

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

**Location of Meeting
Frontier Building, 3601 C Street, Room 890/896**

FINAL MINUTES OF MEETING

April 18, 2008

8:00 a.m.

Committee Members Present:

Dharna Vakharia Begich, Pharm.D.
Marvin Bergeson, MD
Heidi Brainerd, MS R.Ph
Amber L. Briggs, Pharm.D.
Richard E. Brodsky, MD
Robert H. Carlson, MD (telephonic)
Lucy Curtiss, MD
Jeffrey G. Demain, MD
Traci Gale, PharmD
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS, MPH
Diane Liljegren, MD (telephonic)
Andrzej Maciejewski, MD
Sherrie D. Richey, MD
Janice L. Stables, MSN, ANP
Trish D. White, R.Ph.

Committee Members Absent:

Kelly C. Conright, MD
R. Duane Hopson, MD
Gregory R. Polston, MD

Others Present:

David Campana, R.Ph.
Melinda Sater, Pharm.D, First Health
Edward Bako, MS, R.Ph.
Gloria Black, Staff
Alex Malter, MD, HCS

1. Call to Order – Chair

The meeting was called to order at 8:00 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public/Local Physicians

There were no public comments.

4. Review of Low-sedating Antihistamines

Jon Sonoda: A representative of Sanofi-Aventis discussed Levocetirizine or Xyzal. Levocetirizine is different in that it is an enantiomer that is very potent and has a high affinity for the histamine receptor. It binds to the H1-receptor for 142 minutes, much longer than the other agents. There have been many head-to-head trials and Levocetirizine has been shown to be superior to all other antihistamines in this class. Several studies were mentioned and/or reviewed. Levocetirizine is indicated for both perennial and seasonal allergic rhinitis, as well as chronic idiopathic urticaria. It is very important for specialists to be able to prescribe a potent antihistamine, although there is a tendency for patients to use over-the-counter antihistamines. By using a prescribed potent antihistamine, the physician can tailor future drug therapy for the patients. Levocetirizine should be added to the Medicaid PDL.

Dan Manning: A representative of Schering-Plough discussed Desloratadine or Clarinex. Clarinex is a long acting, oxidizing antihistamine that has been out for several years. For the Medicaid population, Clarinex has a broad range of indications and one of the lowest age ranges in the class including seasonal allergic rhinitis, down to 2 years of age; perennial allergic rhinitis, down to 6 months of age; and chronic idiopathic urticaria, down to 6 months of age. Since this is a non-sedating antihistamine, it is available in several formulations including tablets, oral disintegrating tablets, and a syrup. Clarinex should be considered for the Medicaid PDL.

Dr. Sater gave the First Health presentation on Low-sedating Antihistamines. This is a new classification. There are five available chemical entities. There are many dosage forms and all but Xyzal are available in combination with pseudo-ephedrine. Many of the products are also available over-the-counter, including Zyrtec. Indications vary among the agents. The efficacy and adverse drug reaction profiles are similar. In March there were 732 claims: 48.5% for Zyrtec, 26% for generic Allegra, almost 13% for Clarinex, a little over 10% for Xyzal, and 2.19% for Allegra. There was no previous discussion as this is a new class.

Dr. Demain noted that different medications worked differently in patients. He uses all of these drugs. Xyzal seems to have a longer duration of action, fewer breakthrough symptoms, does not seem to cause any sedation, and is well tolerated by patients. Xyzal is particularly helpful when treating chronic urticaria. Many of these drugs are now available over-the-counter, which has created somewhat of an issue. All these drugs are equally effective, but there are cases where one seems to work better than another. We may want to consider making an OTC available on the PDL, but we certainly need some low-sedating antihistamines available. Certain medicines have a greater impact on reaction time and sedation than a blood alcohol level of .1 or greater so you cannot go back and use generation one antihistamines and maintain a standard of care.

Dr. Brodsky said all narcotics had side effects and the patients should be cautioned when using them.

In response to Dr. Demain, Dr. Bergeson said an OTC could not be added to the PDL, but there is pending regulation changes that would allow an OTC antihistamines on the PDL.

DR. LILJEGREN MOVED A CLASS EFFECT, WITH ONE PREPARATION THAT IS NOT MIXED WITH A DECONGESTANT TO BE INCLUDED ON THE PDL. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

5. Review of Otic Quinolones

There were no public testimonies.

Dr. Sater gave the First Health presentation on Otic Quinolones. There are two chemical entities in this class. There are three available products, two are combinations with Ciprofloxacin and Corticosteroids and the other is Ofloxacin. Indications vary by agent. There are very few head-to-head trials for the drugs in this class. The clinical efficacy and tolerability are similar between the agents. In March there were 189 claims: 44% for Ciprodex, 34% for Floxin, 17% for generic Ofloxacin, and 5.29% for Cipro HC. As this is a new classification, there was no previous discussion.

Dr. Maciejewski felt all the drugs in this class worked well. He uses the agents without hydrocortisone for children.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. GALE. THE MOTION PASSED UNANIMOUSLY.

6. Re-review of Antiemetics

There were no public testimonies.

Dr. Sater gave the First Health presentation on Antiemetics. There are three available agents in this class in a variety of dosage forms. The indications vary by agent. Clinically, all agents are used for all indications. They selectively block 5-HT₃ receptors and have similar efficacy and adverse drug reaction profiles. Head-to-head trials are limited and usually fairly small. In March there were 86 claims: 34% for Ondansetron tablets, 27% for the rapid dissolving Ondansetron, 14% for Zofran, less than 13% for Zofran ODT, 10.47% for Anzemet, 1.16% for generic Kytril, and 1.16% for generic Ondansetron solution. Zofran is currently the preferred agent. There was no previous discussion. There was a motion declaring a class effect, which passed unanimously. Since the last review, generic products have come to the market for both Zofran and Kytril.

Mr. GREEAR MOVED A CLASS EFFECT.

In response to Dr. Richey, Dr. Sater said there was a period of exclusivity for new generic drugs where one manufacturer is given exclusive production rights for at least six months. During that time, they can charge whatever they want so the generic drug may not be cheaper. In this particular case, you cannot assume that the generics will automatically be added to the PDL.

Dr. Richey pointed out that Zofran is a class B and should remain available for pregnant patients. Dr. Brodsky noted that Zofran could be prescribed by writing medically necessary on the prescription. Dr. Richey noted that Zofran had more data and was generally used for pregnant patients.

Ms. White discussed switching patients from previously used generic products to brand name products that are added to the PDL. Dr. Sater noted that the committee was not supposed to consider the prices, but there are ongoing issues where branded products remain significantly more cost effective than generic products. Ms. White said pharmacists question why they have to carry branded products, which are more expensive for them than generic products, for the Medicaid population only.

Mr. Campana discussed the net price of drugs. Although this impacts pharmacies, because they have to carry two different products, Medicaid receives a better price on some of the branded products during the initial six-month exclusivity period for generic drugs.

Dr. Bergeson said physicians encouraged their patients to use generic drugs and it was frustrating when a branded product was preferred on the PDL.

Mr. Greear noted that it looked like the pharmacies were spending a lot of money on the branded products, but they received rebates. The state pays less and the pharmacy makes money, but it is a lot of inventory for them keep on their shelves and branded products are more expensive to keep in stock. By stocking branded products, the pharmacies have to expend more money to keep their inventory, but they are still making money in the long run.

Ms.. White agreed with Mr. Greear that the pharmacies made money on the branded products when they were on the PDL. However, once the PDL changes, no one is paying for the branded product and the pharmacy still has them sitting on their shelves.

MR. GREEAR MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED WITH THREE OPPOSED.

7. Re-review of Antimigraine Agents

Aaron Butikofer: A representative of Merck Pharmaceuticals discussed Rizatriptan or Maxalt. Maxalt is indicated for the treatment of migraine attacks with or without aura in adults. It is not intended for the prophylactic therapy of migraines or for use in the management of hemiplegic or basal migraines. The safety and efficacy of Maxalt has not been established for cluster headaches. Maxalt should not be given to patients with ischemic heart disease or other significant underlying cardiovascular disease, uncontrolled hypertension, or within 24 hours of any ergot type medication or other 5-HT₁ agonists. The efficacy of Maxalt tablets was established in four multi-center, randomized, placebo controlled trials. Maxalt, 10 milligrams, demonstrated 2-hour response rates defined as a reduction of moderate to severe pain down to mild or no pain in 67-77%. Similar trials have been conducted to assess the efficacy of Maxalt, 10 milligrams, in patients with menstrual migraines without aura. In two separate menstrual migraine studies, the 2-hour response rates for the treatment of moderate to severe menstrual migraine pain was 70-73% and the 4-hour response rates were 82-90%. Maxalt can be given in strengths of 5 and 10 milligrams, and is available as a tablet or oral disintegrating wafer. Additional doses can be given separated by two hours, not to exceed 30 milligrams in a 24-hour period. The safety of treating more than four headaches in a 30-day period has not been established. Liquid is not necessary for the administration of Maxalt MLT oral disintegrating wafers. Maxalt and Maxalt MLT offer fast, effective relief of migraine pain for patients. Maxalt MLT can be taken without water and is ideal for times when it is difficult for patients to swallow liquids. Maxalt MLT is the number one prescribed oral disintegrating triptan for the treatment of migraines in the United States and Alaska. It is also available on the formularies at Native health and military facilities alike. I urge you to retain Maxalt and Maxalt MLT on the Alaska State Medicaid PDL.

Jennifer Brzana: A representative of GlaxoSmithKline discussed Sumatriptan or Imitrex. It is indicated for the acute treatment of migraine headaches with or without aura in adults, as well as

cluster headaches. Imitrex has unsurpassed pain-free efficacy. Seventy-five percent of migraine patients who use Sumatriptan, 100 milligrams, early in the migraine are pain free in two hours. Sumatriptan is now the fastest acting oral triptan on the market. The data consistently shows that speed is critical to stopping the migraine process. Sumatriptan, 100-milligram tabs, now have an onset of pain relief as early as 20 minutes, the nasal sprays at 15 minutes, and the injection at 10 minutes. Sumatriptan is the only triptan available in three formulations allowing patients the flexibility to treat their migraines with the most appropriate route of administration. With unsurpassed pain-free efficacy, speed of onset, and flexible routes of administration, Sumatriptan should remain a preferred agent on the Alaska State Medicaid PDL.

Dr. Sater gave the First Health presentation on Antimigraine Agents. There are seven available chemical entities. Imitrex, Maxalt, and Zomig are available in a variety of dosage forms and are considered short acting. Axert and Relpax are considered intermediate acting. Amerge and Frova are considered long acting. All agents are indicated for the treatment of migraines with or without aura. Imitrex is also indicated for cluster headaches. Efficacy and adverse drug reaction profiles are similar among all agents. There are very slight differences in 5-HT₂ receptor subtype activity between the agents. In March there were 154 claims: 34% for Imitrex tablets, 27% for Maxalt MLT, 9% for Relpax, 8.4% for Imitrex cartridges, 7.14% for Maxalt tablets, 5% for Imitrex nasal spray, 3% for Imitrex injectables, and less than 5% for all the rest of them. In the previous discussion, patient variability and response was discussed, as was the need for multiple dosage forms to be available as preferred agents. Quantity limits were briefly mentioned. A motion for class effect, to include one or more agents with multiple dosage forms, passed unanimously. There have been no significant changes to the drugs in this class since the last review.

Dr. Liljegren felt Imitrex should be included on the PDL, because it is the only drug available in the injectable formulation. Dr. Bergeson noted that with only 3% of the market share, physicians could write medically necessary on the prescription for Imitrex injectable.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. RICHEY. THE MOTION PASSED WITH ONE OPPOSED.

8. Re-review of Nasal Steroids

Jon Sonoda: A representative of Sanofi-Aventis discussed Triamcinolone or Nasacort AQ, which is currently on the PDL. The committee was urged to retain Nasacort on the PDL due to its efficacy. Several studies were mentioned. Nasacort AQ has no relation to increased cataract formation. It does not effect bone velocity changes in children from 2 to 5 years of age. It also has effects on ocularparitis. Patient preference data demonstrates that Nasacort AQ is the preferred inhaled corticosteroid and has very low adverse effects.

Meredith Zarling: A representative of GlaxoSmithKline discussed Fluticasone Furoate or Veramyst. Veramyst is indicated for the treatment of the symptoms of both seasonal and perennial allergic rhinitis in patients 2 years of age and older. It is administered once a day and offers a flexible dosing option based on patient's symptom control. It is a unique corticosteroid molecule with a high binding affinity to the glucocorticoid receptor with 1.7 times more binding affinity than Fluticasone Propionate. Veramyst is the only nasal steroid proven to help relieve not only all four nasal symptoms, but also ocular symptoms such as itching, burning, tearing, watering and redness in patients 12 years and older with seasonal allergic rhinitis. Several studies were discussed. Adverse events in clinical trials were

similar to those seen with other nasal steroids and were comparable to placebo. Common side effects reported in clinical studies were headache and epistaxis. The unique device, which is innovative and designed based on patient and physician feedback, is an important attribute of the product. It has a side actuator, which releases a constant dose of low-volume mist, half that of Flonase, which decreases the amount of product that runs down the back of the patient's throat. It also has a shorter nozzle, which assists in the ease of administration, especially in pediatric patients. Veramyst is approved under the age of 2 for both seasonal and perennial allergic rhinitis. It is the only nasal steroid with proven ocular symptom improvement in prospective replicated trials. It is available in a unique nasal delivery system. Based on these advantages, Veramyst should be available to the Medicaid patients in the State of Alaska.

Dan Manning: A representative of Schering-Plough discussed Mometasone or Nasonex. Nasonex is both scent free and alcohol free. It has a broad range of indications including the treatment of seasonal and perennial allergic rhinitis down to 2 years of age. It is the only NIS approved for the prophylaxis of seasonal allergic rhinitis and nasal polyps. In clinical studies, Nasonex has shown ocular benefits in allergy patients. It has a total low systemic bioavailability of less than 0.1%. It is indicated down to 2 years of age, which is one of the lowest in this class. Nasonex should be considered for the Alaska Medicaid PDL.

Dr. Sater gave the First Health presentation on Nasal Steroids. There are six available chemical entities and seven available products. All agents are FDA approved for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis. There are other indications, which are summarized in the review materials. All are available as sprays. Flunisolide is available in aerosol form. Contraindications, warnings, adverse effects, and drug interactions are all similar. All the agents have similar efficacy and tolerability. The currently preferred agents are Nasonex, Masacort AQ, and Flonase. In March there were 539 claims: 57% for Nasonex, 12% for generic Flunisolide, 11% for Nasacort AQ, 9.3% for Fluticasone, 5.8% for Veramyst, 2.8% for Rhinocort AQ, and less than 2% for the rest. There was very limited discussion previously. The agents were deemed equivalent for efficacy. A motion for a class effect, preferentially including one aqueous non-alcohol containing preparation, passed unanimously. Since the last review, Veramyst was added to the market place.

Dr. Demain said unlike antihistamines, nasal steroids have unique properties. The alcohol preparations are somewhat irritating and patients do not tolerate them very well. Nasarel is not well tolerated by patients with 44% complaining of nasal irritation. The aqueous preparation is necessary for patients with sensitivities. Rhinocort Aqua is the only category B product. He felt a class effect could be declared, but one aqueous preparation included on the PDL.

DR. DEMAIN MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING ONE AQUEOUS, NON-ALCOHOL PREPARATION. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Leukotriene Inhibitors

There were no public testimonies.

Dr. Sater gave the First Health presentation on Leukotriene Inhibitors. There are two available products in this class. Both are FDA approved for prophylaxis and treatment of asthma in adults.

Zafirlukast is indicated for the treatment of asthma in children 5 years of age and older and Montelukast for children 12 months and older. Montelukast or Singulair is also indicated for the symptomatic relief of seasonal allergic rhinitis for adults and children, perennial allergic rhinitis for adults and children 6 months or older, and prophylaxis of exercise induced asthma for patients age 15 years and older. Zafirlukast or Accolate has a poor drug interaction profile and must be dosed twice a day on an empty stomach, which makes it less tolerated by patients. In March there were 844 claims: 836 for Singulair, which is our only preferred product. There was no previous discussion. The motion for class effect, with Singulair preferentially preferred, passed unanimously. Since the last review, there was a warning issued cautioning about an increased risk of suicide with Singulair.

Dr. Demain felt Zyflo should not be considered for the PDL, because it has a significant risk of hepatic toxicity. Accolate is dosed twice daily, has a significant impact if taken with food, and has a significantly higher side effect rate. Montelukast is the only reasonable choice. There was a case recently where a teenager was prescribed Montelukast and two weeks later committed suicide. The question was raised, since cognitive side effects have been identified in a small percentage of patients using Singulair, if the medication was a contributing factor. In reviewing the literature, it is believed that there is no correlation between the use of Singulair and suicide. However, based on post- and pre-marketing data, there is an ongoing study specifically looking at that as a primary endpoint, but the results will not be available for 9 to 12 months. We are talking to our patients so they will be aware of any potential risks, but there is no box warning or FDA warning.

DR. DEMAIN MOVED A CLASS EFFECT, TO INCLUDE MONTELUKAST AS THE PREFERRED AGENT. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

10. Re-review of Inhaled Steroids

Randy Legg: A representative of Astra Zeneca discussed Pulmicort Respules, Pulmicort Flexhaler, and Symbicort. Pulmicort Respules is the only inhaled, nebulizable corticosteroid available in the United States. It is a category B with a safety pregnancy rating. It comes in three strengths, .25 milligram, .5 milligram, and 1 milligram. It is available in both once a day and twice a day dosing. It is indicated for the maintenance and treatment of asthma in children ages 12 months to 8 years of age. Pulmicort Respules has multiple safety trials. Pulmicort Flexhaler is a dry powder inhaler. It is a reformulation of the old Pulmicort Turbohaler. It is the only category B, FDA pregnancy rated, inhaled steroid in the United States. It is indicated for the maintenance treatment of asthma for patients 6 years of age and above. It has two strengths, 180 micrograms and 90 micrograms. It is currently dosed BID. It has a dose counter and less than 1 milligram of lactose per inhalation. Symbicort is our combination inhaler. It has been available since June of 2007. It is an HFA formulation and comes in two strengths. Its current indication for dosing is two puffs BID for age 12 and above for asthma. Several studies on Symbicort were reviewed.

Steven Zhang: A representative of Abbott Labs discussed Azmacort. Azmacort is approved for the treatment of mild and persistent asthma both in adults and pediatric patients. According to a report in 2006 in the State of Alaska, there were about 37,000 adults with asthma with one-third of the patients having weekly symptoms. Several months ago, the National Heart, Lung, and Blood Institute released new asthma diagnoses and management guidelines. The major difference between the old and new guidelines is the emphasis on the importance of symptom control. Azmacort is the most potent and

consistently effective long-term control medication. It is the only preferred treatment for mild, persistent asthma. More importantly, the new guidelines recommended use of a spacer to enhance drug delivery and minimize the possibility of potential adverse events. Azmacort is the only inhaled corticosteroid with a built-in spacer. Besides efficacy, Azmacort has an excellent safety record with about 5.3 million prescriptions. It has indications for both adult and pediatric patients. Combining all these factors, Azmacort is an important drug in the treatment of asthma and should be included on the Alaska Medicaid PDL.

Meredith Zarling: A representative of GlaxoSmithKline discussed Advair Diskus and Advair HFA. Advair should be retained as a preferred agent on the Alaska Medicaid PDL. Advair treats the two main components of asthma, inflammation and bronchial constriction. The National Heart, Lung and Blood Institute panel of experts issued very clearly defined guidelines last fall on the management of asthma. The panel concluded that strong evidence had shown that the preferred treatment for moderate to severe asthma in adults and children, greater than 5 years of age, should be the combination of an inhaled corticosteroid with a long acting beta agonist or a medium dose inhaled corticosteroid. This leaves Advair Diskus as your only choice for combination therapy in patients who are 4 to 12 years of age. Advair is the only combination product in the United States approved for COPD associated with chronic bronchitis. Unlike other combination products, Advair has been available in the United States for 7 years. It is the only combination product available in both a metered dose inhaler and an easy to use diskus device, which contains a dose counter. The dose counter allows patients to see how much drug remains in the device, improving compliance and providing patients with the ability to know how many doses remain, which can keep them from running out of the medication. No other combination product has a dose counter at this time. Advair Diskus and HFA are the only combination products available in three strengths of low, medium, and high dose corticosteroids, which allows clinicians to adjust the dose to the individual's response. Advair is a maintenance medication and improvement following administration can occur within 30 minutes of beginning treatment. All of our products include a class warning in their product labeling. Salmeterol, one of the active ingredients in Advair, may increase the risk of asthma related death. Advair should remain on the PDL without restriction based on the data, the recommendations of the guidelines, and the fact that Advair is indicated down to the age of 4, is available in three strengths, and has a dose counter.

Dan Manning: A representative of Schering-Plough discussed Asmanex. It is the only drug FDA approved for once daily administration and maintenance treatment of asthmatic patients. As of a month ago, it is indicated down to 4 years of age. Asmanex offers a proven safety and tolerability profile and side effects in clinical trials were mild to moderate. It is a dry powder inhaler and it has a dose counter on it. Asmanex is FDA approved for once daily administration and is indicated down to 4 years of age.

Dr. Sater gave the First Health presentation on Inhaled Steroids. There are six available agents. Fluticasone is available in several combinations. All agents are approved for maintenance and prophylaxis treatment of asthma. There are two major delivery devices, the dry powder inhaler and the MDI. All agents have similar efficacy and tolerability when used in equal potent doses. Other warnings, adverse drug reactions, and drug interactions are similar for all agents. In March there were 674 claims: 305 for single agent entities and 369 for the combinations. Of the single entity products, 72% for Flovent HFA and the remaining was primarily for QVAR and then split among the rest. For the combination products, 91% for Advair Diskus, less than 7% for Symbicort, and more than 2% for Advair HFA. There was extensive previous discussion about combinations, the procedure for approving combination products, the different potency of agents, and the availability of a nebulized

product. The motion to include a low to medium potency and a high potency agent, and prefer Budesonide in all forms, passed with two opposed. Since the last review, the Pulmicort Turbohaler was replaced by the Pulmicort Flexhaler. Revised asthma treatment guidelines were published as well.

Dr. Demain noted that in the summary of the Stepwise Approach for Managing Persistent Asthma from the NAEPP Expert Panel, half of the data had been excluded. He distributed a handout containing all of the data. It is important to be somewhat discriminating in this class and include low, medium and high potency formulations. There should be a strong consideration for pregnancy acceptability. The only drug that is category B in pregnancy is Budesonide. Since asthma is the most common high-risk condition of pregnancy, Budesonide plays a significant role. A recent study showed that Budesonide has a very low expression in a mother's breast milk as well. There is also some distinction among the combination products. Advair is approved down to 4 years of age in moderate to severe asthmatics. A long-acting bronchodilator, in addition to a long-acting steroid, is one of the preferred treatments. Although in children a preferred treatment is also simply increasing the inhaled steroid. Onset of action makes a significant difference when we look at Symbicort, because one of its advantages is rapid onset of action. In the European data, Symbicort is being used as an as-needed medication and a single agent, although that is not yet approved in the United States. Flunisolide is not well tolerated and has a foul taste. Another distinction among this class is particle size. When treating small airway disease, you want particles that are less than 2.5 microns. Budesonide and Beclomethasone both have those smaller particles.

DR. DEMAIN MOVED TO INCLUDE A LOW TO MEDIUM POTENCY AND A HIGH POTENCY AGENT, AND PREFERENTIALLY PREFER BUDESONIDE IN ALL FORMS. SECONDED BY DR. BERGESON.

Dr. Malter asked Dr. Demain to discuss why, when there is concern about increased mortality with the long-acting beta agonists, that step three is still preferential with long acting beta agonists as opposed to another approach.

Dr. Demain said that question has drawn considerable discussion. When we look at the weight of benefit versus the weight of the risk, the risk, although it is significant, we are still talking about fairly small numbers. The death rate is about 7 per 25,000 in that group of patients. In the study, patients were not necessary controlled on inhaled steroids. With the box warning that the FDA applied, there has been some curtailment in the use of the combined products. In previous years, anyone that coughed or wheezed was getting a combination product. The prescribing patterns are now matching up more with the recommendations of moderate to severe asthma. The warning is real, but clinicians are aware of it and are monitoring their patients.

In response to Dr. Brodsky, Dr. Demain felt inhaled steroids were clearly superior to leukotriene modifiers, which are generally used as an add-on therapy and allows us to decrease the inhaled steroid dose by 50%. Several other uses for leukotriene modifiers were discussed.

THE MOTION PASSED UNANIMOUSLY.

11. Re-review of Short Acting Beta Agonists

Meredith Zarling: A representative of GlaxoSmithKline discussed Ventolin HFA. It is a short acting beta agonist indicated for the treatment and prevention of bronchospasm and exercise induced bronchospasm in adults and children, 4 years of age and older, with reversible obstructive airway disease. Ventolin is the only brand of Albuterol that has a dose counter. This provides patients with the ability to know how many doses remain in their rescue inhaler, and perhaps keeps them from finding it empty during an asthma exacerbation. In a random telephone interview with 500 families with asthma in the United States, 25% of the patients found their inhaler empty during an asthma exacerbation. In a second survey of patients with asthma, 75% of patients did not know the number of doses remaining in their inhaler. Many patients are using an empty inhaler and putting their lives at risk, because they don't know whether their inhaler contains any more medication. It is well known that shake testing is misleading and the floatation method has been shown to be both inaccurate and potentially damaging to the product. The only FDA approved approach is for patients to keep track of doses as they use them. Based on the fact that Ventolin HFA is the only Albuterol product with a dose counter on the market, it should be available to Medicaid patients in Alaska.

Dan Manning: A representative of Schering-Plough discussed Proventil HFA. The CFC formulations of Albuterol have been phased out. Proventil HFA is indicated down to 4 years of age. Since the Albuterol products are lifesaving products, we would like the Alaska Medicaid Board to consider several products on the PDL, including Proventil HFA.

Dr. Sater gave the First Health presentation on Short Acting Beta Agonists. There are two distinct delivery mechanisms in this class, inhalers and solution for nebulization. Four agents are available as inhalers and three agents are available for nebulization. All products are indicated for the treatment of bronchospasm, are relative selective for beta-₂ receptors, and have similar efficacy and tolerability. In March there were 1,588 claims: 1,200 were for the inhaler products. Xopenex HFA is the only preferred inhaler and accounted for 36% of the market share, 21.4% for Proventil HFA, 21% for ProAir, 19% for Albuterol CFC, 2.7% for Ventolin HFA, 2 claims for Maxair and 1 claim for Alupent. For the nebulization products, generic Albuterol is our preferred agent, which accounted for 87% of the claims, 8.5% for Xopenex, 3.6% for generic Accuneb, and 1% for Accuneb. At the last review there was limited discussion on the efficacy of Levalbuterol versus Albuterol. The motion for a class effect, including at least one HFA product, passed unanimously. There have been no significant changes since the last review.

Dr. Demain felt all the products in the class worked. It comes down to side effect issues. Metaproterenol and Pirbuterol are not as beta-₂ selective and tend to have a higher rate of side effects. Since they are probably not shifting over to an HFA product, they will be going away in a few months. Levalbuterol and Albuterol are both effective. There have been reported benefits for patients using drugs containing a long-acting bronchodilator. Levalbuterol seems to be a more effective rescue therapy than Albuterol. There are studies that report lower side effect profiles for Levalbuterol, although that also is debatable. Levalbuterol and Albuterol are comparable products.

DR. DEMAIN MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE ALBUTEROL HFA, AND METAPROTERENOL AND PIRBUTEROL BE SPECIFICALLY EXCLUDED. SECONDED BY DR. LILJEGREN.

In response to Dr. Brainerd, Dr. Demain said there was an issue with Benzeconium Chloride in the multi-dose vial of Albuterol, which should not be used. Benzeconium Chloride, at certain doses, can

provoke bronchospasm. We should specify that we want the unit dose preservative free ampules, which come in a generic form as well.

DR. DEMAIN AMENDED THE MOTION TO INCLUDE ONLY UNIT DOSE AMPULES OF SOLUTION FOR NEBULIZATION. SECONDED BY DR. BERGESON. THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

12. Re-review of Long Acting Beta Agonists

Meredith Zarling: A representative of GlaxoSmithKline discussed Serevent. It is indicated for the long-term treatment of asthma for exercise-induced bronchospasm and for the prevention of bronchospasm in patients with COPD. It is approved for use in adults and children, 4 years of age and older, and has convenient dose counter. Onset of action is 30 to 60 minutes.

Dr. Sater gave the First Health presentation on Long Acting Beta Agonists. There are three available chemical entities in this class. Salmeterol is available in combination with Fluticasone. Formoterol is available in combination with Budesonide and as a solution for nebulization. Arformoterol is available only as a nebulization solution. Agents available as inhalers are indicated for maintenance treatment of asthma, exercise induced bronchospasm, and broncho constrictions in patients with COPD. Nebulized agents are only indicated for the treatment of COPD. Formoterol has a more rapid onset of action, however neither agent is currently indicated as a rescue medication. Tolerability and efficacy is equivalent among the agents. Our currently preferred agents are Foradil and Serevent Diskus. In March there were 10 claims. We had 2 claims for Brovana, which is a nebulized agent. In previous discussion, the safety issues and prior authorizations were discussed. The motion for class effect, with preauthorization required, passed with one opposed. Since the last review, Perforomist was added to the market.

The committee discussed the necessity for prior authorization for the inhalers.

DR. DEMAIN MOVED THAT FORMOTEROL AND SALMETEROL BE PREFERRED. SECONDED BY DR. MACIEJEWSKI. THE MOTION PASSED WITH ONE OPPOSED.

13. Re-review of COPD Inhalant Drugs

Rhalene Patajo: A representative of Boehringer Ingelheim discussed Spiriva. Spiriva Handihaler is indicated for long-term, once daily maintenance treatment of COPD bronchospasm associated with COPD, including chronic bronchitis and emphysema. Long-acting bronchodilators, such as Spiriva, are recommended in expert guidelines as first-line maintenance therapy. Several studies were reviewed. Treatment with Spiriva improves pulmonary function and decreases hyperinflation leading to a significant increase in medium exercise endurance time. The impact of this on exercise endurance time on activities of daily living has not been established. In clinical trials, the most commonly reported adverse drug reaction was dry mouth, which resolved over time with continuous use. Other reactions included constipation, increased heart rate, blurred vision, glaucoma, urinary difficulty, and urinary retention. As a predominantly renally excreted drug, Spiriva should be closely monitored in patients with moderate to severe renal impairment. Overall, Spiriva has an established safety profile with an estimated 8 million patients worldwide.

In response to Dr. Demain, Ms. Patajo said there were a couple of Spiriva trials that showed a slight increase in side effects with dry mouth being one of them. The recommendation is that patients taking Spiriva should not take Atrovent, but this is not a contraindication and is left up to the practitioner.

Dr. Sater gave the First Health presentation on COPD Inhalant drugs. There are two available entities in this class, Tiotropium and Ipratropium. Only the duration of action differs between the two agents. The duration of action for Ipratropium is 3 to 4 hours and up to 6 hours in some patients. The duration of action for Tiotropium is 24 hours. The adverse event profiles are similar. Combivent, Spiriva, generic Atrovent for nebulization, and Atrovent HFA are current preferred agents. In March there were 338 claims: 50% for Combivent, 24% for Spiriva, 14% for generic Duoneb, 6% for generic Atrovent for nebulization, 5.6% for Atrovent HFA, and less than 1% for Duoneb. The previous discussion centered on the use of Spiriva, its benefit in patients with moderate to severe COPD, and the Gold Guidelines. The motion for a class effect, preferentially including Spiriva and one combination product, passed unanimously. There have been no significant changes since the last review. Two letters from physicians were received asking that Spiriva be retained on the PDL.

Dr. Demain felt Spiriva was an excellent drug for the treatment of COPD and felt the recommendation from last year should be carried forward.

DR. DEMAIN MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING SPIRIVA AND AT LEAST ONE COMBINATION PRODUCT. SECONDED BY DR. BERGESON.

In response to Dr. Malter, Dr. Demain said these medications did not increase longevity of life, but clearly improved the quality of life.

THE MOTION PASSED UNANIMOUSLY.

14. Re-review of 2nd & 3rd Generation Cephalosporins

There were no public testimonies.

Dr. Sater gave the First Health presentation on 2nd Generation Cephalosporins. There are three available agents in this class. They show less gram-positive coverage, but expanded gram-negative coverage compared to 1st generation Cephalosporins. All the agents are available in generic form. The indications vary between the agents. For many community-acquired infections, these agents can be considered therapeutically equivalent. Drug interactions, contraindications, and warnings are similar among most agents, however the drug interactions and warnings for Cefaclor are poorer than the others. In March there were 82 claims: 40% for Cefprozil suspension, 26% for Cefuroxime, 11% for Ceftin suspension, 10% for Cefzil suspension, 7% for Cefprozil tablets, 2.4% for Cefaclor suspension, 2 claims for Cefuroxime suspension, and 1 claim for Cefprozil tablets. There was no previous discussion. The motion for class effect, preferentially excluding Cefaclor and including Cefzil suspension, passed unanimously.

Dr. Bergeson felt Cefaclor should be excluded from the PDL and a good-tasting pediatric formulation included. Dr. Sater noted that Cefzil was preferentially included on the PDL for its taste.

MR. GREEAR MOVED A CLASS EFFECT, EXCLUDING CEFACTOR. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

Dr. Sater gave the First Health presentation on 3rd Generation Cephalosporins. There are five available agents. The indications vary by agent. Therapeutic efficacy for many community-acquired infections is equivalent amongst the agents. The adverse reaction, drug interactions, warnings, and contraindications are similar. In March there were 388 claims: 45% for Omnicef suspension, 35% for Cefdinir suspension, 9.2% for Omnicef capsules, 6% for Cefdinir capsules, 2.5% for Vantin tablets, 1.29% for Suprax suspension, and less than 1% for the others. At the last review there was a brief discussion about the treatment of STDs and Otitis Media. The motion for class effect, preferentially including Omnicef, passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING OMNICEF ON THE PDL. SECONDED BY DR. DEMAIN.

Ms. White noted that if the six-month window for generic Omnicef had passed, it might not be necessary to include branded Omnicef on the PDL. The committee discussed the fact that branded Omnicef had been included on the PDL for its taste and discussed whether the generic would be acceptable.

DR. BERGESON MOVED TO MODIFY THE MOTION TO MAKE IT A CLASS EFFECT, PREFERENTIALLY INCLUDING CEFDINIR ON THE PDL. THE SECOND CONCURRED. THE MOTION PASSED WITH ONE OPPOSED AND ONE ABSTAINING.

THE MOTION, AS AMENDED, PASSED WITH ONE OPPOSED AND ONE ABSTAINING.

15. Re-review of 2nd and 3rd Generation Quinolones

Fred Meister: A representative of Schering-Plough discussed Avelox. The committee is familiar with the drug Avelox, its indications and safety profile. You have experience with the drug since it is currently on the PDL. It is the only drug in the class that has an indication for monotherapy for Intra-abdominal infections. Fluoroquinolones have been shown to be fairly equivalent in efficacy with regard to the approved indications. The recommendations of the IDSA indicate that when selecting a fluoroquinolone, you should use the most active agents, Moxifloxacin or Gemifloxacin, due to the lower incidents of propagating resistance. A safety study was reviewed. Avelox has been shown to have the potential to decrease the propagation of bacterial resistance.

Levita Hidayat: A representative of Ortho McNeil discussed Levaquin. Levaquin is the fluoroquinolone of choice due to its utility, retained susceptibility and its outstanding efficacy and safety profile. In the State of Alaska, Levaquin has 93% formulary compliance. All Alaska hospitals, except for the Veterans Administration, have Levaquin on their formulary. Placing Levaquin on the PDL will allow continuity of care. Levaquin has retained susceptibility and excellent in vitro of gram-negative and gram-positive. In Alaska, Levaquin maintained more than 98% activity against *S. pneumoniae* in the past 11 years. We currently have 11 FDA approved indications and an outstanding efficacy in a variety of infections including respiratory tract, urinary tract infections, and others. We have three approved indications for high dose, short course therapies. Over 500 million patients

worldwide have used Levaquin. The most common adverse reaction is headache, constipation and dizziness. Several trials have demonstrated comparable safety from 750 milligrams to 500 milligrams.

Dr. Sater gave the First Health presentation on 2nd Generation Quinolones. There are three available agents in the class. All the agents are effective for UTI. Other indications vary between the agents. Ciprofloxacin is the only agent available in suspension. Adverse events, drug interactions, warnings, and contraindications are all similar for the drugs in this class. In March there were 148 claims: 140 for Ciprofloxacin tablets, 5 for Cipro suspension, and 3 for Ofloxacin. There was no previous discussed. The motion for a class effect passed unanimously.

Dr. Liljegren felt Noroxin should not be included in class effect.

DR. BERGESON MOVED A CLASS EFFECT. DR. LILJEGREN MOVED TO AMEND THE MOTION TO EXCLUDE NOROXIN FROM THE PDL. DR. DEMAIN SECONDED THE MOTION AND THE AMENDMENT. THE MOTION, AS AMENDED, PASSED WITH ONE ABSTAINING.

Dr. Sater gave the First Health presentation on 3rd Generation Quinolones. There are three available agents in the class, two of which are widely used. They are FDA approved for a variety of indications. There is no clinical evidence to suggest the superiority of one agent over another for respiratory infections. All agents are dosed once daily. In March there were 212 claims: 193 for Levaquin. After limited discussion at the last review, the motion for a class effect, preferentially including Levaquin, passed unanimously.

DR. MACIEJEWSKI MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING LEVAQUIN ON THE PDL. SECONDED BY DR. LILJEGREN. THE MOTION PASSED WITH THREE OPPOSED.

16. Re-review of Ophthalmic Anti-allergy Agents

There were no public testimonies.

Dr. Sater gave the First Health presentation on Ophthalmic Anti-allergy Agents. There are six available agents in this class. All except Alrex are approved for allergic conjunctivitis, which is for seasonal allergic conjunctivitis. They have slightly different mechanisms of action. Head-to-head trials are often limited by comparing agents with a single mechanism of action to agents with multiple mechanisms of actions, and differences in measuring and defining outcomes or study design. In March there were 78 claims: 76% for Patanol, 22% for Pataday, which is essentially the same product, and only 2 claims for something else. The clinical superiority of Patanol was briefly discussed in the last review. The motion for a class effect, with Patanol preferentially included for all ages, passed unanimously.

Dr. Demain felt Patanol and Pataday were the same, but one is dosed once a day and the other is twice a day. They are very well tolerated and do not burn the eyes. Patanol also has other indications that the others do not have. Patanol is a superior product and the one most widely used.

DR. DEMAIN MOVED A CLASS EFFECT, TO INCLUDE OLOPATADINE, IN SOME FORM, ON THE PDL. SECONDED BY DR. MACIEJEWSKI. THE MOTION PASSED UNANIMOUSLY.

17. Re-review of Ophthalmic Mast Cell Stabilizers

There were no public testimonies.

Dr. Sater gave the First Health presentation on Ophthalmic Mast Cell Stabilizers. There are four available products in this class. All are approved for allergic conjunctivitis. Some are approved for other things as well. There is minimal systemic bioavailability and minimal systemic effects. In March there were 2 claims, both for generic Cromolyn. There was no discussion at the last review. The motion for a class effect passed unanimously.

DR. DEMAIN MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Ophthalmic Antibiotics/Quinolones

There were no public testimonies.

Dr. Sater gave the First Health presentation on Ophthalmic Antibiotics/Quinolones. There are five available chemical entities. All agents are FDA indicated for bacterial infections. Ciloxan, Iquix, and Ocuflox are also indicated for corneal ulcers. All agents have similar adverse event profiles and efficacy. In March there were 122 claims: 44% for Vigamox, 26% for Ofloxacin drops, 19.7% for Ciprofloxacin drops, 5.7% for Zymar, and 4.1% for Ciloxan drops. At the last review there was a brief discussion of potentially limiting use of the drugs in this class. The motion for a class effect passed unanimously without restrictions. Since the last review, Iquix was added to the market.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of Ophthalmic Immunomodulators

There were no public testimonies.

Dr. Sater gave the First Health presentation on Ophthalmic Immunomodulators. There is one agent in this class, Restasis. It is approved for keratoconjunctivitis sicca, which is dry eye disease. There was no discussion at the last review. In March there were 16 claims for Restasis, which is the preferred agent and the only drug in the class. The motion to prefer Restasis passed with two opposed.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. GALE. THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Hepatitis C Agents

Vandana Slatter: A representative of Roche discussed PEGASYS. The CDC estimates 3.2 million Americans are chronically infected with hepatitis C virus, which is the leading indication for liver transplantation. At least 30% of HIV infected patients are co-infected with HCV, which has emerged as a major cause of morbidity and mortality in these patients. Selection of the most effective HCV treatment regimen is of critical importance. Since FDA approval in 2002, PEGASYS with Ribavirin has become the most prescribed treatment for patients infected with chronic hepatitis C for five main reasons. First, PEGASYS is the only pegylated interferon approved alone or with Ribavirin for the broadest range of FDA indications. Second, a wealth of clinical data supports the PEGASYS label, some of which were discussed. In 2007, the American Association of Liver Diseases published updated hepatitis B virus guidelines, including PEGASYS as the first-line therapy for chronic hepatitis B viruses. Third, PEGASYS offers durability of response and tolerability. Greater than 99% of patients who achieve an SVR following PEGASYS, along or with Ribavirin, remain HCV RNA negative for up to five years. Fourth, PEGASYS is easy to use. Fifth, Roche remains committed hepatology with an extensive pipeline and continued research to improve response rates.

Isaac Lloyd: A representative of Schering-Plough discussed PEG-Intron. Currently there are very few options for the treatment of patients with hepatitis C. There are three areas that are unique to PEG-Intron. It is a weight-based dose interferon. Since 1960 the average weight of both men and women in the United States has increased by 25 pounds. According to the Alaska Behavioral Risk Factor Surveillance, in Alaska the average weight of males is 194 pounds and females is 158 pounds. Patients weighing more than 165 pounds have a lower sustained virological response rate with flat dose interferon based therapy. PEG-Intron offers individualized weight based dosing at 1.5 micrograms per kilogram per week. In published studies, weight based PEG-Intron and Ribavirin demonstrates similar response rates regardless of weight. PEG-Intron has also demonstrated low relapse rates. We offer a support service for PEG-Intron patients, which is a free service provided by Schering-Plough. It is available to all Medicaid patients and is offered in multiple languages. Each patient will be teamed with nurse/counselor. In addition, it is the only toll-free, 24-hour a day, 7-day a week service available to speak with a live nurse. There are also clinical consultants that are available in every state to provide appropriate staff support at the clinical level. PEG-Intron should be added to the PDL for the treatment of patients with hepatitis C.

Dr. Sater gave the First Health presentation of Hepatitis C Agents. There are two available agents in this class. They have similar adverse drug reaction profiles, drug interactions, warnings and contraindications. Head-to-head trials are small and usually open label, but sustained virological response rates appear to be similar with both agents. In March there were 7 claims: 4 for PEGASYS and 3 for PEG-Intron. There was no discussion at the last review. The motion for a class effect passed unanimously. Dr. Sahagun prefers PEG-Intron in his patients, because of weight base dosing. However, the hepatologist at ANMC would like to see both on the PDL, because there are specific needs for both agents. PEGASYS is currently the preferred agent on the PDL.

Dr. Demain noted that although there were not a lot of claims in this class, it was a high cost item. Dr. Sater said preferring both agents could have a significant cost differential, because interferons to treat hepatitis C averages \$15,000 to \$20,000 per year. It was noted that the medical necessity clause could be used to prescribe whichever drug did not make it on the PDL.

DR. DEMAIN MOVED A CLASS EFFECT. SECONDED BY DR. MACIEJEWSKI.

Dr. Richey noted that it was inappropriate to make the decision based on the cost of the drugs.

THE MOTION PASSED UNANIMOUSLY.

Dr. Sater gave the First Health presentation on Ribavirin products. There are three branded and generic Ribavirin products available in tablets, capsules and solution. The efficacy, adverse drug reactions, warnings, contraindications, and drug interactions are all similar. In March there were 7 claims: 6 for generic Ribavirin and 1 for branded Ribasphere. There was no discussion at the last review. The motion for a class effect passed unanimously.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

21. Re-review of Anti-herpes Agents

Steve Lukshin: A representative of GlaxoSmithKline discussed Valtrex in the treatment of HSV disease. Valtrex is the L-valyl ester product of Acyclovir and is rapidly converted to Acyclovir, which has affinity for the viral enzyme thymidine kinase encoded by HSV and VZV. Valtrex offers consistently greater bioavailability than oral Acyclovir at any dose. In comparing package inserts between the two products, Valtrex has a bioavailability of 45% while Acyclovir is between 10-20%. In the opening paragraphs of the August 2006 CDC STD Treatment Guidelines, the authors state that at least 50 million persons in the United States have genital infections and that the majority of patients effected with HSV have not been diagnosed with genital herpes. Many patients have mild or unrecognized infection, but shed intimately in the genital tract. The majority of genital herpes infections are transmitted by persons unaware that they have the infection or who are asymptomatic when transmission occurs. On the topic of suppressive therapy for recurrent genital herpes, the CDC states that the quality of life is frequently improved in patients with frequent reoccurrences that receive suppressive therapy compared with episodic treatment. It concludes by stating that daily treatment with Valtrex, 500 milligrams, decreases the rate of HSV transmission. Furthermore, under the section entitled Counseling of its STD Treatment Guidelines, the authors stress the importance of the role the provider has to his patients by stating that the goal of counseling is to help patients cope with the infection and to prevent sexual transmission. Persons with genital herpes should be educated concerning the history of the disease with an emphasis on the potential for recurrent episodes, shedding, and the attended risk of sexual transmissions. The CDC ends this section by stating the risk of HSV-2 sexual transmission can be decreased by the use of Valacyclovir by the infected person. Valtrex should be retained on the Alaska Medicaid PDL.

Dr. Sater gave the First Health presentation on Anti-herpes Agents. There are three available agents in this class. All agents are FDA indicated for the treatment of genital herpes infections, both acute and suppressive therapy, and varicella-zoster. Acyclovir is also indicated for the treatment of Varicella. Valacyclovir and Famciclovir are indicated for the treatment of herpes labialis or cold sores. Acyclovir is available in a number of dosage forms. The efficacy, adverse drug reaction profiles, and drug interactions are similar for all agents. Every agent except generic Famciclovir is preferred. In March there were 222 claims: 56% for Valtrex, 29% for Acyclovir tablets, 6% for Acyclovir suspension, 6% for Famciclovir, and 2.7% for branded Famvir. There was no discussion at the last review. The motion for a class effect, to include one oral agent, passed unanimously. Since the last review, generic Famvir became available on the market.

In response to Dr. Demain, Dr. Richey said all the drugs in this class were well tolerated in pregnancy. Pregnant women who have trouble with nausea do not like to take Acyclovir multiple times a day and prefer a once- or twice-a-day preparation.

DR. KILEY MOVED A CLASS EFFECT, TO INCLUDE A ONCE-A-DAY PREPARATION ON THE PDL. THE MOTION FAILED DUE TO LACK OF A SECOND.

DR. KILEY MOVED A CLASS EFFECT, TO INCLUDE A ONCE- OR TWICE-A-DAY PREPARATION. THE MOTION FAILED DUE TO LACK OF A SECOND.

In response to Dr. Demain, Dr. Richey said pregnant women could not tolerate Acyclovir, 800 milligrams twice a day, either.

DR. BRIGGS MOVED A CLASS EFFECT. SECONDED BY DR. GALE. THE MOTION PASSED WITH FOUR OPPOSED.

22. Re-review of Anti-fungal Onychomycosis

There were no public testimonies.

Dr. Sater gave the First Health presentation on Anti-fungal Onychomycosis. Previously, we discussed the Terbinafine Sporanox group and Griseofulvin together. Last year, we added Ciclopirox, the topical agent to this group. There are four available agents in this class, Terbinafine, Itraconazole, Griseofulvin in a number of forms, and Ciclopirox. Three are oral and one is topical. Griseofulvin is fungi static where the others are fungicidal. Ciclopirox is a chelating agent that inhibits fungal growth. Differing formulations of Griseofulvin alter the GI absorption of that drug. Griseofulvin has a less attractive and unique adverse drug reaction profile. The adverse drug reactions with Lamisil and Sporanox are similar. In March there were 46 claims: 34 for either Terbinafine or Sporanox; 80% for generic Terbinafine, 12% for Sporanox capsules, and 9% for generic Itraconazole. In the Griseofulvin grouping, Griseofulvin oral suspension accounted for 60% of the claims, 30% for Grifulvin V tablets, and 10% for Grifulvin V suspension. There was one claim each for branded Penlac and generic Ciclopirox topical. After a very brief discussion, the motion for a class effect passed unanimously. Since the last review, generic Penlac has become available.

Dr. Liljegren felt Griseofulvin should not be the only agent available on the PDL.

DR. LILJEGREN MOVED THAT THE ORAL MEDICATIONS WERE A CLASS EFFECT, BUT GRISEOFULVIN NOT BE THE ONLY ORAL AGENT AVAILABLE ON THE PDL. SECONDED BY DR. RICHEY. THE MOTION PASSED WITH ONE OPPOSED.

23. Review Minutes from November 16, 2007 and January 18, 2008 meeting

Mr. Campana reviewed the meeting minutes. Dr. Gale noted that she had attended the November meeting in person.

WITHOUT OBJECTION, THE MEETING MINUTES FOR NOVEMBER 16, 2007, WERE APPROVED UNANIMOUSLY.

WITHOUT OBJECTION, THE MEETING MINUTES FOR JANUARY 18, 2008, WERE APPROVED UNANIMOUSLY.

24. Final Comments by Chair or Other Members

Dr. Brodsky welcomed Dharna Vakharia Begich as a new committee member. At the last meeting, we talked about the public testimonies by pharmaceutical representatives. A handout outlining what other state did was distributed and reviewed. Most states allow 2 to 5 minutes, but other states do other things. Maryland holds a lottery and only allows 12 pharmaceutical representatives and 3 consumers to testify. We used to allow 5 minutes, but reduced it to 3 minutes.

DR. RICHEY MOVED TO KEEP THE PUBLIC TESTIMONIES BY PHARMACEUTICAL REPRESENTATIVES AT 3 MINUTES. SECONDED BY DR. LILJEGREN. THE MOTION PASSED WITH ONE OPPOSED.

Dr. Brodsky reminded the committee members that they must sign the sign-up sheet in order to receive their honorariums.

Mr. Campana asked if the committee wanted to continue to re-review all the classifications on a yearly basis. We prefer the format of holding only four meetings a year. A few more drug classes will be added to the PDL next year, which will increase the amount of classes reviewed at each meeting. Montana uses a color code system. The “green” classes, which have no new drugs, indications, or studies, are listed on the agenda, but no public testimony is taken. The “orange” classes, which are all preferred, the P&T deemed them a class effect, and there were no changes, is listed on the agenda and can be reviewed at the discretion of the committee. The “red” class, which is a new class or there is new information available, would be reviewed by the committee.

DR. BERGESON MOVED TO ADOPT THE MONTANA MODEL.

Dr. Malter suggested that committee members should have the opportunity to flag a “green” class for review at the next meeting in case they have any concerns.

Dr. Demain asked how the Montana model would affect the bidding process. Dr. Sater described how the process worked in Montana. They go with the last clinical recommendation of the committee. For example, if there is no new information or clinical reason to review a class, the last recommendation of the committee carries forward. In the bidding process the agents could change, but that would be unlikely. This model would free the committee up from revisiting classes where there is no new information or clinical reason to revisit the data, thus allowing you to focus on things that may be more clinically relevant.

In response to Dr. Demain, Mr. Campana said any class that had a new product, new information, or new warnings would be re-reviewed.

In response to Dr. Briggs, Dr. Sater said a classification could be reviewed at the request of a committee member. The agenda could be sent out for comments before it was posted.

In response to Dr. Demain, Dr. Sater said a drug class that received a Cochran report could be put in the “orange” category where the committee would decide whether or not they wanted to review it.

Mr. Campana said he would review the bylaws to see what it would take to move to the Montana model. The Montana model fits within the regulations. New regulations will be coming out for public comments this spring and could be adjusted if necessary to accommodate the Montana model.

SECONDED BY DR. DEMAIN, WITH THE PROVISION THAT ANY COMMITTEE MEMBER COULD REQUEST A CLASS REVIEW.

Dr. Brodsky said the motion could be voted on today, but the details of the plan would need to be reviewed. Mr. Campana said the Montana-type agenda and an explanation would be distributed to the committee members for review.

THE MOTION PASSED UNANIMOUSLY.

Mr. Campana said there would be some new classes on the next agenda. It may be necessary to hold five meetings next year, but with the new Montana model we may be able to keep it at four meetings. The Pharmacy Program is doing very well. The committee members were thanked for all of their hard work. The program compliance rate is in the high 80% range.

25. Adjourn

WITHOUT OBJECTION, THE MEETING WAS ADJOURNED AT 11:05 A.M.