Meeting of the
Pharmacy and Therapeutics Committee
April 29, 2010

Members Present:
Randy Axelrod, M.D., Chair
Mark Oley, R.Ph., Vice Chair
Gill Abernathy, M.S., R.Ph.
Tim Jennings, Pharm.D.
Rachel M. Selby-Penczak, M.D.
Avtar Dhillon, M.D.
Mariann Johnson, M.D.
Sue Cantrell, M.D.
Krishna Madiraju M.D.
James Stewart III, Commissioner and alternate Michele Thomas, Pharm.D.

Absent:
Renita Driver, Pharm.D.

A quorum was present

DMAS Staff:
William A. Hazel Jr., MD, Secretary of Health and Human Resources
Cynthia B. Jones, Acting Agency Director
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
Donna Proffitt R.Ph., Pharmacy Manager
Keith Hayashi, RPh., Clinical Pharmacist
Rachel Cain, Pharm.D., Clinical Pharmacist
Maryanne Paccione, Information Management Consultant
Scott Cannady, Senior Policy Analyst

First Health Staff:

Debbie Moody, R.Ph., Clinical Manager, Virginia
Nancy Eldin Pharm.D., Clinical Manager, Virginia
Doug Brown, R.Ph., MBA Director Rebate Contracting Management
Lisa Comerose, Director Health Services
Donna Johnson, R.Ph., Clinical Manager, Virginia

Guests:
66 representatives from pharmaceutical companies, providers, advocates, associations, etc

Dr. Axelrod welcomed Secretary William Hazel to the meeting and thanked him for his attendance.

Welcome and Comments from Cindi B. Jones, Acting DMAS Director
Cindi Jones welcomed the members of the Committee and thanked them for their continued participation in the PDL program. She reminded the Committee that this meeting was scheduled to address the anticipated review of antipsychotic and antidepressant agents. She informed the Committee that Governor Kaine's introduced budget included language which would allow for the addition of antidepressant, anti-anxiety and antipsychotic drugs to the Preferred Drug List (PDL). However, this language was removed from the final budget submitted to Governor McDonnell for approval; therefore, these agents will not be reviewed at this meeting.

Ms. Jones noted that at a future P&T Committee meeting, DMAS would provide a review of the Health Care Reform and its impact on drug rebates. Ms. Jones then introduced and welcomed Dr. William Hazel, Virginia's Secretary for Health and Human Resources.

Comments from the Secretary of Human Health and Resources, William Hazel, MD
Secretary Hazel provided the Committee with an update on the impact of the Health Care Reform on Medicaid in Virginia. Secretary Hazel discussed the budgetary challenges facing Virginia. He expressed his gratitude for the work the P&T Committee does and its role in managing drug costs. Secretary Hazel commented that he believes that solutions will require looking at healthcare in a fundamentally different way in the future with more care coordination, choosing the most cost effective drug therapies, and providing the right treatment at the right time and right place to maintain quality.

Call to Order: Randy Axelrod, M.D., Chairman called the meeting to order and asked Dr. Avtar Dhillon to provide the Committee with a brief update on the activities of DMAS' Drug Utilization Review (DUR) Board. Dr. Dhillon is a member of both the P&T Committee and DUR Board. Dr. Dhillon explained that the DUR Board consists of an expert panel of practicing physicians, pharmacists and nurse practitioners appointed by the Agency Director. The DUR Board defines the parameters of appropriate medication use within federal and state guidelines; meets quarterly to review, revise and approve new criteria for the use of prescription drugs; and develops DUR criteria by addressing situations in which potential medication problems may arise. The DUR program consists of two components (1) prospective DUR (ProDUR) and (2) retrospective DUR (RetroDUR). The intent of both components is to ensure the health and safety of patients. ProDUR is a review by the pharmacist of the prescription medication order and the patient's drug therapy before each prescription is filled. The review includes an examination of the patient's profile to determine the possibility of potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, drug-allergy interactions, drug dosage or duration of drug treatment. The RetroDUR program examines the medication histories in an effort to identify certain patterns of use. If potentially inappropriate prescribing patterns are identified, the prescriber may be sent an educational letter that describes the issue along with a list of all his/her patients affected. Examples of recurring interventions include Beers List Criteria, Polypharmacy, and most recently, the Board reviewed atypical antipsychotics use in children under the age of six (6).

The Committee and Secretary Hazel had many questions for Dr. Dhillon concerning the Board's findings especially those related to the use of atypical antipsychotics in children ages 0 to 5 years. The Committee expressed a desire to work with the DUR Board and supported the development of criteria for the use of atypical antipsychotics in children under the age of six (6). In particular, the Committee recommended that the DUR Board consider:

- a pharmacy edit requiring all new prescriptions for atypical antipsychotics in children under the age of 6 to be written by a pediatric psychiatrist
- a six month review of all recipients currently on atypical antipsychotic under age 6 by a pediatric psychiatrist
- P&T Committee members attending the May 20th DUR Board meeting
- reviewing any proposed criteria with the Virginia chapter of AAP
- to continue to evaluate data to identify patterns and issues

Secretary Hazel stressed the need for a Coordination of Care program that includes Behavioral Specialists and training for parents. Dr. Madiraju also suggested that pediatric neurologists be included as appropriate prescribers of atypical antipsychotic in children.

Tim Jennings requested that the P&T Committee continue to receive updates on the activities of the DUR Board. He requested that the DUR Board examine the utilization of Seroquel® in the under age 6 population. Dr. Axelrod also asked the DUR Board to examine the utilization of risperidone (generic Risperdal®) in this age group specifically looking for increased prescribing since the marketing of a generic formulation. These requests will be forwarded to the DUR Board and a representative from the Board will be asked to report to the P&T Committee at its next meeting.

PDL Contract Vendor Update. Debbie Moody, from First Health Services, provided the Committee with an update on PDL related issues**.** She explained the changes in the posted "draft" Agenda that included the removal of the following reviews:

- pancreatic enzymes (postponed until the next meeting due to FDA scrutiny)
- scabicidals/products for lice (this was a class recommended by UMASS consultants, but after a DMAS review, the Agency determined that these agents did not value to the PDL)
- neuromuscular blocking agents
- injectable/insertable contraceptives

Ms. Moody explained that the categories of neuromuscular blocking agents and injectable/insertable contraceptives must be administered by a qualified medical professional and are covered under DMAS' Medical Claims Administration. Providers should continue to submit claims for these items to DMAS as a Medical Claim; therefore, the agents do lend themselves to PDL eligibility.

Ms. Moody presented several new prior authorization forms developed at the request of the Committee. These included fax forms for long acting narcotics and Effient®. Jill Abernathy noted that there is a potential for serious side effects if Effient® therapy is not started within 72 hours of stent placement. The fax for Effient® was revised to include criteria for an automatic PA if it is for continuation of therapy or post stent placement. After discussion, the Committee approved the forms with the recommended revisions.

Ms. Moody also presented a prior authorization form for Narcotic Lozenges, which was reviewed and approved for use should the class, be determined to be PDL eligible.

Mark Oley requested clarification on the 72-hour emergency fill policy for drugs requiring a prior authorization. Ms. Moody responded the pharmacist submitting the claim will receive a denial (hard edit) informing the pharmacist that a PA is needed. The pharmacist cannot override this denial at Point-of-Sale but can contact the First Health Services Call Center and a request 72-hour emergency supply of medication for the recipient. The Call Center is available 24 hours a day, 7 days a week.

Ms. Moody also informed the Committee that beginning July 1, 2010, prior authorizations will be referred to as service authorizations (SA) in Virginia.

Approval of minutes from February 9, 2010 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.

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.)*

Dr. Axelrod noted that some clinical materials received by First Health Services are copyright protected. These copyrighted documents cannot be reproduced and distributed to the P&T Committee members for review. In addition, Dr. Axelrod reviewed the following rules for presenters:

- speakers must state their affiliation and disclose if they have received any fees or grants from a pharmaceutical manufacturer within the past 2 years
- there is three (3) minute time limit. Presenters should monitor the clock – a yellow light indicates 30 seconds remaining and a red light means time is up.

Old Business

Dr. Axelrod reminded the Committee that the annual class reviews for Multiple Sclerosis (MS) Agents, Self Administered Drugs for Rheumatoid Arthritis (RA) and Thiazolidinediones (TZDs) were postponed to this meeting with the intent of creating a treatment algorithm for the RA and MS. Dr. Axelrod shared with the Committee his extensive research/findings and concluded that there are many differing opinion concerning treatment algorithms. He noteted there is no consensus among neurologists regarding the pharmacological treatment for MS at this time. With regards to the treatment of RA, Dr. Axelrod reported that rheumatologists are finalizing some treatment recommendations, which should be published within the next 4 to 6 weeks. He noted that research shows that early and aggressive treatment of RA is better than late and non-aggressive therapy. Both classes were made PDL eligible at the February 2010 meeting. The class of TZDs was also made PDL eligible at the February meeting and financials will be discussed during today's confidential session.

Potential New PDL Category

1. ***Cough and Cold Agents:*** Mr. Oley remarked that cough and cold products have been on the market for many years. Iin October 2007 the FDA's Pediatric Advisory Committee recommended that nonprescription cough and cold products containing pseudoephedrine, dextromethorphan, chlorpheniramine, diphenhydramine, brompheniramine, phenylephrine, clemastine, or guaifenesin not be used in children less than six years of age. Also in January 2008, the FDA issued a Public Health Advisory recommending that OTC cough and cold products not be used in infants and children less than two years old. ***Mr. Oley motioned that the cough and cold class be considered as a new PDL eligible class. With the motion seconded, the Committee voted unanimously to consider this entire class as PDL eligible.***

PDL Phase I – New Drug Review (*Therapeutic Class)*

1. ***Adrenaclick®*** (Self-injectable Epinephrine) Ms. Abernathy noted that AdrenaClick® (self-injectable epinephrine) is a new product available in 0.3 mg and 0.15 mg strengths. It is similar to other products previously reviewed in this class with no significant advantages over other products. ***Ms. Abernathy motioned that both Adrenaclick® and the generic formulation be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.***

2. ***Fexofenadine & pseudoephedrine ER (Antihistamines – 2nd generation)*** Mr. Oley noted that fexofenadine & pseudoephedrine ER is in the Antihistamines 2nd generation class and is a new first time generic for Allegra-D®. ***Mr. Oley motioned that the fexofenadine & pseudoephedrine ER be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

3. ***Nizatidine Suspension (Histamine2 Receptor Antagonist)*** Mr. Oley noted that nizatidine suspension, a $Histamine_2$ Receptor Antagonist, is a new dosage form for Axid®. This is just the generic version in suspension with no advantage over other products in the class. ***Mr. Oley motioned that the nizatidine suspension be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

4. ***Perindopril (Angiotensin Converting Enzyme Inhibitor)*** Ms. Abernathy noted that perindopril is a new generic ACE inhibitor. ***Ms. Abernathy motioned that perindopril be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

5. ***Welchol® packets (Liptropics: Bile Acid Sequestrant)*** Ms. Abernathy noted that Welchol® packets are similar to the original Welchol® but is marketed as packets taken once or twice a day. ***Ms. Abernathy motioned that Welchol® packets be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

PDL Phase II – New Drug Review (*Therapeutic Class)*

1. ***Ampyra® (Multiple Sclerosis Agent)***

Speakers:

- **Yashma Patel, MD; Director of the Multiple Sclerosis Center, Sentara Neurology Specialists**

Dr. Jennings noted that studies indicate that the increased walking rate improved by one second compared to placebo, additionally there are no studies that evaluate long-term efficacy. He asked Dr. Patel if she was aware of any study that provided additional information. Dr. Patel responded no, but that the one second improvement in the 25-feet time gate study seen in the clinical trials can result in the patient going from "moderate to minimal disability." She did state the drug should be discontinued if there is no improvement in the time gate study after 30 days on the drug.

Dr. Jennings asked Dr. Patel if in the population she used the drug, has she seen some patients not respond to it. Dr. Patel responded that it does not work all of the time.

The Committee continued discussions with Dr. Patel and the final consensus was that once the product is started, a 25-foot time gate test should be conducted after 30 days and if there is no improvement the product should be discontinued.

Jill Abernathy asked about the drug's major side effects. Dr. Patel responded that seizures are a risk especially if the product is dosed too high or if the dosage interval is less than every12 hours. Other side effects include dizziness, headache, and urinary tract infections.

- **Carolyn Jones, PhD; Pharmaceutical Sciences Regional Scientific Manager Medical Affairs, Acorda Therapeutics**

Dr. Jennings asked if there are any cardiovascular issues with Ampyra® since since its mechanism of action is through potassium channel blockade. Dr. Jones stated there has been no evidence of a QRS elongation or QT changes when evaluated in a subgroup of the 540 individuals enrolled in clinical trials.

Dr. Madiraju asked if there are other agents available similar to Ampyra®. Dr. Jones responded no.

Dr. Dhillon asked how many of the 540 patients in the referenced clinical trial had seizures. Dr. Jones noted that one patient had seizures on the 10 mg twice daily and one on placebo. It is known from early studies, that higher doses can cause seizures. Dr. Dhillon asked how many patients in the early studies on the 20 mg twice a day dosage experienced seizures. Dr. Jones replied three or four.

Dr. Dhillon requested additional information about the Service Hub that was mentioned by Dr. Jones in her presentation. Dr. Jones explained that the Service Hub is responsible for triaging all patients receiving Ampyra® to a limited network of Specialty Pharmacies. The specialty pharmacy is responsible for dispensing the medication and providing the patient with counseling and a medication guide. The specialty pharmacy is required to reinforce the recommended dosage of 10 mg twice daily.

Dr. Jennings asked the name of the walking test. Dr. Jones replied, the Time 25-Foot Walk Test.

Mark Oley inquired about Ampyra®'s contraindications. Dr. Jones responded that Ampyra® is contraindicated in patients with a history of seizures and patients with moderate or severe renal impairment (creatinine clearance ≤ 50mL/min).

Dr. Jennings noted that Ampyra® is a potassium channel blocker so the risk of cardiovascular side effects should be considered. Ampyra® is a reformulation of a compound that has been on the market as a homeopathic agent known as fampridine. Dr. Jennings recommended the following criteria for the use of Ampyra®:

- patient must have a gait disorder associated with MS
- after an 8 week trial, the physician must submit a Time 25-Foot Walk Test for the patient that demonstrates improvement
- patient must have a creatinine clearance ≥ 50mL/min.

Dr. Jennings motioned that Ampyra® be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

2. ***Tamsulosin hydrochloride (Alpha-blocker for BPH):*** Dr. Jennings noted that tamsulosin hydrochloride is a new first time generic of Flomax®. ***Dr. Jennings motioned that the tamsulosin hydrochloride be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

3. ***Cefditoren pivoxil (3rd Generation Cephalosporins):*** Dr. Jennings noted that cefditoren pivoxil (3rd Generation Cephalosporins) new first time generic for Spectracef®. ***Dr. Jennings motioned that the cefditoren pivoxil be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

4. ***Revatio® injectable (PDE-5 Inhibitors – PAH):*** Dr. Jennings noted Revatio® injection is an injectable version of sildenafil; it is an IV phosphodiesterase-5 (PDE-5) inhibitor, for the treatment of pulmonary arterial hypertension. ***Dr. Jennings motioned that the new dosage form be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

5. ***Mirapex ER™ (Non-ergot dopamine agonists):*** Dr. Jennings noted that Mirapex ER™ is a new dosage form available in – 0.375 mg, 0.75 mg, 1.5 mg, 3 mg; 4.5 mg***. Dr. Jennings motioned that the Mirapex® ER™ dosage forms be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

Potential New Therapeutic Class Review

1. Analgesics

Short Acting Analgesics including combination drugs: Dr. Jennings informed the Committee that the classes being considered for inclusion include narcotics analgesics, non-salicylates & barbiturate combinations, narcotic agonist & NSAID combinations, tramadol agents, narcotic lozenge and combination products. He commented that for narcotic lozenges (Fentanyl citrate, Actiq®, Fentora®, and Onsolis®), the indication is for breakthrough cancer pain in a patient that is already receiving and tolerant of opioid therapy for their underlying persistent cancer pain. Fentanyl buccal soluble film has a Black Box warning against substituting fentanyl products for another. ***Dr. Jennings motioned that Short Acting Analgesics including combination drugs be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this new class as PDL eligible***.

2. Central Nervous System

Skeletal Muscle Relaxants: Dr Jennings noted that there are a number of products on the market including dantrolene and baclofen. ***Dr. Jennings motioned that the Skeletal Muscle Relaxants be considered as PDL eligible. With the motion seconded, the Committee voted unanimously to consider this new class as PDL eligible.***

Ms. Abernathy requested the DUR Board to evaluate use of Soma® and report back to the P&T Committee.

Smoking Cessation Aids

Speakers:

- **Earl Ward, PharmD , Medical Director, Pfizer Pharmaceuticals**

  Dr. Dhillon asked how many case reports of suicide attempts have reported. Dr. Ward noted that the FDA has reported 153 suicide attempts with Chantix® and 73 with Zyban® (bupropion SR) but no cause effect has been established.

  Dr. Dhillon asked how many completed suicides have been reported. Dr. Ward replied that information was not included in the FDA's report.

  Jill Abernathy asked if there is any difference in discontinuation rate between placebo and Chantix®. Dr. Ward replied that there was a higher discontinuation rate for the placebo than for Chantix®.

  Dr. Dhillon asked how many cases of Stevens–Johnson syndrome have been reported. Dr. Ward replied that there have been only a few cases reported through post marketing drug surveillance programs.

- **Eletta Hansen, RN Mayo Certified Tobacco Treatment Specialist, Mary Washington Hospital**

  Mark Oley asked how many patients after 6 months returned to smoking and how many people are enrolled in Ms. Hansen's program. Ms. Hansen replied she has 160 people in various

programs and has an 80% success rate at six (6) months. She added that a few of her patients have experienced relapses but does not have specific data to share.

Dr. Cantrell asked if her program enrolled the participants in behavioral or social programs. Eletta Hansen replied she did not, instead she uses the program offered by whatever product the individual was using and attend a weekly support meeting with her.

Mark Oley noted that all of us are supportive of the need to stop smoking. He reviewed the specifics of the Black Box Warning for Chantix® and Zyban®: *"Serious neuropsychiatric events (eg, depression, suicidal ideation, suicide attempt and completed suicide) have been reported in patients taking Chantix® or Zyban®.* ***Mark Oley motioned that Smoking Cessation Aids be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

3. Endocrine and Metabolic Agents

Contraceptives (oral, non-oral)

Speakers:
- Tammy Sherman, Medical Science Liaison, Teva (Seasonique®)
- Christine Arsever, MD Medical Director, Merck (Nuva Ring®)

Dr. Axelrod noted that Seasonique® and Low-Seasonique® are extended cycle oral contraceptives available on in a 91-day supply package. This packaging may conflict with the 34-day supply legislated by the General Assembly. Bryan Tomlinson, DMAS' Director of the Division of Health Care Services, noted that regulatory change would have to occur to allow the dispensing of extended cycle oral contraceptive products.

Mark Oley informed the Committee that Plan B (emergency contraception) is not included in this review. He noted that oral contraceptives; NuvaRing® and Ortho-Evra® all share the Black Box Warning: *"Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptives. Women who use oral contraceptives should not smoke*." ***Mark Oley motioned that oral contraceptives; NuvaRing® and Ortho-Evra® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.***

Estrogens (vaginal): Mr. Oley noted that the vaginal estrogens come in several different dosage forms including creams, tablets and rings. There is a Black Box Warning to keep close clinical surveillance of all women taking estrogens is important due to reports showing an increased risk of endometrial carcinoma in postmenopausal women. Estrogens should not be used during pregnancy. Estrogen therapy during pregnancy is associated with an increased risk of congenital defects in the reproductive organs of the fetus, and possibly other birth defects. ***Mr. Oley motioned that vaginal estrogens be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this new class as PDL eligible.***

Incretin Mimetics *(Endocrine and Metabolic Agents)*

Speakers:
- Marjan Massoudi, PharmD; Clinical Liaison, Amylin Pharmaceuticals (Byetta®)
- Kristie Raker, Medical Science Liaison, Novo Nordisk (Victoza®)

Dr. Jennings asked what are the chemical differences between Victoza® and Byetta®. Ms. Raker replied that Victoza® is 97% homologous to native human GLP-1 with one amino acid difference in the fatty acid side chain. Victozia® is considered the first "human" analog in this class according to Ms. Raker.

Ms. Abernathy noted that both Byetta® and Victoza® are incretin mimetics used to reduce hemoglobin A1C and promote weight loss. Liraglutide is marketed under the brand name Victoza® and has been on the market since January. ***Ms. Abernathy motioned that Incretin Mimetics be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

4. Gastrointestinal

GI Stimulants: Ms. Abernathy noted that these products have a Black Box Warning of tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with use greater then 12 weeks. She asked that a step edit be included to ensure that after12 weeks, the person is re-evaluated. ***Ms. Abernathy motioned that GI Stimulants Class be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.***

Comments from the 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.

The 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. A 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:

PDL Changes Effective July 1, 2010

New PDL Classes

Skeletal Muscle Relaxants: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred with the following exception: Skelaxin® and the generic product metaxalone both will be non-preferred. With the motion seconded, the Committee voted unanimously to include the products as noted.

Suboxone Agents: Mr. Oley made a motion for Suboxone® and buprenorphine SL (generic Subutex®) products to be preferred. With the motion seconded, the Committee voted unanimously to include the products as noted.

Diabetes: (GLP1) Incretin Mimetics: Mr. Oley made a motion for Byetta® to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Smoking Cessation Agents: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Intestinal Motility Stimulants: Mr. Oley made a motion for metoclopramide HCL to be preferred and Metozolv® ODT non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Oral Contraceptives: Mr. Oley made a motion for all generic products plus Yaz® to be preferred and all other brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Intra-vaginal Contraceptives: Mr. Oley made a motion for Nuvaring® to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the product into the PDL as noted.

Transdermal Contraceptives: Mr. Oley made a motion for Ortho Evra® to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the product into the PDL as noted.

Vaginal Estrogen Preparations: Mr. Oley made a motion for Premarin® cream and Vagifem® to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Progestational Agents: Mr. Oley made a motion for the following products to be preferred: medroxyprogesterone acetate, norethindrone acetate, progesterone, Provera®, and Prometrium®. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Narcotic Analgesics - Short-Acting: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Non-Salicylates & Barbiturate Analgesic Combinations: Mr. Oley made a motion for acetaminophen-butalbital, Bupap®, Cephadyn®, Sedapap® to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Narcotic & NSAID Analgesic Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Tramadol Agents: Mr. Oley made a motion for tramadol HCL, tramadol HCL/APAP to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Narcotic Lozenges: Mr. Oley made a motion for only fentanyl citrate to be preferred. With the motion seconded, the Committee voted unanimously to incorporate the product into the PDL as noted. In addition, the Committee reviewed the criteria on the service authorization form drafted for the use of narcotic lozenges. A motion was made to accept the criteria as presented. With the motion seconded, the Committee voted unanimously to accept the criteria as written.

Narcotic & Non-Salicylate Analgesic Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

New Cough and Cold Categories

Dr. Madiraju reminded the Committee that all prescriptions covered by DMAS must be written on a prescription, including cough and cold products. He also suggested that the DUR Committee send educational information to physicians reminding prescribers of the American Association of Pediatricians (AAP) guidelines for cough and cold medications in children. Dr. Jennings asked if DMAS should cover cough and cold medications if the AAP recommends that these products not be used in this age group. Dr. Axelrod asked that the AAP information be included for review at the next meeting. Dr. Axelrod suggested that the Office of Virginia's Secretary of Health and Human Resources might be able to distribute the information regarding appropriate utilization of cough and cold prescriptions in children.

Non-Narcotic Antitussive-First Generation Antihistamine Decongestant Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Expectorants: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Non-Narcotic Antitussive-Expectorant Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Decongestant-Expectorant Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Non-Narcotic Antitussive: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Narcotic Antitussive–Decongestants: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Non-Narcotic Antitussive–Decongestants: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Antihistamine & Decongestant Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Antihistamine First Generation: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Antihistamine First Generation & Decongestant Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Narcotic Antitussive-Expectorant Combinations: Mr. Oley made a motion for all generics products to be preferred and all brand products non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the products into the PDL as noted.

Phase II Review

Mr. Oley made a motion in the Thiazolidinediones Agents class to include Avandia® and Actos® 15mg as preferred. Actos® 30 mg & 45 mg dosage forms will be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the changes into the PDL as noted.

Mr. Oley made a motion in the Thiazolidinediones-Metformin combinations class to include Avandamet® and individual agents Actos®15mg and metformin as preferred. Actoplus® Met will change to non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the changes into the PDL as noted.

Mr. Oley made a motion to make no changes to the Thiazolidinedione-Sulfonylurea Combinations class. With the motion seconded, the Committee voted unanimously to make no change as noted.

Mr. Oley made a motion to make no changes to the Self Administered Drugs for RA class. With the motion seconded, the Committee voted unanimously to make no change as noted.

Mr. Oley made a motion in the Multiple Sclerosis Agents class to maintain as non-preferred Extavia®. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

New Drugs in Phases I & II

Multiple Sclerosis Agents: Mr. Oley made a motion for Ampyra® to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted. In addition, Dr. Jennings motioned that patients prescribed Ampyra® must meet the following utilization criteria:

- The patient must have a gait disorder associated with MS
- After an 8 week trial on Ampyra®, the physician must submit a Time 25-Foot Walk Test demonstrating improvement
- The patient must have a creatinine clearance ≥ 50mL/min

With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Pulmonary HTN: Mr. Oley made a motion for Revatio® injection to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Ace Inhibitors: Mr. Oley made a motion for perindopril to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Low Sedating Antihistamines/Decongestant Combinations: Mr. Oley made a motion for fexofenadine HCL & pseudoephedrine (generic Allegra D® 12HR) to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Histamine$_2$ Receptor Antagonists: Mr. Oley made a motion for nizatidine suspension (generic Axid®) to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Bile Acid Sequestrants: Mr. Oley made a motion for Welchol® Packet to be preferred effective 4/30/10. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Alpha Blockers for BPH: Mr. Oley made a motion for tamsulosin hydrochloride (generic Flomax®) to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Third Generation Cephalosporins: Mr. Oley made a motion for cefditoren pivoxil (generic for Spectracef®) to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Self Injectable Epinephrine: Mr. Oley made a motion for maintain AdrenaClick® (brand and generic) to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Non-ergot Dopamine Agonists: Mr. Oley made a motion for Mirapex ER™ to be non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Generic Watch

Mr. Oley made a motion in the Alpha-Glycoside Inhibitors class to move the generic acrobose to preferred on 4/30/10 and the brand product Precose® to non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Mr. Oley made a motion in the Triptans class to move the generic sumatriptan succinate to preferred on 4/30/10 and the brand product Imitrex ® to non-preferred. With the motion seconded, the Committee voted unanimously to incorporate the change into the PDL as noted.

Criteria

Dr. Axelrod made a motion to accept criteria for Phase I and II new drugs, new classes and re-reviews of Phase II drugs as written with the additions/changes discussed during the meeting. With the motion seconded, the Committee voted unanimously to accept.

The next P&T Committee Meeting is tentatively scheduled for July 15, 2010.

Dr. Axelrod adjourned the meeting.