STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise
Governor

Paul L. Nusbaum
Secretary

West Virginia Department of Health and Human Resources
Bureau for Medical Services
Pharmaceutical and Therapeutics (P & T) Committee
July 9, 2003 - 11:00 a.m.
DHHR Building - 350 Capitol Street
Lower Level Conference Rooms B10/11
Charleston, West Virginia

M I N U T E S

Members Present:
David Avery, M.D.
James D. Bartsch, R.Ph.
John D. Justice, M.D.
Kristy H. Lucas, PharmD
Steven R. Matulis, M.D.
Kevin W. Yingling, R.Ph., M.D.
Tom Harward, PA-C
Barbara Koster, MSN, RNC-ANP
Teresa Dunsworth, PharmD

Members Absent:
Harriet Nottingham, R.Ph.
Thomas L. Gilligan, R.Ph., D.O.

DHHR/BMS Staff Present:
Nancy V. Atkins, Commissioner
Nora Antlake, Counsel
Sandra J. Joseph, M.D., Medical Director
Peggy King, Pharmacy Director
Gail Goodnight, Rebate Coordinator
Randy Myers, Deputy Commissioner
Lynda Edwards, Secretary

Contract Staff/Provider Synergies Present:
Steve Liles, PharmD

Other Contract Staff Present:
Stephen Small, RDTP

Other State Government Agency Staff Present:
Felice Joseph, PEIA

Also Present:

Abbott Laboratories: Mark C. Warmus, Lynnette R. Suawanasri, William H. Cranney
Alcon Labs: Steve Sciacabba, Brad Fuller, Matthew Murphy, R. E. O'Connor
AstraZeneca: Mark A. DiMaio, Larry Swann
Boehringer Ingelheim: Kevin Wemett
Bristol Myers Squibb: John Hyman, Dave Croft
Forest Laboratories: Wayne A. Miller, Dean Burris
Glaxo Smith Kline: Steve Mitchell
Government Relation Specialist: Thom Stevens
Johnson & Johnson: Raymona Kinneberg
Lewis Glasser: Gloria Thomas
Merck: Bob Kelley
Novartis: Steve Mitchell
Pfizer: Kent Hunter, Brian Adams, Kevin, Kirk, Jonathan Kashovty, Kit Francis, Glenn Self, Sherry Stottlemyer, Lindsey Werner, Shawnee Lewis
Pharma: John Brown
Roche: Brian Caldwell, Archie Shew, Steve Haid
Schering-Plough: Ronnie Coleman, John Falkenstein
Takeda: Donald A. Zowader
TAP: Stacey W. Poole, Jim Knott
Other Interested Parties: Gloria J. Thomas, Susan Prausa, Cathy Shznor

I. Call to Order:

Dr. Steven Matulis, Chairperson, called the meeting to order at 11:30 a.m.

II. Housekeeping:

Commissioner Nancy Atkins was recognized, and she advised the audience on how the meeting would be conducted. Commissioner Atkins introduced Peggy King, who would be serving as fire marshal. Mrs. King gave the audience exit instructions in case the fire alarm sounded.

III. Introductions:

All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations.

IV. Approval of Minutes from 4/30/03 Meeting:

Chairman Matulis asked for approval of the minutes from the last meeting. A motion was made and seconded, votes were taken and the motion carried to approve the minutes as submitted.

VI. Public Comment Period:

Chairman Matulis explained that the public comment period would be a 45-minute session. He then recognized Commissioner Atkins to speak to the Committee.

In regard to the public comment period, Commissioner Atkins explained that attendees planning to speak need to personally sign and print their name on the speaker list prior to the meeting. She

also reiterated that there is a five minute limit per presentation and that the session is not interactive. The following individuals took the floor:

- John Falkenstein, Schering Pharmaceuticals: Mr. Falkenstein spoke about hepatitis treatment and Peg-Intron. The difference between their product and the product made by Roche is that Peg-Intron uses weight-based dosing and Roche's is a one size fits all. He asked that both products be available, because there are definite advantages to having the weight-based dosing. He stated that one in 50 adults has Hepatitis C, and the number of cases is expected to increase in the next few years. He encouraged the Bureau to keep all products available to these patients for the best possible outcome.

Commissioner Atkins stated that the Bureau has made a policy decision that patients currently taking hepatitis drugs would be grandfathered.

- Robert O'Connor, Alcon Pharmaceuticals: Dr. O'Connor spoke about the fourth generation fluoroquinolone, oxyfloxicin or Bigomox, produced by Alcon and requested that the Bureau add it to the Preferred Drug List. Ten years ago fluoroquinolones were exciting new drugs in the antibiotic world, especially in eye surgery. Fast emergence of resistance, primarily to gram positive isolates became a problem. Eighty percent of eye infections are gram positive in nature and coverage is needed for that purpose. There is reason to hope that fourth generation fluoroquinolones may develop resistance less quickly than the second and third generation fluoroquinolones. Because they are not widely used in the treatment of disease, secondly they have not been used in animal feed, veterinary medicine or agriculture, and their design involves two sites of action requiring two simultaneous gene mutations to achieve resistance. Also, the pharmacokenetics of fourth generation fluoroquinolones is better for eye penetration than the second generation quinolones. Between the two fourth generation fluoroquinolones, moxifloxicin and gatofloxicin, moxifloxican penetrates the cornea roughly three times faster and achieves treatment levels six times higher than gatofloxicin according to a study from the Portland Oregon Ophthalmology Department. In addition, dosing frequency can be reduced to three times a day instead of the four times a day. At this point, moxifloxicin is the only one not requiring benzalkonium chloride as a preservative, which is slightly toxic to the cornea. Since moxifloxicin is self-preserved any corneal toxicity could be averted. He encouraged the Bureau to approve moxifloxicin for the Preferred Drug List (PDL).

V. Implementation Schedule:

Peggy King, Pharmacy Director, stated that the drug decicisons from the last meeting had been implemented and that no comments had been received. Steve Small gave a quick update on how the PA process has been going for the PDL. He explained that the process has been going smoothly and that a high volume of calls usually develops for about a six-week period when each phase is implemented and then it decreases after a short time. He explained that educational opportunities have been used to inform physicians about the process. Peggy King stated that the prior authorization for Straterra has been removed and those calls should stop.

A committee member asked that if she wrote a prescription that required prior authorization, what would be the turnaround? Steve said that an hour and a half is usually the fax turnaround time and sometimes it will be a little longer if he needs additional information from the physician in order to make a decision. A committee member asked if RDTP was getting any closer to having a system that would maintain a history or database that would decrease the need to repeat calls. Mr. Small

stated that prior approval is usually for one year. He also stated that when the new processing system is implemented it will provide more information available to RDTP.

A motion was made to move the Executive Session to the end of the Agenda and continue with the other agenda items. Motion was seconded, voted upon and carried.

IX. Therapeutic Category Reviews:

There were four categories of drugs scheduled for review. Dr. Steve Liles gave an overview at the beginning of each category. The Committee reviewed and discussed each category and made the following recommendations:

A. Insulin Pens:

Dr. Liles stated that the Bureau had directed Provider Synergies to investigate if there was a cost-effective way to be able to provide some delivery system other than the traditional insulin, vial and syringe. Pharmaceutical companies were asked for more information and offers on alternative devices. Novo Nordis made the Innolet device and it was more reasonable for the State. Dr. Liles recommended adding the Innolet device to the list for PDL inclusion. A motion was made, seconded, votes were taken and the motion carried.

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***
INSULIN PENS	Novolin Innolet (N, R, 70/30)	All other insulin pens and insulin pen systems

B. Ophthalmic Antibiotics:

Dr. Liles stated that one of the drugs in this category, natamycin (Natacyn), is not an antibiotic, but an antifungal. He recommended that the older agents still be on the preferred drug list, because they are very cost effective in a majority of infections. After some discussion, it was decided by the Committee that Natacyn be listed as preferred and the other recommendations by Provider Synergies be approved. A motion was made, seconded and the motion was approved to accept the recommendation.

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***
OPHTHALMIC ANTIBIOTICS	*bacitracin*◆ *chloramphenicol (Chloroptic)* *ciprofloxacin (Ciloxan)* *erythromycin*◆ *gentamicin*◆ *moxifloxacin (Vigamox)* *natamycin (Natacyn)* *ofloxacin (Ocuflox)* *tobramycin*◆	*gatifloxacin (Zymar)* *levofloxacin (Quixin)*

C. Hepatitis C Treatment Agents:

Dr. Liles informed the Committee that the benefits seem to be similar between the available drugs. In terms of value of a treatment of Hepatitis C the PEGASYS and COPEGUS combination outshone Rebatron and Rebatol. Grandfathering was discussed and Ms. King said that the process should be seamless. A motion was made to accept the list as recommended by Provider Synergies. The motion was seconded, votes were taken, and the motion carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
HEPATITIS C AGENTS	IFN a2a (Roferon-A) PEG IFN-2a (PEGASYS) ribavirin (COPEGUS)	IFN a2b (Intron-A) IFN alfacon-1 (Infergen) PEG IFN-2b (PEG-Intron) ribavirin (Rebetol) ribavirin / IFN a2b (Rebetron)

D. Antiparkinson Drugs:

Dr. Liles stated that pergolide is not well tolerated and that was a clinical reason to have it on the non-preferred list. Tasmar has a black box warning from the FDA because of the incidence of hepatic damage or acute fulminant liver failure. This has not occurred with Comtan so this is another case where one drug is superior to another based on safety. The recommendation would be to include all the Antiparkinson drugs except for Tasmar, because of the black box warning and pergolide because of low tolerance to the medication. A Committee member also said another reason to not include pergolide is that the Mayo Clinic has found that this drug may cause valve degeneration. A motion was made to accept the recommendations by Provider Synergies, the motion was seconded, votes were taken and the motion carried.

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
ANTIPARKINSON AGENTS	**Anticholinergic** benztropine♦ procyclidine (Kemadrin) trihexyphenidyl♦ **COMT inhibitor** entacapone (Comtan) **Dopamine agonist** pramipexole (Mirapex) ropinirole (Requip) **Other** levodopa (Larodopa) levodopa/carbidopa♦ selegiline♦	**COMT inhibitor** tolcapone (Tasmar) **Dopamine agonist** pergolide♦

X. Next Meeting:

The next meeting date of the P & T Committee will be posted on the website.

XI. Other Business:

A discussion ensued about how new drug additions would be reviewed at future meetings. A motion was made to have drugs only be reviewed when the drug class comes up for an annual review or receives a priority classification from the FDA. An annual review of the drug classes will begin in September or October 2003. The contracts with the pharmaceutical companies for the bids are good for a year or longer. The contracts are set up so that drug companies will honor the supplemental rebate as long as their drugs remain on the Preferred Drug List.

XII. Adjournment:

A motion was made, was seconded, votes were taken and the motion carried to adjourn the meeting of the Pharmaceutical and Therapeutics Committee.

VII. Executive Session:

A previous motion was made to skip the Executive Session until the end of the meeting. The motion was seconded and carried. The Committee adjourned to Executive Session at 11:45 a.m.