West Virginia Department of Health and Human Resources

Bureau for Medical Services

Pharmaceutical and Therapeutics (P & T) Committee

October 23, 2002 - 11:00 a.m.

DHHR Building - 350 Capitol Street

Lower Level Conference Rooms B10/11

Charleston, West Virginia

MINUTES

Members Present:

Kevin D. Yingling, R.Ph., M.D.
Steven R. Matulis, M.D.
David Avery, M.D.
Thomas L. Gilligan, R.Ph., D.O.
Teresa Dunsworth, PharmD
Harriet Nottingham, R.Ph.
Kristy H. Lucas, PharmD
Tom Harward, PA-C
Barbara Koster, MSN, RNC-ANP

Members Absent:

John D. Justice, M.D. James D. Bartsch, R.Ph.

DHHR/BMS Staff Present:

Paul L. Nusbaum, Secretary, DHHR
Phillip A. Lynch, Deputy Secretary, DHHR
Nancy V. Atkins, Commissioner
Nora Antlake, Attorney, BMS
Peggy King, Pharmacy Director
Gail Goodnight, Rebate Coordinator
Vicki Cunningham, DUR Coordinator

Susan Dolly, Administrative Secretary Carol Jackson, Office Assistant

Contract Staff/Provider Synergies

Present:

Terry Taylor, R.Ph. Todd Wandstrat, PharmD

Other Contract Staff Present:

Jennifer Carpenter, ACS Dusti Prisock, ACS Rob Earnest, ACS Stephen Small, RDTP

Other State Government Agency

Staff Present:

Felice Joseph, PEIA

Also Present:

Sepracor: Sue Ellen Shrout, Tim Hermes, Joe Fry

Watson Pharma: Leslie McLaughlin

Eli Lilly: Myrna Miller, Joe Sellys, H.K. Lee, Chad Wagner, Lisa Copeland

Schering: Gordon Rosenberry

Pharmacia: Gary Grote, Steve Babineaux, Kevin Wemett

Pfizer: Kit Francis, Mike Bolen, Kent Hunter, Pamela Smith, Dan Moore, Shawnee Lewis, Glenn Self,

Kent Alt

Novartis: Steve Mitchell, Jason Gruse, Marshall Jacks

Aventis: Walter Gose **PhRMA**: Greg Bailey

Johnson & Johnson: Jim Cannon, Raymona Kinneberg

Merck/Astra Zeneca: Larry Swann

Solvay: Rich Stump

Mental Health Association: Ellen Ward

Lewis Glasser: Gloria Thomas

Wyeth: Phillip Reale

Abbott Labs: Rob Fitzgerald, Dana Riley

WSAZ: Ray Blake, Scott Saxton

Boehringer Ingelheim: Matt Sheffield

GSK: Steve Mitchell **NAMI WV**: Michael Ross **Bristol-Myers**: Karen Long

Purdue: Sean Sorell, Julia Radlund, Deanna Finnell

Takeda Pharmaceutical: Don Zowaden, Brian Nye, Dr. Nash Halem, Bill Hollyfield, Brad Kincaid,

Cindy Campbell, Brant Williams

WV Psychological Association : Jimelle Rumberg, Ken Devlin

Medical Student: David Wang

WV Association of Physicians Assistants: K.C. Lovin Government Relations Specialist: Thom Stevens

Diabetes Advocate: Jennifer Honaker

Novo Nordisk: Clink Houck, Kipper Linville

Sankyo Pharma: Glenn E. Dooley, Joe Greer, Ted Duty

Physician: Robert Holley, M.D.Physician: Timothy Saxe, M.D.Astra Zeneca: JoAnn Shoup

Sanofi: Dana Godfrey, Mike Bowen **Janssen**: Steve Miller, Mark Akers **OMP**: Jeff Bumgardner, Pam Lester

Biovail: Ashley Morris

Parent Advocate: Mark Honaker KOS: Michael Dudley, Kim Anderson

Physician: Tim Deer, M.D.

Arthritis Advocate: Ruth E. Lewis

Forest Labs: Wayne Miller, Bruce Rutledge Brown Communications: John Brown

MetroNews: Chris Lawrence

Alcon: Matt Murphy

WVAFP: Lester Labus, M.D. **Hoffman-Roche**: Stephen Haid

WVU School of Pharmacy: Amber Nailler WVU School of Pharmacy: Elaine Perkins

Merck: Bob Kelley, Michael Tu

Call to Order:

Dr. Steven Matulis, Chairperson, called the meeting to order at 11:00 a.m. He asked the Committee for permission to change the order of the agenda to allow old business to be addressed following the Executive Session in the afternoon. Commissioner Nancy Atkins was recognized and advised the audience how the meeting would be conducted.

II. Introductions:

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

III. Opening Remarks:

Paul L. Nusbaum, Secretary of DHHR, addressed the Committee and on behalf of Governor Wise, thanked them for their willingness to participate in what he considers to be a very important role in Medicaid's future.

IV. Approval of Minutes from Previous Meeting:

Chairman Matulis asked for approval of the minutes from the last meeting. Dr. Gilligan, Committee Member, asked that R.Ph. be added to his credentials when listed, and Dr. Avery advised the Committee he had not received a copy of the minutes. A motion was made and seconded, vote taken and motion carried to note the change and approve the minutes as submitted.

V. Implementation Schedule:

Chairman Matulis next recognized Peggy King, Pharmacy Director for the Bureau, who announced that the phase-in of the PDL classes will begin on January 1, 2003.

VI. Public Comment Period:

Commissioner Atkins opened the floor to the public for 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:

- Chad Wagner from Eli Lilly: Mr. Wagner, as a medical liaison with Eli Lilly, spoke to the Committee about Evista, which is used for both treatment and prevention of osteoporosis. Mr. Wagner addressed how Evista could assist in the post-menopausal needs of women in West Virginia.
- ▼ <u>Deanna Finnell, PharmD, Purdue Pharma. L.P.</u>: Dr. Finnell, a medical liaison with Purdue Pharma, addressed the Committee about the critical role OxyContin plays in treating patients with pain. In an effort to assist the practitioners of West Virginia, Purdue has partnered with the State to provide pain education.
- ▼ <u>Timothy Saxe, M.D. of Huntington</u>: Dr. Saxe is a solo practitioner in Barboursville and is the Medical Director of Ebenezer Medical Outreach, which provides indigent care in the

Huntington area. Dr. Saxe stated that cases of diabetes are rising to epidemic proportions, and asked the Committee not to make the preferred drug list or prior approval process another impediment to treating his patients to goal.

- ▼ Nash Halem, Veterinarian, Takeda Pharmaceutical: Dr. Nash, a medical liaison for Takeda Pharmaceuticals, came before the Committee to speak about Actos, a member of the Thiazolidinediones class of hypoglycemics which can be used with insulin. He wanted to thank the Committee for the open forum.
- ▼ <u>Jennifer Honaker, Diabetes Advocate</u>: Ms. Honaker, as a parent of a son with diabetes, wanted to express her concern about limiting the selection of insulin for diabetics. She stated that all diabetics must be treated on a case by case basis.
- Ken Devlin, M.A., WV Psychological Assoc.: Dr. Devlin is a practicing psychologist in both the private and public sectors. The Association recognizes the Department's efforts to reign in medical costs and acknowledges the difficult challenge the committee has before it. The Association supports the Committee's efforts in cost containment and shares the common interest of effective patient care, while minimizing the burden placed on the physicians.
- K.C. Lovin, PA-C, WV Association of Physicians Assistants: Ms. Lovin came before the Committee to state that Physicians Assistants' are part of the health care team and are advocates for patients. She wants to make sure that the prior authorized drugs this Committee approves are on the WV Association of PA's formulary. She also asked the Committee to grandfather drugs that some recipients are using that have stabilized their current conditions. She is concerned that the drug companies will decrease the number of free samples of drugs, and also reduce or discontinue to other indigent care programs.
- ▼ <u>Lester Labus, M.D., WV Academy of Family Physicians</u>: Dr. Labus is a family physician and spoke on behalf of the Academy of Family Physicians of West Virginia. The family physicians have great concerns over the implementation of any restrictions on any type of drug. They are concerned about the extra time the PDL will require physicians to change therapies.
- Tim Deer, M.D.: Dr. Deer is an anesthesiologist who practices pain management, and came to speak about COX-2 inhibitors. Dr. Deer would like for the Committee to consider placing all three presently available COX-2 inhibitors on the PDL. The availability of all COX-2

inhibitors may prevent the use of stronger drugs such as opiates.

- Mike Bolen, Pfizer: Mr. Bolen wanted to address comments that he said were repeated after the Executive session of the Committee meeting on September 25, accusing Pfizer of being a greedy company, since they would not participate in the supplemental rebate process. Mr. Bolen went on to give examples of the generosity of Pfizer to the citizens of West Virginia.
- ▼ Robert Holley, M.D of Point Pleasant.: As a lipids specialist and primary care physician, Dr. Holley wanted to speak with the Committee about combination therapy. Currently, there is nothing on the state's formulary that carries FDA approval for use in combination with the statins. He recommends the addition of WelChol to the PDL.

∀||. **Executive Session**:

A motion was made to adjourn to Executive Session. The motion was seconded and carried. The Committee adjourned to Executive Session at 12:30 p.m. Commissioner Atkins announced the room must be vacated, and the Committee would reconvene at 1:45 p.m.

VIII. Old Business:

Chairman Matulis called the meeting back to order at 2:00 p.m. and asked Dr. Wandstrat to begin discussions concerning the drugs under old business that were referred back to Provider Synergies for further input.

A. **Xopenex:**

Dr. Wandstrat advised the Committee that Provider Synergies is currently in conversation with the makers of Xopenex to possibly find a method to make the drug more cost effective. He asked for the discussion to be tabled and placed on the agenda for discussion at the next meeting. A motion was made and seconded, vote taken and motion carried.

B. **Ditropan XL**:

Dr. Wandstrat advised the Committee that Provider Synergies was directed during the last meeting to discuss with the makers of Ditropan XL the possibility of making the drug more cost effective. He informed the Committee there have been no changes since the last discussion. At this time, Dr. Avery made a motion to defer Ditropan XL to the next meeting to allow time for more

discussion between the manufacturer and Provider Synergies. Dr. Avery feels Ditropan XL is an important drug and reiterated his reasons. A motion was made and seconded, vote taken and motion carried.

C. Tricor:

Dr. Wandstrat informed the Committee that Provider Synergies was directed to discuss with the makers of Tricor a method to make the drug more cost effective, so that it could be added to the PDL. Provider Synergies informed the Committee that their negotiations were successful and advised the Committee to include Tricor on the PDL at this time. A motion was made and seconded, vote taken and motion carried.

IX. Therapeutic Category Reviews:

There were 15 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. Narcotics Analgesics:

Dr. Matulis stated that he discussed this list with several oncologists and they concurred that they are all effective drugs. There were no objections by the Committee to the suggested selections. A motion was made to accept the list as recommended, and seconded, vote taken and motion carried as follows:

DRUG CLASS PREI	FERRED NON-PREFERRED	
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Narcotics Analgesics	all generics acetaminophen/caffeine/dihydrocod eine bitartrate (Panlor) fentanyl transdermal (Duragesic) hydrocodone/acetaminophen (Maxidone®) morphine sulfate ER (Kadian) morphine sulfate ER (Avinza) oxycodone (Roxicodone) tablets oxycodone/acetaminophen (Roxicet®) tramadol/acetaminophen (Ultracet)	aspirin/caffeine/dihydrocodeine bitartrate (Synalgos-DC) fentanyl citrate (Actiq) hydrocodone bitartrate/ibuprofen (Vicoprofen) oxycodone (Roxicodone Intensol) oxycodone CR (OxyContin) propoxyphene napsylate (Darvon-N)
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B. **NSAIDS**:

Dr. Gilligan inquired if generic Naprosyn would still be on the list. Provider Synergies clarified that it would still be available. Dr. Gilligan also asked for clarification if Provider Synergies was referring to generic or brand name Ponstel. Peggy King and Dr. Wandstrat verified the Bureau was using the brand name. Barbara Koster commented that the list showed good representation of COX-2 inhibitors. Dr. Yingling expressed his apprehension at recommending Ponstel to practitioners. He stated that in his 25 years as a pharmacist and physician, he has never written a prescription for Ponstel, nor would be recommend that someone write one. The Committee agreed that they would prefer to see all three COX-2's on the PDL. Dr. Matulis asked if adding all three would have a negative financial impact. Terry Taylor, President of Provider Synergies, stated that it would have a significant financial impact if all three were added. Dr. Avery recommended that Celebrex be added to the list. Barbara Koster reiterated that by adding Celebrex to the list, it would have a negative financial impact. Dr. Gilligan stated that he felt the people of West Virginia would be better served by prescribing recipients drugs from the COX-2 class, as opposed to narcotic analgesics, especially in light of the problems we are having with hydrocodone and other members of that drug family. There being no further discussion, a motion was made to approve the list as recommended, with the exception of adding Celebrex to the list and removing Ponstel. The motion was seconded, vote taken, motion carried as follows:

DRUG CLASS	PRFFFRRFD	NON-PRFFFRRFD
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Nonsteroidal Anti- inflammatory Drugs (NSAIDs)	rofecoxib (Vioxx)valdecoxib (Bextra)celecoxib (Celebrex)	 diclofenac/misoprostol (Arthrotec) meloxicam (Mobic) meclofenamic acid (Ponstel)

C. Hypoglycemics, Insulins:

Dr. Matulis and Dr. Avery shared comments from their colleagues stating they would like to see the long acting drug, Lantus, on the list. Dr. Matulis asked Provider Synergies if this would have a negative financial impact. Terry Taylor stated that if Lantus was used in place of the other insulins, then it would have a significant financial impact on the state. A motion was taken to accept the list, as is, and the motion did not carry. Chairman Matulis called for more discussion. Dr. Gilligan stated that the endocrinologists he has spoken with would like to see Lantus and Humolog added to the list. After considerable discussion, a motion was made to accept the list as offered, with the addition of Lantus, seconded, vote taken and motion carried, as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Hypoglycemics, Insulins	human insulin (Novolin, Novolog)human insulin (Relion)insulin glargine (Lantus)	•human insulin (Humulin, Humalog)

D. Hypoglycemics, Thiazolidinediones:

A motion was made to add Actos to the list. Dr. Avery stated these are both different drugs, and in some instances, one will work when the other will not. Barbara Koster agreed with Dr. Avery, stating that both have similar efficacy. A motion was made to accept the list as offered, with the addition of Actos, and was seconded, vote taken and motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Thiazolidinedione (TZD) Hypoglycemics	•rosiglitazone (Avandia) •pioglitazone (Actos)	

E. Macrolides:

Teresa Dunsworth stated that the estolate form of erthyromycin has more toxicities associated with its use. Dr. Avery stated that in discussions with his infectious disease colleagues, they felt

the long acting clarithromycin could be eliminated. Dr. Gilligan asked Provider Synergies when clarithromycin would become a generic, and it was noted they have at least two years left on their patent. A motion was made to accept the list as offered with the exception of removing erthyromycin estolate from the PDL. The motion was seconded, vote taken and carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Macrolides	 azithromycin (Zithromax) clarithromycin (Biaxin) clarithromycin (Biaxin XL) erythromycin (many) (generic) 	•dirithromycin (Dynabac) •troleandomycin (Tao) •ertyhromycin estolate

F. Bone Resorption Suppression Agents:

Dr. Avery expressed concern that we have different groups combined into one. He feels that Evista is a different category and cannot be compared with the other drugs in this category. Barbara Koster asked if adding Evista to the drug list would have a negative impact on the financial savings. Terry Taylor stated that adding this particular drug would have a negative impact on the financial savings. After considerable discussion regarding Evista, a motion was made to accept the list as is, with Provider Synergies continuing to work with the manufacturers of Evista to find a method to make the drug more cost effective. The motion was seconded, voted upon and carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Bone Resorption Suppression Agents	•alendronate (Fosamax)•calcitonin-salmon (Miacalcin)•etidronate (Didronel)•risedronate (Actonel)	•raloxifene (Evista)

G. Angiotensin II Receptor Blockers (ARBs):

There was considerable discussion regarding the benefits of ARBs. The Committee had no objections to the suggested drugs. A motion was made to accept the list as recommended, seconded, voted upon and motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Angiotensin II Receptor Blockers	•eprosartan (Teveten) •losartan (Cozaar) •losartan/HCTZ (Hyzaar) •olmesartan (Benicar) •telmisartan (Micardis) •telmisartan/HCTZ (Micardis HCT) •valsartan (Diovan) •valsartan/HCTZ (Diovan HCT)	•candesartan (Atacand) •candesartan/HCTZ (Atacand HCT) •irbesartan (Avapro) •irbesartan/HCTZ (Avalide)

H. Antifungals, Topical:

Dr. Yingling asked if the inclusion of Naftin on the PDL would have a negative impact on the savings. Terry Taylor replied that it would not. The Committee had no objections to the suggested drugs. A motion was made to accept the list as recommended, seconded, vote taken and motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Antifungals, Topical	•clotrimazole/betamethasone (Lotrisone) (generic) •ketoconazole (Nizoral) (generic) •naftifine (Naftin) •nystatin (Mycostatin) (generic) •nystatin/triamcinolone (Mycolog) (generic) •sulconazole (Exelderm)	•butenafine (Mentax) •ciclopirox (Loprox) •ciclopirox (Penlac) •econazole (Spectazole) •oxiconazole (Oxistat)

| Antifungals, Oral:

Dr. Yingling expressed concern regarding having griseofulvin on the list because of its toxicities. There was a motion to accept the recommendations with the exception of griseofulvin, which would be removed from the list. The motion was seconded, voted upon and motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED	
DRUG CLASS	FREFERRED		

Antifungals, Oral	•clotrimazole (Mycelex Troche) •fluconazole (Diflucan) •ketoconazole (Nizoral) (generic) •nystatin (generic) •terbinafine (Lamisil)	•flucytosine (Ancobon) •itraconazole (Sporanox) •griseofulvin (generic)
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J. ACE/CCB Combinations:

Kristy Lucas expressed the concern that amlodipine was not included as a preferred calcium channel blocker. Yet it is included in one of the combination agents that is suggested. Dr. Yingling stated that it was their original decision that the second generation calcium channel blockers were equivalent. Dr. Gilligan inquired as to when Lotrel would become generic. Terry Taylor stated that it would be within the next two years. A motion was made to accept the list as recommended, seconded, vote taken, and motion carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
ACE Inhibitor/Calcium Channel Blocker Combinations	•amlodipine/benazepril (Lotrel) •verapamil SR/trandolapril (Tarka)	•felodipine/enalapril (Lexxel)

K. Hypoglycemics, Post-prandial Hypoglycemic:

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

DRUG CLASS	PREFERRED	NON-PREFERRED
Meglitinide Hypoglycemics Hypoglycemics, Post- prandial Hypoglycemic	•nateglinide (Starlix) •repaglinide (Prandin)	

L. Estrogen Agents, Oral and Transdermal:

The Committee had no objections to the suggested drugs. A motion was made to accept the list as recommended, seconded, voted upon and carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Estrogen Agents, Oral and Transdermal	Transdermal patch: •All brands and generics Oral: •conjugated estrogens (Premarin) •esterified estrogens (Menest) •estradiol (Estrace) (generic) •estropipate (Ortho-Est, Ogen) (generic)	•synthetic conjugated estrogens (Cenestin)

M. Hypoglycemics, Sulfonylureas:

Barbara Koster recommended the first generation drugs not be included on the list. Dr. Matulis concurred with Ms. Koster. A motion was made to accept the list as recommended, with the exception of Dymelor, Diabinese, Tolinase and Orinase, seconded, voted upon and carried as follows:

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

N. Estrogen Agents, Combination:

The Committee felt there was no significant differences in this class of drugs and had no objections to the suggested list. A motion was made to accept the list as recommended, seconded, voted upon and carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
DROG CLASS	INLILINALD	INOIN-I KLI LKKLD

Estrogen Agents, Combination	•17ß-estradiol/norethindrone acetate (Activella) •17ß-estradiol/norethindrone acetate (Combipatch) •17ß-estradiol/norgestimate (Ortho- Prefast) •conjugated estrogens/medroxyprogesterone acetate (Premphase)	•conjugated estrogens/medroxyprogesterone acetate (Prempro) •esterified estrogens/methyltestosterone (Estratest, HS) •ethinyl estradiol/norethindrone acetate (Femhrt)

O. Hypoglycemics, Biguanides:

The Committee felt there was no significant differences in this class of drugs and had no objections to the suggested list. A motion was made to accept the list as recommended, seconded, voted upon and carried as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED
Hypoglycemics, Biguanides	 metformin (Glucophage) (generic) metformin XR (Glucophage XR) metformin/glyburide (Glucovance) 	

X. **Next Meeting:**

A motion was made, seconded, voted upon and carried to hold the next meeting of the P & T Committee on Tuesday, November 19, 2002 at 11:00 a.m. at the Diamond Building Lower Level Conference Rooms B10/11.

XI. Other Business:

Dr. Yingling expressed concern in regard to the dissemination of information being sent to them because of the activities of the Committee. Dr. Yingling also wanted to clarify what the charge was of the Committee. The charge, as read by Commissioner Atkins during the first meeting, is to review, discuss and recommend the drugs that are to be placed on the preferred drug list (PDL). It does not include such areas as implementation or prior authorization, which are the responsibilities of the Bureau or other committees already in place. Dr. Yingling made the following motion, of which there were eight parts:

- 1 It is the individual members preference to see, hear, or read information, or meet with individuals regarding a class of drugs or a particular drug.
- 2 If the information is sent to an individual member, it is not sent to the Committee. The member has no responsibility to disseminate that information.
- 3 Materials for the Committee's purpose should be sent to Peggy King.
- 4 Materials that are sent to Ms. King will be directed to Provider Synergies.
- 5 Provider Synergies will use the materials in their analysis process.
- 6 Input to all members will be insured through the analysis process.
- 7 Charge to review, discuss, and recommend the drugs that will be placed on the preferred drug list (PDL). That does not include implementation of the decisions of the P & T Committee.
- 8 This motion will be read at the next public meeting of the P & T Committee.

Chairman Matulis called for any discussion on the motion. Commissioner Atkins asked that Dr. Yingling submit the motion in writing to the secretary. The motion was seconded, voted upon and carried. Chairman Matulis reminded everyone that the members of the Committee are here as volunteers, in hopes they will be doing something that will be good for the State.

Mr. Harward asked to pose a question to Todd Wandstrat and Terry Taylor of Provider Synergies. Mr. Harward wanted to know, specifically, if Provider Synergies received any renumeration for their services, outside of what their contract provides for. Terry Taylor stated that Provider Synergies does not receive any money or compensation for the development of the West Virginia Medicaid PDL other than through their contract with the State of West Virginia. Provider Synergies staff are specifically prohibited from taking grants or accepting compensation for attending functions. They do not collect any other fees or administrative fees.

XII. Adjournment:

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