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
October 29, 2003 - 11:00 a.m.
The Summit Conference Center - 129 Summers Street
Continental Room 2nd Floor
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
Thomas L. Gilligan, R.Ph., D.O.

Members Absent:
Tom Harward, PA-C

DHHR/BMS Staff Present:
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
Vicki Cunningham, DUR Coordinator

Contract Staff/Provider Synergies Present:
Steve Liles, PharmD

Other Contract Staff Present:
Stephen Small, RDTP

Other State Government Agency Staff Present:
Felice Joseph, PEIA

Present:

Abbott Laboratories: William H. Cranney
AstraZeneca: Mark A. DiMaio, Jenny M. Phillips, Janice Carpenter, Frank G. Salopek, JoAnn Shoup
Aventis: Walter L. Gose
Baxter: Jim Hrabovsky
Bayer: Ted Salyer, Ralph Williams
Biovail: Maureen Stasi, Gary Starr
Boehringer Ingelheim: Kevin WeMett, Robert Vincent, Leslie McLaughlin
Bristol Myers Squibb: Karen Long, Trent Bower, Rich Damous, John Hyman, Bob Beatty

Bill J. Crouch & Associates: Raymona Kinneberg
Dey: Larry Green, Adam Kopp
Eisai: Mike Wert
Forest Pharmaceuticals: Wayne A. Miller, Scott Stinson
Glaxo Smith Kline: Steve Mitchell, Robin Turnbull, Gary Browning
Ivax: Glenn R. Oneidas
Janssen: Mark Akers, Bert Wickey, Todd Houldworth
Johnson & Johnson: James F. Cannon
King Pharmaceuticals: Thom S. Martin
Lewis Glasser: Gloria Young
Lilly: Ronald H. Hart
Merck: Tony Fabiano, Larry Swann, Dr. Emmanuel Mahlis, Dr. Russell Clayton
Novartis: Cathi McGeehan, Steve Mitchell
Novo Nordisk: Clint Houck
Ortho McNeil: Jeff Bumgardner
Pfizer: Kent Hunter, Michael J. Bolen, Steve Swindell, Chuck Dent, Missy Sutphin, Carolyn Sinko, Gary Mueller, Richard M. Francis, Dan Moore, Jay Townson, Pamela Smith, Glenn Self, Shawnee Lewis
PHRMA: Bryan Brown
Purdue: Sean Sorell
Sankyo Pharma: Holli Hill, John M. O'Brien, Joe Greer
Sanofi~Synthelabo: Michael Bowen, Thomas Yeargin, Andy McGinnis, Dana Godfrey
Schering-Plough: Ronnie Coleman, Robert Marsh, Kyle Kilchrist
Sepracor: Tony Severoni, Sue Ellen Shrout
Solvay Pharmaceuticals: Richard Stump
Takeda: Donald A. Zowader, Bill Hollyfield, Khalid Daher, Brent Williams
TAP: Stacey W. Poole, Jim Knott
Watson Pharma: Trish McAdoo, Tracy Watts
WVU: Dr. Reyaz Haque, Dr. Richard Granese, Katrina Stanley, Dr. Lawrence B. Kelly, Dr. Robert Touchon
Whelan Medical Clinic: Dr. F. Joseph Whelan
Wyeth: John Palya, Ben Haynes, Craig Jerman, Emily Bright, Phil Reale
Other Interested Parties: Dr. Mark Casdorph

I. Call to Order:

Dr. Steven Matulis, Chairperson, called the meeting to order at 11:20 a.m.

II. Housekeeping:

Peggy King, Pharmacy Director, was recognized, and she advised the audience on how the meeting would be conducted.

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 July 9, 2003 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:

Chairman Matulis explained that the public comment period would be a 45-minute session.

In regard to the public comment period, Peggy King 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. She informed the audience that 9:00 a.m. would be the new start time for signing up to speak at the next meeting. She told them that a photo identification would be required and that no one could sign in for another person. The following individuals took the floor:

- Lawrence Kelly, M.D., WVU School of Medicine: Dr. Kelly wanted the Committee to carve out drugs for psychiatric patients and cardiology patients, etc., when prescribed by a specialist. He stated that when the experts need to give care that they give full care not limited care. Dr. Kelly informed the Committee that the President of the United States has come up with a new Freedom Commission on Mental Health. The guidelines are that everyone recognizes that mental health is essential for overall health. There is a need to reduce burdensome regulatory barriers and that the best available treatments need to be available not limited. The Freedom Commission wanted to expand new practices and new treatments. Dr. Kelly asked that Zoloft not require prior authorization.

- Richard Granese, M.D., WVU School of Medicine: Dr. Granese wanted an open formulary and a carve out for the specialists. He urged the Committee to put Zoloft and Effexor on the formulary. He also wanted Zoloft to remain on the formulary because it is a safe treatment for children, pregnant women, breast-feeding females and the elderly.

- Joseph Whelan, M.D., Whelan Medical Clinic: Dr. Whelan discussed articles that reported depressed people committing murder. He expressed the need for Zoloft to be on the formulary. He also commented that Detrol LA, Ditropan, Klonopin Wafers and Lexapro needed to be available on the PDL.

- Mark Casdorph, D.O.: Dr. Casdorph expressed his thanks to the Committee for Zoloft on the formulary last year. He discussed an article about giving children too many drugs. He stated that Zoloft was needed for children and the elderly. He also explained that Zoloft has the least amount of drug-drug interactions and that was important in the elderly and pregnant population. He said that the prior authorization process was not working.

- Reyaz Hague, M.D., Cardiologist, WVU: He stated that Norvasc has the best efficacy and safety data. He said that if blood pressure control is not achieved, amlodipine has to be added to the regimen. He felt that amlodipine was the best choice because it is the only approved medicine that is not only safe but has a beneficial effect when patients also have heart failure.

- Robert Touchon, M.D., Professor of Medicine, WVU: Dr. Touchon requested that the

Committee move the ACE inhibitor, ramipril, to preferred status. The Hope Trial documented that ramipril did in fact reduce cardiovascular events, improved outcomes, in a five-year study. He stated that ACE inhibitors are not all created equal. The FDA allowed ramipril's product insert to show that it can properly be used in preventing future cardiovascular events.

- Trent Bower, Bristol Myers Squibb: Mr. Bower stated that Avapro was significant in reducing systolic and diastolic blood pressures in patients in a study. In clinical trials in patients with hypertension, Avapro has demonstrated overall safety and tolerability similar to placebo therapy.

- Emmanuel Mahlis, M.D., Merck: Dr. Mahlis stated that cardiovascular disease is the leading cause of death in West Virginia. He said that Cozaar has been proven to reduce organ failure in addition to lowering blood pressure.

- Russell Clayton, M.D., Pediatric Pulmonologist, Merck: Dr. Clayton stated that Singular has been shown in placebo control studies to be as effective as monotherapy in adults and children with mild persistent asthma. Singular reduces symptoms, increases lung function and has an excellent safety profile.

- Larry Green, Dey Labs: Mr. Green spoke to the Committee about Accuneb and Duoneb. He stated that lower dosing enables children to be able to sleep at night and it has fewer side effects. He also discussed Duoneb, which is used in COPD patients, and how they get better results from this drug. Mr. Green asked the Committee to consider putting these drugs on the Preferred Drug List.

Peggy King, Pharmacy Director, 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.

VII. 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 11:45 a.m.

VIII. Therapeutic Category Reviews:

There were fifteen 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. ACE Inhibitor/CCB Combination:

Steve Liles recommended the following list for PDL inclusion. A motion was made, seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ACE INHIBITOR/CALCIUM CHANNEL BLOCKER, COMBINATIONS	amlodipine/benazepril (Lotrel) verapamil SR/trandolapril (Tarka)	felodipine/enalapril (Lexxel)

B. ACE Inhibitors:

Steve Liles recommended that the following list be approved. A Committee member stated that the current list has been very beneficial and the non-preferred agents are available with prior authorization. A motion was made, seconded and the motion was approved to accept the recommendation.

DRUG CLASS	PREFERRED	NON-PREFERRED
ACE INHIBITORS	benazepril (Lotensin) benazepril/HCTZ (Lotensin HCT) captopril (Capoten)# captopril/HCTZ (Capozide)# enalapril (Vasotec)# enalapril/HCTZ (Vasoretic)# fosinopril (Monopril) fosinopril/HCTZ (Monopril HCT) lisinopril (Prinivil/Zestril)# lisinopril/HCTZ (Prinzide/Zestoretic)# moexipril (Univasc)# moexipril/HCTZ (Uniretic) quinapril (Accupril) quinapril/HCTZ (Accuretic) trandolapril (Mavik)	perindopril (Aceon) ramipril (Altace)

C. Angiotensin II Receptor Blockers:

Steve Liles recommended to the Committee that the drugs in this class on the PDL remain the same. 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
ANGIOTENSIN II RECEPTOR BLOCKERS	eprosartan (Teveten) eprosartan/HCTZ (Teveten HCT) losartan (Cozaar) losartan/HCTZ (Hyzaar) olmesartan (Benicar) olmesartan/HCTZ (Benicar HCT) telmisartan (Micardis) telmisartan/HCTZ (Micardis HCT) valsartan (Diovan) valsartan/HCTZ (Diovan HCT)	candesartan (Atacand) candesartan/HCTZ (Atacand HCT) irbesartan (Avapro) irbesartan/HCTZ (Avalide)

D. Antifungals, Oral:

Steve Liles stated that no new clinical data has been provided to Provider Synergies that would make any changes to this class. Provider Synergies did want to recommend adding Grifulvin V, the liquid dosage form, to the Preferred Drug List. A short discussion ensued about Grifulvin V and that it is used by pediatricians for tinea capitis. A motion was made to accept the recommendations by Provider Synergies with the addition of griseofulvin suspension added to the Preferred Drug List, the motion was seconded, votes were taken and the motion carried. A Committee member made

a motion that the Drug Utilization Review Board look at the prior authorization process for Lamisil and other drugs that need prior approval. The motion was seconded, votes were taken, and the motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIFUNGALS, ORAL	clotrimazole (Mycelex Troche) fluconazole (Diflucan)† ketoconazole (Nizoral)#** nystatin# nystatin (Mycostatin pastilles) terbinafine (Lamisil)** griseofulvin suspension (Grifulvin V suspension)** (PA after 12 years of age)	flucytosine (Ancobon) itraconazole (Sporanox) griseofulvin (brand & generic) voriconazole (Vfend)

E. Antifungals, Topical:

Steve Liles stated that no new clinical data has been provided to Provider Synergies that would make any significant changes to this class. Provider Synergies did want to recommend that Loprox and Loprox shampoo be off the Preferred Drug List. 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
ANTIFUNGALS, TOPICAL	butenafine (Mentax) clotrimazole (Lotrimin)# clotrimazole/betamethasone (Lotrisone)# econazole (Spectazole) ketoconazole (Nizoral)# ketoconazole shampoo (Nizoral) naftifine (Naftin) nystatin (Mycostatin)# nystatin/triamcinolone (Mycolog)# oxiconazole (Oxistat) sulconazole (Exelderm)	ciclopirox (Penlac) terbinafine (Lamisil) ciclopirox shampoo (Loprox) ciclopirox (Loprox)

F. Beta Agonist Bronchodilators:

Steve Liles stated that Provider Synergies would recommend adding Foradil to the Preferred Drug List. The reasoning for this change is that a black box warning has been added to Serevent warning of life-threatening asthma episodes or asthma-related deaths. Provider Synergies also wanted to recommend that Maxair be removed from the Preferred Drug List. 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
BETA AGONISTS (INHALED & PERORAL)	albuterol/ipratropium MDI (Combivent) albuterol HFA MDI (Proventil HFA) albuterol syrup, tablets, CFC MDI, inhalation solution # metaproterenol syrup, tablets, inhalation solution # formoteral DPI (Foradil) salmeterol (Serevent Diskus) terbutaline # levalbuterol inhalation solution (Xopenex) albuterol SR tablets (Vospire ER)	albuterol/ipratropium inhalation solution (Duoneb) albuterol HFA MDI (Ventolin HFA) albuterol inhalation solution (Accuneb) albuterol SR tablets (Volmax) metaproterenol MDI (Alupent) pirbuterol MDI (Maxair, Maxair Autohaler)

G. Beta-Blockers:

Steve Liles stated that no new clinical data has been provided to Provider Synergies that would make any changes to this class except for a new drug, an extended release form of propanolol, which he recommended to be non-preferred. A short discussion ensued about Coreg and Toprol XL. 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
BETA-ADRENERGIC RECEPTOR BLOCKING AGENTS	acebutolol (Sectral)# atenolol (Tenormin)# betaxolol (Kerlone)# bisoprolol (Zebeta)# carvedilol (Coreg) labetalol (Normodyne, Trandate)# metoprolol (Lopressor)# metoprolol XL (Toprol XL) nadolol (Corgard)# pindolol (Visken)# propranolol (Inderal)# propranolol LA (Inderal LA) sotalol (Betapace)# timolol (Blocadren)#	carteolol (Cartrol) penbutolol (Levatol) sotalol (Betapace AF) propranolol (Innopran XL)

H. Bladder Relaxant Preparations:

Steve Liles stated that a new product (Oxytrol) has come out in this class. Since the drug is new there is not a lot of data to compare it to the other agents and Provider Synergies wanted to recommend that it not be on the Preferred Drug List. A short discussion ensued about Detrol and Detrol LA not being on the Preferred Drug List. A motion was made to accept Provider Synergies recommendations with the exception to try to work out an agreement with the manufacturer to have the drugs, Detrol and Detrol LA as preferred products, the motion was seconded, votes were taken and the motion failed. A motion was made to table the entire class until the next meeting and have

Provider Synergies reopen bids from the manufacturers, the motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
BLADDER RELAXANT PREPARATIONS	flavoxate (Urispas) oxybutynin (Ditropan)# tolterodine (Detrol) tolterodine extended-release (Detrol LA)	oxybutynin transdermal (Oxytrol) oxybutynin extended-release (Ditropan XL)

I. Calcium Channel Blockers:

Steve Liles stated that Provider Synergies would like to recommend the following list for inclusion on the Preferred Drug List. A motion was made to table Norvasc and have Provider Synergies speak with the manufacturer again to have the drug preferred and accept the list as recommended. The motion was seconded, votes were taken and the motion carried. A motion was made to move nicardipine generic, nifedipine generic, and immediate release to non-preferred, motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
CALCIUM CHANNEL BLOCKERS	diltiazem (Cardizem)# diltiazem SR (Cardizem SR, Cardizem CD, Dilacor XR)# diltiazem ER (Cardizem LA) felodipine (Plendil) isradipine (Dynacirc) isradipine SR (Dynacirc CR) nifedipine SR (Adalat CC, Procardia XL)# nisoldipine (Sular) verapamil (Calan, Isoptin)# verapamil ER (Verelan PM) verapamil SR (Calan SR, Isoptin SR)#	amlodipine (Norvasc) bepridil (Vascor) nicardipine (Cardene)# nicardipine SR (Cardene SR) nifedipine IR (Adalat, Procardia) generic and brand verapamil ER (Covera-HS) verapamil SR (Verelan) diltiazem SR (Tiazac) nimodipine (Nimotop) nicardipine (IR) generic and brand

J. Corticosteroids, Inhalation:

Steve Liles stated that Provider Synergies would like to make some changes to this class. Provider Synergies wanted to recommend adding Azmacort and removing Aerobid and Advair from the Preferred Drug List. A short discussion ensued about Advair. A motion was made to accept the recommendations by Provider Synergies with the exception of Advair. The Committee wanted Provider Synergies to speak with the manufacturer again to have the drug, Advair, as preferred. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
CORTICOSTEROIDS, INHALED	beclomethasone CFC (Vanceril) fluticasone MDI (Flovent) fluticasone/salmeterol DPI (Advair Diskus)* triamcinolone MDI (Azmacort) fluticasone DPI (Flovent Diskhaler)	beclomethasone HFA (QVAR) budesonide DPI (Pulmicort Turbuhaler) budesonide suspension (Pulmicort Respules)*** flunisolide MDI (Aerobid, Aerobid M)

K. Corticosteroids, Nasal:

Steve Liles stated that no new clinical data has been provided to Provider Synergies that would make any changes to this class. A short discussion ensued about a non-floral nasal spray. A motion was made to add Nasacort AQ as preferred to the list and accept the other recommendations by Provider Synergies, the motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
CORTICOSTEROIDS, NASAL	flunisolide (Nasalide)# fluticasone (Flonase) mometasone (Nasonex) flunisolide (Nasarel) triamcinolone AQ (Nasacort AQ)	beclomethasone AQ (Beconase AQ) budesonide aqua (Rhinocort Aqua) triamcinolone (Nasacort)

L. Leukotriene Modifiers:

Steve Liles stated that Provider Synergies recommended that Singulair remain on the Preferred Drug List and Accolate as non-preferred. 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
LEUKOTRIENE RECEPTOR AGONISTS	montelukast (Singulair)	zafirlukast (Accolate)

M. Proton Pump Inhibitors:

Steve Liles stated that there is a generic over-the-counter product available, which is Prilosec OTC. He addressed the fact that Prilosec OTC is less expensive than the other preferred agents. Provider Synergies came to the conclusion that this class of drugs was basically equivalent, clinically. No significant new clinical data has been provided to Provider Synergies to alter this conclusion. Their role is to provide as many choices as possible, therefore, they recommended the following list for addition to the Preferred Drug List. A short discussion ensued about Prilosec OTC and the financial impact it would have as being the only drug preferred, since clinically all the drugs are basically the same. Steve Liles stated that it could possibly equal to $3 million a quarter or about $10 million a year, but Providers Synergies would have to reevaluate the class to make sure of the amounts. Provider Synergies wanted to provide the Committee with as many choices as possible instead of

restricting themselves to one agent. A motion was made to table the PPI class and to continue as it is now until the January meeting, until Provider Synergies can go back and further discuss with manufacturers about putting a single agent as preferred. The motion was seconded, vote taken and the motion carried. A short discussion ensued about prior authorization and having the DUR Board and Bureau review the decision of prior authorization before the next Pharmaceutical and Therapeutics Committee meeting. Another motion was made to keep the PPI list as it is with the addition of Prilosec OTC and have Provider Synergies go back to the manufacturers to clarify offers. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
PROTON PUMP INHIBITORS	lansoprazole (Prevacid)** rabeprazole (AcipHex)** Prilosec OTC**	esomeprazole (Nexium) omeprazole (Prilosec) pantoprazole (Protonix)

N. Anxiolytics:

Steve Liles stated that Provider Synergies wanted to recommended the following list for the Preferred Drug List. A Committee member recommended that meprobamate, clorazepate, and Xanax XR not be on the preferred list. A Committee member stressed the importance of Xanax XR for anxiety disorder, and as a prior authorized drug, would give doctors access treatment for anxiety disorders. A motion was made to accept the recommendations by Provider Synergies with the exception of meprobamate and clorazepate to non-preferred status, the motion was seconded, votes were taken and the motion carried.

DRUG CLASS	***PREFERRED***	***NON-PREFERRED***
ANXIOLYTICS	alprazolam (Xanax) # buspirone (Buspar) # chlordiazepoxide (Librium) # diazepam (Valium) # lorazepam (Ativan)# oxazepam (Serax) #	alprazolam ER (Xanax XR) meprobamate (Equanil) clorazepate (Tranxene)

O. Antidepressants, SSRIs:

Steve Liles stated that there have been changes in the products for this class since the last review. Provider Synergies recommended as non-preferred, Prozac Weekly, Paxil and Zoloft. A short discussion ensued about Paxil generic. A motion was made to accept the recommendations by Provider Synergies but include generic Paxil and have them go back to the manufacturer to negotiate Zoloft for preferred status. Zoloft would remain preferred until the next meeting. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIDEPRESSANTS, SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIs)	citalopram (Celexa) fluoxetine (Prozac)# fluvoxamine (Luvox)# paroxetine (Paxil)# paroxetine CR (Paxil CR) sertraline (Zoloft)* *escitalopram (Lexapro*)	fluoxetine ER (Prozac Weekly) fluoxetine (Sarafem)

X. Next Meeting:

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

XI. Other Business:

No other business was discussed.

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.

- generic
* - status pending
** - prior authorization required