committee.

Mr. Oley, vice-chairman, presented the following recommendations for the drug classes deemed PDL eligible by the P&T Committee:

New PDL Drug Classes Effective April 1, 2010

Mr. Oley made a motion to add the new class of Androgenic Agents to the current PDL with Androderm[®], Androgel[®] and Testim[®] as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Long-Acting Insulins to the current PDL with Levemir[®] Vial, Lantus[®] Vial and Levemir[®] Pen as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Rapid-Acting Insulins to the current PDL with Humalog Vial, Humalog® Cartridge, Humalog® Pen, Novolog® Vial, Novolog® Cartridge, and Novolog® Flexpen Syringe as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Insulin Mix to the current PDL with Humulin Humalog[®] Mix 75/25 Vial, Novolog[®] Mix 70/30 Vial, Novolog[®] Mix 70/30 Pen, Humalog[®] Mix 75/25 Pen, Humalog[®] Mix 50/50 Vial, and Humalog[®] Mix 50/50 Pen as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Insulin 70/30 to the current PDL with Humulin® 70/30 Vial, Novolin® 70/30 Vial, Humulin® 70/30 Pen and Novolin 70/30 pen* (*Novolin 70/30 pen has been discontinued by the manufacturer) as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Insulin N to the current PDL with Humulin® N Vial, Novolin® N Vial, Humulin® N Pen, as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Insulin® R to the current PDL with Humulin® R Vial and Novolin® R Vial as preferred agents. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to add the new class of Hypoglycemics: Injectable Agents Amylin Analogs Insulins to the current PDL with the following agents Non-preferred Symlinpen[®] and Symlin[®]. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

PDL Changes Effective July 1, 2010

Mr. Oley made a motion to include only the following products as preferred in the ADHD stimulants class (Antihyperkinesis): methylphenidate, dextroamphetamine, amphetamine salt combinations, Focalin[®]XR, Vyvanse[®],Concerta[®] and Strattera.[®] With the motion seconded, the Committee voted unanimously to make the changes as noted.

Mr. Oley made a motion to include only the following products as preferred in the Topical Agents & Anesthetics* class: Voltaren® Gel and Flector® Patch. With the motion seconded, the Committee voted unanimously to make the change as noted. (*a step edit applies to these products see the NSAID criteria)

Mr. Oley made a motion to include only the following products as preferred in the benzoyl peroxide, clindamycin and combination class: clindamycin and benzoyl peroxide. With the motion seconded, the Committee voted unanimously to make the changes as noted.

Mr. Oley made a motion that the PDL Serotonin Receptor Agonists (Triptans) class remain the same with the exception of making Maxalt MLT[®] a preferred agent and Maxalt[®] non-preferred. With the motion seconded, the Committee voted unanimously to make the changes as noted.

Mr. Oley made a motion to include only the following product as preferred in the Calcitonin class: Miacalcin[®]. With the motion seconded, the Committee voted unanimously to make the change as noted.

Mr. Oley made a motion to include only the following products as preferred in the Topical Retinoids: Differin[®] Gel***, Retin-A Micro[®], Retin-A Micro[®] Pump and Tretinoin[®]. With the motion seconded, the Committee voted unanimously to make the change as noted. ***Differin[®] cream was omitted from the list of preferred agents in Mr. Oley's motion. Differin[®] cream is included on the PDL.

Mr. Oley made a motion to re-evaluate Multiple Sclerosis Agents at the April meeting. With the motion seconded, the Committee voted unanimously to make no changes at this time and re-evaluate this class at the April meeting.

Mr. Oley made a motion to make no changes to the Ophthalmic Antihistamines. With the motion seconded, the Committee voted unanimously to make no changes to the Ophthalmic Antihistamines.

Mr. Oley made a motion to re-evaluate Thiazolidinediones Agents at the April meeting with the motion seconded, the Committee voted unanimously to make no changes until the class is re-evaluated at the April meeting.

Mr. Oley made a motion to re-evaluate Thiazolidinediones-Metformin combinations and Thiazolidinediones-Sulfonylurea combinations Agents at the April meeting. The preferred DPP-IV

Inhibitor and Combinations agents are Onglyza[®] and Januvia[®]. With the motion seconded, the Committee voted unanimously to make no changes to the Thiazolidinediones-Metformin Combinations and Thiazolidinediones-Sulfonylurea Combination Agents classes at this time and re-evaluate at the April meeting.

Mr. Oley made a motion for Janumet[®] to be the preferred agent in the DPP-IV Inhibitors and Biguanide combination class. With the motion seconded, the Committee voted unanimously to maintain the preferred product as noted.

Mr. Oley made a motion to make no changes to the Alpha-Glucosidase Inhibitors. With the motion seconded, the Committee voted unanimously to make no changes to the Alpha-Glucosidase Inhibitors.

Mr. Oley made a motion to make no changes to the Meglitinides, second Generation Sulfonylureas and Biguanides Products. With the motion seconded, the Committee voted unanimously to make no changes to these classes.

Mr. Oley made a motion to add the new class of Platelet Inhibitors to the current PDL with the following agents preferred ticlopidine HCL, Dipyridamole[®], Aggrenox[®] and Plavix[®]. With the motion seconded, the Committee voted unanimously to add the new class with the noted preferred products.

Mr. Oley made a motion to make to make all agents preferred in the Oral Antifungals class (see correction below**). With the motion seconded, the Committee voted unanimously to make the changes as noted (**The motion should have been stated as "the following agents are preferred: GRIS-PEG®, Griseofulvin Oral® Susp and Grifulvin V® Tablets and terbinafine. The following agents remain non-preferred itraconazole, Sporanox Solution®, Sporanox Capsules®, Lamisil® and Lamisil® Granules (diagnosis tinea capitis).

Mr. Oley made a motion to change the current PDL Oral Agents for Gout class to make Allopurinol, Colchicine, Probenecid-Colchicine and Probenecid preferred agents. With the motion seconded, the Committee voted unanimously to make the changed as noted.

Mr. Oley motioned no changes in the following classes:

ARB/CCB combinations

Long Acting Narcotics

NSAIDs includeds Cox-2 Inhibitors

Second Generation Cephalosporins

Third Generation Cephalosporins

Macrolides (Adult and Pediatric)

Quinolones Systemic

Bisphosphonates

Alpha-two Adrenergic Agents Glaucoma

Beta Blockers Glaucoma

Carbonic Anhydrase Inhibitors Glaucoma

Prostaglandin Analogs Glaucoma

Leukotriene Receptor Antagonist (Formation Inhibitors and Modifiers)

Influenza

Intranasal Antihistamines

Ophthalmic Antibiotics (Quinolones and Macrolides)

Ophthalmic Mast Cell Stabilizers

Self Administered Drugs for Rheumatoid Arthritis**

Topical Antivirals
Ketolides
Non-Ergot Dopamine Receptor Agonists
Otic Quinolones
Ophthalmic Anti-Inflammatory (NSAIDS)
Topical Agents for Psoriasis
Topical antibiotics

With the motion seconded, the Committee voted unanimously to make no changes to the classes identified.

**Was read as no change but Self Administered Drugs for Rheumatoid Arthritis class will be finalized at the April meeting.

Dr. Axelrod made a motion to accept the Phase I and Phase II criteria as written with the additions/changes discussed during the meeting. With the motion seconded, the Committee voted unanimously to accept the criteria.

The next P&T Committee Meeting is scheduled for April 2010.

Dr. Axelrod adjourned the meeting at 1:25 p.m.