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
April 21, 2004 - 11:00 a.m.
The Diamond Building - 350 Capitol Street
Rooms B10 and B11
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.
Harriet Nottingham, R.Ph.
Barbara Koster, MSN, RNC-ANP
Teresa Dunsworth, PharmD
Tom Harward, PA-C

Members Not Present
Thomas L. Gilligan, R.Ph., D.O.

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

Contract Staff/Provider Synergies Present:
Steve Liles, PharmD
Chris Andrews, PharmD

Other Contract Staff Present:
Stephen Small, RDTP

Present:

Alzheimer's Association: Nancy Cipoletti
AstraZeneca: Russ Nixon, Marty McClellan, Drake Nakaishi, Walter Nixon, Marty McClellan, Mark A. DiMaio, Janice Carpenter, Robert Smith, Frank G. Salopek, Thomas Farrah, JoAnn Shoup, Tammy Anderson
Aventis: Walter L. Gose
Bayer: Ted Salyer
Bristol Myers Squibb: Steve Long, Deidra Montague, Robert Beatty, John Hymen, Cynthia Kraus, Kimberly Patton

Bill J. Crouch & Associates, Inc.: Raymona Kinneberg
Eisai: Mike Wert
Forest Pharmaceuticals: Wayne A. Miller
Glaxo Smith Kline: Gary Browning, Michael Caston
Government Relations: Thom Stevens
Home Care Pharmacy: Anthony Womack
Janssen: Todd Houldsworth, Evelyn Grasso-Sirface, Bert Wickey
Johnson & Johnson: Charles Chartier, James Cannon
Lilly: Steven Babineaux, Todd Bledsoe, Mark Russom, Darrell Evans, Nick Alvaro, Ronald Hart
MedPointe: Tracy L. Thorne, Robert Paul, Douglas Waddell, Samer Nasher-Alneam, Scott Strauss, Jason Vanhoose
Mental Health Association: Ellen Ward
Merck: Robert Kelley, Ruth Stolz, Thomas McCormick, Larry Swann, Michael Tu
NAMI of WV: Michael Ross
Novartis: Ralph Cruz
Novo Nordisk: Clinton Houck, Robert Fulford
Organon: Carolyn Jones, Charles Roth
Ortho McNeil: Jeff Bumgardner, Claudia George, Thomas Knox
Pfizer: Lewis Jenkins, Joseph McCoy, Shawne Lewis, Richard Williams, Brian Adams, David Allred, Steve Swindell, Harold Duncan, Meneleo Cinco, Michael J. Bolen, Gary Mueller, Kevin Kirk, Pamela Smith, Glenn Self
Prestera: Dr. Stephen Durrenberger
Purdue Pharma: Sean Sorell
Reliant: Paul Coon, Bill Gergely
Sanofi-Synthelabo: George Aiello, Troy Thornburg, Kathryn Lavrine, Timothy Birner, George Aiello, Mike Bowen
Schering-Plough: Rob Fonte, Feng Ho
Sepra Cor: Sue Shrout, Anthony Severoni
Takeda: William Williams, Bill Hollyfield, Jeffrey Sheetz, Halem Nashaat, Charles Kelly
Thrush & Clark Allergists: James Clark, M.D.
WVU: Dr. Reyaz Haque
Whelan Medical Clinic: Dr. F. Joseph Whelan
Wyeth: John Palya, Ben Haynes, Timothy Atchison,Vincent Sanfilippo, Lori Kelly, Craig Jerman
Other Interested Parties: Lawrence Kelly, M.D., Sidney Lerfald, M.D., Sasidharan Taravath, M.D., Ahmad Intikah, Timothy Saxe, Judy Curtis, PharmD, Gina Black, Dori Lynn Schaum, Michael Steidle

I. Call to Order:

Dr. Steven Matulis, Chairperson, called the meeting to order at 11:15 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 January 21, 2004 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.

V. Public Comment Period:

Commissioner Atkins explained that the public comment period would be a 45-minute session.

In regard to the public comment period, Commissioner Atkins explained that attendees planning to speak need to personally sign the speaker list prior to the meeting. She informed them that a photo identification would be required before signing the sheet to speak. She also reiterated that there is a five minute limit per presentation and that the session is not interactive and that no slide presentation or handouts would be distributed during the meeting. She informed the audience that materials they wanted to be submitted to the Committee had to be submitted to Peggy King prior to the meeting, and that no one could sign in for another person. The following individuals took the floor:

- Bill Gergely, Reliant: Mr. Gergeley discussed Lescol XL. He stated that this drug was one of the safest and most efficacious on the market. He also explained that this statin has a long-acting delivery system, does not cause myalgia, and the possibility of drug-drug interactions. He stated that 95% of patients can be brought to goal using this agent.

- Stephen Durrenberger, MD, Prestera: Dr. Durrenberger stated that he was there to represent psychiatric patients. He said that he wanted an open formulary for psychiatry. He stated that psychiatric patients who end up in the hospital usually are there for a month. He uses Zyprexa and it stabilizes his patients, and he said that if patients gain weight he usually stabilizes them with Abilify. He also had some trouble getting Effexor approved for a patient who was stable on this drug when he lived out of state. He wanted Effexor, Zyprexa and Abilify medications to be approved and consideration for a carve out for psychiatric patients.

- Joseph Whelan, M.D., Whelan Medical Clinic: Dr. Whelan expressed the need to get the drugs he uses approved. He also commented that Ambien should stay on the list because it is a safe non-addictive medication. He wants to keep Aricept, Exelon, Reminyl for people with Alzheimer's disease and also keep Namenda, which works with these drugs. Wellbutrin XL was also recommended. He also requested that the atypical antidepressants, such as Abilify, Seroquel, Zyprexa, Risperdal and Geodon needed to be on the preferred list.

- Sidney C. Lerfald, M.D.: Dr. Lerfald said the recent news that combination therapy is more effective for Alzheimer's Disease. He stated that Effexor XR is a broad acting agent and is much more effective. He said that Wellbutrin XL is also useful as an antidote to the side effects of the other antidepressants and well as augmenting the effect of the other antidepressants. He would not exclude Zyprexa, Seroquel, Risperdal or any drug that has metabolic parameters, because he could pick and choose when to use those drugs. He would keep Geodon and Abilify. He has experience with both and there are very robust effects with

both of these medications. He would also support the carve out.

- Lawrence Kelly, M.D.: Dr. Kelly stated that chronic severe mentally ill patients suffering from schizophrenia, schizodefective disorder, all various interpretations of bi-polar illness are devastating illnesses that do not go away, they require constant treatment, there is no cure and he does not think there will be one in his lifetime. Geodon, Abilify, Seroquel, Risperdal, Zyprexa and clozapine; all work, but they do not work for all. He stated that there are not enough treatment options as there is and to throw road blocks in the way of treatment only furthers the illness of the patient, increases the utilization of the emergency room and the hospital. He urged the Committee to open the formulary because these medicines are needed and there are not enough of them yet to satisfy the treatment needs for these illnesses.

- Steven Babineaux, M.S., R.Ph., Lilly: He stated that he wanted to share information that was not available to the Committee when they first reviewed the atypical antipsychotic class over a year ago. He shared with the Committee the terms of the outcomes and the value associated with using Zyprexa to treat patients with severe mental illness. He said that Zyprexa patients take their medication as prescribed and they stay on it longer.

- Timothy Birner, PharmD, M.B.A., Sanofi: Dr. Birner stated that Ambien will lose its patent in 2005 and will become available generically. He said that it is approved for the short term treatment of insomnia. Controlled clinical studies have showed Ambien to decrease sleep latency, which is the onset of time to sleep and also to increase the duration of sleep versus placebo. Ambien has a unique mechanism of action. It has a hypnotic effect and it is not an anticonvulsant. A 5 mg. dose is appropriate for elderly patients and patients who are in end stage renal disease and are undergoing dialysis. Ambien does not accumulate. He stated that there are no safety concerns regarding Ambien.

- Saravath Sasidhran, Neurology: Dr. Sasidhran wanted to talk about the treatment of migraines. He stated that they have two triptans on the list. He said that if a patient does not respond to one triptan they may respond to another triptan. Normally if a patient fails three times with a triptan they should be switched to another triptan. To have a third choice would be helpful.

- Reyaz Hague, M.D., Cardiology, WVU: Dr. Hague stated that he came to talk about Lipitor and coronary artery disease. He said that coronary artery disease is a major healthcare problem and is associated with hypercholesterolemia. Lowering cholesterol levels decreases cardiac events. There are several primary prevention studies and secondary prevention studies that show that treatment of hypercholesterolemia reduces cardiac events. There are some concern about the safety of statin drugs at higher dosages. Coronary events are decreased with the higher dose of Lipitor and getting the cholesterol down lower. All the studies show that Lipitor was very well tolerated with no significant increase in side effects.
- Carolyn Jones, Ph.D.: Dr. Jones wanted to talk about pain. She stated that Avinza was a once-daily treatment and has a steady release throughout 24 hours, unlike the other morphine extended compounds where the drug is entered into the body in the first eight hours. Also because Avinza is a capsule, it offers you some alternative routes of administration and can be opened up and sprinkled over apple sauce for dysphasic patients as well as gastric tube administration. She also talked about Duragesic being used in the treatment of pain, the fentanyl patch, there are reports of leaks associated with the patches. There was a study that showed that anywhere from 20 to 85% of the fentanyl still remains in the patch. Formulation can make a difference in treatment outcome and Avinza is a true once-daily sustained release morphine compound that offers some benefits over what is existing in the market. She said

that there are not enough weapons in the arsenal to treat pain, so it is important to continue to develop new compounds. She stated that it was also helpful to reformulate existing compounds because formulation can make a difference.

Commissioner Atkins advised the audience that persons who did not have the opportunity to speak would be at the top of the list for the next meeting.

VI. Executive Session:

A motion was made to move to the Executive Session. The motion was seconded and carried. The Committee adjourned to Executive Session at 12:00 p.m.

When the Committee returned from the Executive Session, Commissioner Atkins stated that the charge to the Committee is to serve in an advisory capacity and to recommend to the Bureau those drugs which they think are most medically appropriate. A policy decision on carving out certain classes of drugs is not an option of this Committee, that is a policy decision that would be made at DHHR Bureau for Medical Services' level. She wanted to clarify this information based on the speakers requests that we made earlier in the meeting.

Dr. Steven Matulis, Chairperson, stated that the Committee is being asked at each meeting to carve out classes. Dr. Matulis and the Committee felt that was not their option or that they had the capability to do this, nor did the Committee feel that they should be in the position to recommend a carve out of the classes.

VII. Old Business

A. Antimigraine Agents, Triptans:

Steve Liles recommended the following drugs for the Preferred Drug List based on the new offers from the manufacturers. The Committee had asked Provider Synergies to go back to all the manufacturers and speak with them about better rebates on the Antimigraine Agents to increase the number of choices. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIMIGRAINE AGENTS (TRIPTANS)	almotriptan (Axert) sumatriptan (Imitrex)	eletriptan (Relpax) frovatriptan (Frova) naratriptan (Amerge) rizatriptan (Maxalt) zolmitriptan (Zomig)

B. Lipotropics, Statins:

Steve Liles made recommendations for inclusion on the Preferred Drug List based on the new offers from the manufacturers. The Committee had asked Provider Synergies to go back to all the manufacturers and speak with them about better rebates on the statins. Dr. Liles compared the drugs in regard to drug-drug interactions, metabolic clearance of these drugs, and their safety. There was a discussion as to the importance of having "clean" statins on the PDL, Lescol being the low potency one and Pravachol being high potency, and that Pravachol was available through the

prior authorization process. Another discussion ensued regarding the new high-potency agent, Crestor. Although there were cautions regarding the use of high doses and there is minimal long-term data available, the literature indicates this drug is efficacious at low doses. After continued discussion, a motion was made to accept the recommendations of Provider Synergies, and to add Crestor as a preferred drug (as shown below). The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
LIPOTROPICS, STATINS	fluvastatin (Lescol) fluvastatin XL (Lescol XL) lovastatin ER (Altocor) rosuvastatin (Crestor) simvastatin (Zocor)	atorvastatin (Lipitor) pravastatin (Pravachol) pravastatin/buffered aspirin (Pravigard PAC) **lovastatin (brand and generic)**

VIII. Therapeutic Category Reviews:

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

A. Hypoglycemics, Alpha-Glucosidase Inhibitors:

Steve Liles recommended the following list for PDL inclusion. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, ALPHA-GLUCOSIDASE INHIBITORS	miglitol (Glyset)	acarbose (Precose)

B. Hypoglycemics, Biguanides:

Steve Liles recommended that the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, BIGUANIDES	glipizide/metformin (Metaglip) rosiglitazone/metformin (Avandamet) metformin (Glucophage)# metformin XR (Glucophage XR)# metformin/glyburide (Glucovance) metformin (Riomet)	

C. Hypoglycemics, Insulins:

Steve Liles recommended that the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, INSULINS	human insulin (Novolin, Novolog) human insulin (Relion) insulin glargine (Lantus)	human insulin (Humulin, Humalog)

D. Hypoglycemics, Meglitinides:

Steve Liles recommended that nateglinide (Starlix) be the preferred agent in this class and that repaglinide (Prandin) be non-preferred. After some discussion a motion was made to add Prandin back to the Preferred list (as shown below). The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, MEGLITINIDES	nateglinide (Starlix) repaglinide (Prandin)	

E. Hypoglycemics, Sulfonylureas:

Dr. Liles stated that last year the Committee moved all the older first generation sulfonylureas to the non-preferred side because they were clinically inferior to the newer agents. Provider Synergies recommends to maintain that non-preferred status for the older agents. He also recommends that second generation generic agents be on the preferred list and make Amaryl a non-preferred drug. The Committee decided to add Amaryl to the list because of market share and having to grandfather all the patients. A motion was made to have the following list as preferred/non-preferred. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, SULFONYLUREAS	glipizide (Glucotrol)# glipizide XL (Glucotrol XL)# glyburide (Micronase, DiaBeta)# glyburide extended release (Glynase)# glimepiride (Amaryl)	acetohexamide (Dymelor and generic) chlorpropamide (Diabinese and generic) tolazamide (Tolinase and generic) tolbutamide (Orinase and generic)

F. Hypoglycemics, Thiazolidinediones:

Steve Liles recommended that the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, THIAZOLIDINEDIONES	rosiglitazone (Avandia) pioglitazone (Actos)	

G. Nasal Preparations, Other:

Steve Liles recommended that both the available agents in this class be non-preferred. A short discussion ensued and a motion was made to add Astelin to the preferred list (as shown below). The motion was seconded, votes were taken and the motion carried.

A.DRUG CLASS	PREFERRED	NON-PREFERRED
NASAL PREPARATIONS, OTHER	azelastine (Astelin)	ipratropium nasal (Atrovent and generic)

H. Analgesics, Narcotics:

Steve Liles recommended the list of narcotic analgesic agents as preferred or non-preferred. A Committee member asked for a discussion regarding the newly available generic OxyContin since there have been inquiries from practitioners and concerns that this would be a lower cost, highly abusable drug. Dr. Liles said that there is only one strength available so titration of patients up or down would require obtaining a prior authorization for OxyContin. As more strengths are available and as more companies market their generic products, the costs would decrease for these products. However, the abuse potential is still there with the generic product as well as it is with brand OxyContin. The recommendation at this point would be to maintain generic oxycodone CR as a non-preferred agent. A motion was made to accept the recommendations of Provider Synergies with the exception of having Avinza off the preferred list (as shown below). The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
NARCOTIC ANALGESICS *Implement 2/5/03*	all generics acetaminophen/caffeine/dihydrocodeine bitartrate (Panlor) fentanyl transdermal (Duragesic) hydrocodone/acetaminophen (Maxidone) **hydrocodone bitartrate/ibuprofen (Vicoprofen)#** morphine sulfate ER (Kadian) oxycodone (Roxicodone) tablets oxycodone/acetaminophen (Roxicet) tramadol/acetaminophen (Ultracet)†	aspirin/caffeine/dihydrocodeine bitartrate (Synalgos-DC) fentanyl citrate (Actiq) oxycodone CR (OxyContin and generics) propoxyphene napsylate (Darvon-N) morphine sulfate ER (Avinza)

I. Sedative Hypnotics:

Steve Liles recommended that the following list be approved. A discussion ensued regarding the abuse potential of Ambien. A Committee member stated that he had concerns with a number of patients who were abusing Ambien. He suggested taking the issue to the DUR Board for their review. A motion was made to refer utilization of Ambien to the DUR Board. Karen Reed, DUR Board chairperson wold communicate back to with the Committee. The motion was seconded, votes were taken and the motion carried. A motion was made to accept the recommendations of Provider Synergies (as shown below). The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
SEDATIVES/ HYPNOTICS	estazolam (ProSom)# temazepam (Restoril)# zolpidem (Ambien)	quazepam (Doral) zaleplon (Sonata) chloral hydrate (Noctec and generic) flurazepam (Dalmane and generic) triazolam (Halcion and generic) temazepam (Restoril 7.5mg)

J. Alzheimer's Agents:

Steve Liles recommended that the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ALZHEIMER'S AGENTS	donepezil (Aricept) galantamine (Reminyl) rivastigmine (Exelon) memantine (Namenda)	tacrine (Cognex)

K. Antidepressants, Other:

Steve Liles recommended the list of drugs to be preferred or non-preferred in this class. A question was asked about the financial impact of adding Effexor XR. Dr. Liles responded that the impact would be minimal considering the number of prior authorizations that were being approved. Another Committee member raised his concerns about the risk of falling in the elderly when trazodone was prescribed. A motion was made to accept the recommendations of Provider Synergies and to add Effexor XR as preferred (as shown below). The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIDEPRESSANTS, OTHER	bupropion (Wellbutrin)# bupropion SR (Wellbutrin SR or generic) **mirtazapine (Remeron SolTab)** trazodone (Desyrel)# venlafaxine (Effexor XR)	venlafaxine (Effexor) nefazodone (Serzone and generic) **mirtazapine (Remeron)#** bupropion XL (Wellbutrin XL)

L. Antipsychotics, Atypical:

Steve Liles recommended that the list stay as it is currently for this class. A lengthy discussion ensued regarding adding Zyprexa to the preferred list. Dr. Justice informed the Committee that he had received 27 letters wanting this drug added and that he wanted this as well. Another member stated that with the PA process in place, and the acceptance of the process, that he did not see the need to add the drug. Dr. Liles was questioned as to the financial impact of adding this drug, and he responded that the impact would be significantly negative. A motion was made to accept the recommendations of Provider Synergies, but to add Zyprexa and Symbax if the pricing was equal to or less than the components separately (as shown below). The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIPSYCHOTICS, ATYPICAL	clozapine (Clozaril)# quetiapine (Seroquel) risperidone (Risperdal) ziprasidone (Geodon) olanzapine (Zyprexa) **olanzapine/fluoxetine (Symbax)**	aripiprazole (Abilify) olanzapine (Zyprexa Zydis)

IX. Next Meeting:

The next meeting date of the P & T Committee will be July 21, 2004.

X. Other Business:

Peggy King stated that implementation of these classes reviewed today will be July 1, 2004.

XI. Adjournment:

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

\# - generic
* - status pending
** - prior authorization required
*** - no prior authorization required for children through 8 years of age