Minutes of the November 16, 2006
Drug Utilization Review (DUR) Board Meeting

Members Attending: Billy Brown, Pharm D; Harold Blakely, R.Ph.; Randy Calvert, R.Ph.; Frank Marascalco, R.Ph.; Lee Montgomery, M.D.; Andrea Phillips, M.D.

Members Absent: Troy Griffin; Wallace Strickland

Also Present: DOM Staff: Judith Clark, R.Ph., Director of the Medicaid Pharmacy Bureau; Vicky Donaho

HID Staff: Dennis Smith, R.Ph.; Sam Warman, R.Ph.; Kathleen Burns, R.N.

Randy Calvert, R.Ph., acting chair called the meeting to order at 2:15 p.m.

Updates

Cost Management Analysis:
Mr. Smith presented a brief report on the total cost of claims for the top 15 therapeutic classes from July 1, 2006 through August 31, 2006. This list was led by antipsychotic agents and anticonvulsants. The top 25 drugs based on the number of claims from July 1, 2006 thru August 31, 2006 were led by hydrocodone with acetaminophen followed by Zyrtec. The Top 25 drugs based on total claims cost from July 1, 2006 thru August 31, 2006 were led by Risperdal, followed by Seroquel.

Retrospective Drug Utilization Review (RDUR) Activities Update:
Mr. Warman reported on RDUR activities for the periods of October thru December 2005, and November 2005 thru January 2006. The RDUR initiatives reported on included the encouragement of ACE inhibitor or ARB use in patients with diabetes and/or chronic kidney disease, the appropriate use of antihypertensive medications in patients at risk for cardiovascular disease. Another issue reported on was the encouragement of appropriate use of hydroxyurea in patients with sickle cell anemia. The recommendation was made to continue all criteria in place and to report after another 90 days.

Pharmacy Program Updates:
Ms. Clark presented information regarding the new Preferred Drug List (PDL) becoming effective January 1, 2007. She pointed out that the new PDL will be available on the Division of Medicaid website in the near future. Ms. Clark distributed information regarding a new outreach project for chronic obstructive pulmonary disease that may become available through several sources for physicians to distribute to targeted patients. Due to the lack of a quorum, all voting was postponed until the next board meeting.

New Business:
Mr. Smith presented several suggested RDUR intervention modules. The concurrent use of Restasis® and medications with anticholinergic properties was discussed. Information

was presented to reflect the incidence of this concurrent use at approximately 30 percent. Based on these findings, a RDUR criterion was recommended to identify patients who may benefit from a change in therapy that may allow for discontinuation of Restasis®.

The next intervention discussed was the concurrent use of triptans with SSRI or SNRI antidepressants. This is a result of a recent FDA action regarding the risk of serotonin syndrome in patients taking these medications concurrently. Approximately 14 percent of patients who were treated with a triptan also received one or more prescriptions for an SNRI or SSRI during the report period. A RDUR criterion was recommended to identify patients who may be at risk for serotonin syndrome due to the concurrent use of members of these drug classes.

The new inhaled insulin product, Exubera®, was discussed. Mr. Smith highlighted the appropriate use of the product and presented possible concerns, such as potential waste due to complicated dosing regimens. While the development of inhaled insulin is an exciting step in the evolution of diabetes therapy, its release to the market may be tempered by concerns around appropriate use. Mr. Smith recommended that in addition to being subject to prior authorization, RDUR criteria are recommended to support the use of Exubera® within the parameters of its approved labeling.

Several other general recommended RDUR criteria were introduced. Due to the lack of a quorum, however, these criteria were held for the next meeting of the board.

Next, Mr. Smith presented a brief synopsis of recent actions surrounding modafinil (Provigil®). Primarily, the recent FDA decision to not allow the marketing of a version of modafinil with an indication for ADHD was discussed. The possible concern for Medicaid is the apparent off-label use of Provigil® for ADHD. A one page Prescribing Information Update document was introduced to the board. The document is intended for use by the HID academic detailers to reinforce with prescribers the appropriate FDA-approved use of this product.

Mr. Smith also presented a study of the relationship between compliance and hospitalizations in children. This study focused on the use of inhaled corticosteroids in children with asthma. In brief, the findings supported the hypothesis that consistent use of inhaled corticosteroids decreases the risk of asthma-related hospitalizations. It was interesting to note that approximately two-thirds of children who had at least one asthma-related hospitalization had no prescription claims for these products.

The last new business topic discussed was the treatment of opioid dependence with buprenorphine and naloxone (Suboxone®). Mr. Smith summarized the treatment recommendations for this product and history of its approval for office-based treatment of patients who had previously had only the option of methadone treatment. The board discussed possible cooperation with the manufacturer in supporting this treatment option for appropriate Medicaid beneficiaries.

Boxed Warning Updates:

Mr. Smith presented the following black box warnings, labeling changes or other actions by the FDA**:**

Coumadin (warfarin sodium)
Audience: Pharmacists, other healthcare professionals, and patients
[Posted 10/06/2006]
FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin, to include a new patient Medication Guide as well as reorganization and highlighting of the current safety information to better inform providers and patients.

Isotretinoin - Accutane and generic isotretinoin
Audience: Dermatological, other healthcare professionals and patients
[Posted 10/06/2006]
FDA and the iPLEDGE program notified healthcare professionals and patients of an update to iPLEDGE, a risk management program to reduce the risk of fetal exposure to isotretinoin, which will eliminate one element of the program, the 23 day lock-out period for males and females of non-child bearing potential. This change does not affect female patients of child-bearing potential.

Lamictal (lamotrigine)
Audience: Neurologists, obstetricians, other healthcare professionals, and patients
[Posted 09/29/2006]
The FDA notified healthcare professionals and patients of new preliminary information from the North American Antiepileptic Drug Pregnancy Registry that suggests that babies exposed to Lamictal, indicated to treat seizures and bipolar disorder, during the first three months of pregnancy may have a higher chance of being born with a cleft lip or cleft palate. More research is needed to be sure about the possibility of the increased chance of cleft lip or cleft palate developing in babies of pregnant women who take Lamictal. Women who take Lamictal and are pregnant or are thinking of becoming pregnant should talk with their doctor. Patients should not start or stop using Lamictal without talking to their doctor.

Ortho Evra (norelgestromin/ethinyl estradiol)
Audience: Gynecologists, other healthcare professionals and consumers
[Posted 09/20/2006]
Ortho-McNeil and FDA notified healthcare professionals and patients about revisions to the prescribing information to inform them of the results of two separate epidemiology studies that evaluated the risk of developing a serious blood clot in women using Ortho Evra compared to women using a different oral contraceptive. The first study found that the risk of non-fatal venous thromboembolism (VTE) associated with the use of Ortho Evra contraceptive patch is similar to the risk associated with the use of oral contraceptive pills containing 35 micrograms of ethinyl estradiol and norgestimate. The second study found an approximate two-fold increase in the risk of medically verified VTE events in users of Ortho Evra compared to users of norgestimate-containing oral contraceptives containing 35 micrograms of estrogen. Although the results of the two

studies differ, the results of the second study support FDA's concerns regarding the potential for Ortho Evra use to increase the risk of blood clots in some women. Prescribing information for Ortho Evra continues to recommend that women with concerns or risk factors for thromboemboli disease talk with their healthcare professionals about using Ortho Evra versus other contraceptive options.

Ibuprofen and Aspirin Taken Together
Audience: Consumers and healthcare professionals
[Posted 09/08/2006]
FDA notified consumers and healthcare professionals that taking Ibuprofen for pain relief and aspirin at the same time may interfere with the benefits of aspirin taken for the heart. Ibuprofen can interfere with the anti-platelet effect of low dose aspirin (81 mg per day), that may render aspirin less effective when used for cardioprotection and stroke prevention. Although it is all right to use Ibuprofen and aspirin together, FDA recommends that consumers contact their healthcare professional for more information on the timing of when to take these two medicines, so that both medicines can be effective.

Dexedrine (dextroamphetamine sulfate)
Audience: Psychiatrists, pediatricians, mental healthcare professionals, pharmacists and consumers
[Posted 08/21/2006]
The FDA and GlaxoSmithKline notified healthcare professionals of changes to the BOXED WARNING, WARNINGS and PRECAUTIONS sections of the prescribing information for Dexedrine (dextroamphetamine sulfate), approved for the treatment of Attention-Deficit Hyperactivity Disorder and narcolepsy. The warnings describe reports of sudden death in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems.

Aptivus (tipranavir)
Audience: Infectious disease specialists, pharmacists, and other healthcare professionals
[Posted 06/30/2006]
Boehringer Ingelheim and FDA informed healthcare professionals of important new safety information for Aptivus (tipranavir) capsules, co-administered with ritonavir (500mg/ receiving Aptivus capsules in combination antiretroviral therapy in clinical trials 200mg), that includes an addition to the drug's Black Box Warning regarding reports of both fatal and non-fatal intracranial hemorrhage (ICH). Boehringer Ingelheim identified 14 reports of intracranial hemorrhage events, including 8 fatalities, in 6,840 HIV-1 infected individuals.

Next Meeting information:
Ms. Clark reminded the Board of the next scheduled meeting on February 15, 2007. Randy Calvert adjourned the meeting at 4:30 p.m.

Respectfully Submitted:
Health Information Designs