West Virginia Department of Health and Human Resources

Bureau for Medical Services

Pharmaceutical and Therapeutics (P & T) Committee

September 25, 2002 - 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:

Kevin D. Yingling, R.Ph., M.D.
Steve R. Matulis, M.D.
David Avery, M.D.
John D. Justice, M.D.
Teresa Dunsworth, PharmD
James D. Bartsch, R.Ph.
Harriet Nottingham, R.Ph.
Kristy H. Lucas, PharmD
Tom Harwood, PA-C
Barbara Koster, MSN, RNC-ANP

Members Absent:

Thomas L. Gilligan, D.O.

DHHR/BMS Staff Present:

Phillip A. Lynch, Deputy Secretary, DHHR
Nancy V. Atkins, Commissioner
Randy Myers, Deputy Commissioner
Peggy King, Pharmacy Director
Gail Goodnight, Rebate Coordinator
Vicki Cunningham, DUR Coordinator
Candace Smith, Executive Secretary
Carol Jackson, Office Assistant
Stacey Shamblin, Budget Planning & Reporting

Contract Staff/Provider Synergies

Present:

Terry Taylor, R.Ph.
Todd Wandstrat, PharmD
Steve Liles, PharmD

Other Contract Staff Present:

Jennifer Carpenter, ACS
Becky Garrigan, ACS
Rob Earnest, ACS
Stephen Small, RDTP
Amber Nailler, RDTP

Other State Government Agency Staff Present:

Felice Joseph, PEIA

Also Present:

Sepracor: Dean Handley, Sue Shrout, Tim Hermes, John Pauley, Jeff Irwin and Sue Ann Martin, Michael Warren
Watson Pharmacy: Trish McAdoo
Mylan: Eric Belldina
Eli Lilly: Wayne Covert, Myrna Miller, A.K. Reed, Joe Sellys
Schering: Rob Marsh, Gordon Rosenberry
Tareda Clarke: Don Zowader
Pharmacia: Gary Grure, Martin Mekkelsen, Steve Babineaux, Kevin Wemett

Fujisawa: Jim Turner
Pfizer: Kit Francis, Mary Staples, Tina Smith, Mike Bolen, Kent Hunter, Pamela Smith
NAMI WV: Franki Capocefalo
Ortho McNeil: Jeff Bumgardner
Novartis: Steve Mitchell
Bayer: Cathi McGirhan
Aventis: Walter Gose
PhRMA: Greg Bailey, John Brown, Bryan Brown
Johnson & Johnson: Jim Cannon
Merck/Astra Zeneca: Larry Swann;
Merck: Bob Kelley, Kerry Edwards
TAP: Stacey Poole
Astra Zeneca: Mark DiMaio
WV Seizure Support Group: Jean Grace
K & T Public Affairs: R. Thompson
Maple Creative: James Wester
Solvay: Kari Peyatte
Mental Health Association: Ellen Ward
WCHS-TV: Brad Rice
Lewis Glasser: Gloria Thomas
Wyeth: John Palya, Dennis Hanley, Phillip Reale
Psychiatric Assistant: Jay McClanahan
L & L: Helen Cook
Government Relations Specialists: Thom Stevens
Abbott Labs: Rob Fitzgerald
WVMHCA: David Sanders
WCHS Radio: Nicky Walters
WSAZ: John Green
Boehringer Ingelheim: Anne Rice
WOWK 13: Rob Spencer
GSK: Steve Mitchell
Charleston Daily Mail: Deanna Wrenn
J & J: Raymona Kinneberg
Associated Press: L. Meyer
NAMI WV: Michael Kees
Wallace Pharmacy: Doug Waddell
WV Pharmacists Association: Richard Stevens
Bristol-Myers: John Hymen, Karen Long, Dick Ridenour

I. **Call to Order**:

Commissioner Nancy Atkins called the meeting to order at 11:00 a.m., advised the audience how the meeting would be conducted and that she would serve as Chair for this first meeting. Ms. Atkins discussed the purpose of the Committee resulting from the passage of HB 4666. The Committee will hold three meetings this year in September, October and November, and quarterly thereafter. Provider Synergies will present several classes of drugs to the committee to review at each meeting, and the Committee's role is to review, discuss and recommend the drugs that will be placed on the Preferred Drug List (PDL). While cost is certainly a consideration, Ms. Atkins stressed that the first consideration of the Committee will be the benefit of the recipients.

II. **Introductions**:

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

III. **Opening Remarks**:

Phillip A. Lynch, Deputy Secretary, spoke on behalf of Secretary Paul L. Nusbaum, who was unable to attend as planned.

Deputy Secretary Lynch discussed the current Medicaid deficit, in particular the rapid growth of the Pharmacy Program and the increased cost of pharmaceuticals. Mr. Lynch discussed the background of Provider Synergies and their role in the process of establishing the PDL. Mr. Lynch stressed also that the Committee's charge will be the benefit of the recipients first, with cost savings being secondary.

IV. **Approval of By-Laws:**

Ms. Atkins presented the by-laws to the Committee with a recommendation to include an addition under Article III - Membership, Section II - Size and Representation of Membership, stating that "the Secretary may expand the membership of this Committee as he/she deems appropriate."

A motion was made and seconded to accept the by-laws with the amendment. The motion carried

to accept the by-laws as revised.

V. **Election of Officers**:

Ms. Atkins asked the Committee to elect a Chairperson and a Vice Chairperson, and called upon the members for nominations.

The floor was opened for nominations for Chairperson. Dr. Steve Matulis and Barbara Koster were both nominated. The Committee voted and elected Dr. Steve Matulis as Chairman. The floor was opened for nomination for Vice Chairperson. Barbara Koster and James Bartsch were nominated, and Barbara Koster was elected.

VI. **Proposed Process for PDL Development**:

Todd Wandstrat took the floor and explained to the Committee the process that Provider Synergies uses to research and collect data for the drugs they will present to the Committee at each meeting for review. The process includes extensive research, using peer reviewed studies and clinical trials, as well as cost efficiency studies. The result is the development of a clinical monograph for each drug group that will be presented to the Committee for their review prior to each meeting.

VII. **Public Comment Period**:

Ms. Atkins opened the floor to the public for the comments. She explained that the guidelines include a five minute limit per speaker and the session is not interactive. There should be no slide presentations, and speakers must sign up prior to the meeting. The following individuals took the floor:

- John Brown from PhRMA: Mr. Brown expressed his concerns about the PDL as to the effects it will have; he believes there are alternatives to a PDL and offered the assistance of a specialist to the Department. He thinks the role of the Committee is limited in that medicine is being rationed and they are being asked to decide who gets what and who does not; the patient should be considered first. Mr. Brown said he views this as a restrictive formulary that will interfere with access to clinically necessary drugs. He also has concerns about therapeutic switching and discussed a task force that was conducted in 1998 that did not recommend a

formulary.

- Helen Cook, a Care Giver: Ms. Cook works with the disabled and her concerns were that disabled recipients' views would not be considered, and that care givers would not be given the opportunity of having a voice. She also stated that advocate groups need a voice, and there is a need for quality care for these families.

- Jean Gore, a Citizen with Epilepsy: Ms. Gore expressed her concerns that some patients should not switch drugs, especially those with epilepsy who must control their seizures. These patients can function in the world if they are stabilized, but they must have their medicines to do so.

- Ellen Ward, Mental Health Association: Ms. Ward's concerns were about the prior authorization process, should a needed drug not be placed on the list. She noted an incident with her sister's insurance company 3 years ago that resulted in delayed recovery from her illness. Ms. Ward feels that physicians do not want to deal with the PA process. Also, some people will go ahead and purchase the drugs themselves, but those with very limited incomes do not have this option. Ms. Ward feels there is some other way to deal with the problem of drug costs.

- Richard Stevens, Executive Director of the WV Pharmacists Association: Mr. Stevens advised that his group, the West Virginia Pharmacists Association, voted unanimously to support the Preferred Drug List and feels this Committee will make the proper choices. They also support the prior authorization process and have recommended an expansion of that process.

- Dean Hanley, Sepracor: Mr. Hanley spoke on behalf of asthmatics, of which he is one. He feels the drug Xopenex should not require prior authorization, as it is given to those in need of acute care. Mr. Hanley said 1/3 of all asthmatics presenting to the ER are mild, 1/3 are moderate, and 1/3 are severe cases. He said Xopenex constitutes 1/10 of 0.1% of drug expenditures in West Virginia and there are advantages to using this drug.

VIII. **Executive Session Break:**

A motion was made to adjourn to Executive Session. The motion was seconded and carried. The

Committee adjourned to Executive Session at 12:00 p.m. Ms. Atkins announced the room must be vacated, and the Committee would reconvene at 1:30 p.m.

IX. **Therapeutic Category Reviews:**

There were 13 categories of drugs scheduled for review. Dr. Wandstrat gave an overview at the beginning of each category, then turned the process over to the Chairperson. The Committee reviewed and discussed each category and made the following decisions:

A. **Proton Pump Inhibitors**:

Teresa Dunsworth said she approved of this selection and Dr. Matulis advised they are all effective drugs. There were no objections by the Committee to the suggested selections. A motion was made and seconded, vote taken and motion carried as follows:

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***
PROTON PUMP INHIBITORS Effective 10/1/02	• ***lansoprazole (Prevacid)*** • ***rabeprazole (AcipHex)***	• ***esomeprazole (Nexium)*** • ***omeprazole (Prilosec)*** • ***pantoprazole (Protonix)***

B. **HMG-COA Reductase Inhibitors**:

The Committee had no objections to the recommended drugs. A motion was made and seconded, vote taken, motion carried as follows:

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***
HMG-CoA REDUCTASE INHIBITORS Effective 10/1/02	▾ ***fluvastatin (Lescol)*** ▾ ***fluvastatin XL (Lescol XL)*** ▾ ***lovastatin (Mevacor) generic only*** ▾ ***lovastatin ER (Altocor)*** ▾ ***simvastatin (Zocor)***	▾ ***atorvastatin (Lipitor)*** ▾ ***pravastatin (Pravachol)***

C. **Minimally Sedating Antihistamines:**

The Committee discussed the fact that Claritin will become OTC and/or generic in January 2003, but it is not known whether it will be a 5 or 10 mg strength. Dr. Yingling questioned why both Clarinex and Claritin are being suggested and Dr. Wandstrat responded they were trying to

provide as many choices as possible. A motion was made and seconded, vote taken and motion carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
MINIMALLY SEDATING ANTIHISTAMINES AND COMBINATIONS Effective 10/1/02	▼ ***desloratadine (Clarinex)*** ▼ ***loratadine (Claritin)*** ▼ ***loratadine/pseudoephedrine (Claritin-D 12 hour, Claritin-D 24 hour)***	▼ ***cetirizine (Zyrtec)*** ▼ ***cetirizine/pseudoephedrine (Zyrtec-D)*** ▼ ***fexofenadine (Allegra)*** ▼ ***fexofenadine/pseudoephedrine (Allegra-D)***

D. **Leukotriene Receptor Antagonists**:

The Committee expressed their approval of this suggestion; a motion was made and seconded, vote taken and motion carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
LEUKOTRIENE RECEPTOR AGONISTS Effective 10/1/02	▼ ***montelukast (Singulair)***	▼ ***zafirlukast (Accolate)*** ▼ ***zileuton (Zyflo)***

E. **Beta Agonists (inhaled and peroral):**

Dr. Avery objected to the exclusion of Xopenex; Barbara Koster and Dr. Matulis were in agreement with Dr. Avery. Dr. Wandstrat advised there is no MDI for this drug, and the cost is high, although you may see fewer adverse effects with this drug. Dr. Avery felt the utilization does not create a significant problem and Dr. Matulis questioned whether accepting the drug would cause a market change. Dr. Liles advised that their aim was to suggest drugs that provided therapy for the majority of people. It was questioned whether the drug is marketed as a maintenance or a rescue drug.

Mr. Taylor advised that Provider Synergies would be willing to go back to the manufacturer again and discuss the price, then come back to the Committee for additional review. With this in mind, a motion was made, seconded, voted upon and motion carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
BETA AGONISTS (INHALED & PERORAL) Effective 10/1/02	▼ ***albuterol/ipratropium MDI (Combivent)*** ▼ ***albuterol HFA MDI (Proventil HFA)*** ▼ ***albuterol syrup, tablets, CFC MDI, inhalation solution (generics)*** ▼ ***metaproterenol syrup, tablets, inhalation solution (generic only)*** ▼ ***pirbuterol MDI (Maxair, Maxair Autohaler)*** ▼ ***salmeterol (Serevent, Serevent Diskus)*** ▼ ***terbutaline (generic only)***	▼ ***albuterol/ipratropium inhalation solution (Duoneb)*** ▼ ***albuterol HFA MDI (Ventolin HFA)*** ▼ ***albuterol inhalation solution (Accuneb)*** ▼ ***albuterol SR tablets (Volmax)*** ▼ ***formoterol MDI (Foradil)*** ▼ ***levabuterol inhalation solution (Xopenex)**** ▼ ***metaproterenol MDI (Alupent)***

The Committee requests that Provider Synergies continue to work with the manufacturer of Xopenex in an effort to get this drug added to the PDL, and will review again at the next meeting

F. **Calcium Channel Blockers:**

Dr. Wandstrat advised Nimotop was added, although it is very expensive, because it is a very effective drug. Dr. Yingling felt there was no use for nifedipine but Teresa Dunsworth disagreed in that it is used for treatment of pre-term labor. She advised this is a small group, but no other drug seems to work. Dr. Yingling discussed the safety issue with nifedipine; Jim Bartsch felt requiring prior authorization would not be a problem for this small group. A motion was made, seconded, voted upon and carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*

CALCIUM CHANNEL BLOCKERS Effective 10/1/02	▼ ***diltiazem (Cardizem) generic only*** ▼ ***diltiazem SR (Cardizem SR,Cardizem CD, Dilacor XR, Tiazac) generic only*** ▼ ***felodipine (Plendil)*** ▼ ***isradipine (Dynacirc)*** ▼ ***isradipine SR (Dynacirc CR)*** ▼ ***nicardipine (Cardene) generic only*** ▼ ***nifedipine SR (Adalat CC, Procardia XL) generic only*** ▼ ***nimodipine (Nimotop)*** ▼ ***nisoldipine (Sular)*** ▼ ***verapamil (Calan, Isoptin) generic only*** ▼ ***verapamil ER (Verelan PM)*** ▼ ***verapamil SR (Calan SR, Isoptin SR) generic only***	▼ ***amlodipine (Norvasc)*** ▼ ***bepridil (Vascor)*** ▼ ***nicardipine SR (Cardene SR)*** ▼ ***nifedipine (Adalat, Procardia) generic and brand*** ▼ ***verapamil ER (Covera-HS)*** ▼ ***verapamil SR (Verelan)***

G. **Histamine 2 Antagonists:**

The Committee had no objections to the suggested drugs; a motion was made, seconded, voted upon and motion carried as follows:

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***
HISTAMINE 2 ANTAGONISTS Effective 10/1/02	***H. cimetidine (Tagamet) generic only*** ***I. famotidine (Pepcid) generic only*** ***J. nizatidine (Axid) generic only*** ***K. ranitidine (Zantac) generic only*** ***L. ranitidine syrup (Zantac)***	***M. famotidine orally disintegrating (Pepcid RPD)*** ***N. famotidine suspension (Pepcid)*** ***O. ranitidine 150mg (Zantac EFFERdose)***

H. **Antimigraine, Triptans**:

Dr. Matulis noted the large market share of the drugs not recommended for inclusion. About half the prescriptions in this class written in West Virginia are not included. Dr. Matulis asked if prior authorization would be a problem if not included on the list; Jim Bartsch felt it would not be a problem since a 3-day emergency supply is available if needed. A motion was made, seconded, vote taken and motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIMIGRAINE (TRIPTANS) *Effective 10/1/02*	▼ **almotriptan (Axert)** ▼ **sumatriptan (Imitrex) all forms**	▼ **frovatriptan (Frova)** ▼ **naratriptan (Amerge)** ▼ **rizatriptan (Maxalt)** ▼ **zolmitriptan (Zomig)**

I. **Anti-incontinence Agents**:

Dr. Avery said he just finished participating in a review of these drugs and thinks we should reconsider Ditropan XL. The Committee asked that Provider Synergies go back to the manufacturer again for a better price. A motion was made, seconded, voted upon and motion carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
ANTIINCONTINENCE AGENTS *Effective 10/1/02*	▼ ***flavoxate (Urispas)*** ▼ ***oxybutynin (Ditropan) generic only*** ▼ ***tolterodine (Detrol)*** ▼ ***tolterodine LA (Detrol LA)***	▼ ***oxybutynin XL (Ditropan XL)****

The Committee recommended the following drug be excluded from the PDL: Ditropan XL.

The Committee requests that Provider Synergies continue to work with the manufacturer of Ditropan XL in an effort to get this drug added to the PDL and will review it again at the next meeting.

J. **Lipotropics, Other:**

Teresa Dunsworth questioned why the drug Niaspan was on the list, and Dr. Avery said it was a good drug but you could hardly get anyone to take it. He would like the Committee to consider Tricor instead. Dr. Justice asked why Colestid was on the list. Dr. Wandstrat felt the evidence supported the drug. A motion was made, seconded, voted upon and carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
LIPOTROPICS, OTHER ***Effective 10/1/02***	▼ ***cholestyramine (Questran) generic only*** ▼ ***cholestyramine light (Questran Light) generic only*** ▼ ***colestipol (Colestid)*** ▼ ***gemfibrozil (Lopid) generic only*** ▼ ***niacin ER (Niaspan)***	▼ ***colesevelam (WelChol)*** ▼ ***niacin ER/lovastatin (Advicor)*** ▼ ***fenofibrate (Tricor)****

The Committee requests that Provider Synergies work further with the manufacturer of Tricor on pricing and the Committee will review again at the next meeting.

K. **Glucocorticoids, Inhaled**:.

The Committee had no objections to the suggested drugs. A motion was made, seconded, vote taken and motion carried as follows:

DRUG CLASS	*PREFERRED*	*NON-PREFERRED*
GLUCOCORTICOIDS, INHALED ***Effective 10/1/02***	▼ ***beclomethasone CFC (Vanceril)*** ▼ ***flunisolide (Aerobid, Aerobid M)*** ▼ ***fluticasone (Flovent, Flovent Rotadisk)*** ▼ ***fluticasone/salmeterol (Advair)***	▼ ***beclomethasone HFA (QVAR)*** ▼ ***budesonide (Pulmicort Turbuhaler)*** ▼ ***budesonide (Pulmicort Respules)*** ▼ ***triamcinolone (Azmacort)***

L. **Beta Blockers**:

Barbara Koster felt Coreg should be included on the list and we might want to do further review. Dr. Matulis wondered why the market share for that drug is so low. Dr. Avery thought it might be limited to the severely ill. Teresa Dunsworth suggested Inderal LA be included on the PDL because it works. Mr. Taylor advised there is no effect on cost savings by adding either of these drugs. Dr. Matulis asked if the Bureau could look at utilization of these drugs to see if it increases with their addition to the list, and Ms. Atkins agreed that could be done. A motion was made, seconded, voted upon and carried to add Coreg to the list. A motion was made, seconded, voted upon and carried to add Inderal LA to this list. A motion was made, seconded, voted upon and carried as follows:

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***

BETA-ADRENERGIC RECEPTOR BLOCKING AGENTS Effective 10/1/02	▼ ***acebutolol (Sectral) generic only*** ▼ ***atenolol (Tenormin) generic only*** ▼ ***betaxolol (Kerlone) generic only*** ▼ ***bisoprolol (Zebeta) generic only*** ▼ ***carvedilol (Coreg)*** ▼ ***labetalol (Normodyne, Trandate) generic only*** ▼ ***metoprolol (Lopressor) generic only*** ▼ ***metoprolol XL (Toprol XL)*** ▼ ***nadolol (Corgard) generic only*** ▼ ***pindolol (Visken) generic only*** ▼ ***propranolol (Inderal) generic only*** ▼ ***propranolol LA (Inderal LA)*** ▼ ***sotalol (Betapace) generic only*** ▼ ***timolol (Blocadren) generic only***	▼ ***carteolol (Cartrol)*** ▼ ***penbutolol (Levatol)*** ▼ ***sotalol (Betapace AF)***

M. **Corticosteroids, Nasal**:

The Committee felt there was no significant differences in this class of drugs and had no objections to the suggested list.

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***

CORTICOSTEROIDS, NASAL ***Effective 10/1/02***	▼ ***flunisolide (Nasarel, Nasalide) generic*** ▼ ***fluticasone (Flonase)*** ▼ ***mometasone (Nasonex)***	▼ ***beclomethasone (Beconase, Vancenase)*** ▼ ***beclomethasone AQ (Beconase AQ, Vancease AQ)*** ▼ ***budesonide (Rhinocort)*** ▼ ***budesonide aqua (Rhinocort Aqua)*** ▼ ***triamcinolone (Nasacort)*** ▼ ***triamcinolone AQ (Nasacort AQ)***

X. **Next Meeting Date:**

A motion was made, seconded, voted upon and carried to hold the next meeting of the P & T Committee on Wednesday, October 23, 2002 at 11:00 a.m. at the Diamond Building Lower Level Conference Rooms B10/11. A motion was made, seconded, voted upon and carried to hold another meeting of the P & T Committee on November 13, 2002, the time to be decided upon at the October 23, 2002 meeting.

XI. **Other Business:**

There was no additional business for discussion. Ms. Atkins clarified to the audience that the public comment period could include specific drug information as well as any other comments relating to the PDL. Written comments would also be accepted and distributed to the P & T Committee members.

XII. **Adjournment:**

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