Preferred Drug List Committee Meeting
Meeting Minutes, Open Session
December 10, 2008

Preferred Drug List Committee Meeting Minutes, Open Session EDS / Forbes Field Capital / Cedar Crest Room Topeka, KS December 10, 2008	**Members Present:** Michael Burke, M.D, Ph.D., Chair; Matthew Schlotterback, M.D. Brenda Schewe, M.D. Dennis D. Tietze, M.D. Glenn Harte, Pharm.D. Kenneth Mishler, Pharm.D. **KHPA Staff Present:** LeAnn Bell, Pharm.D. Aimee Grubb, Recorder Shelly Liby Margaret Smith, M.D. **EDS Staff Present:** Lisa Todd, R.Ph. Karen Kluczykowski, R.Ph.	**Representatives:** Mike LaFond – Abbott Stephanie Miller – Amgen Michele Puyear – Amgen Randy McGinley – Bayer Richard Mesquias – Eli Lilly Don Larsen – Forest Ann Gustafson – GlaxoSmithKline Matthew Stafford – Merck Janice Lopez – OBI/Johnson & Johnson Phil King – Pfizer
TOPIC	**DISCUSSION**	**DECISION AND/OR ACTION**
I. Call to Order	Dr. Michael Burke called the Meeting of the Preferred Drug List (PDL) Advisory Committee to order at 10:05 am with six members present.	
II. Announcements	Dr. Margaret Smith introduced the new KHPA staff. LeAnn Bell, Pharm.D. is the Pharmacy Program Manager, Shelly Liby is the Assistant Pharmacy Program Manager, and Aimee Grubb is the Administrative support staff for Pharmacy and Dr. Smith. Dr. Burke asked for Public Disclosure statements for those who wanted to present. Ms. Todd announced that each drug has a five minute time limit and that the Committee wants to hear about comparison trials and head-to-head studies rather than how the drug works.	

III. Review and Approval of June 4, 2008 Minutes	No changes to the minutes.	Dr. Schlotterback moved to approve the minutes. Dr. Schewe seconded the motion and it carried by a unanimous vote.
IV. Hormone Replacement Therapy – Oral, Transdermal, and Topical a. Public Comment b. Committee Discussion c. Committee Recommendation / Action	Dr. Burke indicated therapies fall into three categories based on delivery method; oral, transdermal, and topical. He proposed that we look at a Hormone Replacement Therapy in terms of the three separate routes of administration and that products containing something other than estrogen be eliminated. No public comment. Dr. Burke stated that this is a new review. He spoke with a Professor of OB/GYN at KU in terms of thoughts that might inform the committee. The professor's position was that there was no difference between generic or brand and that there was no clinically significant difference, from a population standpoint, with regard to estradiol vs. premarin. He also felt that any formulary should make all delivery systems available (oral, transdermal, and topical). Dr. Burke stated, in terms of materials that were provided for background, that clearly there will be interpatientn differences, tolerability issues, and perhaps efficacy. **Oral** Dr. Tietze stated that in his experience oral estrogens are clinically equivalent. Dr. Burke asked for a motion stating that oral estrogens are clinically equivalent.	Dr. Schewe moved that oral estrogens are clinically equivalent. Dr. Mishler seconded and it carried with a unanimous vote.

	Transdermal Dr. Burke asked for a motion. **Topical** Dr. Schewe had some concerns about lumping creams and rings into one group. Dr. Burke suggested calling the group intravaginal instead of topical. Dr. Tietze stated that he doesn't have a problem with choosing one delivery method as preferred.	Dr. Tietze moved that transdermal estrogens are clinically equivalent. Dr. Schlotterback seconded and it carried with a unanimous vote. After board discussion of different delivery methods, Dr. Mishler moved that all estrogen only containing HRT products are clinically equivalent, but oral, transdermal, and intravaginal delivery methods should be available as preferred. Dr. Schewe seconded and it carried with a unanimous vote.
V. Oral Contraceptives a. Public Comment b. Committee Discussion c. Committee Recommendation/Action	Previously reviewed October, 2002. At that time it was decided that all oral contraceptives are clinically equivalent based on dosage and chemistry on a given formulation. No public comment. Dr. Burke stated that the primary outcome is to prevent pregnancy and in that regard no product is superior over another. Articles published in The Cochrane Library suggested that monophasic be the preferred agent because that is where most of the data is. Dr. Burke reported that Dr. Brown, a Gynecologist at KU, recommended multiple options be available. There should be access to all subclasses; monophasic, biphasic, and triphasic. Generic agents are clinically equivalent to brand agents. The committee's position in 2002 was that	Dr. Tietze moved that all oral contraceptives are clinically equivalent based on chemistry and dosage in a particular formulation. All subclasses (categorized by monophasic, biphasic, triphasic and progestin only) should be represented in the preferred drug list. Dr. Harte seconded and it carried with a unanimous vote.

	products with different components were found to be clinically equivalent based on chemistry and dosage. There have been no significant changes since 2002, but there are more triphasic options available. All oral contraceptives are available currently. Dr. Burke recommended that all oral contraceptives with the same chemistry and strength in particular formulation are clinically equivalent.	
VII. Erythropoiesis-Stimulating Agents a. Public Comment* b. Committee Discussion c. Committee Recommendation/Action	Janice Lopez, Johnson & Johnson, stated that there are two FDA approved drugs for four diseases. Aranesp® is only approved for two diseases. Procrit® has ten additional compendia approved uses. Aranesp® has only one. Michelle Puyear, Amgen, stated that there has been a decreased use over the years and more to come because of FDA changes (REMS program). Dr. Schlotterback asked if there is a particular hemoglobin level at which therapy is recommended. Ms. Puyear stated there is not for nephrology but for oncology it is a hemoglobin less than 10. Dr. Schewe stated that she spoke with Dr. Sweet and she has no preference for one agent over another. With no further discussion, a motion was made.	Dr. Mishler moved that all Erythropoiesis-Stimulating Agents are clinically equivalent. Dr. Schewe seconded and it carried with a unanimous vote.

VIII. Antiemetics – Serotonin 5HT3 Antagonists a. Aloxi – New Medication to the Class b. Public Comment c. Committee Discussion d. Committee Recommendation/Action	No public comment. Dr. Burke said that antiemetics were previously reviewed 8/23/06. At that time it was decided that all oral 5HT3 antagonists are clinically equivalent. This is a re-review because there is a new agent, Aloxi, to the class.	Dr. Schlotterback moved that all oral 5HT3 antagonists are clinically equivalent. Dr. Tietze seconded and it carried with a unanimous vote.
IX. Adjournment	Dr. Burke asked if there was a preference on having the materials sent on a CD or hard copy. Dr. Burke would still like hard copies of the materials, but the rest of the committee would prefer CD. Ms. Todd reminded the public that they should park in the lot behind the building. A question was raised about how frequently the PDL Committee meetings happen. There is no requirement on the frequency of the meetings. Dr. Smith stated that meetings should occur every six months. Dr. Burke called for a motion to adjournment.	Dr. Schlotterback moved to adjourn. Dr. Tietze seconded and it carried with a unanimous vote.