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 30, 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.
Harriet Nottingham, R.Ph.
Kevin W. Yingling, R.Ph., M.D.

Members Absent:
Thomas L. Gilligan, R.Ph., D.O.
Tom Harward, PA-C
Barbara Koster, MSN, RNC-ANP
Teresa Dunsworth, PharmD

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
Vicki Cunningham, DUR Coordinator
Randy Myers, Deputy Commissioner
Lynda Edwards, Secretary

Contract Staff/Provider Synergies Present:
Todd Wandstrat, PharmD

Other Contract Staff Present:
Stephen Small, RDTP

Other State Government Agency Staff Present:
Felice Joseph, PEIA

Also Present:

Abbott Laboratories: Karl J. Slivka, William H. Cranney
AstraZeneca: Mark A. DiMaio
Aventis: Walt Gose, Nicole Wootten, Justin O'Reilley
Bayer: Catharine M. McGeehan, Bob Kidd, Mark Spangler, Bob Williams, Ted Salyer, Ralph Williams, Bill Moeslein
Boehringer Ingelheim: Matt Sheffield
Diabetes Advocate: Vince Stricker
Forest Laboratories: Wayne A. Miller, Dean Burris
Gazette: Dawn Miller
Genentech: Michael Zymowski, Lisa Brock, Sandra Braem
Glaxo Smith Kline: Steve Mitchell, Gary Browning
Government Relation Specialist: Thom Stevens
Janssen Pharmaceuticals: Bert G. Wickey
Johnson & Johnson: Jim Cannon, Raymona Kinneberg
Lewis Glasser: Gloria Thomas
Eli Lilly & Company: Wayne "Jabo" Covert, Dan Wahby, Mark Russom, H. K. Lee, Brian Reed, Ron Hart, Nick Alvaro, Lindsey Hendress, Roy Sewell
Lewis Glasser: Gloria Thomas
Medpointe Pharma: Doug Waddell
Merck: Michael Tu, Bob Kelley
Novo Nordisk Pharmaceuticals: Kipper Linville, Clint Houck
PFE: Joe McCoy
Pfizer: Chuck Dent, Kent Hunter, Jon Brumfield, Glenn Self, Shawnee Lewis
Roche: DeeAnn Stahly
Schering-Plough: Ronnie Coleman, Robert E. Marsh
Sepracor: Sue Shrout
TheraSense: Russ Golan, Suzanne Stewart, Tracy Rose
WV Psychiatric Services: Jay McClanahan
WV Psychological Association: Jimelle Rumberg
WVU Neurology: Adriana Palade, MD
WVU Pediatrics: Kevin Lewis, RN; James M, Lewis, MD
WVU School of Medicine: Richard Granese, MD

I. Call to Order:

Dr. Steven Matulis, Chairperson, called the meeting to order at 11:00 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 1/22/03 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.

V. Implementation Schedule:

Peggy King, Pharmacy Director, addressed the implementation schedule of the Preferred Drug List (PDL). The last two phases of the drug list had been implemented; Phase III was implemented on March 5, and Phase IV was implemented on April 9, 2003. She also explained that there was a computer glitch in grandfathering the atypical antipsychotics and that ACS had corrected the problem.

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.

Those who do not get to speak at the present session will be given first priority at the next meeting. She also reiterated that there is a five minute limit per presentation and that the session is not interactive. No slide presentations or distribution of written materials to Committee members will be allowed. The following individuals took the floor:

- Roy Sewell, Eli Lilly Pharmaceuticals: Mr. Sewell spoke about Forteo. It is the only FDA approved anabolic agent on the market for the treatment of osteoporosis. It is an injectable product administered similar to an insulin pen. Once a patient has fractures, there are no other anabolic agents that can be given. The only alternative is treatment with multiple medications. A fracture risk reduction occurs with the product. It is dosed for 18 to 24 months. The fracture risk reduction is maintained for up to two years beyond that point. Serum calcium was elevated in some patients but later tests showed a reduction in the serum calcium as early as four to six hours after the first test. Forteo is the only drug that increases and builds new bones. It really addresses a medical need in the community for patients that are experiencing high risk and/or fractures.

- Adriana Palade, MD, Assistant Professor of Neurology, WVU: Dr. Palade discussed the medical benefits of eletriptan. She stated that eletriptan is the only treatment that was proven to have superior efficacy compared to sumatriptan. Headaches are the second most common neurological complaint seen in the outpatient setting. What patients want most is quick relief from their headaches. Eletriptan has a rapid onset of action, works even when taken after the headache progresses, and has a low incidence of side effects. It has also been shown to significantly improve the relief of headaches, which has never been proven before. In addition

to improving patient functionality and symptoms, it has the lowest incidence of chest pain of all the triptans.

- Tracy Rose, RN, Therasense: Mrs. Rose spoke about the Freestyle glucose meter. Therasense launched the Freestyle meter about three years ago. What makes this meter different from all other meters on the market is the strip technology called kilometry. All other meters use anthrimetric technology. The benefit of kilometry is the measurement of the glucose charge across the strip and within the entire glucose sample. This results in the smallest sample needed. Freestyle is the faster growing meter and the second fastest growing strip in the nation at this time. This means a small puncture wound and less pain. Most patients agree that Freestyle is virtually painless and pain is the greatest reason that patients avoid testing. In addition, patients have a full minute to reapply blood after the first attempt. This equals less wasting of test strips. A second reason to use Freestyle is accuracy. Sampling of Freestyle readings are 98% within target of hospital readings. Many substances interfere with home glucose monitoring such as aspirin, acetominophen, oxygen, and hematocrit. Due to the Freestyle strip technology, glucose readings with Freestyle are not affected by any of these substances. And lastly, Freestyle is a high quality product available at a reasonable and competitive price. Freestyle has recently been chosen one of the preferred providers for MediCal.

- Bill Moeslein, R.Ph., Bayer Diagnostics: Mr. Moeslein spoke about Bayer Blood Glucose Meters. Bayer was the first company to have a patient blood glucose meter and produced the first blood glucose meter with memory. Their meters are very simple and very convenient, use a very small sample size, are very accurate, and offer alternate site testing on all meters. Bayer provides patient education for diabetic patients that is written on a fifth grade level and the information is also available in multiple languages. One of the great advantages for choosing Bayer as the meter for the Medicaid population is that physicians, health care providers, and pharmacists in West Virginia are very familiar with the Bayer product. Additionally it would mean that health care providers would not have to remember multiple products based on which types of patients that they are seeing. Medicaid would be able to team with the West Virginia Public Employees Insurance Agency, the retail pharmacists, and health care providers to make meters freely available at the site of service.

- Kevin Lewis, RN, CDE, WVU Pediatrics: Mr. Lewis spoke about growth hormones, blood glucose strips and insulin pens. In reference to growth hormones, Mr. Lewis recommended that the Bureau give at least three to five months of notice because of retraining issues. Each company uses a different device and compliance is going to be a big issue. In reference to blood glucose strips, a three-month notice would be greatly appreciated. Products in his practice are the Accu-Check products, the Bayer products, the Freestyle meter, and the One Touch Ultra from Life Scan. A three to four month turnover time to retrain patients would be very helpful. Although it was not on the agenda, Mr. Lewis stated his concern regarding insulin pens. They are convenient and it is easy to teach a patient how to use them. There are safety issues involved with mixing insulins. It is convenient for the patients to measure the correct dose, inject their dose, and carry the pen in their pockets. It is truly a convenience issue. For the pediatric population, currently pen devices require prior authorization. One of the reasons prior authorization is given is because of the educational setting. Since every one of these

prior authorizations is approved, he requested that prior authorization be removed to eliminate a barrier for care in the pediatric population. In the adult population, there is a move to use insulin earlier. He stated that he would like to go with one agent and consider adding insulin early in treatment. For the adult population, because of the convenience of being able to teach the use of these pen devices in a few minutes, it decreases the number of diabetes education programs necessary throughout the State and will decrease the number of medication errors.

- James Lewis, MD, Professor, WVU Pediatrics: The president of WVU Pediatrics has received comments from other pediatricians in the area asking for the Committee's consideration to place Strattera on the preferred drug list. Children with ADHD may represent 5 to 10% of the school age population, which means that there are one to two children per classroom. Only about 50% of these children are diagnosed with ADHD and probably less than 50% of them are treated. He stated that their practice is primarily 2/3 to 3/4 Medicaid patients. Strattera has been available since January and is the first new medication to receive an indication from the FDA for ADHD. Because it works selectively as a norepinephrine reuptake inhibitor and seems to be quite effective, he has used it for four months with good success. Since it is a new medication, not a stimulant, and is not a controlled substance, it eases some of the concerns parents have. It is more effective in certain patients, particularly kids with tics. Practicing pediatricians can have samples available and phone in refills, which are major issues with the stimulants. Indications for the medication in adults will be helpful, because so many of the parents also have ADHD, which is a problem in terms of insuring the best care for the children themselves.

- Vince Stricker, Diabetes Advocate: Mr. Stricker talked about his nine-year-old daughter, Katy, who was diagnosed with diabetes at the age of three. He is a very active diabetes advocate in the State of West Virginia and has also traveled to Washington, D.C. as an advocate for funding diabetes research, stem cell research, etc. Mr. Stricker and his daughter visit all newly diagnosed children in the Southern part of West Virginia and visit children in the hospital setting to deliver the Bag of Hope and the Teen Pack. His sister died at the age of 44 from an autoimmune disease. Less than a year later his daughter was diagnosed with Type I diabetes which is also an autoimmune disease. A co-worker's brother also had diabetes, but died when he was 30. At that point, Mr. Stricker made a pledge to give Katy the best care he possibly could and of course diabetes education was an important issue. Mr. Stricker came to the meeting to advocate patient choice for choosing their diabetic equipment and glucose meters. Since Katy was diagnosed six years ago, she has used four different meters from four different companies. The most important feature to him is accuracy, because trying to get good glucose control is most important. His daughter had several hypoglycemic events and was taking ten blood sugar sticks a day. Her fingers would become callused and it was very important to have an alternate site testing. He tested glucometers on himself and the least amount of blood is the one that did the job. He also stated that the latest figures on diabetes indicate the cost for treatment of diabetes in the U.S. is $137 billion a year. The cost of the testing materials to comply with diabetes treatment is a small fraction of the costs associated with hospital visits, emergency room visits, dialysis, etc. When visiting these children at the hospital, the Bag of Hope and the Teen Pack include a glucometer. There are two different glucometers in the bags, and he tells the parents what the features are, and what he likes about them. Mr. Stricker said he would hate to tell them that they won't be able to use this because Medicaid only allows the use of one meter.

- Richard Granese, MD, WVU School of Medicine: Dr. Granese was here on behalf of the American Psychiatric Association to represent psychiatrists and patients who could not be in attendance. He said he was fortunate to have to opportunity to use all psychotropic medications during his training. This, however, would not be the case for future psychiatrists who choose to train in West Virginia. He told a story about a boy who was dismissed from school and, after committing several compulsive crimes, was incarcerated. He wanted to know what this boy's future would have been if he had been treated for his condition. One medication to treat conditions like the little boy's is Strattera. Strattera is a new medication for the treatment of ADHD that is unlike any others. Dr. Granese stated that he already has had many successes with Strattera since its limited time on the market. His patients can go to the pharmacy and get the medication very easily. They don't have to worry about running out of this medication, because Dr. Granese can call in another prescription for them. Many of the patients that are treated also have Medicaid as their payer source for medication and are faced with the limitations of acquiring their medicine. He asked the Committee to consider permitting physicians to prescribe newer medications like Strattera, Abilify and Lexapro as first line treatment for patients.

- Bill Cranney, Abbott Laboratories: Mr. Cranney wanted to talk about one feature of the Precision Extra that makes it unique. One thing that sets it apart from all the other meters is its ability to test blood ketones. This is an important clinical advance that can improve the quality of care to insulin dependent diabetics. Of the costs of medical management of Type I diabetes, diabetic ketoacidosis (DKA) accounts for 25% of those costs. Detecting ketosis early can hopefully prevent a Type I diabetic from going into DKA. Ketone testing is also indicated anytime glucose levels are consistently above 300. One clinical study compared Precision Extra and a regular glucose meter plus urine ketone sticks. The study tracked these patients over a number of months and the group that used Precision Extra had 46% fewer diabetes emergency room visits, and 64% fewer diabetes related hospitalizations. The ADA prefers blood ketone testing because it is a real-time measurement of the metabolic state of that diabetic. Urine strips reflect a six to eight-hour delay. The blood ketone test measures betahydroxybuterate which is the predominate ketone body in DKA. Whereas, the urine test measures acetoacetate which is not the predominant ketone associated with DKA. Abbott offers the only evidence-based outcomes data for comparing blood glucose meters. He stated that using Precision Extra is a very good way to improve the quality of care for Type I diabetics.

VII. Executive Session:

A motion was made to adjourn to Executive Session. The motion was seconded and carried. The Committee adjourned to Executive Session at 11:45 a.m.

VIII. Old Business:

Chairman Matulis called the meeting back to order at 1:45 p.m. and asked Dr. Wandstrat to begin discussions concerning the drugs under Old Business. These drugs had been referred to Provider Synergies for further evaluation.

A. Famvir:

Dr. Wandstrat advised the Committee that Provider Synergies was directed at the last meeting to discuss with the maker of Famvir the possibility of making the drug more cost effective. Dr. Wandstrat stated that there was no new additional data to share. Dr. Avery moved to include Famvir on the Preferred Drug List. Dr. Avery stated that Famvir is not like the other drugs in this category. After some discussion the motion was seconded, voted upon and the motion carried.

B. RenaGel:

Dr. Wandstrat advised the Committee that Provider Synergies was directed during the last meeting to discuss the possibility of making RenaGel more cost effective with its manufacturer. He informed the Committee there had been no changes since the last discussion. Dr. Yingling made a motion to add RenaGel to the list. The motion was seconded, voted upon and the motion carried.

Todd Wandstrat wanted the Committee to know that at the last meeting a topical, antifungal called ciclopirox (Loprox) was overlooked and needed to be added to the Preferred Drug List. A motion was made, the motion was seconded, voted upon and the motion carried.

IX. Therapeutic Category Reviews:

Dr. Wandstrat gave an overview at the beginning of each category for discussion on the agenda. The Committee reviewed and discussed each category and made the following recommendations:

A. OTC Claritin:

Dr. Wandstrat stated that the Bureau had directed Provider Synergies to evaluate the new drugs entering into classes that had previously been reviewed. Dr. Wandstrat recommended OTC Claritin products for PDL inclusion. A motion was made, seconded, votes were taken and the motion carried. It was noted that Claritin RX is in short supply. Dr. Avery asked if OTC versions would be paid for when a prescription was written for those specific drugs. It was confirmed.

DRUG CLASS	***PREFERRED***	***NONPREFERRED***
MINIMALLY SEDATING ANTIHISTAMINES AND COMBINATIONS	loratadine (Claritin, Claritin Redi-Tabs) OTC loratadine/pseudoephedrine (Claritin-D 12 Hour, Claritin-D 24 Hour) OTC	loratadine rapidly-disintegrating tablets (Alavert)

B. Avodart:

Dr. Wandstrat stated that Avodart is approved by the FDA for Benign Prostatic Hyperplasia. Adverse side effects of this agent are similar to those of the drugs already on the PDL, but fewer side effects when compared to Proscar. He recommended that Avodart be added as a preferred drug. A motion was made, seconded and the motion was approved to accept the recommendation.

DRUG CLASS	*PREFERRED*	*NONPREFERRED*
BENIGN PROSTATIC HYPERPLASIA (BPH)/MICTURITION AGENTS	dutasteride (Avodart)	

C. Strattera:

Dr. Wandstrat informed the Committee that Strattera is being used to treat ADHD. It has comparable efficacy to immediate release methylphenidate. It has some of the adverse side affects you would see with stimulants, such as mild blood pressure elevations and some weight loss, although it is not a stimulant. It was recommended that Strattera not be placed on the Preferred Drug List. It was stated that many kids being treated for ADHD did not have the condition. The parents were abusing the medication or were dependent. Strattera is not a stimulant and non-addictive, and therefore, less likely to be misused. Dosing was discussed and it was agreed that package dosing would be sufficient and the Drug Utilization Review (DUR) Board would review when necessary. A motion was made to put Strattera on the list as preferred as a first line agent. The motion was seconded, votes were taken, and the motion carried as follows:

DRUG CLASS	*PREFERRED*	*NONPREFERRED*
STIMULANTS	atomoxetine (Strattera)	

D. Forteo:

Dr. Wandstrat stated that this was a new drug that recently became available for the treatment of osteoporosis and for menopausal women who are at risk for fractures. It also has FDA indications for increasing the bone mass in men who are also at high risk for fractures. He said adverse effects were similar to other bone resorption suppression agents, except for some gastrointestinal and some injection site adverse effects. It should be used as a secondary line agent. 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*	*NONPREFERRED*
BONE RESORPTION SUPPRESSION AGENTS		teriparatide (Forteo)

E. Relpax:

Dr. Wandstrat stated that this drug was a new addition to this class and asked that this drug be pended until the next P & T meeting. He wanted more time to gather adequate financial data, comparative studies, and federal rebate information. A motion was made to table this discussion until the next P & T meeting. The motion was seconded, votes were taken and the motion carried as follows:

DRUG CLASS	*PREFERRED*	*NONPREFERRED*
ANTIMIGRAINE (TRIPTANS)		eletriptan (Relpax)

F. Cipro XR:

Dr. Wandstrat stated that Cipro XR is specifically for the treatment of urinary tract infections. It is similar in adverse affects compared to others. It does offer three day treatment for urinary tract infection and that is an advantage over the others in that category. Dr. Wandstrat recommended that Cipro XR be placed on the Preferred Drug List. A motion was made to accept this recommendation. The motion was seconded, votes were taken, and the motion carried.

DRUG CLASS	*PREFERRED*	*NONPREFERRED*
QUINOLONES	ciprofloxacin extended release (Cipro XR)	

G. Growth Hormone:

Dr. Wandstrat stated that growth hormones are available for certain disorders in treatment in adults and children. All of these drugs were approved by the FDA for treatment in children. The recommendations for inclusion were made by Dr. Wandstrat. A short discussion ensued about the financial impact of adding all the growth hormone agents to the preferred list. A motion was made to include all agents as preferred. The motion was seconded, votes were taken, and the motion carried as follows:

DRUG CLASS	*PREFERRED*	*NONPREFERRED*
GROWTH HORMONE	Genotropin Humatrope Norditropin Nutropin Nutropin AQ Nutropin Depot Protropin Saizen Serostim	

H. Blood Glucose Strips:

Dr. Wandstrat asked that this class of drugs be tabled due to some of the HIPAA guidelines. Peggy King stated that Provider Synergies was asked to review this class, particularly because of PEIA's history of having an exclusive strip, and being able to get the monitors free. Mrs. King asked that the discussion for this class be delayed until billing issues could be resolved. Dr. Yingling stated that we should have a deadline for when this class should be reviewed again, because the

availability of glucose monitoring to diabetic patients in this system is incredibly important. A short discussion followed. A motion was made to review this class in October and it would be tabled at this time. The motion was seconded, votes were taken, and the motion carried.

I. Nicotine Products:

Dr. Wandstrat stated that tobacco dependence is usually a condition that requires repeated intervention. With that in mind, on the market currently there are a variety of different products that are used for nicotine replacement or smoking cessation. There are differences in the amount of nicotine present with the delivery system and the route of administration, whether it be gum, inhaler, lozenge, nasal spray or patch. These different dosage forms are similar in efficacy. They are similar in tolerance and compliance. Compliance can be very erratic and require multiple treatments and such. There are similar efficacy and adverse effect profiles between these agents. He recommended the following list to the Committee. Some discussion ensued about the efficacy of patches, gum and lozenges. The Quit Line was also discussed. A motion was made to accept the list as recommended. That motion was seconded, votes were taken, and the motion carried.

DRUG CLASS	***PREFERRED***	***NONPREFERRED***
NICOTINE REPLACEMENT AGENTS	Nicotine gum (Watson only) Commit Lozenge Nicoderm CQ patch	Nicotine gum (all other brands and generics) Nicotrol Inhaler Nicotrol NS Nicotine patch (all other brands and generics)

X. Next Meeting:

A motion was made, seconded, voted upon and accepted to hold the next meeting of the P & T Committee on Wednesday, July 9, 2003, at 11:00 a.m. in the Diamond Building, Lower Level Conference Rooms B10/11.

A discussion ensued about how new drug additions would be reviewed at future meetings. A motion was made to have line extensions only be reviewed when the drug class comes up for an annual review. Any new drug that the FDA has given priority status could be reviewed at the next regularly scheduled meeting. The motion was seconded, votes were taken and the motion carried.

XI. Other Business:

A motion was made to review the Benzodiazapine Class in the next meeting. Todd Wandstrat stated a new drug in this class will soon be available. However, it may not be available by the next meeting. If not, it would be reviewed the following year when the class would be reopened. The motion was seconded, votes were taken and the motion carried.

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.