South Carolina
Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Pharmacy and Therapeutics (P&T) Committee Meeting
October 6, 2004
MINUTES

1. Call To Order

A meeting of the P&T Committee convened at 4:00 p.m. on Wednesday, October 6, 2004.

2. Preliminary Comments

James Bracewell welcomed everyone to the offices of the South Carolina Pharmacy Association and to the P&T Committee meeting. Mr. Bracewell pointed out the availability of refreshments and announced several "housekeeping" notes.

Also, Mr. Bracewell informed the Committee of the success of the RxAlert program, which has been operational for one year. RxAlert is a public service provided by the S. C. Pharmacy Association that allows pharmacies to share information about crimes ranging from store theft to illegitimate prescriptions. The RxAlert program includes a daily report sent to health care providers alerting them to such incidents in an effort to deter prescription drug crimes.

3. Welcome

Dr. LaCroix opened the meeting by stating that the P&T Committee meetings are held in compliance with the Freedom of Information Act's (FOIA) mandate that the public is notified when the public's business is being done, and that furthermore, the public has been notified that this facility is accessible to individuals with disabilities, and special accommodations could have been provided if requested in advance.

Chairperson LaCroix welcomed all Committee members and meeting attendees. Dr. Kevin Baugh, cardiologist, was introduced as the newest Committee member.

Committee Members Present:

J. Kevin Baugh, M.D.	Mark A. O'Rourke, M.D.
Edward M. Behling, M.D.	Thomas Phillips, R.Ph.
Matthew K. Cline, M.D.	Deborah J. Tapley, R.Ph.
Albert Humphrey, M.D.	George E. Vess, Pharm.D.
Jerome E. Kurent, M.D.	Wayne Weart, Pharm.D.
Robin K. LaCroix, M.D	Harry H. Wright, M.D.
James M. Lindsey, M.D.	

Committee Members Absent:

Joseph A. Horvath, M.D. Jamee Lucas, M.D.

DHHS Staff Present:

James Assey	Deirdra Singleton	Caroline Sojourner
Susan Bowling	Byron Roberts	James Bradford
Marion Burton, M.D.	Melanie Giese	Linda Van Hoose

Other Representation:

First Health Services Corporation – Mary Roberts, R.Ph.

Pharmaceutical Industry Representatives

5. Discussion Topics

A. Committee Meeting Minutes, Wednesday, August 4, 2004

Draft minutes were amended to reflect that Dr. LaCroix thanked the South Carolina Pharmacy Association for allowing the Committee to have meetings at that location.

B. General Issues

Dr. LaCroix advised the speakers that presentations are limited to three (3) minutes in duration. Regarding presentations at future P&T meetings, Chairperson LaCroix requested that information regarding a speaker's name, title, credentials, or curriculum vitae should be submitted to DHHS no later than seven (7) days prior to the meeting date.

Dr. LaCroix advised Committee members to inform the group prior to therapeutic class discussion of their intent to withdraw from the vote due to any association with a manufacturer of a drug within that class.

C. Public Comment

The following speakers discussed the drugs listed below:

	Company	Speaker	Drug
1)	Aventis	Melvin Clark, Pharm.D.	Lantus®
2)	Aventis	Melvin Clark, Pharm.D.	Amaryl®
3)	Novo Nordisk	Patricia Ashley, ARNP, MSN, CDE	Novolog®, Novolog Mix®
4)	Novo Nordisk	Patricia Ashley, ARNP, MSN, CDE	Prandin®
5)	Novartis	Kathryn Trenery, Regional Scientific Assoc. Director, Novartis Pharmaceuticals	Starlix®

	Company	Speaker	Drug
6)	GlaxoSmithKline	John L. Culleton, M.D., Endocrinologist, Carolina Health Care, Florence, SC	Avandia®, Avandamet®
7)	Takeda	Deanna S. Jackson, Pharm.D., Regional Scientific Mgr., Takeda	Actos®
8)	AstraZeneca	Tim Briscoe, Pharm.D., Senior Medical Information Scientist	Crestor®
9)	KOS Pharmaceuticals	Steve Newman	Advicor®
10)	Merck	Kerry Edwards, M.D.	Zocor®
11)	Reliant Pharmaceuticals	Kimberly N. Thornton, Pharm.D. Medical Science Liaison, Reliant Pharmaceuticals	Lescol®, Lescol XL®
12)	Pfizer	James Spann, M.D., Clinical Professor, MUSC Dept. of Cardiology	Lipitor®
13)	Pfizer	Gerald Fishman, M.D., Family Medicine, Columbia, SC	Caduet®
14)	Schering Plough	Dr. Larry Shapiro, Schering Plough Medical Science Specialist	Zetia®
15)	Schering Plough	Fred Krainin, M.D., Cardiologist	Vytorin®
16)	Alpharma	Eleanya Ogburo, M.D. Director, Midlands Neurology & Pain, Columbia, SC	Kadian®
17)	Janssen	Kristen Mack, Pharm.D., Assist. Director, Regional Medical Svcs, Janssen Medical Affairs	Duragesic®
18)	Organon	Craig Gelband, Ph.D.	Avinza®
19)	Purdue Pharma	Maribeth Kowalski, Pharm.D., Medical Liaison, Purdue Pharma	OxyContin®
20)	Lilly	Green B. Neal, M.D.	Humalog®

Following the period of public comment, Dr. LaCroix thanked each speaker for his or her individual presentation.

D. <u>PDL Discussions And Selections For The Following Drug Classes</u>

Mary Roberts, R.Ph., First Health Corporation led the discussion for the following drug classes:

Insulins	Alpha Glucosidase Inhibitors
Oral Sulfonylureas Second Generation	Thiazolidinediones
Biguanides and Combinations	Statins
Meglitinides	Long Acting Opioids

The P&T Committee agreed to submit the following recommendations to DHHS:

No PA Required "Preferred"	PA Required
INSULINS	
Novolin L® Novolin N® Novolin R® Novolin 70/30® Novolog® Novolog 70/30 ® Humulin U ® Humalog 75/25® Humulin 50/50® Lantus®	Humulin L® Humulin R® Humulin N® Humulin 70/30® Humalog®
Prior to the Committee's discussion of "Insulins," Dr. Weart announced his intent to recuse himself from voting on this class.	
ORAL HYPOGLYCEMICS	
ALPHA-GLUCOSIDASE INHIBITORS	
Glyset® (miglitol) Precose® (acarbose)	
BIGUANIDES	
Glucophage XR® 750mg Metformin (generic for Glucophage®) Metformin ER 500mg	Fortamet® Glucophage® (generic available without PA) Glucophage XR® 500mg (generic available without prior authorization) Riomet®
BIGUANIDES COMBINATION PRODUCTS	
Avandamet® Glucovance® Glyburide/Metformin	Metaglip®
MEGLITINIDES	
Starlix® (nateglinide)	Prandin® (repaglinide)
THIAZOLIDINEDIONES	
Actos® (pioglitazone) Avandia® (rosiglitazone)	

No PA Required "Preferred"	PA Required
SULFONYLUREAS SECOND GENERATION	
Glipizide (generic for Glucotrol®) Glipizide ER (generic for Glucotrol XL®) Glyburide (generic for Diabeta®) Glyburide micronized (generic for Glynase®)	Amaryl ® Glucotrol® (generic available without PA) Glucotrol XL® (generic available without PA) Diabeta® (generic available without PA) Glynase® (generic available without PA) Micronase® (generic available without PA)
LIPOTROPICS	
STATINS	
Advicor® Altoprev® Crestor® Lescol ® Lescol XL® Lipitor® Lovastatin (generic for Mevacor®) Pravachol® Zocor®	Altocor® Mevacor® (generic available without PA) Pravigard PAC®
Prior to discussion of the "statins," Drs. Baugh, Humphrey, and Weart announced their intent to recuse themselves from voting on this class. As a point of clarification, Mary Roberts explained to the Committee that Altocor® has been renamed Altoprev®. Since there are active NDC's for Altocor®, the drug will be considered non-preferred to prevent billing errors. The Committee had discussion regarding the safety of Crestor®. Although there were some high risk individuals identified, based on current information, the Committee decided to allow the drug as one of the preferred.	
LIPOTROPIC ADJUNCT THERAPY	
	Caduet® Vytorin® Zetia®
Prior to discussion of "lipotropic adjunct therapy," Drs. Baugh, Humphrey, and Weart announced their intent to recuse themselves from voting on this class. The Committee recommended an electronic step edit to allow Caduet® in the presence of a dihydropyridine calcium channel blocker or a statin in the patient's drug history. The Committee also recommended to allow Vytorin® or Zetia® with the presence of a statin in the patient's drug history.	

No PA Required "Preferred"	PA Required
EXTENDED RELEASE OPIOIDS	
Avinza® Kadian® Morphine Sulfate ER (generic for MS Contin®)	Duragesic® Patch MS CONTIN® (generic available without PA) Oramorph SR® (generic available without PA) OxyContin® Oxycodone ER Palladone® *(expected market entry Qtr 1-05)*
Dr. LaCroix advised the Committee that discussion concerning this class should be limited to clinical merits and safety issues of drugs within the class. The Committee was asked to review PA criteria for OxyContin® and Duragesic® and to provide feedback to DHHS within the next two weeks. The Committee discussed concerns that the drugs listed as preferred in this class may be incorrectly perceived by prescribers as the *only* preferred pain management medications. It was agreed that the listing would contain information to advise prescribers that drug availability in therapeutic classes not yet discussed remains unaffected (available with no PA required).	

6. Old Business

A. Vioxx® Voluntary Withdrawal

Dr. LaCroix mentioned that Vioxx® had been voluntary withdrawn from the market effective September 30, 2004. P&T Committee members discussed the point that, based upon the Committee's recommendations submitted to DHHS following the June 2004 P&T Committee meeting, Celebrex® was the only preferred drug in the COX-2 class. The Committee discussed the merits of adding Bextra® as an additional preferred agent. Due to safety concerns, it was decided to allow the previous recommendation to stand.

7. New Business

A. Selection/Designation of Drug Classes for PDL Formulary

The following drug classes were presented as classes for potential discussion at the December 1st meeting:

Macrolides
Second and Third Generation Quinolones
Ophthalmic Prostaglandin Agonists
Ophthalmic Carbonic Anhydrase Inhibitors
Ophthalmic Beta Blockers
Ophthalmic Alpha Agonists
Inhaled Anticholinergic Agents
Serotonin Antagonist Antiemetics
Ribavirins
Pegylated Interferon Alpha Products

B. Consultant Request

Due to the planned discussion of glaucoma agents at the December meeting, the Committee requested the expertise of an ophthalmologist to provide guidance during the discussion of these products. Dr. Burton agreed to request the services of an ophthalmologist to provide his/her expertise.

C. Criteria Guidelines for Prior Approval

The Committee was asked to review current PA criteria guidelines and to provide feedback to DHHS.

D. Presenter Question/Answer Period

The Committee discussed ideas that may be employed to effectively utilize the question and answer period. The Committee discussed the importance of obtaining a clear understanding of the material being presented while avoiding a prolonged discussion.

The Committee requested that they receive a hard copy listing of all speakers who will be presenting at the meeting.

E. Submission of Product Information

James Assey requested that manufacturers' representatives submit product information no later than seven days prior to the scheduled P&T meeting date.

F. P&T Committee Information

James Assey distributed letters from Robert Kerr, DHHS Director, to Committee members regarding roles and responsibilities. Members were instructed to review, sign, and return the documents to DHHS within the next several weeks.

G. Recognition of Guests

Dr. LaCroix introduced Susan Bowling, Deputy Director Medical Services, to the Committee. Ms. Bowling thanked the Committee for their work. James Assey introduced First Health's provider education representatives. Mary Roberts described their roles and contributions to the PDL process.

8. Resolved Items

Recommendations regarding PDL status for drugs in the following drug classes were approved for submission to DHHS:

Insulins
Oral Sulfonylureas Second Generation
Biguanides and Combinations
Meglitinides
Alpha Glucosidase Inhibitors
Thiazolidinediones
Statins
Long Acting Opioids

9. Unresolved Items

None.

10. Closing Comments

Dr. LaCroix thanked the Pharmacy Association for hosting the P&T Committee meeting.

11. Adjournment

The meeting adjourned at 6:30 p.m.