MINUTES OF THE OCTOBER 14, 2008 PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

MEMBERS ATTENDING: John Cook, M.D.; Joyce Brewer, PhD, CNM, C.F.N.P, William Sorey, M.D.; Ryan Harper, Pharm.D.; Jeff Jones, R.Ph.; Garry McFerrin, R.Ph.; Deborah Minor, Pharm.D.; Carolyn M. Tingle, M.D.; Pearl Wales, Pharm.D.

Also present: Judith Clark, R.Ph., Pharmacy Director, DOM; Paige Clayton, Pharm.D., DOM; Terry Kirby, R.Ph., DOM; Steve Liles, Pharm.D., Provider Synergies; Alyssa Hoover, Pharm.D., Provider Synergies

MEMBERS ABSENT: Michael O'Dell, M.D.; Manisha Sethi, M.D.; **CALL TO ORDER:** Acting Chairman Dr. John Cook called the meeting to order at 10:15 am.

INTRODUCTIONS: Ms. Clark welcomed committee members and guests in the audience. She thanked Committee members for volunteering their time, and thanked the members who are continuing to serve on the Committee even though their terms have expired one year ago. Ms. Clark noted that the P&T Committee is a volunteer group of practicing physicians and pharmacists that is charged with making PDL recommendations based on safety, efficacy and cost. Ms. Clark announced that Dr. Cook would chair the committee meeting in place of Dr. O'Dell's absence. Ms. Clark introduced members of the DOM Pharmacy staff and thanked them for their hard work and dedication. Ms. Clark presented a brief overview of the Medicaid program, its purpose, funding, and eligibility requirements.

EXECUTIVE DIRECTOR'S COMMENTS: Ms. Clark stated that Phyllis Williams, the Deputy Administrator of DOM, was not able to attend today's meeting.

ADMINISTRATIVE MATTERS: Ms. Clark presented an overview of the proceedings of today's meeting. She stated that Provider Synergies would make a clinical presentation and present recommendations for each therapeutic class. She stated that her staff would present those recommendations to the Executive Director, who would make the final PDL decisions. She noted that the decisions from this meeting would be posted on the website on December 1, 2008. Ms. Clark noted that the PDL classes being reviewed at this and the November meeting would all be implemented on January 1, 2009. Ms. Clark stated that, pursuant to the Open Meetings Act, the Committee is required to record the minutes of the meeting within thirty days after the meeting is recessed or adjourned.

Ms. Clark asked guests to sign in ten minutes prior to the start of the meeting and that those signed up to speak would be given three minutes per drug/per class/per manufacturer. She stated the speakers will present in order they are listed on the sign in sheet. She stated that speakers may only provide oral presentations, visual or audio aids would not be allowed. She also established that questions and comments from the audience would not be accepted unless granted by two-thirds of the present members at the meeting.

Ms. Clark reminded the Committee and guests that the meeting room must be left clean and that no food or drinks are allowed. She asked that cell phones, pagers and PDAs be silenced or turned off during the meeting. She also requested that guests leave the room only during breaks to minimize noise and distractions. Ms. Clark reviewed the safety

exits for the meeting room and for the building. She explained that the meeting room is limited to a maximum capacity of ninety persons and that at no time would more than ninety be allowed to remain in the room due to state fire regulations.

Ms. Clark indicated that voting will be done by hand and/or voice vote, rather than paper ballots. She announced that meetings are no longer being taped for the purpose of recording minutes. She stated that as of July 1, 2008, DOM will no longer accept one-page dossiers from the manufacturers. Ms. Clark called Committee members' attention to their packets that contain a copy of the state's PDL, a PA form, and a colorized version of the External Cost Sheets that had previously been sent by Provider Synergies and their travel vouchers. She instructed members to fill out travel vouchers and return them before leaving the meeting.

APPROVAL OF MAY 13, 2008 MEETING MINUTES: Dr. Cook asked if there were additions, changes or deletions to the minutes of the last meeting. None were brought to the attention of the Committee. A motion was made to approve the minutes of the May 13, 2008 meeting as presented. Mr. McFerrin seconded the motion. The motion passed unanimously.

THERAPEUTIC CLASS REVIEWS: Dr. Liles gave a brief overview of Providers Synergies' methods for drug literature evaluation and the standards by which the PDL recommendations are decided. Dr. Liles moderated the therapeutic class reviews.

ANALGESICS/ANESTHETICS, TOPICAL

Dr. Liles noted that the only drug in this class reviewed by the Committee to date has been Flector. He described the differences among the drugs in this class, primarily with regards to indications and dosage, and presented clinical trial data. Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
FLECTOR (TOPICAL)	OFF	OFF
LIDODERM (TOPICAL)	NR	ON
VOLTAREN (TOPICAL)	NR	ON

Chris Kottenslette of Alpharma spoke on behalf of Flector Patch.

Dr. Minor commented that the Flector patch offers a good alternative to other topical forms of analgesics and recommended that the committee approve it as well based on its uniform dose deliver, decrease in adverse events, and ease of care.

Mr. Jones made a motion to accept Provider Synergies' recommendations with the addition of the Flector patch to the PDL. The motion was seconded by McFerrin. Dr. Cook asked members to raise their hands if they approved of the motion. The motion passed unanimously, 9-0.

ANALGESICS, NARCOTICS-SHORT ACTING

Dr. Liles stated that there was not much in the way of new clinical information for the drugs in this class. He briefly mentioned some of the more significant considerations outlined in the American Pain Society guidelines. Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
APAP / CODEINE (ORAL)	ON	ON
ASA / CODEINE (ORAL)	ON	ON
BUTALBITAL COMPOUND W/CODEINE (ORAL)	ON	ON
CODEINE (ORAL)	ON	ON
DARVON-N (ORAL)	OFF	OFF
DIHYDROCODEINE / APAP / CAFFEINE (ORAL)	ON	ON
FENTANYL (BUCCAL)	ON	OFF
FENTORA (BUCCAL)	OFF	OFF
HYDROCODONE / APAP (ORAL)	ON	ON
HYDROCODONE / IBUPROFEN (ORAL)	ON	ON
HYDROMORPHONE (ORAL)	ON	ON
LEVORPHANOL (ORAL)	ON	OFF
MEPERIDINE (ORAL)	ON	ON
MORPHINE IR (ORAL)	ON	ON
OPANA (ORAL)	OFF	OFF
OXYCODONE (ORAL)	ON	ON
OXYCODONE / APAP (ORAL)	ON	ON
OXYCODONE / ASA (ORAL)	ON	ON
OXYCODONE / IBUPROFEN (ORAL)	NR	ON
PANLOR DC (ORAL)	OFF	OFF
PENTAZOCINE / APAP (ORAL)	ON	ON
PENTAZOCINE / NALOXONE (ORAL)	ON	ON
PROPOXYPHENE (ORAL)	ON	ON
PROPOXYPHENE / APAP (ORAL)	ON	ON
TRAMADOL (ORAL)	ON	ON
TRAMADOL/APAP (ORAL)	ON	ON

Matt Wieman, M.D. of Endo spoke on behalf of Opana IR.

Mr. Jones commented on the high prescription utilization of the Hydrocodone/ APAP product. Ms. Clark stated that the DUR Board is working toward eventually setting a monthly limit for utilization of all hydrocodone products.

Mr. McFerrin made a motion to accept the recommendations as presented. Dr. Harper seconded the motion. Dr. Cook asked members to raise their hands if they approved of the motion. The motion passed unanimously, 9-0.

ANALGESICS, NARCOTICS-LONG ACTING

Dr. Liles stated that there was not much in the way of new clinical information for the drugs in this class. He briefly mentioned some of the more significant considerations

outlined in the American Pain Society guidelines. Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
AVINZA (ORAL)	ON	OFF
DURAGESIC (TRANSDERM.)	OFF	ON
FENTANYL (TRANSDERM)	ON	ON
KADIAN (ORAL)	ON	ON
METHADONE (ORAL)	ON	ON
MORPHINE ER (ORAL)	ON	ON
OPANA ER (ORAL)	OFF	OFF
OXYCODONE ER (ORAL)	OFF	OFF
OXYCONTIN (ORAL)	OFF	OFF
ULTRAM ER (ORAL)	OFF	OFF

Matt Wieman, MD, from Endo spoke on behalf of Opana ER.

<u>Dr. Wales made a motion to accept the recommendations as presented.</u> The motion was seconded by Mr. Jones. Dr. Cook asked for a hand vote of those in favor and opposed. The motion was approved 9-0, by hand vote.

NSAIDs

Dr. Liles discussed the similarities and differences of the drugs in this class. He reviewed the data regarding COX-II selectivity and GI and cardiovascular effects, noting that Vioxx, now off the market, was the most COX-II selective NSAID. Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ARTHROTEC (ORAL)	OFF	OFF
CELEBREX (ORAL)	OFF	OFF
DICLOFENAC (ORAL)	ON	ON
ETODOLAC (ORAL)	ON	ON
FENOPROFEN (ORAL)	ON	ON
FLURBIPROFEN (ORAL)	ON	ON
IBUPROFEN OTC (ORAL)	NR	ON
IBUPROFEN RX (ORAL)	ON	ON
INDOMETHACIN (ORAL/RECTAL)	ON	ON
KETOPROFEN (ORAL)	ON	ON
KETOROLAC (ORAL)	ON	ON
MECLOFENAMATE (ORAL)	ON	OFF
MEFENAMIC ACID (ORAL)	ON	OFF
MELOXICAM (ORAL)	ON	ON
NABUMETONE (ORAL)	ON	ON
NAPROXEN RX (ORAL)	ON	ON
OXAPROZIN (ORAL)	ON	ON
PIROXICAM (ORAL)	ON	ON

PREVACID NAPRAPAC (ORAL)	OFF	OFF
SULINDAC (ORAL)	ON	ON
TOLMETIN (ORAL)	ON	ON

Dr. John Huntwork from Pfizer spoke on behalf of Celebrex.

Discussion based on Dr. Huntwork's Celebrex data occurred among the committee members. Dr. Cook indicated that Celebrex had been recommended for approval last year by the committee, but was not approved for PDL status by the state. Dr. Minor opposed adding Celebrex to the PDL based on AHA recommendations.

Ms. Clark clarified that the Ibuprofen OTC product is only the suspension formulation.

<u>Dr. Minor moved to accept the NSAIDs PDL recommendations as is.</u> Dr. Harper seconded the motion. Dr. Cook asked for a hand vote of those in favor and opposed. The motion failed by a vote 3-6 with Dr. Cook, Dr. Brewer, Dr. Sorey, Mr. Jones, Mr. McFerrin, Dr. Wales not in agreement with the motion.

Mr. Jones moved to add Celebrex to the PDL. Mr. McFerrin seconded the motion. Dr. Cook asked for a hand vote of those in favor and opposed. The motion passed by a majority vote 6-3 with Dr. Minor, Dr. Tingle, and Dr. Harper not in agreement with the motion.

OPHTHALMICS, NSAIDs

Dr. Liles presented two relatively new clinical trials of bromfenac (Xibrom) and nefafenac (Nevanac). Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ACULAR LS (OPHTHALMIC)	ON	ON
ACULAR PF (OPHTHALMIC)	ON	ON
DICLOFENAC (OPHTHALMIC)	ON	OFF
FLURBIPROFEN (OPHTHALMIC)	ON	ON
NEVANAC (OPHTHALMIC)	ON	ON
XIBROM (OPHTHALMIC)	ON	OFF

No speakers addressed the Committee. Ms. Clark noted that imposing a maximum 14 day quantity limitation would be addressed by the DUR Board as a safety measure for this therapeutic class.

<u>Dr. Minor made a motion to accept the recommendations as presented.</u> Dr. Minor's motion was seconded by Mr. Jones. Dr. Cook asked for those in favor of the motion to signify by hand vote. The motion passed 9-0.

OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS

Dr. Liles noted that this class consists of antihistamines, anti-inflammatory agents and mast cell stabilizers, along with a few compounds that have both antihistaminic and mast cell stabilizing activity. He outlined that there are issues with most of the clinical trials that make an evidence based comparison challenging, including the fact that many trials are single dose only, use an artificial allergen challenge and have a low number of

subjects. He reviewed the AOA guidelines for treatment of allergic conjunctivitis and presented two more recent clinical trials. Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ACULAR (OPHTHALMIC)	NR	OFF
ALAMAST (OPHTHALMIC)	ON	OFF
ALOCRIL (OPHTHALMIC)	ON	OFF
ALOMIDE (OPHTHALMIC)	OFF	OFF
ALREX (OPHTHALMIC)	OFF	ON
CROMOLYN SODIUM (OPHTHALMIC)	ON	ON
ELESTAT (OPHTHALMIC)	ON	ON
EMADINE (OPHTHALMIC)	OFF	OFF
KETOTIFEN RX (OPHTHALMIC)	ON	OFF
KETOTIFEN OTC (OPHTHALMIC)	OFF	ON
OPTIVAR (OPHTHALMIC)	ON	ON
PATADAY (OPHTHALMIC)	OFF	ON
PATANOL (OPHTHALMIC)	ON	ON

No speakers addressed the Committee.

<u>Dr. Minor made a motion to accept the recommendations.</u> Dr. Brewer seconded the motion. The motion was approved, 9-0, by hand vote.

OPHTHALMICS, GLAUCOMA AGENTS

Dr. Liles outlined the basic pharmacological groups and indications represented in this class. He described some differences seen among older agents in the class in directly comparative clinical trials, noting that IOP reduction is fairly similar among the drugs. He then discussed several clinical trials involving comparing combination agents to their components and comparing PG analogs to each other. Following the presentation, he made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALPHAGAN P (OPHTHALMIC)	ON	OFF
AZOPT (OPHTHALMIC)	ON	ON
BETAXOLOL (OPHTHALMIC)	ON	ON
BETIMOL (OPHTHALMIC)	ON	ON
BETOPTIC S (OPHTHALMIC)	ON	OFF
BRIMONIDINE (OPHTHALMIC)	ON	ON
CARTEOLOL (OPHTHALMIC)	ON	ON
COMBIGAN (OPHTHALMIC)	ON	ON
COSOPT (OPHTHALMIC)	ON	ON
DIPIVEFRIN (OPHTHALMIC)	ON	ON
ISTALOL (OPHTHALMIC)	ON	ON
LEVOBUNOLOL (OPHTHALMIC)	ON	ON
LUMIGAN (OPHTHALMIC)	ON	OFF
METIPRANOLOL (OPHTHALMIC)	ON	ON

PILOCARPINE (OPHTHALMIC)	ON	ON
TIMOLOL (OPHTHALMIC)	ON	ON
TRAVATAN / TRAVATAN Z (OPHTHALMIC)	ON	ON
TRUSOPT (OPHTHALMIC)	ON	ON
XALATAN (OPHTHALMIC)	ON	ON

George Kitchens of Allergan spoke on behalf of Lumigan. Dr. Harper asked Ms. Clark if it was acceptable to approve only one size of the Lumigan. Ms. Clark indicated it was acceptable.

<u>Dr. Harper made a motion to add Lumigan 2.5 ml to the PDL recommendations.</u> The motion was seconded by Mr. Jones. Dr. Cook asked for a hand vote of those in favor; the motion passed 9-0.

OPTHALMICS, QUINOLONES & MACROLIDES

Dr. Liles outlined the differences among the drugs in this class with regards to in vitro susceptibility. He presented clinical trials comparing the fourth generation quinolones. Dr. Liles discussed the two newest drugs in the class - Azasite and Iquix - and reviewed the AOA and AAO guidelines for treatment of bacterial conjunctivitis. He then presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AZASITE (OPHTHALMIC)	ON	ON
CILOXAN OINTMENT (OPHTHALMIC)	OFF	OFF
CIPROFLOXACIN SOLUTION (OPHTHALMIC)	ON	OFF
ERYTHROMYCIN (OPHTHALMIC)	NR	ON
IQUIX (OPHTHALMIC)	NR	ON
OFLOXACIN (OPHTHALMIC)	ON	OFF
QUIXIN (OPHTHALMIC)	OFF	OFF
VIGAMOX (OPHTHALMIC)	OFF	ON
ZYMAR (OPHTHALMIC)	ON	OFF

George Kitchens of Allergan spoke on behalf of Zymar.

David Braden of Brookhaven Children's Clinic spoke on behalf of Vigamox.

<u>Dr. Wales made a motion to accept the PDL recommendations as is.</u> The motion was seconded by Dr. Harper. Dr. Cook asked for a hand vote of those in favor; the motion passed 9-0.

OTIC FLUOROQUINOLONES

Dr. Liles reviewed the drugs in this class, noting that Floxin Otic is now available generically. He presented and overview of clinical guidelines for AOE and AOM. Dr. Liles presented Provider Synergies' PDL recommendations for this class:

Brand Name	Current PDL Status	PDL Recommendation
CIPRO HC (OTIC)	OFF	OFF

CIPRODEX (OTIC)	ON	ON
FLOXIN (OTIC)	ON	ON
OFLOXACIN (OTIC)	ON	OFF

Mr. Jones made a motion to accept the recommendations; and the motion was seconded by Mr. McFerrin. The motion passed 9-0.

FLUOROQUINOLONES, ORAL

Dr. Liles noted that the Therapeutic Class Review includes the indications, pharmacokinetics and adverse effect profiles of the oral fluoroquinolones. He stated the concerns with quinolone-induced dysglycemia primarily centered on gatifloxacin, which is now off the market. Dr. Liles reviewed the data on QTc interval prolongation, including data from CAPRIE. He mentioned the AAP recommendation on the use of fluoroquinolones in the pediatric population, noting that ciprofloxacin has a new pediatric indication as second line therapy for complicated UTI and pyelonephritis. He then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
AVELOX (ORAL)	ON	ON
CIPRO SUSPENSION (ORAL)	OFF	OFF
CIPROFLOXACIN ER (ORAL)	ON	OFF
CIPROFLOXACIN TABLETS (ORAL)	ON	ON
FACTIVE (ORAL)	OFF	OFF
LEVAQUIN (ORAL)	OFF	OFF
NOROXIN (ORAL)	OFF	OFF
OFLOXACIN (ORAL)	ON	OFF
PROQUIN XR (ORAL)	OFF	ON

Domenic Mantella of Ortho McNeil Janssen spoke on behalf of Levaquin.

<u>Dr. Minor made the motion to accept the PDL recommendations as presented.</u> The motion was seconded by Mr. Jones. Dr. Cook called for those approving of the motion to signify by raising their hands; the motion passed 9-0.

CEPHALOSPORINS AND RELATED ANTIBIOTICS

Dr. Liles presented an overview of the drugs in this class, noting the limitations of most of the clinical trials of these drugs - changes in susceptibility patterns over time, high dropout rates and generally similar outcomes in comparative studies. After reviewing some of the differentiating factors of these drugs, including dosage forms, frequency and duration of therapy and age ranges of indications, she presented an overview of the role of cephalosporins in the IDSA/ATS CAP guidelines and the CDC recommendations on treatment of gonorrhea. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AMOXICILLIN/CLAV SUSPENSION (ORAL)	ON	ON
AMOXICILLIN/CLAV TABLET (ORAL)	ON	ON

AUGMENTIN XR (ORAL)	ON	ON
CEDAX (ORAL)	OFF	
CEFACLOR (ORAL)	ON	ON
CEFADROXIL (ORAL)	ON	ON
CEFDINIR (ORAL)	ON	ON
CEFPODOXIME (ORAL)	ON	OFF
CEFPROZIL (ORAL)	ON	ON
CEFUROXIME (ORAL)	ON	ON
CEPHALEXIN (ORAL)	ON	ON
RANICLOR (ORAL)	OFF	OFF
SPECTRACEF (ORAL)	OFF	OFF
SUPRAX (ORAL)	ON	ON

<u>Dr. Brewer made a motion to approve the recommendations.</u> After being seconded by Dr. Sorey, the Committee approved the motion, 9-0.

MACROLIDES/KETOLIDES

Dr. Liles noted that the Therapeutic Class Review includes the standard drug information and studies regarding this class and that there is not any significant new clinical data. Dr. Liles then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
AZITHROMYCIN (ORAL)	ON	ON
CLARITHROMYCIN (ORAL)	ON	ON
CLARITHROMYCIN ER (ORAL)	ON	OFF
ERYTHROMYCIN (ORAL)	ON	ON
KETEK (ORAL)	OFF	OFF
ZMAX (ORAL)	OFF	OFF

No speakers addressed the Committee.

<u>Dr. Sorey made a motion to accept Provider Synergies' recommendations.</u> The motion was seconded by Dr. Harper. Dr. Cook called for a show of hands of those approving the motion; the motion passed 9-0.

Dr. Cook adjourned the Committee for lunch. The meeting reconvened at 13:15 with Ms. Clark making several introductions with the P & T Board and the DUR Board. Ms. Clark introduced Dr. Clayton, who is the DUR Board coordinator, described the duties and function of the DUR Board.

Dr. Liles continued the class reviews.

ANTIBIOTICS, VAGINAL

Dr. Liles presented an overview of this drug class. He specifically reviewed several directly comparative clinical trials of clindamycin cream and clindamycin ovules or oral metronidazole. Dr. Liles presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
CLEOCIN (VAGINAL)	OFF	ON
CLINDAMYCIN (VAGINAL)	ON	ON
CLINDESSE (VAGINAL)	ON	OFF
METRONIDAZOLE (VAGINAL)	ON	ON

Dr. Minor addressed the Committee about the benefits of Cleocin Ovules versus the cream formulation. Dr. Cook and Ms. Brewer agreed that the ease of application may be beneficial.

<u>Dr. Harper made a motion to approve the recommendations.</u> The motion was seconded by Mr. McFerrin and passed by the Committee, 8-1 with Dr. Minor not in agreement with the motion.

ANTIFUNGALS, ORAL

Dr. Liles presented an overview of this class, noting that there are few quality comparative clinical trials of the older drugs in the group. He noted two new products in the class - terbinafine, the generic form of Lamisil and Lamisil granules, which are indicated for children four years of age and older. Dr. Liles presented the following PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ANCOBON (ORAL)	OFF	OFF
CLOTRIMAZOLE (MUCOUS MEM)	ON	ON
FLUCONAZOLE (ORAL)	ON	ON
GRIFULVIN V TABLETS (ORAL)	ON	OFF
GRISEOFULVIN SUSPENSION (ORAL)	OFF	ON
GRIS-PEG (ORAL)	ON	ON
ITRACONAZOLE (ORAL)	ON	OFF
KETOCONAZOLE (ORAL)	ON	ON
LAMISIL GRANULES (ORAL)	ON	OFF
NOXAFIL (ORAL)	NR	OFF
NYSTATIN (ORAL)	ON	ON
TERBINAFINE (ORAL)	ON	ON
VFEND (ORAL)	OFF	OFF

Sophie Wimberly of Schering-Plough addressed the Committee on behalf of Noxafil.

<u>Dr. Minor made a motion to accept the PDL recommendations as is.</u> Dr. Wales seconded the motion. Dr. Cook asked for all in favor of this motion to raise their hands. The motion passed by a vote of 9-0.

ANTIVIRALS, ORAL

Dr. Liles reviewed the similarities of the antiherpetic agents, noting the various dosage regimens. He discussed several trials of the effect of these drugs on HIV transmission and co-infection. He then gave an overview of the 2008 ACIP guidelines on the

prevention of herpes zoster. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ACYCLOVIR (ORAL)	ON	ON
FAMVIR (ORAL)	OFF	OFF
VALTREX (ORAL)	ON	ON

No speakers addressed the Committee.

<u>Dr. Brewer made a motion to accept the recommendations as presented;</u> the motion was seconded by Dr. Tingle. Dr. Cook asked those in favor to raise their hands; the motion passed by a vote of 9-0.

HEPATITIS C AGENTS

Dr. Liles presented an overview of the drugs in this class and discussed the AGA Medical Position Statement on the Management of Hepatitis C as well as the EPIC-3 study. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
INFERGEN (SUBCUTANE.)	NR	OFF
PEGASYS (SUBCUTANE.)	NR	ON
PEG-INTRON (SUBCUTANE.)	NR	OFF
PEG-INTRON REDIPEN (SUBCUTANE.)	NR	OFF

Robert Cortes, M.D. of Schering-Plough spoke on behalf of Peg Intron.

Dereck Terry, Pharm.D. of Roche spoke on behalf of Pegasys.

Mr. Jones made a motion to accept the recommendations with the exception of adding <u>Peg Intron to the PDL</u>. The motion was seconded by Dr. Harper. Dr. Cook asked those in favor to raise their hands; the motion passes 8-1 with Dr. Sorey not in agreement with the motion.

ANTIBIOTICS, GI

Dr. Liles noted that the drugs in this group have a variety of indications, so are not all directly comparable. He specifically reviewed the specific uses and indications of the newer drugs in the group. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALINIA (ORAL)	ON	ON
FLAGYL ER (ORAL)	OFF	OFF
METRONIDAZOLE (ORAL)	ON	ON
NEOMYCIN (ORAL)	NR	ON
TINDAMAX (ORAL)	OFF	ON
VANCOCIN HCL (ORAL)	OFF	OFF
XIFAXAN (ORAL)	NR	OFF

<u>Dr. Brewer made a motion to accept the recommendations as presented</u>. The motion was seconded by Dr. Tingle. Dr. Cook asked those in favor to raise their hands; the motion passed by a vote of 9-0.

PANCREATIC ENZYMES

Dr. Liles reviewed the FDA approval process that has been required for all of the drugs in this class, noting that several of the products may not be available after about 18 months or so. He stated that there are no quality clinical trials of these drugs. Dr. Liles presented the following PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
CREON (ORAL)	NR	ON
DYGASE (ORAL)	NR	ON
LAPASE (ORAL)	NR	ON
LIPRAM (ORAL)	NR	ON
PANCREASE MT (ORAL)	NR	ON
PANCRECARB MS (ORAL)	NR	OFF
PANCRELIPASE (ORAL)	NR	ON
ULTRASE (ORAL)	NR	ON
VIOKASE (ORAL)	NR	ON

No Speakers addressed the Committee.

Mr. Jones made a motion to accept the recommendations. The motion was seconded by Dr. Wales. Dr. Cook asked those in favor to raise their hands; the motion passes by a vote of 9-0.

OTHER BUSINESS

Ms. Clark reminded Committee members to complete and submit the travel vouchers in their packets, and to return the external cost sheets provided by Provider Synergies. She stated that the minutes from this meeting would be posted within 30 days.

NEXT MEETING DATE

Ms. Clark stated that the next P&T Committee meeting would be November 5, 2008.

ADJOURNMENT

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

i Revised 10-31-2008 jpc/aw