

**MINUTES OF THE September 13, 2011  
PHARMACY AND THERAPEUTICS (P&T) COMMITTEE MEETING**

**MEMBERS ATTENDING:** Deborah Minor, Pharm.D. (Chair); Hosan Azomani, M.D.; Anne Norwood, Ph.D.; Sharon Dickey, Pharm.D.; Ryan Harper, Pharm.D.; Carol Tingle, M.D.; Geri Lee Weiland M.D.; Wilma Wilbanks, R.Ph.

Also present: Judith Clark, R.Ph., Pharmacy Director, DOM; Terri Kirby, R.Ph., DOM; Shannon Hardwick, R.Ph. DOM; Rick Pope, Pharm.D., Clinical Account Manager, Provider Synergies. Leslie Leon, Pharm.D. ACS-Xerox, Kyle Null, Pharm.D., University of Mississippi School of Pharmacy.

**MEMBERS ABSENT:** Lonnie Hicks, R.Ph.; Lee Voulters M.D., John Mitchell, M.D. and Billy Brown, Pharm.D.

**CALL TO ORDER:** Dr. Minor called the meeting to order.

**INTRODUCTIONS:** Ms. Clark welcomed attendees to the meeting including the audience, vendors, committee members and Division of Medicaid staff. She introduced new Committee member Anne Norwood, FNP, Ph.D. and welcomed her to the Committee. She requested that everyone at the table introduce themselves. She thanked the Committee members for their background work, their diligence as well as their public work. Ms. Clark gave a special thanks to Mr. Delvin Taylor of the DOM staff for all his work in overseeing the logistics for the meeting. Ms. Clark thanks the remainder of the DOM staff for their hard work and dedication. Ms. Clark then reintroduced Dr. Leslie Leon of ACS, Dr. Kyle Null of the University of Mississippi DUR project and Dr. Rick Pope of Provider Synergies.

**ADMINISTRATIVE MATTERS:** Ms. Clark outlined procedural and safety guidelines for the meeting. She noted that the P&T Committee is an advisory committee and that the DOM has the final say regarding the PDL. She stated that the minutes from this and each P&T Committee meeting would be posted to the DOM website within 30 days of the meeting. The final approved PDL decisions for classes reviewed at this and each meeting will be posted to the website no later than 30 days before implementation; implementation of the classes reviewed at this meeting will be on January 1, 2012

Ms. Clark reminded audience members of the sign in requirements as well as the time limitations for speakers and advocates. Advocates will receive five minutes while manufacturer representatives will receive three minutes per drug, not per speaker. There are also not handouts or brochures to be distributed at the meeting.

Ms. Clark reminded all in attendance of the requirements to keep the building clean and that there was not to be any food or drink in the room except for Committee members. Finally, Ms Clark reviewed the emergency procedures for the building and measures to be taken in the event of an emergency.

Ms. Clark said that, due to the current DOM workload, she is not accepting appointments with pharmaceutical manufacturers at this time. She stated that she may begin doing so when the department's workload decreases.

Finally, Ms. Clark once again thanked the Committee members for their service and diligence and closed her remarks.

**APPROVAL OF APRIL 12, 2011 MEETING MINUTES:** Dr. Minor noted no corrections

to the minutes and moved they be approved. The motion carried and the minutes approved.

**ADVOCATES:** Advocate Kay Donneault of the Mental Health Association of Southern Mississippi spoke on behalf of open access for mental health drugs.

**THERAPEUTIC CLASS REVIEWS:** Ms. Clark then turned the meeting over to Dr. Pope.

Dr. Pope thanked Ms. Clark for her cooperation and the Committee for the opportunity to review the selected therapeutic classes.

**ALZHEIMERS AGENTS**

Dr. Pope noted that there were no new entries into the class and that the class is seeing an increased number of generic products entering the market. Dr. Pope then presented the PDL recommendations for the class:

Brand Name	Current PDL Status	PDL Recommendation
ARICEPT (ORAL)	PDL	PDL
ARICEPT 23 MG (ORAL)	PDL	NPD
ARICEPT ODT (ORAL)	PDL	PDL
DONEPEZIL (ORAL)	NPD	NPD
DONEPEZIL ODT (ORAL)	NPD	NPD
EXELON (TRANSDERM.)	PDL	PDL
EXELON CAPSULES (ORAL)	PDL	PDL
EXELON SOLUTION (ORAL)	PDL	NPD
GALANTAMINE ER (ORAL)	NPD	NPD
GALANTAMINE SOLUTION (ORAL)	NPD	NPD
GALANTAMINE TABLET (ORAL)	NPD	NPD
NAMENDA SOLUTION (ORAL)	PDL	NPD
NAMENDA TAB DS PK (ORAL)	PDL	PDL
NAMENDA TABLET (ORAL)	PDL	PDL
RAZADYNE SOLUTION (ORAL)	NPD	NPD
RIVASTIGMINE CAPSULES (ORAL)	NPD	NPD

Dr. Shampa De-Oertel presented on Namenda for Forest Pharmaceuticals.

Julia Compton of Novartis was to speak on behalf of Exelon but stated she would yield her time back to the Committee.

There was no significant discussion among the Committee members and Dr. Tingle made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Dr. Dickey. The motion passed unanimously.

**ANTIBIOTICS, VAGINAL**

Dr. Pope noted that there is no significant new clinical information for this class and that the recommendations had not changed. He then presented the PDL recommendations for the class:

Brand Name	Current PDL Status	PDL Recommendation
CLEOCIN CREAM (VAGINAL)	PDL	<b>PDL</b>
CLEOCIN OVULES (VAGINAL)	PDL	<b>PDL</b>
CLINDAMYCIN (VAGINAL)	PDL	<b>PDL</b>
CLINDESSE (VAGINAL)	NPD	<b>NPD</b>
METRONIDAZOLE (VAGINAL)	PDL	<b>PDL</b>
VANDAZOLE (VAGINAL)	PDL	<b>PDL</b>

There was no public testimony for this class.

There was no discussion among Committee members. Dr. Harper made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Ms. Wilbanks. The motion passed unanimously.

**ANTIDEPRESSANTS, OTHER**

Dr. Pope noted that this class has two newer products, Oleptro ER and Viibryd. Neither product presents a distinct clinical advantage over other members of the class, otherwise there was no new clinical information for this class. Dr. Pope presented the following PDL recommendations for consideration:

Brand Name	Current PDL Status	PDL Recommendation
APLENZIN (ORAL)	NPD	<b>NPD</b>
BUPROPION (ORAL)	PDL	<b>PDL</b>
BUPROPION SR (ORAL)	PDL	<b>PDL</b>

BUPROPION XL (ORAL)	PDL	<b>PDL</b>
EFFEXOR XR (ORAL)	NPD	<b>NPD</b>
EMSAM (TRANSDERMAL)	NPD	<b>NPD</b>
MARPLAN (ORAL)	NPD	<b>NPD</b>
MIRTAZAPINE (ORAL)	PDL	<b>PDL</b>
MIRTAZAPINE ODT (ORAL)	PDL	<b>PDL</b>
NEFAZODONE (ORAL)	PDL	<b>PDL</b>
OLEPTRO ER (ORAL)	NPD	<b>NPD</b>
PARNATE (ORAL)	NPD	<b>NPD</b>
PHENELZINE (ORAL)	NPD	<b>NPD</b>
PRISTIQ (ORAL)	PDL	<b>PDL</b>
TRANLYCYPROMINE SULFATE (ORAL)	NPD	<b>NPD</b>
TRAZODONE (ORAL)	PDL	<b>PDL</b>
VENLAFAXINE (ORAL)	NPD	<b>NPD</b>
VENLAFAXINE ER CAPSULES (ORAL)	NPD	<b>NPD</b>
VENLAFAXINE ER TABLETS (GENERIC) (ORAL)	NPD	<b>NPD</b>
VENLAFAXINE ER TABLETS (ORAL)	NPD	<b>NPD</b>
VENLAFAXINE ER TABLETS (ORAL)	NPD	<b>NPD</b>
VIIBRYD (ORAL)	NPD	<b>NPD</b>
WELLBUTRIN XL (ORAL)	PDL	<b>PDL</b>

Dr. Minor expressed some concerns regarding the class due to the lack of information available regarding Viibryd in the TCR.

Pauline Patrick of Forest Pharmaceuticals was to speak on behalf of Viibryd and Lee Ann Griffin of Pfizer was to speak on Pristiq but both stated they would yield their time back to the Committee as the class was tabled.

Dr. Weiland made a motion to table the class until October. Ms. Wilbanks seconded the motion, which passed unanimously.

**ANTIDEPRESSANTS, SSRIs**

Dr. Pope discussed the fact that this class like many others in the mental health arena is increasing a generic class with Lexapro going generic in early 2012. Dr. Pope also noted that availability issues and cost were responsible for the recommended changes. Dr. Pope presented the following PDL recommendations for consideration:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
CITALOPRAM SOLUTION (ORAL)	PDL	<b>PDL</b>
CITALOPRAM TABLET (ORAL)	PDL	<b>PDL</b>
FLUOXETINE 10 MG TABLET (ORAL)	PDL	<b>PDL</b>
FLUOXETINE 20 MG TABLET (ORAL)	PDL	<b>PDL</b>
FLUOXETINE CAPSULE (ORAL)	PDL	<b>PDL</b>
FLUOXETINE CAPSULE DR (ORAL)	NPD	<b>NPD</b>
FLUOXETINE SOLUTION (ORAL)	PDL	<b>PDL</b>
FLUVOXAMINE (ORAL)	PDL	<b>PDL</b>
LEXAPRO SOLUTION (ORAL)	NPD	<b>NPD</b>
LEXAPRO TABLET (ORAL)	NPD	<b>NPD</b>
LUVOX CR (ORAL)	PDL	<b>PDL</b>
PAROXETINE CR (ORAL)	NPD	<b>NPD</b>
PAROXETINE SUSPENSION (ORAL)	PDL	<b>NPD</b>
PAROXETINE TABLET (ORAL)	PDL	<b>PDL</b>
PAXIL SUSPENSION (ORAL)	NPD	<b>PDL</b>
PEXEVA (ORAL)	NPD	<b>NPD</b>
SARAFEM (ORAL)	NPD	<b>NPD</b>
SERTRALINE CONC (ORAL)	PDL	<b>PDL</b>
SERTRALINE TABLET (ORAL)	PDL	<b>PDL</b>

Pauline Patrick of Forest Pharmaceuticals spoke to the Committee on behalf of Lexapro.

The Committee had little discussion of this class. Dr. Azomani made a motion to accept Provider Synergies' recommendations. The motion was seconded by Dr. Tingle. The motion passed unanimously.

## **ANTIFUNGALS, ORAL**

Dr. Pope noted that the only significant clinical information for this class involved the pregnancy warnings following use of high-dose diflucan. Dr. Pope clarified that this warning involved only routine doses of 400mg to 800mg and not the single 150mg dose of diflucan used for vaginal candidiasis. Dr. Pope then presented the PDL recommendations to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
ANCOBON (ORAL)	NPD	<b>NPD</b>
CLOTRIMAZOLE (MUCOUS MEM)	PDL	<b>PDL</b>
FLUCONAZOLE SUSPENSION (ORAL)	PDL	<b>PDL</b>
FLUCONAZOLE TABLET (ORAL)	PDL	<b>PDL</b>
GRIFULVIN V TABLETS (ORAL)	PDL	<b>PDL</b>
GRISEOFULVIN SUSPENSION (ORAL)	PDL	<b>PDL</b>
GRIS-PEG (ORAL)	PDL	<b>PDL</b>
ITRACONAZOLE (ORAL)	NPD	<b>NPD</b>
KETOCONAZOLE (ORAL)	PDL	<b>PDL</b>
LAMISIL GRANULES (ORAL)	NPD	<b>NPD</b>
NOXAFIL (ORAL)	NPD	<b>NPD</b>
NYSTATIN POWDER (ORAL)	PDL	<b>PDL</b>
NYSTATIN SUSPENSION (ORAL)	PDL	<b>PDL</b>
NYSTATIN TABLET (ORAL)	PDL	<b>PDL</b>
ORAVIG (BUCCAL)	NPD	<b>NPD</b>
SPORANOX SOLUTION (ORAL)	NPD	<b>NPD</b>
TERBINAFFINE (ORAL)	PDL	<b>PDL</b>

TERBINEX KIT (MISCELL)	NPD	<b>NPD</b>
VFEND SUSPENSION (ORAL)	NPD	<b>NPD</b>
VFEND TABLET (ORAL)	NPD	<b>NPD</b>
VORICONAZOLE TABLETS (ORAL)	NPD	<b>NPD</b>

No public testimony on this class was provided nor was there Committee discussion.

Ms. Wilbanks made a motion to approve the recommendations as presented by Provider Synergies. The motion was seconded by Dr. Azomani and passed unanimously.

### **ANTIPSYCHOTIC AGENTS**

Dr. Pope noted some of the newer agents in the class but emphasized that no new breakthrough agents had gained recent approval. Dr. Pope, with Ms. Clark's approval, detailed the movement toward generics the class will see over the next year. Dr. Pope presented the PDL recommendations for this class:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
<b>ABILIFY DISCMELT (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>ABILIFY SOLUTION (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>ABILIFY TABLET (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>AMITRIPTYLINE / PERPHENAZINE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>CHLORPROMAZINE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>CLOZAPINE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>CLOZARIL (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>FANAPT TAB DS PK (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>FANAPT TABLET (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>FAZACLO (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>FLUPHENAZINE CONC (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>FLUPHENAZINE ELIXIR (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>FLUPHENAZINE TABLET (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>GEODON (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>HALOPERIDOL (ORAL)</b>	<b>PDL</b>	<b>PDL</b>

<b>HALOPERIDOL LACTATE CONC (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>INVEGA (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>LATUDA (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>MOBAN (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>ORAP (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>PERPHENAZINE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>RISPERDAL TABLET (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>RISPERIDONE ODT (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>RISPERIDONE SOLUTION (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>RISPERIDONE TABLET (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>SAPHRIS (SUBLINGUAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>SEROQUEL (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>SEROQUEL XR (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>SYMBYAX (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>THIORIDAZINE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>THIOTHIXENE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>TRIFLUOPERAZINE (ORAL)</b>	<b>PDL</b>	<b>PDL</b>
<b>ZYPREXA (ORAL)</b>	<b>NPD</b>	<b>NPD</b>
<b>ZYPREXA ZYDIS (ORAL)</b>	<b>NPD</b>	<b>NPD</b>

There were several presenters giving public testimony for this class. These included: Mr. Bill Clark of BMS on behalf of Abilify; Lee Ann Griffin of Pfizer on behalf of Geodon; Dr. Jack Putman of Merck & Company on behalf of Saphris; and Judy Norton of Sunovion on behalf of Latuda. Additionally, Dr. John Norton on behalf of both Latuda and Fanapt as an interested practitioner.

Dr.. Azomani made the motion to accept the recommendations, which was seconded by Dr. Harper. The motion passed unanimously.

#### **ANTIVIRALS, ORAL**

Dr. Pope reiterated that this group did not include the inhaled influenza agents Tamiflu and Relenza. They are handled separately by the State. Dr. Pope stated that there was



no significant new clinical information for this class and no change in recommendations. Dr. Pope presented the PDL recommendations to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
ACYCLOVIR CAPSULE (ORAL)	PDL	<b>PDL</b>
ACYCLOVIR SUSPENSION (ORAL)	PDL	<b>PDL</b>
ACYCLOVIR TABLET (ORAL)	PDL	<b>PDL</b>
FAMCICLOVIR (ORAL)	NPD	<b>NPD</b>
VALACYCLOVIR (ORAL)	PDL	<b>PDL</b>
VALTREX (ORAL)	NPD	<b>NPD</b>

There was no public testimony for this class.

Dr. Tingle made a motion to accept the PDL recommendations as presented. The motion was seconded by Dr. Dickey and passed unanimously.

## **CEPHALOSPORINS AND RELATED AGENTS**

Dr. Pope stated that there was no significant new clinical information for this class. The class continues to become a generic class. Dr. Pope presented the PDL recommendations:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
AMOXICILLIN/CLAV 250 SUSPENSION (ORAL)	PDL	<b>PDL</b>
AMOXICILLIN/CLAV 250 SUSPENSION BRAND (ORAL)	PDL	<b>PDL</b>
AMOXICILLIN/CLAV SUSPENSION (ORAL)	PDL	<b>PDL</b>
AMOXICILLIN/CLAV TABLET (ORAL)	PDL	<b>PDL</b>
AMOXICILLIN/CLAV XR (ORAL)	PDL	<b>PDL</b>
AMOXICILLIN/CLAV XR BRAND (ORAL)	PDL	<b>NPD</b>

AUGMENTIN 125 SUSPENSION (ORAL)	PDL	<b>PDL</b>
AUGMENTIN XR (ORAL)	PDL	<b>PDL</b>
CEDAX CAPSULE (ORAL)	NPD	<b>NPD</b>
CEDAX SUSPENSION (ORAL)	NPD	<b>NPD</b>
CEFACTOR CAPSULE (ORAL)	PDL	<b>PDL</b>
CEFACTOR SUSPENSION (ORAL)	PDL	<b>PDL</b>
CEFACTOR TABLET ER (ORAL)	PDL	<b>PDL</b>
CEFADROXIL CAPSULE (ORAL)	PDL	<b>PDL</b>
CEFADROXIL SUSPENSION (ORAL)	PDL	<b>PDL</b>
CEFADROXIL TABLET (ORAL)	PDL	<b>PDL</b>
CEFDINIR CAPSULE (ORAL)	NPD	<b>PDL</b>
CEFDINIR SUSPENSION (ORAL)	NPD	<b>NPD</b>
CEFDITOREN (ORAL)	NPD	<b>NPD</b>
CEFPODOXIME SUSPENSION (ORAL)	NPD	<b>NPD</b>
CEFPODOXIME TABLET (ORAL)	NPD	<b>NPD</b>
CEFPROZIL SUSPENSION (ORAL)	PDL	<b>PDL</b>
CEFPROZIL TABLET (ORAL)	PDL	<b>PDL</b>
CEFTIN SUSPENSION (ORAL)	NPD	<b>NPD</b>
CEFUROXIME SUSPENSION (ORAL)	PDL	<b>NPD</b>
CEFUROXIME TABLET (ORAL)	PDL	<b>PDL</b>
CEPHALEXIN CAPSULE (ORAL)	PDL	<b>PDL</b>
CEPHALEXIN SUSPENSION (ORAL)	PDL	<b>PDL</b>
CEPHALEXIN TABLET (ORAL)	PDL	<b>PDL</b>
SPECTRACEF (ORAL)	NPD	<b>NPD</b>
SUPRAX SUSPENSION (ORAL)	PDL	<b>PDL</b>
SUPRAX TABLET (ORAL)	PDL	<b>PDL</b>

There was no public testimony for this therapeutic class.

Dr. Azomani noted his preference that cefuroxime suspension, (generic Ceftin), remain a preferred product, and made that recommendation

Dr. Dickey made a motion to accept the amendment from Dr. Azomani. The motion was seconded by Dr. Azomani. The motion passed without dissent.

## **FLUOROQUINOLONES, ORAL**

Dr. Pope stated that there was no significant new clinical information for this class and that like many others generics entries were becoming more the rule than branded products. Dr. Pope presented the PDL recommendations to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
AVELOX (ORAL)	PDL	<b>PDL</b>
CIPRO SUSPENSION (ORAL)	NPD	<b>NPD</b>
CIPROFLOXACIN ER (ORAL)	NPD	<b>NPD</b>
CIPROFLOXACIN TABLET (ORAL)	PDL	<b>PDL</b>
FACTIVE (ORAL)	NPD	<b>NPD</b>
LEVAQUIN SOLUTION (ORAL)	NPD	<b>NPD</b>
LEVAQUIN TABLET (ORAL)	NPD	<b>NPD</b>
LEVOFLOXACIN SOLUTION (ORAL)	NPD	<b>NPD</b>
LEVOFLOXACIN TABLET (ORAL)	NPD	<b>NPD</b>
NOROXIN (ORAL)	NPD	<b>NPD</b>
OFLOXACIN (ORAL)	NPD	<b>NPD</b>
PROQUIN XR (ORAL)	NPD	<b>NPD</b>

Dr. Jack Putnam of Merck & Co. was listed to speak on behalf of Avelox, but decided to yield his time back to the Committee.

There was no significant discussion among Committee members.

Dr. Dickey made a motion to accept the recommendations as presented. The motion was seconded by Dr. Norwood and passed unanimously. It should be noted that Dr. Tingle was out of the room for this vote.

## HEPATITIS C AGENTS

Dr. Pope stated the new clinical information for this class revolved around the two new protease inhibitor products indicated for this disease, Incivik and Victrelis. Dr. Pope additionally stated that the remainder of the class was basically without new clinical information. Dr. Pope then related an overview of the new treatment protocols for the protease inhibitors including warnings, length of service, dosing protocols and the need for absolute adherence. Dr. Pope also stated that if a patient stopped therapy they were not eligible for a rechallenge with either new agent. Dr. Pope presented the PDL class recommendations to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
INCIVEK (ORAL)	NPD	<b>NPD</b>
INFERGEN (SUBCUTANE.)	NPD	<b>NPD</b>
PEGASYS (SUBCUTANE.)	PDL	<b>PDL</b>
PEGASYS KIT (SUBCUTANE.)	PDL	<b>PDL</b>
PEG-INTRON (SUBCUTANE.)	NPD	<b>NPD</b>
PEG-INTRON REDIPEN (SUBCUTANE.)	NPD	<b>NPD</b>
VICTRELIS (ORAL)	NPD	<b>NPD</b>

There were manufacturer representatives to give public testimony for this class. These included: Mr. Barrie Stevens of Genentech on behalf of Pegasys; Dr. Jack Putman of Merck & Company on behalf of Peg-Intron and Victrelis; and Barrie Stevens on behalf of Incivik for Vertex Pharmaceuticals.

The Committee did discuss whether one of the new agents presented a significant advantage over the other drug and it was agreed that no distinct advantage was seen and that both drugs were too new to make that determination.

Ms. Wilbanks made a motion to accept the recommendations as listed with the Smart PA edits based on approval criteria and prescribing information as discussed. The motion was seconded by Dr. Harper. The motion passed with all members voting in favor.

## IMMUNOSUPPRESIVES, ORAL

Dr. Pope stated that there were no changes for this class and that all agents were listed as preferred. Dr. Pope presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AZASAN (ORAL)	PDL	PDL
AZATHIOPRINE (ORAL)	PDL	PDL
CELLCEPT CAPSULE (ORAL)	PDL	PDL
CELLCEPT SUSPENSION (ORAL)	PDL	PDL
CELLCEPT TABLET (ORAL)	PDL	PDL
CYCLOSPORINE CAPSULE (ORAL)	PDL	PDL
CYCLOSPORINE SOLUTION (ORAL)	PDL	PDL
CYCLOSPORINE, MODIFIED CAPSULE (ORAL)	PDL	PDL
CYCLOSPORINE, MODIFIED SOLUTION (ORAL)	PDL	PDL
MYCOPHENOLATE MOFETIL CAPSULE (ORAL)	PDL	PDL
MYCOPHENOLATE MOFETIL TABLET (ORAL)	PDL	PDL
MYFORTIC (ORAL)	PDL	PDL
NEORAL CAPSULE (ORAL)	PDL	PDL
NEORAL SOLUTION (ORAL)	PDL	PDL
PROGRAF (ORAL)	PDL	PDL
RAPAMUNE SOLUTION (ORAL)	PDL	PDL
RAPAMUNE TABLET (ORAL)	PDL	PDL
SANDIMMUNE CAPSULE (ORAL)	PDL	PDL
SANDIMMUNE SOLUTION (ORAL)	PDL	PDL
TACROLIMUS (ORAL)	PDL	PDL
ZORTRESS (ORAL)	PDL	PDL

Marilyn Ripoli of Astellas Pharmaceuticals was to speak to the Committee on behalf of Prograf, but decided to yield her time back to the Committee.

Dr. Azomani made a motion to approve the PDL as recommended. The motion was seconded by Dr. Weiland and was passed unanimously.

Following the vote, Dr. Azomani retired from the meeting and the remainder of the Committee broke for lunch.

### **MACROLIDES-KETOLIDES**

Dr. Pope stated that there was no significant new clinical information for this class and that potential changes in the recommendations were solely based on possible savings. Dr. Pope presented the PDL scenario recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AZITHROMYCIN PACKET (ORAL)	PDL	PDL
AZITHROMYCIN SUSPENSION (ORAL)	PDL	PDL
AZITHROMYCIN TABLET (ORAL)	PDL	PDL
CLARITHROMYCIN ER (ORAL)	NPD	NPD
CLARITHROMYCIN SUSPENSION (ORAL)	PDL	PDL
CLARITHROMYCIN TABLET (ORAL)	PDL	PDL
E.E.S. 200 SUSPENSION (ORAL)	PDL	NPD
E.E.S. 400 TABLET (ORAL)	PDL	PDL
ERYPED 400 SUSPENSION (ORAL)	PDL	PDL
ERY-TAB (ORAL)	PDL	NPD
ERYTHROCIN (ORAL)	PDL	NPD
ERYTHROMYCIN BASE CAPSULE DR (ORAL)	PDL	NPD
ERYTHROMYCIN BASE TABLET (ORAL)	PDL	NPD
KETEK (ORAL)	NPD	NPD
PCE (ORAL)	PDL	PDL
ZITHROMAX PACKET (ORAL)	NPD	NPD
ZMAX (ORAL)	NPD	NPD

There was no public testimony for this class.

The Committee and the DOM stated that past changes in this class were not well received and created significant issues for the call center. It was recommended that no changes be made to the preferred statuses in this class.

Ms. Wilbanks made a motion not to accept recommendations and keep the status quo for the class. Dr. Dickey seconded the motion, which passed unanimously.

#### **OPHTHALMIC ANTIOTBIOTIC-STERIOD COMBINATIONS**

Dr. Pope stated that there was no significant new clinical information for this class and no new agents for consideration. Dr. Pope presented two PDL recommendation scenarios to the Committee for consideration:

Brand Name	Current PDL Status	PDL Recommendation	PDL Recommendation 2 <sup>ND</sup> Scenario
BLEPHAMIDE (OPHTHALMIC)	PDL	PDL	PDL
BLEPHAMIDE S.O.P. (OPHTHALMIC)	PDL	PDL	PDL
NEOMYCIN/BACITRACIN/POLY/HC (OPHTHALMIC)	PDL	PDL	PDL
NEOMYCIN/POLYMYXIN/DEXAMETHASONE (OPHTHALMIC)	PDL	PDL	PDL
NEOMYCIN/POLYMYXIN/HC (OPHTHALMIC)	PDL	PDL	PDL
POLY-PRED (OPHTHALMIC)	PDL	PDL	PDL
PRED-G DROPS SUSP (OPHTHALMIC)	PDL	PDL	PDL
PRED-G OINT. (OPHTHALMIC)	PDL	PDL	PDL
SULFACETAMIDE / PREDNISOLONE (OPHTHALMIC)	PDL	PDL	PDL
TOBRADEX OINTMENT (OPHTHALMIC)	PDL	PDL	PDL
TOBRADEX ST (OPHTHALMIC)	PDL	PDL	PDL
TOBRADEX SUSPENSION (OPHTHALMIC)	PDL	PDL	PDL
TOBRAMYCIN / DEXAMETHASONE SUSPENSION (OPHTHALMIC)	PDL	PDL	NPD
ZYLET (OPHTHALMIC)	PDL	PDL	PDL

There were no presenters for this category and no Committee discussion within the Committee for this class.

Dr. Harper made a motion to accept recommendation number two as presented. Ms. Wilbanks seconded the motion, which passed unanimously.

#### **OPHTHALMIC ANTIBIOTICS**

Dr. Pope stated that there was no significant new clinical information for this class and one new product of note, Moxeza which was developed to be the successor of Vigamox. Dr. Pope presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AZASITE (OPHTHALMIC)	PDL	NPD
BACITRACIN (OPHTHALMIC)	PDL	PDL

BACITRACIN/POLYMYXIN B SULFATE OINT. (OPHTHALMIC)	PDL	<b>PDL</b>
BESIVANCE (OPHTHALMIC)	NPD	<b>NPD</b>
CILOXAN OINTMENT (OPHTHALMIC)	NPD	<b>NPD</b>
CIPROFLOXACIN SOLUTION (OPHTHALMIC)	NPD	<b>NPD</b>
ERYTHROMYCIN (OPHTHALMIC)	PDL	<b>PDL</b>
GARAMYCIN DROPS (OPHTHALMIC)	NPD	<b>NPD</b>
GARAMYCIN OINT. (OPHTHALMIC)	NPD	<b>NPD</b>
GENTAMICIN DROPS (OPHTHALMIC)	PDL	<b>PDL</b>
GENTAMICIN OINT. (OPHTHALMIC)	PDL	<b>PDL</b>
IQUIX (OPHTHALMIC)	PDL	<b>PDL</b>
LEVOFLOXACIN (OPHTHALMIC)	NPD	<b>NPD</b>
MOXEZA (OPHTHALMIC)	NPD	<b>PDL</b>
NATACYN (OPHTHALMIC)	NPD	<b>NPD</b>
NEOMYCIN-POLYMYXIN-GRAMICIDIN (OPHTHALMIC)	PDL	<b>PDL</b>
NEO-POLYCIN (OPHTHALMIC)	NR	<b>NPD</b>
OFLOXACIN (OPHTHALMIC)	NPD	<b>NPD</b>
POLYMYXIN/TRIMETHOPRIM (OPHTHALMIC)	PDL	<b>PDL</b>
SULFACETAMIDE (OPHTHALMIC)	PDL	<b>PDL</b>
TERRAMYCIN W/POLYMYXIN (OPHTHALMIC)	NR	<b>NPD</b>
TOBRAMYCIN (OPHTHALMIC)	PDL	<b>PDL</b>
TOBREX OINTMENT (OPHTHALMIC)	PDL	<b>NPD</b>
TRIPLE ANTIBIOTIC (OPHTHALMIC)	PDL	<b>PDL</b>
VIGAMOX (OPHTHALMIC)	PDL	<b>NPD</b>
ZYMAR (OPHTHALMIC)	NPD	<b>NPD</b>
ZYMAXID (OPHTHALMIC)	NPD	<b>NPD</b>

There were no public presentations for this class and no substantive Committee discussion.

Dr. Weiland made a motion to accept the recommendations presented by Dr. Pope. The motion was seconded by Dr. Dickey and accepted unanimously.



### **OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS**

Dr. Pope stated there were no new entries for this class and no significant new clinical information other than an increase of generic entries in this class. Dr. Pope presented the PDL scenario recommendation to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
ALAMAST (OPHTHALMIC)	NPD	<b>NPD</b>
ALOCRIAL (OPHTHALMIC)	NPD	<b>NPD</b>
ALOMIDE (OPHTHALMIC)	NPD	<b>NPD</b>
ALREX (OPHTHALMIC)	PDL	<b>NPD</b>
AZELASTINE (OPHTHALMIC)	NPD	<b>NPD</b>
BEPREVE (OPHTHALMIC)	NPD	<b>NPD</b>
CROMOLYN SODIUM (OPHTHALMIC)	PDL	<b>PDL</b>
ELESTAT (OPHTHALMIC)	PDL	<b>PDL</b>
EMADINE (OPHTHALMIC)	PDL	<b>PDL</b>
EPINASTINE (OPHTHALMIC)	NPD	<b>NPD</b>
KETOTIFEN OTC (OPHTHALMIC)	PDL	<b>NPD</b>
LASTACRAFT (OPHTHALMIC)	NPD	<b>NPD</b>
OPTIVAR (OPHTHALMIC)	PDL	<b>PDL</b>
PATADAY (OPHTHALMIC)	PDL	<b>PDL</b>
PATANOL (OPHTHALMIC)	PDL	<b>PDL</b>

There was no public testimony for this class.

The only discussion centered on keeping ketotifen OTC preferred due to the brand/generic limitation for Medicaid recipients.

Ms. Wilbanks made a motion to approve the recommendations with the amendment to keep Ketotifen OTC as preferred. The motion was seconded by Dr. Harper. All members voted in favor of the recommendations.

### **OPHTHALMIC ANTI-INFLAMMATORIES**

Dr. Pope stated there were no new entries for this class and no significant new clinical information. Dr. Pope presented the following PDL recommendations:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
ACUVAIL (OPHTHALMIC)	NPD	<b>NPD</b>
BROMDAY (OPHTHALMIC)	NPD	<b>NPD</b>
BROMFENAC (OPHTHALMIC)	NR	<b>NPD</b>
DEXAMETHASONE (OPHTHALMIC)	PDL	<b>PDL</b>
DICLOFENAC (OPHTHALMIC)	PDL	<b>PDL</b>
DUREZOL (OPHTHALMIC)	NPD	<b>NPD</b>
FLAREX (OPHTHALMIC)	PDL	<b>PDL</b>
FLUOROMETHOLONE (OPHTHALMIC)	PDL	<b>PDL</b>
FLURBIPROFEN (OPHTHALMIC)	PDL	<b>PDL</b>
FML (OPHTHALMIC)	NPD	<b>NPD</b>
FML FORTE (OPHTHALMIC)	PDL	<b>PDL</b>
FML S.O.P. (OPHTHALMIC)	PDL	<b>PDL</b>
KETOROLAC (OPHTHALMIC)	NPD	<b>NPD</b>
KETOROLAC LS (OPHTHALMIC)	NPD	<b>NPD</b>
LOTEMAX (OPHTHALMIC)	PDL	<b>PDL</b>
MAXIDEX (OPHTHALMIC)	PDL	<b>PDL</b>
NEVANAC (OPHTHALMIC)	PDL	<b>PDL</b>
PRED MILD (OPHTHALMIC)	NPD	<b>NPD</b>
PREDNISOLONE ACETATE (OPHTHALMIC)	NR	<b>PDL</b>
PREDNISOLONE SOD PHOSPHATE (OPHTHALMIC)	NR	<b>PDL</b>
VEXOL (OPHTHALMIC)	PDL	<b>PDL</b>
XIBROM (OPHTHALMIC)	NPD	<b>NPD</b>

There was no public testimony for this class.

Dr. Dickey made a motion to approve the recommendations. The motion was seconded by Ms. Wilbanks and passed unanimously.

## OPHTHALMICS, GLAUCOMA AGENTS

Dr. Pope stated that there was no significant new clinical information nor were there any new branded products for the class. Dr. Pope again related this was another class rapidly going generic in its make-up. Dr. Pope presented two PDL recommendations for the Committee to consider:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>	<b>PDL Recommendation 2<sup>ND</sup> Scenario</b>
ALPHAGAN P 0.1% (OPHTHALMIC)	NPD	PDL	PDL
ALPHAGAN P 0.15% (OPHTHALMIC)	NPD	NPD	NPD
AZOPT (OPHTHALMIC)	PDL	PDL	PDL
BETAXOLOL (OPHTHALMIC)	PDL	PDL	PDL
BETIMOL (OPHTHALMIC)	PDL	PDL	PDL
BETOPTIC S (OPHTHALMIC)	NPD	NPD	NPD
BRIMONIDINE (OPHTHALMIC)	PDL	PDL	PDL
BRIMONIDINE P 0.15% (OPHTHALMIC)	NPD	NPD	NPD
CARTEOLOL (OPHTHALMIC)	PDL	PDL	PDL
COMBIGAN (OPHTHALMIC)	PDL	PDL	PDL
DORZOLAMIDE (OPHTHALMIC)	PDL	PDL	PDL
DORZOLAMIDE / TIMOLOL (OPHTHALMIC)	PDL	PDL	NPD
ISTALOL (OPHTHALMIC)	PDL	PDL	PDL
LATANOPROST 2.5 ML (OPHTHALMIC)	NPD	NPD	NPD
LEVOBUNOLOL (OPHTHALMIC)	PDL	PDL	PDL
LUMIGAN 2.5ML (OPHTHALMIC)	NPD	NPD	NPD
LUMIGAN 5ML (OPHTHALMIC)	NPD	NPD	NPD
LUMIGAN 7.5ML (OPHTHALMIC)	NPD	NPD	NPD
METIPRANOLOL (OPHTHALMIC)	PDL	PDL	PDL
OPTIPRANOLOL (OPHTHALMIC)	NPD	NPD	NPD
PILOCARPINE (OPHTHALMIC)	PDL	PDL	PDL

TIMOLOL (OPHTHALMIC)	PDL	<b>PDL</b>	<b>PDL</b>
TIMOPTIC (OPHTHALMIC)	NPD	<b>NPD</b>	<b>NPD</b>
TRAVATAN / TRAVATAN Z 2.5 ML (OPHTHALMIC)	PDL	<b>PDL</b>	<b>PDL</b>
TRAVATAN / TRAVATAN Z 2.5 ML (OPHTHALMIC)	PDL	<b>PDL</b>	<b>PDL</b>
TRAVATAN / TRAVATAN Z 5 ML (OPHTHALMIC)	PDL	<b>PDL</b>	<b>PDL</b>
XALATAN 2.5 ML (OPHTHALMIC)	PDL	<b>PDL</b>	<b>PDL</b>

There was no public testimony for this class.

The Committee held little discussion deciding to endorse the first PDL scenario presented.

Ms. Wilbanks made a motion to approve the recommendations contained in scenario one. The motion was seconded by Dr. Weiland. The motion was approved unanimously.

## **OTIC ANTIBIOTICS**

Dr. Pope stated that there was no significant new clinical information for this class nor any new recommendations. Dr. Pope presented the PDL recommendations to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>
CETRAXAL (OTIC)	PDL	<b>PDL</b>
CIPRO HC (OTIC)	NPD	<b>NPD</b>
CIPRODEX (OTIC)	PDL	<b>PDL</b>
COLY-MYCIN S (OTIC)	PDL	<b>PDL</b>
CORTISPORIN-TC (OTIC)	PDL	<b>PDL</b>
NEOMYCIN/POLYMYXIN/HC DROPS SUSP (OTIC)	PDL	<b>PDL</b>
NEOMYCIN/POLYMYXIN/HC SOLUTION (OTIC)	PDL	<b>PDL</b>
OFLOXACIN (OTIC)	NPD	<b>NPD</b>

There was no public testimony for this class.

Dr. Dickey made a motion to approve the recommendations as presented. The motion was seconded by Dr. Weiland and passed unanimously by the Committee.

### **STIMULANTS AND RELATED AGENTS**

Dr. Pope stated that there was no significant new clinical information for this class nor were there any new agents since the spring 'out of cycle reviews'. Dr. Pope presented two PDL recommendation scenarios to the Committee:

<b>Brand Name</b>	<b>Current PDL Status</b>	<b>PDL Recommendation</b>	<b>PDL Recommendation 2<sup>ND</sup> Senario</b>
ADDERALL (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
ADDERALL XR (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
AMPHETAMINE SALT COMBO (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
AMPHETAMINE SALT COMBO ER (GLOBAL) (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
AMPHETAMINE SALT COMBO ER (TEVA) (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
CONCERTA (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
DAYTRANA (TRANSDERMAL)	PDL	<b>PDL</b>	<b>PDL</b>
DESOXYN (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
DEXEDRINE (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
DEXMETHYLPHENIDATE (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
DEXTROAMPHETAMINE CAPSULE ER (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
DEXTROAMPHETAMINE TABLET (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
FOCALIN (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
FOCALIN XR (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
INTUNIV (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>

KAPVAY (ORAL) (1OF2 OTHER)	PDL	<b>PDL</b>	<b>PDL</b>
KAPVAY (ORAL) (1OFMANY)	PDL	<b>PDL</b>	<b>PDL</b>
METADATE CD (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
METHAMPHETAMINE (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
METHYLIN CHEWABLE TABLETS (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
METHYLIN SOLUTION (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
METHYLPHENIDATE (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
METHYLPHENIDATE ER (CONCERTA) (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
METHYLPHENIDATE ER (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
METHYLPHENIDATE SOLUTION (ORAL)	PDL	<b>NPD</b>	<b>NPD</b>
NUVIGIL (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
PROCENTRA (ORAL)	NPD	<b>NPD</b>	<b>PDL</b>
PROVIGIL (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
RITALIN LA (ORAL)	NPD	<b>NPD</b>	<b>NPD</b>
STRATTERA (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>
VYVANSE (ORAL)	PDL	<b>PDL</b>	<b>PDL</b>

Jenny Blackham of Eli Lilly was to speak on behalf of Strattera and Jamie McEntee of Shire was to speak on Intuniv but both stated they would yield their time back to the Committee.

The Committee held a brief discussion deciding to endorse the first PDL scenario presented and top accept Procentra as preferred but with an age edit only granting access for patients from three to six year of age.

Dr. Tingle made a motion to accept the recommendations as presented on the first scenario and endorsing the edits discussed for Procentra. The motion was seconded by Dr. Dickey and approved unanimously.

## TETRACYCLINES

Dr. Pope stated that there was no significant new clinical information for this class and the only item of note was the trend toward obtaining new indications for select dermatological diseases being treated with existing medications. Dr. Pope presented the PDL recommendation scenario to the Committee:

<b>Brand Name</b>	<b>Current Status</b>	<b>PDL Recommendation</b>
DEMECLOCYCLINE (ORAL)	NPD	<b>NPD</b>
DORYX (ORAL)	NPD	<b>NPD</b>
DOXYCYCLINE HYCLATE CAPSULE (ORAL)	PDL	<b>PDL</b>
DOXYCYCLINE HYCLATE TABLET (ORAL)	PDL	<b>PDL</b>
DOXYCYCLINE HYCLATE TABLET DR (ORAL)	PDL	<b>NPD</b>
DOXYCYCLINE MONOHYDRATE 100 MG CAPSULE (ORAL)	PDL	<b>PDL</b>
DOXYCYCLINE MONOHYDRATE 100 MG CAPSULE BRAND (ORAL)	PDL	<b>NPD</b>
DOXYCYCLINE MONOHYDRATE 150 MG CAPSULE (ORAL)	PDL	<b>NPD</b>
DOXYCYCLINE MONOHYDRATE 50 MG CAPSULE (ORAL)	PDL	<b>PDL</b>
DOXYCYCLINE MONOHYDRATE 50 MG CAPSULE BRAND (ORAL)	PDL	<b>PDL</b>
DOXYCYCLINE MONOHYDRATE 75 MG CAPSULE (ORAL)	PDL	<b>NPD</b>
DOXYCYCLINE MONOHYDRATE TABLET (ORAL)	PDL	<b>NPD</b>
MINOCYCLINE CAPSULES (ORAL)	PDL	<b>PDL</b>
MINOCYCLINE ER (ORAL)	NPD	<b>NPD</b>
MINOCYCLINE TABLETS (ORAL)	PDL	<b>NPD</b>

ORACEA (ORAL)	NPD	<b>NPD</b>
SOLODYN (ORAL)	NPD	<b>NPD</b>
TETRACYCLINE (ORAL)	PDL	<b>PDL</b>
VIBRAMYCIN SUSPENSION (ORAL)	NPD	<b>NPD</b>
VIBRAMYCIN SYRUP (ORAL)	NPD	<b>NPD</b>

There was no public testimony for this class.

The Committee again held a brief discussion deciding to endorse only the change in status for the one doxycycline monohydrate 100 mg capsule Brand but to keep all other products on the PDL as preferred.

Ms Wilbanks made a motion to accept the recommendations as presented on the first scenario and the motion was seconded by Dr. Harper and approved unanimously.

#### **NEXT MEETING DATE**

Dr. Pope announced the completion of the PDL review ahead of the scheduled time frame. Ms. Clark stated that the next P&T Committee meeting is scheduled October 11, 2011.

#### **ADJOURNMENT**

There being no further business, Dr. Minor adjourned the meeting.