

**MINUTES OF THE March 8, 2011  
PHARMACY AND THERAPEUTICS (P&T) COMMITTEE MEETING**

**MEMBERS ATTENDING:** Deborah Minor, Pharm.D. (Chair); Hosan Azomani, M.D.; Joyce Brewer, Ph.D.; Billy Brown, Pharm.D.; Sharon Dickey, Pharm.D.; Ryan Harper, Pharm.D.; Lonnie Hicks, R.Ph.; John Mitchell, M.D.; Carol Tingle, M.D.; Lee Voulters 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; Steve Liles, Pharm.D., Sr. Director of Pharmacy, Provider Synergies

**MEMBERS ABSENT:** none

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

**INTRODUCTIONS:** Ms. Clark welcomed attendees to the meeting. She introduced new DOM Pharmacist Shannon Hardwick, as well as the new Provider Synergies Clinical Account Manager for Mississippi, Dr. Rick Pope. She requested that everyone at the table introduce themselves. She thanked her staff and the Committee members for their work and introduced the other members of the DOM pharmacy staff and Dr. Leslie Leon from ACS. Ms. Clark announced that DOM has contracted the University of Mississippi School Of Pharmacy as the new DUR vendor. She stated that Dr. Kyle Null is heading up this program for the University.

**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 60 days before implementation; implementation of the classes reviewed at this meeting will be on July 1, 2011.

Ms. Clark reviewed the recent FDA announcement that many cough and cold medications are to be removed from the market. She stated that DOM has been holding any PDL changes to the cough and cold drugs in anticipation of this FDA action. DOM will be working with Provider Synergies over the next several weeks to determine the implications of this announcement on the PDL.

Ms. Clark announced that DOM's PA program has been brought in house and that the SmartPA program has been enhanced. She noted that DOM has determined that 25-30% of PAs are for brands with generics. She encouraged providers to use the web portal for PA submissions, stating that training sessions will be held in the near future. Ms. Clark stated that it is not likely that the legislature will be addressing the current limit on brand medications during this session. She said that DOM is reviewing the 90 day maintenance list.

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.

**APPROVAL OF OCTOBER 12, 2010 MEETING MINUTES:** Dr. Minor asked for changes or a motion to approve the minutes from the October 12, 2010 P&T Committee meeting. Dr. Tingle noted that there were misspellings in the minutes that needed to be corrected. With those changes, the minutes were approved.

**THERAPEUTIC CLASS REVIEWS:** Dr. Pope provided the Committee with a brief overview of his professional background prior to beginning the therapeutic class reviews.

**ANGIOTENSIN MODULATOR COMBINATIONS**

Dr. Pope noted that there was no significant new clinical information regarding this class, although the trend toward combining single agents into multiple combination agents continues. In general these combination agents offer not true clinical advantage over the single agents. Dr. Pope then presented two potential PDL recommendations for the class:

| Brand Name                      | Current PDL Status | PDL Recommendation | PDL Recommendation 2 <sup>nd</sup> Scenario |
|---------------------------------|--------------------|--------------------|---|
| AMLODIPINE / BENAZEPRIL (ORAL)  | PDL                | PDL                | NPD   |
| AZOR / TRIBENZOR (ORAL)         | PDL                | PDL                | PDL   |
| EXFORGE / EXFORGE HCT (ORAL)    | PDL                | PDL                | PDL   |
| LOTREL (ORAL)                   | PDL                | PDL                | PDL   |
| TEKAMLO / AMTURNIDE (ORAL)      | NPD                | NPD                | NPD   |
| TRANDOLAPRIL / VERAPAMIL (ORAL) | NPD                | NPD                | NPD   |
| TWYNSTA (ORAL)                  | NPD                | NPD                | NPD   |
| VALTURNA (ORAL)                 | NPD                | NPD                | NPD   |

Kathleen Pinto of BMS was to speak on behalf of Avalide but stated she would yield her time back to the Committee. Tom Woods of Daiichi Sankyo spoke on behalf of Azor.

Drs. Harper and Minor discussed the removal of amlodipine/benazepril from the PDL as it relates to compliance and DOM's prescription limit. Dr. Voulters stated that compliance is the responsibility of the patient. Dr. Minor expressed concern that removal of this combination product from the PDL could encourage use of the preferred ARB/CCB combination agents that are not appropriate for first line therapy.

Dr. Azomani made a motion to accept Provider Synergies' recommendation number two as presented. The motion was seconded by Dr. Voulters. The motion passed with Ms. Wilbanks and Mr. Hicks voting against.

**ANGIOTENSIN MODULATORS**

Dr. Pope noted that there is no significant new clinical information for this class.

He then presented the PDL recommendations for the class:

| <b>Brand Name</b>              | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|--------------------------------|---------------------------|---------------------------|
| ACEON (ORAL)                   | NPD                       | NPD                       |
| ATACAND / HCT (ORAL)           | NPD                       | NPD                       |
| AVAPRO / AVALIDE (ORAL)        | PDL                       | PDL                       |
| BENAZEPRIL / HCTZ (ORAL)       | PDL                       | PDL                       |
| BENICAR / BENICAR HCT (ORAL)   | PDL                       | PDL                       |
| CAPTOPRIL / HCTZ (ORAL)        | PDL                       | PDL                       |
| DIOVAN / HCT (ORAL)            | PDL                       | PDL                       |
| ENALAPRIL / HCTZ (ORAL)        | PDL                       | PDL                       |
| FOSINOPRIL / HCTZ (ORAL)       | PDL                       | PDL                       |
| LISINOPRIL / HCTZ (ORAL)       | PDL                       | PDL                       |
| LOSARTAN / HCTZ (ORAL)         | PDL                       | PDL                       |
| MICARDIS / MICARDIS HCT (ORAL) | PDL                       | PDL                       |
| MOEXIPRIL / HCTZ (ORAL)        | NPD                       | NPD                       |
| PERINDOPRIL (ORAL)             | NPD                       | NPD                       |
| QUINAPRIL / HCTZ (ORAL)        | PDL                       | PDL                       |
| RAMIPRIL (ORAL)                | PDL                       | PDL                       |
| TEKTURNA / TEKTURNA HCT (ORAL) | NPD                       | NPD                       |
| TEVETEN / TEVETEN HCT (ORAL)   | NPD                       | NPD                       |
| TRANDOLAPRIL (ORAL)            | PDL                       | PDL                       |

Kathleen Pinto of BMS was listed to speak on behalf of Avapro but stated she would yield her time back to the Committee.

Dr. Azomani made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Dr. Harper. The motion passed unanimously.

### **ANTIBIOTICS, TOPICAL**

Dr. Pope noted that this is the first time this class has been reviewed for the PDL. He stated that there are no head to head trials of Altabax and mupirocin.

Dr. Pope presented the following PDL recommendations for the class:

| <b>Brand Name</b>              | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|--------------------------------|---------------------------|---------------------------|
| ALTABAX (TOPICAL)              | NR                        | <b>NPD</b>                |
| BACITRACIN (TOPICAL)           | NR                        | <b>PDL</b>                |
| BACITRACIN/POLYMYXIN (TOPICAL) | NR                        | <b>PDL</b>                |
| BACTROBAN CREAM (TOPICAL)      | NR                        | <b>PDL</b>                |
| GENTAMICIN SULFATE (TOPICAL)   | NR                        | <b>PDL</b>                |
| MUPIROCIN OINTMENT (TOPICAL)   | NR                        | <b>PDL</b>                |

No public testimony on this class was provided for this class.

Dr. Brewer made a motion to accept the recommendations as presented. Ms. Wilbanks seconded the motion, which passed unanimously.

### **ANTICOAGULANTS**

Dr. Pope noted that this class, which had previously been limited to injectable agents, has been expanded to include oral anticoagulants. He presented an overview of the new oral agent, Pradaxa.

Dr. Pope presented two PDL scenario recommendations for the class:

| <b>Brand Name</b>       | <b>Current PDL Status</b> | <b>PDL Recommendation</b> | <b>PDL Recommendation 2<sup>nd</sup> Scenario</b> |
|-------------------------|---------------------------|---------------------------|---|
| ARIXTRA (SUBCUTANE.)    | PDL                       | <b>NPD</b>                | <b>NPD</b>  |
| ENOXAPARIN (SUBCUTANE.) | NPD                       | <b>NPD</b>                | <b>NPD</b>  |
| FRAGMIN (SUBCUTANE.)    | PDL                       | <b>PDL</b>                | <b>PDL</b>  |
| INNOHEP (SUBCUTANE.)    | NPD                       | <b>NPD</b>                | <b>NPD</b>  |
| LOVENOX (SUBCUTANE.)    | PDL                       | <b>PDL</b>                | <b>PDL</b>  |
| PRADAXA (ORAL)          | NPD                       | <b>PDL</b>                | <b>NPD</b>  |
| WARFARIN (ORAL)         | PDL                       | <b>PDL</b>                | <b>PDL</b>  |

Susan Wood from Boehringer Ingelheim spoke on behalf of Pradaxa.

Dr. Azomani made a motion to accept Provider Synergies' recommendations with the exception of making Pradaxa Non-Preferred, (scenario number two). The motion was seconded by Ms. Wilbanks. The Committee discussed PA and clinical criteria for the drug. Drs. Voulters, Minor and Harper discussed the drug's clinical data. Dr. Voulters

noted that he would like to have an alternative to warfarin. Ms. Wilbanks expressed concerns about the shelf life of the drug. These concerns were addressed by Susan Wood from Boehringer Ingelheim. The motion passed unanimously.

## ANTICONVULSANTS

Dr. Pope noted that there is no significant new clinical information for this class.

Dr. Pope then presented the PDL recommendations to the Committee:

| <b>Brand Name</b>               | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|---------------------------------|---------------------------|---------------------------|
| BANZEL (ORAL)                   | NPD                       | NPD                       |
| CARBAMAZEPINE (ORAL)            | PDL                       | PDL                       |
| CARBAMAZEPINE XR (ORAL)         | PDL                       | PDL                       |
| CARBATROL (ORAL)                | PDL                       | PDL                       |
| CELONTIN (ORAL)                 | NPD                       | NPD                       |
| DEPAKOTE (ORAL)                 | NPD                       | NPD                       |
| DEPAKOTE ER (ORAL)              | PDL                       | PDL                       |
| DEPAKOTE SPRINKLE (ORAL)        | PDL                       | PDL                       |
| DILANTIN INFATAB (ORAL)         | PDL                       | PDL                       |
| DIVALPROEX (ORAL)               | PDL                       | PDL                       |
| DIVALPROEX ER (ORAL)            | PDL                       | PDL                       |
| DIVALPROEX SPRINKLE (ORAL)      | PDL                       | PDL                       |
| EQUETRO (ORAL)                  | PDL                       | PDL                       |
| ETHOSUXIMIDE (ORAL)             | PDL                       | PDL                       |
| FANATREX (ORAL)                 | NPD                       | NPD                       |
| FELBATOL (ORAL)                 | NPD                       | NPD                       |
| GABAPENTIN (ORAL)               | PDL                       | PDL                       |
| GABITRIL (ORAL)                 | PDL                       | PDL                       |
| KEPPRA SOLUTION (ORAL)          | NPD                       | NPD                       |
| KEPPRA TABLETS (ORAL)           | NPD                       | NPD                       |
| KEPPRA XR (ORAL)                | NPD                       | NPD                       |
| LAMICTAL (ORAL)                 | NPD                       | NPD                       |
| LAMICTAL ODT (ORAL)             | PDL                       | PDL                       |
| LAMICTAL XR (ORAL)              | PDL                       | PDL                       |
| LAMOTRIGINE (ORAL)              | PDL                       | PDL                       |
| LEVETIRACETAM SOLUTION (ORAL)   | PDL                       | PDL                       |
| LEVETIRACETAM TABLETS (ORAL)    | PDL                       | PDL                       |
| OXCARBAZEPINE SUSPENSION (ORAL) | PDL                       | PDL                       |

|                              |     |     |
|------------------------------|-----|-----|
| OXCARBAZEPINE TABLETS (ORAL) | PDL | PDL |
| PEGANONE (ORAL)              | NPD | NPD |
| PHENYTEK (ORAL)              | PDL | PDL |
| PHENYTOIN (ORAL)             | PDL | PDL |
| SABRIL (ORAL)                | NPD | NPD |
| STAVZOR (ORAL)               | NPD | NPD |
| TEGRETOL XR (ORAL)           | PDL | PDL |
| TOPAMAX SPRINKLE (ORAL)      | NPD | NPD |
| TOPAMAX TABLETS (ORAL)       | NPD | NPD |
| TOPIRAMATE SPRINKLE (ORAL)   | PDL | PDL |
| TOPIRAMATE TABLETS (ORAL)    | PDL | PDL |
| TRILEPTAL SUSPENSION (ORAL)  | PDL | PDL |
| TRILEPTAL TABLETS (ORAL)     | NPD | NPD |
| VALPROIC ACID (ORAL)         | PDL | PDL |
| VIMPAT (ORAL)                | NPD | NPD |
| ZONISAMIDE (ORAL)            | PDL | PDL |

No public testimony on this class was provided.

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

### **ANTIPARKINSON'S AGENTS**

Dr. Pope noted that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations for this class:

| <b>Brand Name</b>               | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|---------------------------------|---------------------------|---------------------------|
| AZILECT (ORAL)                  | NPD                       | NPD                       |
| BENZTROPINE (ORAL)              | PDL                       | PDL                       |
| BROMOCRIPTINE (ORAL)            | PDL                       | PDL                       |
| CARBIDOPA / LEVODOPA (ORAL)     | PDL                       | PDL                       |
| CARBIDOPA / LEVODOPA ODT (ORAL) | PDL                       | PDL                       |
| COMTAN (ORAL)                   | NPD                       | NPD                       |
| MIRAPEX (ORAL)                  | NPD                       | NPD                       |
| MIRAPEX ER (ORAL)               | NPD                       | NPD                       |
| PRAMIPEXOLE (ORAL)              | NPD                       | NPD                       |
| REQUIP XL (ORAL)                | NPD                       | NPD                       |

|                        |     |            |
|------------------------|-----|------------|
| ROPINIROLE (ORAL)      | PDL | <b>PDL</b> |
| SELEGILINE (ORAL)      | PDL | <b>PDL</b> |
| STALEVO (ORAL)         | PDL | <b>NPD</b> |
| TASMAR (ORAL)          | NPD | <b>NPD</b> |
| TRIHEXYPHENIDYL (ORAL) | PDL | <b>PDL</b> |
| ZELAPAR (ORAL)         | NPD | <b>NPD</b> |

There was no public testimony for this class.

Dr. Voulters noted that Tasmар should be Non-Preferred due to its side effect profile.

Dr. Dickey made the motion, which was seconded by Dr. Brewer. The motion passed unanimously.

### **ANTIVIRALS, TOPICAL**

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations to the Committee:

| <b>Brand Name</b>          | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|----------------------------|---------------------------|---------------------------|
| DENAVIR (TOPICAL)          | NR                        | <b>PDL</b>                |
| XERESE (TOPICAL)           | NR                        | <b>NPD</b>                |
| ZOVIRAX CREAM (TOPICAL)    | NR                        | <b>NPD</b>                |
| ZOVIRAX OINTMENT (TOPICAL) | NR                        | <b>PDL</b>                |

There was no public testimony for this class.

Dr. Voulters made a motion to accept the PDL recommendations as presented. The motion was seconded by Ms. Wilbanks and passed unanimously.

### **BETA BLOCKERS**

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations:

| <b>Brand Name</b>                    | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|--------------------------------------|---------------------------|---------------------------|
| ACEBUTOLOL (ORAL)                    | PDL                       | <b>PDL</b>                |
| ATENOLOL / CHLORTHALIDONE (ORAL)     | PDL                       | <b>PDL</b>                |
| BETAXOLOL (ORAL)                     | NPD                       | <b>NPD</b>                |
| BISOPROLOL / HCTZ (ORAL)             | PDL                       | <b>PDL</b>                |
| BYSTOLIC (ORAL) (NO RESTRICTIONS)    | PDL                       | <b>PDL</b>                |
| CARVEDILOL (ORAL)                    | PDL                       | <b>PDL</b>                |
| COREG CR (ORAL)                      | NPD                       | <b>NPD</b>                |
| INNOPRAN XL (ORAL)                   | NPD                       | <b>NPD</b>                |
| LABETALOL (ORAL)                     | PDL                       | <b>PDL</b>                |
| LEVATOL (ORAL)                       | NPD                       | <b>NPD</b>                |
| METOPROLOL / HCTZ (ORAL)             | PDL                       | <b>PDL</b>                |
| METOPROLOL XL (ORAL)                 | PDL                       | <b>PDL</b>                |
| NADOLOL / BENDROFLUMETHIAZIDE (ORAL) | PDL                       | <b>PDL</b>                |
| PINDOLOL (ORAL)                      | PDL                       | <b>PDL</b>                |
| PROPRANOLOL / HCTZ (ORAL)            | PDL                       | <b>PDL</b>                |
| PROPRANOLOL ER (ORAL)                | PDL                       | <b>PDL</b>                |
| SOTALOL (ORAL)                       | NPD                       | <b>NPD</b>                |
| TENORMIN / TENORETIC (ORAL)          | NPD                       | <b>NPD</b>                |
| TIMOLOL (ORAL)                       | PDL                       | <b>PDL</b>                |
| TOPROL XL (ORAL)                     | NPD                       | <b>NPD</b>                |

Dr. Malcolm Taylor of Forest was listed to speak on behalf of Bystolic but stated he would yield his time back to the Committee unless there were any questions.

Dr. Minor noted that she was not in favor of keeping Bystolic on the PDL.

Dr. Azomani made a motion to accept the recommendations as presented. The motion was seconded by Dr. Brewer. The motion passed with Dr. Minor voting against.

### **BLADDER RELAXANT PREPARATIONS**

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations to the Committee:



| Brand Name            | Current PDL Status | PDL Recommendation |
|-----------------------|--------------------|--------------------|
| DETROL (ORAL)         | NPD                | NPD                |
| DETROL LA (ORAL)      | PDL                | PDL                |
| DITROPAN XL (ORAL)    | NPD                | NPD                |
| ENABLEX (ORAL)        | PDL                | NPD                |
| GELNIQUE (TRANSDERM.) | PDL                | PDL                |
| OXYBUTYNIN (ORAL)     | PDL                | PDL                |
| OXYBUTYNIN ER (ORAL)  | NPD                | NPD                |
| SANCTURA XR (ORAL)    | NPD                | NPD                |
| TOVIAZ (ORAL)         | PDL                | PDL                |
| TROSPIUM (ORAL)       | NPD                | NPD                |
| VESICARE (ORAL)       | NPD                | NPD                |

Greg Johnson of Pfizer was listed to speak on behalf of Toviaz and Detrol LA but decided to yield his time back to the Committee.

Dr. Azomani made a motion to accept the recommendations as presented. The motion was seconded by Dr. Weiland and passed unanimously.

### **BPH TREATMENTS**

Dr. Pope stated that there was no significant new clinical information for this class. Dr. Pope also stated that the recent update to the AUA guidelines endorsed dual-therapy for persons exhibiting enlarged prostate and symptoms of LUTS.

Dr. Pope presented two PDL scenario recommendations to the Committee:

| Brand Name         | Current PDL Status | PDL Recommendation | PDL Recommendation 2 <sup>nd</sup> Scenario |
|--------------------|--------------------|--------------------|---|
| AVODART (ORAL)     | PDL                | PDL                | PDL   |
| CARDURA XL (ORAL)  | NPD                | NPD                | NPD   |
| DOXAZOSIN (ORAL)   | PDL                | PDL                | PDL   |
| FINASTERIDE (ORAL) | PDL                | PDL                | PDL   |
| JALYN (ORAL)       | PDL                | PDL                | NPD   |
| PROSCAR (ORAL)     | NPD                | NPD                | NPD   |
| RAPAFLO (ORAL)     | NPD                | NPD                | NPD   |
| TAMSULOSIN (ORAL)  | PDL                | PDL                | NPD   |

|                  |     |     |     |
|------------------|-----|-----|-----|
| TERAZOSIN (ORAL) | PDL | PDL | PDL |
| UROXATRAL (ORAL) | PDL | PDL | PDL |

Kenneth Leslie of GSK spoke on behalf of Jalyn and Avodart.

Dr. Brewer made a motion to accept recommendation number one as presented. The motion was seconded by Dr. Weiland. The motion passed with all members voting in favor with the exception of Drs. Azomani and Minor and Mr. Hicks, all of whom voted against the motion.

### **CALCIUM CHANNEL BLOCKERS**

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations to the Committee:

| <b>Brand Name</b>         | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|---------------------------|---------------------------|---------------------------|
| AMLODIPINE (ORAL)         | PDL                       | PDL                       |
| CARDENE SR (ORAL)         | NPD                       | NPD                       |
| CARDIZEM CD 360 MG (ORAL) | NPD                       | NPD                       |
| COVERA-HS (ORAL)          | PDL                       | PDL                       |
| DILTIAZEM (ORAL)          | PDL                       | PDL                       |
| DILTIAZEM LA (ORAL)       | NPD                       | NPD                       |
| DYNACIRC CR (ORAL)        | PDL                       | PDL                       |
| FELODIPINE ER (ORAL)      | PDL                       | PDL                       |
| ISRADIPINE (ORAL)         | NPD                       | NPD                       |
| NICARDIPINE (ORAL)        | PDL                       | PDL                       |
| NIFEDIPINE ER (ORAL)      | PDL                       | PDL                       |
| NIFEDIPINE IR (ORAL)      | PDL                       | PDL                       |
| NISOLDIPINE (ORAL)        | NPD                       | NPD                       |
| VERAPAMIL (ORAL)          | PDL                       | PDL                       |
| VERAPAMIL ER PM (ORAL)    | NPD                       | NPD                       |

There was no public testimony.

Dr. Voulters made a motion to approve the PDL as recommended. The motion was seconded by Ms. Brown and was passed unanimously.

## ERYTHROPOIESIS STIMULATING PROTEINS

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented two PDL scenario recommendations to the Committee:

| Brand Name          | Current PDL Status | PDL Recommendation | PDL Recommendation 2 <sup>nd</sup> Scenario |
|---------------------|--------------------|--------------------|---|
| ARANESP (INJECTION) | PDL                | PDL                | NPD   |
| EPOGEN (INJECTION)  | NPD                | NPD                | NPD   |
| PROCRIT (INJECTION) | PDL                | PDL                | PDL   |

Megan Jones of Johnson & Johnson was listed to speak on behalf of Procrit but stated she would yield her time back to the Committee.

Mr. Hicks noted that there had been some supply issues with Procrit. Megan Jones of OMJPI informed the Committee that these shortages had been resolved.

Dr. Azomani made a motion to accept recommendation number two as presented. Dr. Tingle seconded the motion, which passed unanimously.

The Committee recessed for lunch.

Upon return, Ms. Clark announced that DOM was considering a review of diabetic supplies at an upcoming meeting.

## LIPOTROPICS, OTHER

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented two PDL scenario recommendations to the Committee:

| Brand Name             | Current PDL Status | PDL Recommendation | PDL Recommendation 2 <sup>nd</sup> Scenario |
|------------------------|--------------------|--------------------|---|
| ANTARA (ORAL)          | NPD                | PDL                | PDL   |
| CHOLESTYRAMINE (ORAL)  | PDL                | PDL                | PDL   |
| COLESTIPOL (ORAL)      | PDL                | PDL                | PDL   |
| FENOFIBRATE (ORAL)     | PDL                | PDL                | NPD   |
| FENOFIBRIC ACID (ORAL) | NPD                | NPD                | NPD   |

|                    |     |     |     |
|--------------------|-----|-----|-----|
| FENOGLIDE (ORAL)   | NPD | NPD | NPD |
| FIBRICOR (ORAL)    | NPD | NPD | NPD |
| GEMFIBROZIL (ORAL) | PDL | PDL | PDL |
| LIPOFEN (ORAL)     | NPD | NPD | NPD |
| LOVAZA (ORAL)      | PDL | PDL | PDL |
| NIACOR (ORAL)      | PDL | PDL | PDL |
| NIASPAN (ORAL)     | PDL | PDL | PDL |
| TRICOR (ORAL)      | PDL | PDL | PDL |
| TRIGLIDE (ORAL)    | NPD | NPD | NPD |
| TRILIPIX (ORAL)    | PDL | PDL | PDL |
| WELCHOL (ORAL)     | NPD | NPD | NPD |
| ZETIA (ORAL)       | NPD | NPD | NPD |

Dr. Pam Sardo of Abbott was listed to speak on behalf of Niaspan, Tricor and Trilipix but stated she would yield her time back to the Committee. Tom Woods of Daiichi Sankyo spoke on behalf of Welchol. Dr. Jonathan Jaffe of Merck spoke on behalf of Zetia.

Dr. Harper spoke about the use of Welchol in his patient population. Dr. Minor noted that some of the agents in this class had limited efficacy. Dr. Voulters concurred, stating that the drugs in this class were second line agents.

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

## LIPOTROPICS, STATINS

Dr. Pope stated that there was no significant new clinical information for this class, but there was a new entry to this group, Livalo.

Dr. Pope presented two PDL scenario recommendations to the Committee:

| Brand Name                | Current PDL Status | PDL Recommendation | PDL Recommendation 2nd Scenario |
|---------------------------|--------------------|--------------------|---------------------------------|
| ADVICOR (ORAL)            | NPD                | NPD                | NPD                             |
| ALTOPREV (ORAL)           | NPD                | NPD                | NPD                             |
| CADUET (ORAL)             | PDL                | PDL                | PDL                             |
| CRESTOR (ORAL)            | NPD                | NPD                | PDL                             |
| LESCOL / LESCOL XL (ORAL) | PDL                | PDL                | PDL                             |
| LIPITOR (ORAL)            | PDL                | PDL                | PDL                             |
| LIVALO (ORAL)             | NPD                | NPD                | NPD                             |
| LOVASTATIN (ORAL)         | PDL                | PDL                | PDL                             |
| PRAVASTATIN (ORAL)        | PDL                | PDL                | PDL                             |

|                    |     |     |     |
|--------------------|-----|-----|-----|
| SIMCOR (ORAL)      | NPD | NPD | NPD |
| SIMVASTATIN (ORAL) | PDL | PDL | PDL |
| VYTORIN (ORAL)     | NPD | NPD | NPD |

Dr. Voulters questioned the addition of Crestor to the PDL.

Dr. Dan Teat of AstraZeneca spoke on behalf of Crestor. Dr. Pam Sardo of Abbott spoke on behalf of Simcor. Dr. Jonathan Jaffe of Merck spoke on behalf of Vytorin. Greg Johnson of Pfizer was listed to speak on behalf of Lipitor but stated he would yield his time back to the Committee.

Ms. Clark noted that the Lipitor offer was valid for the full fiscal year.

Dr. Azomani made a motion to accept the alternative model presented by Dr. Pope, (scenario number two). The motion was seconded by Dr. Voulters and accepted unanimously.

## MS AGENTS

Dr. Pope stated that there were two new, significant additions to this class. One, Gilenya was the first oral agent in this class and had similar performance to the other agents. The second was Ampyra, which did not alter disease progression, but did help with ambulation and gait endurance.

Dr. Pope presented two PDL scenario recommendations to the Committee:

| Brand Name             | Current PDL Status | PDL Recommendation | PDL Recommendation 2nd Scenario |
|------------------------|--------------------|--------------------|---------------------------------|
| AMPYRA (ORAL)          | NPD                | NPD                | NPD                             |
| AVONEX (INTRAMUSC.)    | PDL                | PDL                | PDL                             |
| BETASERON (SUBCUTANE.) | PDL                | PDL                | PDL                             |
| COPAXONE (SUBCUTANE.)  | PDL                | PDL                | PDL                             |
| EXTAVIA (SUBCUTANE.)   | NPD                | NPD                | NPD                             |
| GILENYA (ORAL)         | NPD                | NPD                | NPD                             |
| REBIF (SUBCUTANE.)     | PDL                | PDL                | NPD                             |

Phillip Kenner of Acorda spoke on behalf of Ampyra. Andrea Bloodworth of Novartis spoke on behalf of Gilenya. Debbie Kennedy of Biogen Idec was listed to speak on behalf of Avonex but stated she would yield her time back to the Committee.

Dr. Voulters stated that Ampyra should be Non-Preferred

Dr. Voulters made a motion to approve the recommendations in scenario number one. The motion was seconded by Dr. Weiland. All members voted in favor of the recommendations with the exception of Dr. Azomani, who voted against the motion.

Dr. Voulters was excused for the remainder of the meeting.

### **PAH AGENTS, ORAL AND INHALED**

Dr. Pope stated that, within the past week, the FDA removed the box warning regarding hepatotoxicity and LFT monitoring from the prescribing information for Letairis.

Dr. Pope presented the following PDL recommendations:

| <b>Brand Name</b>     | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|-----------------------|---------------------------|---------------------------|
| ADCIRCA (ORAL)        | NPD                       | <b>PDL</b>                |
| LETAIRIS (ORAL)       | PDL                       | <b>PDL</b>                |
| REVATIO (ORAL)        | PDL                       | <b>PDL</b>                |
| TRACLEER (ORAL)       | PDL                       | <b>PDL</b>                |
| TYVASO (INHALATION)   | NPD                       | <b>NPD</b>                |
| VENTAVIS (INHALATION) | NPD                       | <b>NPD</b>                |

Tom Brock of United Therapeutics spoke on behalf of Tyvaso but decided to yield back his time on Adcirca. Dr. John Peterson of Gilead was scheduled to speak on behalf of Letairis but decided to yield back his time.

Dr. Tracy Smith of Actelion was also scheduled to speak on behalf of Ventavis and Tracleer but yielded any time back to the committee

Dr. Harper made a motion to approve the recommendations. The motion was seconded by Mr. Hicks and passed unanimously.

### **PHOSPHATE BINDERS**

Dr. Pope stated that there was no significant new clinical information for this class. Dr. Pope also stated that Renagel continues to be available with no announced end date.

Dr. Pope presented the PDL recommendations to the Committee:

| <b>Brand Name</b>      | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|------------------------|---------------------------|---------------------------|
| CALCIUM ACETATE (ORAL) | PDL                       | <b>PDL</b>                |
| ELIPHOS (ORAL)         | PDL                       | <b>PDL</b>                |
| FOSRENOL (ORAL)        | NPD                       | <b>NPD</b>                |

|                |     |            |
|----------------|-----|------------|
| PHOSLO (ORAL)  | PDL | <b>PDL</b> |
| RENAGEL (ORAL) | PDL | <b>PDL</b> |
| RENVELA (ORAL) | PDL | <b>NPD</b> |

Urvashi Vashee of Shire spoke on behalf of Fosrenol.

Dr. Azomani made a motion to approve the recommendations. The motion was seconded by Ms. Wilbanks. The motion was approved unanimously.

### **PLATELET AGGREGATION INHIBITORS**

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations to the Committee:

| <b>Brand Name</b>   | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|---------------------|---------------------------|---------------------------|
| AGGRENOX (ORAL)     | PDL                       | <b>PDL</b>                |
| DIPYRIDAMOLE (ORAL) | PDL                       | <b>PDL</b>                |
| EFFIENT (ORAL)      | NPD                       | <b>NPD</b>                |
| PLAVIX (ORAL)       | PDL                       | <b>PDL</b>                |
| TICLOPIDINE (ORAL)  | NPD                       | <b>NPD</b>                |

Dr. Shawn Boykin of Lilly spoke on behalf of Effient. Kathleen Pinto of BMS was listed to speak on behalf of Plavix but stated she would yield her time back to the Committee.

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

### **SEDATIVE HYPNOTICS**

Dr. Pope stated that there was no significant new clinical information for this class.

Dr. Pope presented the PDL recommendations to the Committee:

| <b>Brand Name</b>      | <b>Current PDL Status</b> | <b>PDL Recommendation</b> |
|------------------------|---------------------------|---------------------------|
| AMBIEN CR (ORAL)       | NPD                       | <b>NPD</b>                |
| CHLORAL HYDRATE (ORAL) | NR                        | <b>Remove</b>             |
| DORAL (ORAL)           | NPD                       | <b>NPD</b>                |
| EDLUAR (SUBLINGUAL)    | NPD                       | <b>NPD</b>                |

|                          |     |            |
|--------------------------|-----|------------|
| ESTAZOLAM (ORAL)         | PDL | <b>PDL</b> |
| FLURAZEPAM (ORAL)        | PDL | <b>PDL</b> |
| LUNESTA (ORAL)           | PDL | <b>PDL</b> |
| RESTORIL 7.5 MG (ORAL)   | NPD | <b>NPD</b> |
| ROZEREM (ORAL)           | NPD | <b>NPD</b> |
| SILENOR (ORAL)           | NPD | <b>NPD</b> |
| TEMAZEPAM (ORAL)         | PDL | <b>PDL</b> |
| TEMAZEPAM 22.5 MG (ORAL) | NPD | <b>NPD</b> |
| TEMAZEPAM 7.5 MG (ORAL)  | NPD | <b>NPD</b> |
| TRIAZOLAM (ORAL)         | PDL | <b>PDL</b> |
| ZALEPLON (ORAL)          | PDL | <b>PDL</b> |
| ZOLPIDEM (ORAL)          | PDL | <b>PDL</b> |
| ZOLPIDEM ER (ORAL)       | NPD | <b>NPD</b> |
| ZOLPIMIST (ORAL)         | NPD | <b>NPD</b> |

There was no public testimony for this class.

Dr. Tingle inquired about the preferred status of triazolam, noting that she had some concerns with its side effect profile.

Ms. Wilbanks made a motion to accept the recommendations a presented. The motion was seconded by Dr. Weiland and approved unanimously.

### **OTHER BUSINESS**

There was no other business.

### **NEXT MEETING DATE**

Ms. Clark stated that the next P&T Committee meeting is scheduled for April 12, 2011. She noted that ACS would be giving a live demonstration of the web portal at the meeting.

Ms. Clark thanked the Committee for its continued diligence and dedication to its work.

### **ADJOURNMENT**

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