

**ALASKA MEDICAID  
PHARMACY AND THERAPEUTICS COMMITTEE**

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

**FINAL MINUTES OF MEETING  
November 14, 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  
Kelly C. Conright, MD (telephonic)  
Lucy Curtiss, MD  
Jeffrey G. Demain, MD  
Traci Gale, PharmD. (telephonic)  
Vincent Greear, R.Ph.  
Daniel P. Kiley, DDS, MPH  
Diane Liljegren, MD (telephonic)  
Claudia Phillips, MD  
Sherrie D. Richey, MD  
Janice L. Stables, MSN, ANP  
Trish D. White, R.Ph. (telephonic)

**Committee Members Absent:**

Andrzej Maciejewski, MD

**Others Present:**

David Campana, R.Ph.  
Melinda Sater, Pharm.D., First Health  
Alex Malter, MD, HCS  
Jeff Monaghan, Pharm.D.

**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 / Health Practitioners**

*(Note: Recording stopped midway through the roll call and started again toward the end of Dr. Stark's comments.)*

**Dr. Hugh Stark:** A psychiatrist with Counseling Solutions discussed the PDL and expressed his appreciation of the “medically necessary clause” in the process.

Dr. Brodsky explained that the PDL was a preferred drug list and not a closed formulary. A physician can prescribe any medication to their patients by writing “medically necessary” on the prescription. The goal of the PDL is to get the best pricing available for the Medicaid system so as much care as possible can be provided.

**Dr. Samson:** A local psychiatrist discussed the antipsychotics. New and improved drugs are continually coming out. Research provides new uses of the older antipsychotics as well. It is imperative that we do not endorse the old-style atypical agents, because they have destructive effects on a patient’s social behavior, cognitive behavior and neurological wellbeing. I have contemplated having “medically necessary” printed on my prescription forms, because I consider it to be medically necessary any time I write a prescription. I encourage the committee to add new drugs to the PDL, which will allow patients that have not benefitted from current treatment to be able to be treated successfully.

**Dr. Janet DiPreta:** A psychiatrist at Anchorage Community Mental Health Service discussed the cost of antipsychotics. Medications represent only one part of the direct cost, which also include inpatient and outpatient treatment, long-term living placements, and even DOC. In 2002, the total amount of direct costs was \$24 billion, of which medications were only \$5 billion or 21%. The portion of cost has shifted with the introduction of atypical antipsychotics. This means that our patients are doing better and staying out of the hospital, not that the atypical antipsychotics cost more. Indirect costs of schizophrenia represent the loss of productivity of our patients and the decreased productivity of their family and caregivers. Indirect costs totaled \$39 billion, which is more than half of the total cost of care. This brings the cost of all medications, not just the antipsychotics, down to 8% of the total cost. Antipsychotics are the most effective tool we have in treatment and the other services depend on the medications working. We should focus on utilizing all six of the atypical drugs freely to maximize decreasing symptoms and improving functions, thereby decreasing the costs that come about by our patients not getting better. Restricting the atypical drugs will limit opportunities for recovery, which will ultimately increase society’s total economic burden of schizophrenia.

**Dr. Alex Von Hafften:** A psychiatrist based in Anchorage discussed antipsychotics. The various classes we are discussing include anxiety, depression, and psychosis. Relatively speaking, we are talking about a very common set of illnesses, syndromes, and symptoms. To properly evaluate and treat psychiatric symptoms or illnesses, it requires a perspective of various sets of dimensions. We need better medications and better systems of care. Too often, the most debilitating illnesses that we treat are crisis driven rather than being proactive. The evidence is starting to show that what we are labeling as psychiatric illnesses are probably more psychological and behavioral symptoms of underlying multi-system illnesses. (*Recording problems.*) The process of the PDL is quality of care, trying to look at evidence-based medicine. With a lot of psychiatric illnesses, after you get to stages two or three there is very limited evidence to tell you exactly what should be done. Access to care and the most efficient allocation of resources is important. If a medication is necessary, it is available by writing “medically necessary” and grandfathering. The third item is reviewing the classes. The most controversial for today is the atypical agents, of which there are six basic medications. They are not therapeutically equivalent or interchangeable, therefore looking at them as a class has significant limitations. The evidence would suggest that Clozapine is the most effective, but it is also the most

problematic and took the longest for the FDA to approve due to its significant potential adverse side effect profile. I would recommend at least one either generic or brand name from each of the six drugs. In the SNRI/NSRI category (*Recording problems*). The antidepressants, other, may have similar efficacy, but they have different mechanisms and are not really a single class. One of each of the agents in that group, preferring a long-acting for better tolerability and higher patient adherence, is recommended. For the SSRI stimulants and sedative/hypnotics, I felt that the motions presented last year were good. For the first generation anticonvulsants, I felt that the motions presented last year were good. The second generation anticonvulsants are not a single class and I would recommend a brand or generic of each of the agents. For the atypical agents, one of each of the six, either brand name or generic, should be included on the PDL.

**Dr. Vern Stillner:** A psychiatrist at Bartlett Regional Hospital in Juneau spoke in favor of retaining the most liberal PDL in the United States. Open access for psychotropic is important for the patient, the clinician, and for the payer. It is incumbent that the prescriber be able to use the broadest range of medications available to decrease the effects of a patient's psychosis and depression. Literature shows us that the sooner that we control the psychotic process, less damage occurs in terms of ongoing illness in both schizophrenia and bipolar illness. The element of acute stabilization and treatment is very important and we need maximum prescribing freedom, which we have through the current PDL process. Mr. Campana has come up with a good plan to liberalize the Clozapine prescribing process, which I support. The following recommendations were made: retain the second generation psychotropics, include Lexapro on antidepressants list, include Cymbalta and Effexor on the SSNRI list, and include Rozerem on the sedative/hypnotic list.

#### **4. Review of Atypical Antipsychotics (Red Category)**

**Stephan Cheng:** A representative of Eli Lilly discussed Zyprexa (Olanzapine). When evaluating clinical effectiveness there are measurable differences between agents, which is where the clinical and financial value of Zyprexa has been clearly demonstrated. Zyprexa results in better use patterns. Several studies were discussed. Zyprexa patients stay on therapy longer. Olanzapine use is associated with greater adherence to medication therapy for longer period of time relative to other antipsychotics. Zyprexa also results in fewer psychiatric hospitalizations compared to other antipsychotics. The evidence has demonstrated an association between Olanzapine use and comparable or lower total direct healthcare service expenditures relative to other antipsychotics. Comparable or lower overall direct healthcare expenditures are seen, despite the higher drug acquisition cost of Zyprexa, driven primarily by lowered in-patient hospitalization rates and costs. Zyprexa should be considered for the PDL.

**Kim Laubmeier:** A representative from Bristol-Myers Squibb discussed Abilify (Aripiprazole). The three key areas to be considered are indications, unique mechanism of action, and important safety information. Aripiprazole is currently FDA approved for 13 indications, which were reviewed. The extensive safety and efficacy data of Aripiprazole in pediatric patients was reviewed. Aripiprazole has unique pharmacological properties relative to the other atypical antipsychotics. The efficacy of Aripiprazole is thought to be mediated through a combination of partial antagonist activity at D-2/D-3, and serotonin 1-A receptors and antagonist activity at serotonin 2-A receptors. There are two boxed warnings, increased mortality in elderly patient with dementia related psychosis and suicidality in antidepressant drugs. Aripiprazole should remain as a first line atypical antipsychotic on the PDL.

**David Gross:** A representative of Pfizer discussed Geodon (Ziprasidone). Geodon provides proven efficacy in both schizophrenia and acute bipolar manic and mixed episodes with a well established safety and favorable tolerability profile. It has a neutral effect on weight and metabolic parameters, with some evidence showing improvements in these metabolic parameters. This favorable metabolic profile may benefit patient's long-term health in terms of greater potential reduction in the risk of developing diabetes and heart disease relative to some of the other atypical antipsychotics. This is important, because it is common in schizophrenia and bipolar disorder to have a significant rate of co-morbid medical conditions such as cardiovascular disease, obesity, diabetes, HIV infection and hepatitis, which translates into a significant elevation in mortality and reductions in lifespan on average of 25 years in this patient population. Several clinical trials were discussed. Geodon is available both as an oral capsule and an IM formulation. Geodon has several therapeutic benefits and proven advantages over other agents in this class. It provides powerful efficacy without compromising overall patient health. Geodon should be available on the PDL.

**Elham Tabarsi:** A representative of AstraZeneca discussed Seroquel XR (Quetiapine). AstraZeneca supports maintaining open access for the class of atypical antipsychotic agents. Seroquel XR is FDA approved for the treatment of schizophrenia, bipolar mania as either monotherapy or adjunct therapy, bipolar depression, and maintenance treatment for bipolar 1 disorder as adjunct therapy. Seroquel XR was developed to allow once a day dosing, instead of the two to three times a day dosing for the Seroquel immediate release formulation. Seroquel XR and Seroquel have the following boxed warnings. Elderly patients with dementia related psychosis are at increased risk of death compared to placebo. Antidepressants increase the risk of suicidal thinking and behavior in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders. Seroquel XR and Seroquel are not approved for use in elderly patients with dementia related psychosis or for those under the age of 18. Please refer to the prescribing information for a complete listing of precautions and warnings. The most commonly observed adverse events associated with the use of Seroquel XR and Seroquel include dry mouth, sedation somnolence, dizziness, and constipation. Seroquel XR is the first medication approved by the FDA for the once-daily acute treatment of both depressive and manic episodes associated with bipolar disorder. Seroquel XR offers the convenience of once-daily dosing, achieving the recommended dose range by the second day of treatment. Seroquel should be included on the PDL.

**Jeanette Grasto:** A member of NAMI Alaska, which is committed to the health and welfare of persons living with mental illnesses. As part of our commitment, we advocate for appropriate access to treatment and support recovery. We believe that individuals with brain disorders must have access to treatments that have been recognized as effective by the FDA or the National Institute of Health. We strongly oppose measures that limit the availability and rights of individuals with brain disorders to receive treatment with new generation medicines. As a matter of policy, we do not endorse any particular treatment or medication. We believe that the clinical decisions should be made by the consumer and their doctors, not a government entity. Those decisions should take into account past treatment history, other medical conditions, potential drug interactions, patient preference, side effects, tolerability, and other important clinical factors. The atypical antipsychotics are largely unrelated medications with unique mechanisms of action and cannot take the place of each other. For many people, atypical antipsychotics play an important role in their recovery by offering relief in the most debilitating symptoms of mental illness. Finding the right medication is critical, because failure to respond or tolerate a medication can lead to costly and devastating relapses. A psychotic or manic episode can result in lasting cognitive impairment, emergency room visits, hospitalization, and even

homelessness, incarceration, and suicide. Ms. Grasto shared her personal story with the committee, which included both of her children being bipolar and her brother being schizophrenic.

**Francine Harbour:** The president of NAMI Alaska discussed the use of atypical antipsychotic drugs. We do not believe the atypical antipsychotic care interchangeable. She shared her personal story. She has bipolar I disorder with mixed states and chronic post traumatic stress disorder. She discussed her medical history and noted that it took six years for her to get the right mix of medications. Geodon was like a miracle drug and took care of the irritability and the meanness within days and should remain on the PDL.

**James Johnson, Sr.:** Francine Harbour submitted and read letters from James Johnson, Sr., and David Citizen (who did not want his full name disclosed), describing their personal stories. James Johnson, Sr., has a son who was diagnosed five years ago with paranoid schizophrenia. He has been in and out of jail over a dozen times due to the lack of effectiveness of his medications. His son's medical history was outlined and it was noted that it was important that mentally ill people have open access of medications. David Citizen's letter outlined his personal experience. Over a period of two and a half years, he and his doctor tried numerous combinations of psychotropic drugs, including two hospital stays and a stay at API, before discovering a successful combination of drugs that adequately attenuated his symptoms of schizo-affective disorder. He advocated for doctors to have open access to drugs to treat people with mental illnesses.

**Mike Coutririer:** A sergeant with the Anchorage Police Department outlined his personal history, including 12 years with the Anchorage Police Department and a 20-year retired Army soldier and officer. I deal with the casualties of a system that does its best, but doesn't always get there. I am part of the original Crisis Intervention Team. I have gone around the State of Alaska helping other police departments, consumer advocacy groups, and small town governments deal with the interaction between law enforcement and consumers. The committee says they are not limiting access, but trying to expand Medicaid's availability, which we appreciate. We also appreciate the fact that you have cost control issues to deal with, which I understand. The eventuality of a social medicine situation is that things get tighter and tighter, and the composition of the committee will change with time. We are not worried about the availability of these drugs today, but the availability of them tomorrow. My daughter, who has had MS for six years, was just granted handicap status on Tuesday, but it took six years. We are all afraid of this turning into that. Please do not let that happen.

**Jackie Panene:** A board member of Fairbanks NAMI and a parent of a child with paranoid schizophrenia discussed her son's medical history. Doctors need to have the freedom to work with their patients to find the medications that work for them. Bringing patients out of psychosis, but leaving them with no life, is not a good option. The cost of hospitalization has got to be far more than putting them on a good medication that gives them a life. Anyone who has experienced having their child's quality of life taken away, and then getting it back through medication, would be willing to pay anything for that. The providers need to be allowed the freedom to interact with their patients to decide what is best for them without being restricted to a list. On behalf of NAMI of Fairbanks, as well as everyone with ill family members, we would like to see the best medications available on the PDL.

Dr. Brodsky noted that utilizing the medically necessary clause does not require anything other than having the physician decide which drug is necessary and writing "medically necessary" on the prescription. All drugs are available.

Dr. Sater gave the First Health review of Atypical Antipsychotics. There are seven available chemical entities, nine available products, and one combination with Fluoxetine. All the single entity products are indicated for the treatment of schizophrenia. Other indications vary by product. These agents were developed in response to problems with the atypical older agents, including lack of efficacy, lack of improvement in negative symptoms, and troublesome adverse drug reactions. Agents are all serotonin dopamine antagonists, although specific receptor binding and affinity varies widely between agents. All agents carry a boxed warning regarding use in elderly patients with dementia related psychosis, and there are numerous other boxed warnings that vary by agent. Clozapine carries more warnings and contraindications than any other drug in this class. All drugs carry a warning about hyperglycemia, sometimes extreme and associated with diabetic ketoacidosis or hyperosmolar coma or death. The newer agents do not demonstrate the level of evidence for hyperglycemic or metabolic issues as the older agents. In September there were 4,908 claims: 25% for Seroquel, 20% for Abilify, 15% for Zyprexa, 14% for generic Risperdal, 9% for branded Risperdal, 7% for Geodon, and the rest of the drugs in combination made up about 6%. This is a new drug class and there is a wealth of psychiatric expertise at the meeting.

Dr. Curtiss, after talking with colleagues, reading and thinking out this, said she had come to the conclusion that all six agents should be included on the PDL.

**DR. BRIGGS MOVED A CLASS EFFECT AND ALL AGENTS SHOULD BE INCLUDED ON THE PDL. SECONDED BY DR. LILJEGREN.**

Dr. Curtiss asked for clarification on “class effect.” Dr. Brodsky agreed that this was not a class effect and all the drugs should be available on the PDL. The committee discussed how specific the motion needed to be. In response to Dr. Sater, Dr. Curtiss said all the single entity agents should be included on the PDL. Dr. Sater suggested having the motion say, “include every chemical entity.”

**DR. BRIGGS WITHDREW HER MOTION. THE SECOND CONCURRED.**

**DR. BRIGGS MOVED A CLASS EFFECT TO INCLUDE ONE OF EACH CHEMICAL ENTITY ON THE PDL. SECONDED BY DR. LILJEGREN.**

The committee discussed the motion. Dr. Richey felt it was contradictory to declare a class effect and include all the chemical entities and would therefore vote against the motion. In response to Dr. Gale, Dr. Sater said the motion would include at least one product from each chemical entity, which would not ensure both short- and long-acting agents in each entity.

In response to Dr. Brainerd’s question on the medically necessary process and the possibility of the structure of the PDL changing in the future, Dr. Malter said he had not heard of any plans to change the structure of the PDL. Mr. Campana said the process was good, compliance was good, they were saving money, and he did not foresee any changes to the process.

Dr. Malter discussed Dr. Richey’s concern with declaring a class effect and including all the entities on the PDL. As I understand the process, by calling this a class effect, even if we include all the agents, it allows our intermediaries to negotiate in a different manner with the various drug manufacturers.

The committee further discussed the motion. Dr. Briggs noted that each agent worked differently and was not as effective for each patient, but all the agents work within these groups of indications. Dr. Brodsky suggested changing the motion to recommend including one of each chemical entity, rather than declaring a class effect. In response to Dr. Conright, Dr. Curtiss felt generic versus brand name was not a significant issue within this group of medications. Dr. Brodsky noted that the prescriber could always write “no generic substitution” on the prescription. In response to Dr. Carlson, Dr. Bergeson said the drugs were all clinically effective, but they were not a class effect. Dr. Demain felt the term “class effect” would improve the negotiating position. Dr. Sater said declaring a class effect would not make a difference in negotiating costs. Her interpretation of the motion was a class effect, or these agents are all effective for their respective indications, and including at least one representative agent in each chemical entity, but we will take more if it is cost beneficial or cost neutral. If the motion says you want to include one of each chemical entity then that is exactly what you will get. Mr. Greear felt the motion reflected the importance of including all of the chemical entities. Dr. Richey suggesting revising the motion to “include at least one from each chemical entity” and not declaring a class effect.

*(Teleconference problems, participants disconnected. Problem resolved.)*

Dr. Monaghan suggested using the term “therapeutic alternatives” rather than “class effect.” The committee concurred.

**DR. BRIGGS WITHDREW HER MOTION. THE SECOND CONCURRED.**

**DR. BRIGGS MOVED ALL THE MEDICATIONS WERE THERAPEUTIC ALTERNATIVES AND AT LEAST ONE OF EACH CHEMICAL ENTITY SHOULD BE INCLUDED ON THE PDL. SECONDED BY DR. RICHEY. THE MOTION PASSED UNANIMOUSLY.**

## **5. Re-Review of Anticonvulsants, 2nd Generation (Red Category)**

**Matthew Bourne:** A representative of UCB discussed Keppra XR, a new advance in anti-epileptic drug treatment. Keppra XR should be added to the PDL. Despite the availability of numerous commercial available AEDs, approximately one million patients in the U.S. remain refractory to treatment, suffering with uncontrolled seizures. Non adherence to epilepsy medication is prevalent and can have devastating consequences such as breakthrough seizures, driving accidents, falls, fractures, hospitalization, and even death. Non compliance increases in-patient and emergency room costs, is more frequent in patients that suffer from side effects, and is the most frequent cause of breakthrough seizures. Less frequent daily dosing, efficacy, and tolerability have all been identified as potential factors that aid adherence. Keppra XR is indicated for adjunctive therapy in treatment of partial onset of seizures in patients 16 years of age and older with epilepsy. It employs a matrix technology and is dosed once a day with an effective starting dose of 1,000 milligrams and may be increased by 1,000 milligrams every two weeks, to a maximum of 3,000 milligrams per day. Keppra XR is available as a 500 milligram tablet and has similar bioavailability to immediate release Levetiracetam. Clinical experience shows us that Keppra XR has no known clinically relevant drug-drug interactions. Several clinical trials were discussed. Keppra XR is effective as adjunctive therapy in refractive adult epilepsy patients with partial onset seizures and is generally well tolerated. These factors, along with a once daily dosing regimen, can help patients obtain seizure control and maintain their adherence in treatment. Keppra XR should be included on the PDL.

**David Gross:** A representative of Pfizer discussed Lyrica. Lyrica has four indications, which were reviewed. During the past two reviews, the committee has made Lyrica available on the PDL without restrictions. The only new information is one of the four key fibromyalgia trials that were published in September, which was reviewed. Last year you saw the value of Lyrica in treating patients with seizures, neuropathic pain, and fibromyalgia. We hope you continue to see its value and continue to make it available to Alaska Medicaid patients.

Dr. Sater gave the First Health presentation on Anticonvulsants, 2nd Generation. There are seven available chemical entities in the 2nd Generation subset of anticonvulsants. There are many branded and generic forms of those seven chemical entities. The mechanisms for some of these are not clearly understood. They vary widely between the agents. The adverse drug reactions and efficacy for the different indications are also varied. The previous discussion was about the merits of including one drug from each mechanism, which generated a very complicated motion that failed. A motion stating that the committee was unable to declare a class effect due to multiple indications for each agent, but the committee agreed to accept the bids received through the NMPI process, passed with one opposed. Since the last review, Keppra XR has come to the market. In September there were 2,353 claims: 30% for Gabapentin, 23% for Topamax, 13% for branded Lamical, 9% for Lyrica, 9% for generic Lamical, 8.6% for Keppra, and the rest were less than 6%.

In response to Dr. Carlson's question on what percentage of the drugs were used for seizure disorders and what percent were off label, Mr. Campana said that information could be provided at the next review. The committee discussed the various off label uses of these drugs.

Dr. Liljegren felt the entire group should be included, because they all had different indications and mechanisms of action. It is important for compliance of seizure disorders to include a long-acting agent.

Dr. Sater noted that with the broadness of last year's motion, every branded and generic product had been included on the PDL.

**DR. KILEY MOVED THAT ALL THE DRUGS WERE THERAPUETIC ALTERNATIVES AND AT LEAST ONE OF EACH CHEMICAL ENTITY SHOULD BE INCLUDED ON THE PDL. SECONDED BY DR. BERGESON.**

Dr. Liljegren felt it was important to include at least one long-acting formulation on the PDL.

**THE MOTION PASSED UNANIMOUSLY.**

## **6. Re-Review of Other Antidepressants (Red Category)**

There were no public testimonies.

Dr. Sater gave the First Health presentation on Other Antidepressants. Last year, the committee chose to review the new generation antidepressants and SNRIs as one group, although there was significant discussion about breaking those out. There are seven available chemical entities in the two groups. There are many different products, both extended and immediate release. The mechanisms of action differ between the agents. The adverse drug reactions vary between agents, but they are all effective

for their respective indications. There was very little previous discussion, although you did discuss breaking these into two distinct classes. The motion to include one product from each chemical entity, to include once daily products where available and all extended release products, passed with five opposed. Since the last review, there has been a new Venlafaxine XR tablet added to the marketplace that has a unique strength that is not available in the other Venlafaxine XR products. Cymbalta was approved for the treatment of fibromyalgia. Pristiq (Desvenlafaxine) was added to the marketplace. In September in the new generation antidepressants there were 1,586 claims: 48% for Trazodone, 15% for generic Wellbutrin XL, 11% for generic Remeron, 9.5% for sustained release Bupropion, 13% for Wellbutrin XL, 3% for generic Bupropion, and the rest combined were less than 2%. In September in the SNRIs there were 1,259 claims: 53% for Cymbalta, 43.4% for Effexor XR, 2% for generic Venlafaxine, 1.3% for Pristiq, and .4% for branded Effexor.

Dr. Curtiss asked if last year's motion meant they had to accept everything that had an extended release formulation and felt there would be more options by including each chemical entity with at least one extended release formulation where available.

**DR. CURTISS MOVED THAT THE DRUGS WERE ALL THERAPEUTIC ALTERNATIVES AND AT LEAST ONE OF EACH CHEMICAL ENTITY, INCLUDING AT LEAST ONE OF THE ONCE DAILY FORMULATIONS WHERE AVAILABLE, SHOULD BE INCLUDING ON THE PDL. SECONDED BY DR. BRIGGS.**

Dr. Conright said she respected the advantage of the medically necessary clause, but felt it was important to include a short-acting formulation on the PDL for geriatric patients. Dr. Curtiss noted that the short-acting formulations had more side effects and she would recommend the long-acting agents for geriatric patients. Dr. Sater noted that the short-acting agents were all generic and it would be unlikely that they would not be included on the PDL.

Dr. Brodsky noted that the SNRI drugs would be considered later in the meeting, so the motion only applies to the other antidepressants and not the SNRIs.

**THE MOTION PASSED WITH ONE OPPOSED.**

## **7. Re-Review of SNRIs (Red Category)**

**Stephen Cheng:** A representative Eli Lilly discussed Cymbalta. Cymbalta is a selective serotonin reuptake inhibitor that has four indications, which were reviewed, with fibromyalgia being the newest indication. MDD efficacy remission should be the goal of antidepressant therapy and it is important to treat patients to full remission as patients who fail to achieve remission face a higher rate of relapse. Several clinical trials were reviewed. Efficacy in pain may be important, because disease state data demonstrates that depressed patients with lingering, painful physical symptoms are associated with greater total medical costs compared to depressed patients without pain. Treatment with Cymbalta significantly improved the endpoint mean pain scores from baseline and increased the proportion of patients with at least a 50% in pain score from baseline. Cymbalta carries the antidepressant boxed warning for increased risk of suicidality in children, adolescents, and young adults. Cymbalta is not approved for use in pediatric patients. The most common adverse reactions were nausea and dry mouth. Cymbalta should be retained on the PDL.

**Mark Tacelosky:** A representative of Wyeth discussed Pristiq. A major depressive disorder is associated with a high unmet treatment need and new antidepressant therapy options are important for patients. Pristiq is the major active metabolite of Desvenlafaxine and is not a stereoisomer. Pristiq should be included on the PDL based on the product's efficacy at a single recommended dose, its tolerability compared to placebo, and the product's pharmacokinetic profile. With regard to efficacy, Pristiq demonstrated statistically significant improvements in HAM-D-17 total scores compared to placebo in four pivotal eight-week placebo controlled trials on patients with MDD. Several clinical studies were discussed. The recommended dose of Pristiq is 50 milligrams a day, with or without meals, and no titration of the product is necessary. With regards to tolerability, at the recommended dose of 50 milligrams a day, the discontinuation rate due to an adverse experience for Pristiq was very similar to placebo with a rate of 4.1% for Pristiq compared to 3.8% for placebo. The most commonly observed adverse reactions were nausea, dizziness, sweating, constipation, and decreased appetite. The prescribing information for all antidepressants, including Pristiq, contains the black boxed warning that describes the risk of suicidality in children, adolescents, and young adults taking antidepressants. With regard to pharmacokinetics, Pristiq differs from Venlafaxine and other members of the SNRI class in that Pristiq is primarily metabolized by conjugation, and only to a minor extent through oxidation. Pristiq should be considered for the PDL based on its efficacy, tolerability, and pharmacokinetic profile.

**Chris Johnson:** A representative of UCB discussed Venlafaxine XR tablets. I am here today to support the information that you have already received today regarding this product. This product just released and launched into the marketplace on October 27. It is a bioequivalent to Effexor XR capsules and contains the same active ingredients as Effexor XR capsules. It is indicated for the treatment of major depressive disorder and social anxiety disorder. It is the only Venlafaxine hydrochloride formulation available in a single 225 milligram dose strength. Market research for 2007 show that approximately 21.3% of patients on Effexor XR have a dose exceeding 150 milligrams, necessitating the use of multiple capsules of Effexor XR per day. We know that the rate of non-adherence is affected by patients taking multiple medications or multiple doses. We ask that the committee consider this in their review of the product, because our dosing offers an additional convenience to support patients in their opportunity and decision to be compliant with their medications. Only Venlafaxine ER tablets offer the 225 dose strength for MDD patients in a single tablet, which may simplify the treatment regimen for those patients.

Dr. Sater gave the First Health presentation on SNRIs. Most of the information was covered in the previous review. Cymbalta is the primary market share holder with 53%. The new Venlafaxine XR tablets are new to the marketplace. Cymbalta is approved for the treatment of fibromyalgia. Pristiq is new to the marketplace.

Dr. Liljgren felt it was difficult to consider these drugs therapeutically equivalent, because of the other indications involved, and felt Cymbalta should be specifically included on the PDL for its indications for diabetic neuropathic pain and fibromyalgia.

**DR. CURTISS MOVED A CLASS EFFECT, INCLUDING AT LEAST DULOXETINE AND VENLAFAXINE FORM, INCLUDING ONCE A DAY PREPARATION WHERE AVAILABLE. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.**

## **8. Re-review of Proton Pump Inhibitors (Red Category)**

**Tim Lemon:** A representative of Takeda asked that Prevacid, both capsules and solutabs, remain on the PDL for 2009 with unrestricted access. This is a safe and effective class of drugs. Prevacid has been on the market for 14 years with proven safety and efficacy. Prevacid was the first PPI that had a category B pregnancy indication, which could be pertinent to this population. The most effective drug therapy is one that is dosed and taken properly. Prevacid has the most administrative options and patient choices to get the medication to the patients in the right way. Our Prevacid capsules can be swallowed whole, and opened up and sprinkled on soft foods. Prevacid solutabs are rapidly dissolving tablets that can be placed on the tongue with or without water. It has uniform granules one-third the size of the capsules and can go down an 8-French NG tube or an oral syringe. With your diverse population and the administrative option available with Prevacid, and with the long standing safety and efficacy of 14 years, I ask that Prevacid capsules and solutabs remain preferred with unrestricted access on the PDL for 2009.

**Kate Ryan:** A representative of AstraZeneca discussed Nexium (Esomeprazole). The new information is the use in pediatric and adolescent patients. Nexium is approved for use for ages 1 to 17 years of age for the short-term treatment of GERD. Several new studies showed significant decreases in GERD related symptoms in adolescents, 12 to 17 years of age, as well as a decrease of 89% in esophageal erosion in children ages 1 to 11 years. The new alternative administrative option for patients who have difficulty swallowing a capsule, Esomeprazole is available in packets for delayed release oral consumption. The capsules can also be opened and the contents given in applesauce or suspended in water and administered via a tube. It is also available as an intravenous formulation and indicated for short-term treatment of GERD in patients with a history of erosive esophagitis.

Dr. Sater gave the First Health presentation on Proton Pump Inhibitors. There are five available chemical entities, six branded products, in this class. The FDA indications vary between the agents, but in the clinical practice all drugs are used for all indications. Adverse drug reaction profiles and efficacy are similar across the class. The currently preferred agents are Nexium and all forms of Prevacid. In September there were 2,320 claims: 37% for Nexium, 25% for Prevacid capsules, 22.5% for generic Omeprazole, 8% generic Pantoprazole, 5% Prevacid rapid tabs, and the rest were less than 3% in total. The previous motion for a class effect with Prevacid preferentially preferred in all dosage forms spurred limited discussion and passed with six opposed. Since the last review, Nexium has garnered a pediatric indication. We received support for retaining Nexium on the PDL from Dr. Brian Sweeny and Mat-Su Health Services in Wasilla.

**DR. CARLSON MOVED A CLASS EFFECT, INCLUDING PREPARATIONS SUITABLE FOR PEDIATRIC PATIENTS AND PEOPLE ON TUBE FEEDINGS OR THE EQUIVALENT. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.**

## **9. Re-Review of Urinary Track Antispasmodics (Red Category)**

**Dr. Dierdra Monroe:** A representative of Allergan discussed Sanctura XR. Although antimuscarinics are first line therapy for OAB, the clinical usefulness of this class has been limited by dose dependant adverse events. As the only quaternary mean antimuscarinic product, there are three areas where Sanctura XR's unique properties can provide benefits when compared to the other antimuscarinic agents, which were reviewed. Several trials were discussed.

**David Gross:** A representative of Pfizer discussed Detrol LA. Over the past year, the market share for Detrol LA with Alaska Medicaid has been over 50%. This illustrates that the efficacy and side effect profile of Detrol LA, and that the providers that treat people with OAB prefer this product. When you review the totality of the evidence of the head-to-head trials, no other OAB drug has been able to show superiority to Detrol LA when you look at the efficacy and side effects. Several clinical trials were discussed. With all classes of medications, greater adherence results in less switching from one product to another, which translates into fewer office visits, lower overall treatment costs, and better outcomes. Detrol LA should remain on the PDL.

**Leigh Platte:** A representative of Astellas discussed VESicare (Solifenacin). The goal of therapy is to obtain bladder control with a minimum of side effects. Several clinical trials were discussed in relation to VESicare and the percentage of dryness. Our newest data is on urgency, the driving symptom of the overactive bladder complex and the most bothersome symptom. Several clinical trials were discussed in relation to urgency. In every trial that we have done at least half of the patients have been dry. There is evidence of 80% persistence rate over one calendar year. All of our trials have demonstrated a decrease in urgency and incontinence episodes, and there is an improvement in warning time for the patients.

**Evie Kniseley:** A representative of Novartis discussed Enablex (Darifenacin). Our newest information is in support of utilizing Enablex after a patient has not responded to another drug. The clinical study was reviewed. The results in the study showed that there was a significant improvement in the perception of bladder conditions for all patients. They were able to show symptom improvement after 12 weeks with a decrease of 86% of urinary urgent incontinent episodes. About 80% of patients achieved at least a 50% reduction in urinary urgent incontinent episodes. The safety profile was reviewed. Based on our safety profile, efficacy for new OAB patients, and patients who have already been on other drugs, Enablex should be considered for the PDL.

Dr. Sater gave the First Health presentation on Urinary Track Antispasmodics. There are five available chemical entities, 10 products both branded and generic, including one transdermal product in this class. There is similar efficacy across the class. The adverse drug reaction profiles differ. The patient tolerability with the newer agents is much higher than with the old Oxybutynin. In September there were 386 claims: 49% for Detrol LA, 14% for VESicare, 13% for Enablex, 16% for generic Oxybutynin both immediate and extended release, and less than 8% for the remainder of the products. There was no previous clinical discussion. A motion for class effect, to include at least one long-acting oral agent, passed unanimously. Since the last review, Sanctura XR has been added to the market. Dr. Kevin Tomara and the urologists at Alaska Native Medical Center prefer Detrol LA. We received a letter from Dr. William Clark from Alaska Urological Associates supporting Enablex.

**DR. KILEY MOVED A CLASS EFFECT, TO INCLUDE ONE LONG-ACTING ENTITY.  
SECONDED BY DR. PHILLIPS.**

In response to Dr. Richey, Dr. Sater said the currently preferred agents were Detrol LA, VESicare, Enablex, Oxybutynin in immediate release, and Oxybutynin in syrup.

In response to Dr. Brodsky, Dr. Sater said the doctors who wrote letters preferred Detrol LA, because they felt it was better tolerated, has no drug interactions, and it works better.

**THE MOTION PASSED UNANIMOUSLY.****10. Re-Review of ADD/ADHD (Blue Category)**

There were no public testimonies.

**Stephen Cheng:** A representative of Eli Lilly discussed Strattera. It is the first non-controlled, non-stimulant ADD/ADHD indicated for children, adolescents, and adults. Earlier this year, we were the first ADHD agent FDA indicated for the maintenance and treatment of ADHD in children and adolescents. Strattera has efficacy superior to placebo in children, adolescents, and adults with ADHD. In clinical trials, Strattera was shown to provide continuous ADHD symptom relief for up to 24 hours. Not all ADHD patients are the same and comorbid conditions are common. Up to 65% of patients have at least one comorbidity, which can impact treatment selection as well as treatment outcomes. Strattera is not a controlled substance and may be a viable option in patients with a history of alcohol or drug abuse. In surveys of Midwestern schools, about 25% of secondary school students and 50% of college students with ADHD have been approached to sell, give away, or trade their stimulant medication. Based on this information, a lack of abuse potential makes Strattera an ideal ADHD treatment in patients with a history of substance abuse. Strattera should be considered for inclusion on the PDL.

**Noam Frey:** A representative of New River discussed Vyvanse. Vyvanse is currently not on the Alaska PDL. Vyvanse has a long-acting biological delivery system, unlike every other long-acting release mechanism it is not mechanical or PS-dependant, and provides less abuse viability. Vyvanse is indicated for the treatment of ADHD in children ages 6 to 12. In the last six months, it received an FDA approval for adults as well. In the last six months, we received FDA approval to present data to show efficacy up to 13 hours, making it the longest acting ADHD medication available. Adverse events were mild to moderate. The dosing formulations were reviewed. Vyvanse has an established 13-hour duration of action, it is soluble in water, it is approved for the use in both children and adults, and it is the only ADHD medication to date that holds a DACON of one. Based on this information, Vyvanse should be added to the PDL.

**Diana Lein:** A representative of Novartis discussed Focalin XR. Yesterday, the FDA approved a 30-minute onset of action for Focalin XR capsules for the treatment of ADHD. This could be a real potential benefit for young parents and families during a very important part of the morning when they are trying to get children ready for school. The new label is based on clinical study data, which was reviewed. Focalin XR should be retained on the Alaska PDL.

Dr. Sater gave the First Health presentation on ADD/ADHD. There are eight available chemical entities in this category. There are many different products, both extended and immediate release, and one transdermal preparation. Currently, Modafinil does not have a pediatric indication. Strattera has a unique mechanism of action. Approximately 11% of our claims are for adult patients. There is similar efficacy for the various indications between all agents, but much variability in patient response. In September there were 1,870 claims: 29% for Concerta, 17% for Adderall XR, 14% for Strattera, 10% for Focalin XR, and the remainder of the products were less than 20%. The currently preferred agents are Concerta, Adderall XR, Strattera, Focalin XR, Amphetamines salt combinations, Methylin, Provigil, the generic Methylphenidate products, the generic Dexedrine products, generic Focalin immediate release, and DextroStat. There was very little previous discussion. A motion to prefer a short- and long-acting Methylphenidate product, including Concerta, a short- and long-acting

Dextroamphetamine product, Strattera and Provigil, passed with three opposed. Since the last review, Liquadd has been added to the market place. Strattera received a pediatric indication. Adderall XR, Concerta, Vyvanse and Focalin XR have received adult ADHD indications.

The committee discussed last year's motion and why certain medications had been preferred by name.

**DR. BERGESON MOVED TO PREFER A SHORT- AND LONG-ACTING METHYLPHENIDATE PRODUCT, INCLUDING BUT NOT LIMITED TO CONCERTA, A SHORT- AND LONG-ACTING DEXTROAMPHETAMINE PRODUCT, STRATTERA AND PROVIGIL. SECONDED BY DR. LILJEGREN.**

The committee discussed the motion. Dr. Bergeson noted that Concerta was included for its duration of action. Provigil was included for narcolepsy and adult shift workers. Strattera is the only non-stimulant in the group and beneficial for people with alcohol and drug abuse problems.

**THE MOTION PASSED WITH SEVEN OPPOSED.**

Ms. White had to leave the meeting.

#### **11. Re-review of Long-Acting Opioids (Blue Category)**

There were no public testimonies.

Dr. Sater gave the First Health presentation on Long-Acting Opioids. There is no new information since the last review. The preferred agents were reviewed. In September there were 484 claims: 30% for OxyContin, 28.5% for generic Morphine sustained release, 21% for Fentanyl patches, 12% for Kadian, 3% for Avinza, 2.7% for Duragesic patches, and less than 2% for the remainder. There was limited discussion regarding the appropriate use of opioids for pain control. A motion to include at least one transdermal and one oral formulation, one long-acting Morphine, and Methadone, passed unanimously.

In response to Dr. Carlson's question on the use of Methadone, Dr. Sater said there were 207 prescriptions for Methadone. Although it was included in last year's motion, Methadone is not part of this class and is not subject to the NPI process.

**MS. STABLES MOVED TO INCLUDE AT LEAST ONE TRANSDERMAL AND ONE ORAL FORMULATION, ONE LONG-ACTING MORPHINE, AND METHADONE. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.**

#### **12. Re-review of Sedative Hypnotics (Blue Category)**

**David Pyle:** A representative of Takeda discussed Rozerem (Ramelteon). The package insert for Rozerem was updated last month, but that information was not submitted because the changes were made after the deadline for information submission. Rozerem is currently on the PDL so I will review the new items on the new package insert. The indication section has changed and now includes new language and efficacy data from long-term clinical trials, which were reviewed. Rozerem is the only FDA approved medication for the treatment of insomnia that is not currently a controlled substance. It has a unique mechanism of action, which was reviewed. Earlier in the meeting Dr. Stillner said

Rozerem may be the hypnotic with the least addictive potential. In fact, there is clinical trial information showing that there is no abuse potential when comparing Rozerem to placebo. Additionally, there were no withdrawal symptoms seen in patients who were given chronic doses of Rozerem. It may be appropriate to keep Rozerem unrestricted on the PDL as it does provide Medicaid patients with a different and unique medication for the treatment of insomnia.

Dr. Sater gave the First Health presentation on Sedative Hypnotics. There are 10 available chemical entities, both immediate and extended release formulations. There are two classifications in this class: Benzodiazepines, both short- and long-acting, and Non-Benzodiazepines. Rozerem has a unique mechanism in this class. In September there were 1,147 claims: 28% for generic Ambien, 27.5% for Ambien CR, 16% for Temazepam, 12% for Lunesta, 11% for Rozerem, 2% for Triazolam, and less than 4% for the remainder. The currently preferred agents are Ambien CR, Temazepam, Rozerem, Triazolam, Flurazepam, and Estazolam. There was very little previous discussion. The motion to include at least one Benzodiazepine, at least one Non-Benzodiazepine, and Rozerem, passed unanimously. Since the last review, the package insert for Rozerem has been changed and generic Sonata has been added to the market place.

Dr. Demain discussed the controversy over whether there was any benefit to Ambien CR over generic Ambien. Mr. Greear noted that Ambien CR had not been preferred, but it was placed on the PDL due to the bidding process.

Dr. Curtiss pointed out that short-acting Ambien was the only drug in the class that was pregnancy category B, whereas the others are pregnancy category C.

Dr. Richey noted that despite the fact that short-acting Ambien was a generic, it did not make the PDL last year. It is one of the most commonly prescribed sedatives in pregnancy and the provider has to write "medically necessary" every time it is prescribed.

**DR. CARLSON MOVED A CLASS EFFECT, INCLUDING A BENZODIAZEPINE, A NON-BENZODIAZEPINE, ROZEREM, AND A SHORT-ACTING ZOLPIDEM PRODUCT. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.**

Dr. Brodsky noted that no public testimonies were allowed for the green category.

### **13. Re-Review of Anticonvulsants, 1st Generation (Green Category)**

Dr. Sater gave the First Health presentation on Anticonvulsants, 1st Generation. There is no new information and no new drugs. For the Carbamazepine derivatives the currently preferred agents were reviewed. In September there were 794 claims: 32% for Trileptal, 22.3% for Oxcarbazepine tablets, 14% for Carbamazepine tablets, 10% for Tegretol XR, 8% for Carbatrol, 5% for generic Tegretol II tablets, 4% for Trileptal oral suspension, and less than 3% for the remainder. The currently preferred agents for the 1st Generation Anticonvulsants were reviewed. In September there were 1,052 claims: 30% for Depakote ER, 18.4% for Depakote, 15.4% for generic Dilantin, 8.5% for branded Dilantin, 7.7% for generic Depakote immediate release, 6.5% for Depakote sprinkle tablets, and less than 20% for the remainder. Last year's motion said the committee was unable to declare a class effect due to multiple indications for each agent and agreed to accept the agents identified by the bids through the NPI process, which passed with one opposed.

**DR. BERGESON MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES AND AT LEAST ONE DRUG FROM EACH CHEMICAL ENTITY SHOULD BE INCLUDED ON THE PDL. SECONDED BY DR. CARLSON.**

The committee discussed the motion and the need to specify including both a short- and long-acting preparation. It was noted that the “medically necessary” clause could be utilized.

**THE MOTION FAILED WITH NINE OPPOSED.**

**DR. DEMAIN MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES AND THAT WE ALLOW THIS TO GO TO THE BID PROCESS. SECONDED BY DR. BRIGGS.**

The committee discussed the lag time if this classification went to bid. Mr. Campana said these classifications would be implemented in late winter or early spring. Usually, 60 days notice is given between implementing the soft edits and the time the hard edits go into effect.

**THE MOTION PASSED WITH FOUR OPPOSED.**

**14. Re-Review of COX-2 Inhibitors (Green Category)**

Dr. Sater gave the First Health presentation on COX-2 Inhibitors. There are two agents for consideration, Celebrex and Meloxicam. There is no new information. At the last review there was very little discussion. A motion for class effect passed with one opposed. The currently preferred agents are Celebrex and Meloxicam. In September there were 218 claims, 156 of which were for Celebrex.

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

**15. Re-Review of Fentanyl, Buccal (Green Category)**

Dr. Sater gave the First Health presentation on Fentanyl, Buccal. At the last review there was no discussion. There are no preferred agents. In September there were 4 claims.

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

Dr. Malter questioned if declaring a class effect, including the orally absorbed Morphine, would encourage more people to use the less expensive Morphine agent. Dr. Sater said generic Morphine could be included on the PDL, but since it has been around for so long that they would not expect to receive any bids for it during the NPI process. Dr. Monahan noted that short-acting oral narcotics were not an Alaska PDL class, because there is no incentive since almost every drug in that class is generic. Dr. Demain disagreed with the concept that if there was no financial incentive then a class should not be considered, because the committee’s objective is to give the Alaska Medicaid population the best choices. Dr. Sater said the committee was free to add anything to the PDL from a therapeutic standpoint, but certain drugs would not be impacted either way by the bid process.

**16. Re-Review of Growth Hormones (Green Category)**

Dr. Sater gave the First Health presentation on Growth Hormones. There is no new information since the last review. The preferred agents are Nutropin and Genotropin. In September there were 15 claims. The motion for class effect passed unanimously.

**DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

**17. Re-Review of H2RA (Green Category)**

Dr. Sater gave the First Health presentation on H2RA. There is no new information since the last review. There was no previous discussed. The motion to declare a class effect and preferentially exclude Cimetidine due to drug interactions, passed unanimously. The preferred agents are Ranitidine and Famotidine. In September there were 748 claims: 80% for Ranitidine in both liquid and tablet forms.

**DR. DEMAIN MOVED A CLASS EFFECT TO INCLUDE A SUSPENSION AND TABLET FORMULATION, AND EXCLUDE CIMETIDINE. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.**

**18. Re-review of SSRI (Green Category)**

Dr. Sater gave the First Health presentation on SSRI. There is no new information since the last review. The currently preferred products are Sertraline, Fluoxetine, Paroxetine, and Citalopram. In September there were 2,946 claims with 14 for liquid products: 27% for generic Sertraline, 24% for Fluoxetine, 21% for Lexapro, 11% for Paroxetine, 11% for Citalopram, and less than 6% for the remainder. There was no previous discussion. The motion to include at least three SSRIs, including either Citalopram, Escitalopram or Sertraline, and preferentially include Fluoxetine solution, passed unanimously.

**DR. RICHEY MOVED TO INCLUDE AT LEAST THREE SSRIs, INCLUDING EITHER CITALOPRAM, ESCITALOPRAM OR SERTRALINE, AND PREFERENTIALLY INCLUDE FLUOXETINE SOLUTION. SECONDED BY DR. CURTISS.**

The committee discussed the need to include a liquid formulation in the motion since there were only 14 claims for liquids in September.

**THE MOTION PASSED WITH THREE OPPOSED.**

**19. Review Minutes from September 2008 Meeting**

Mr. Campana reviewed a few corrections to the meeting minutes.

**DR. BRIGGS MOVED TO APPROVE THE MEETING MINUTES OF SEPTEMBER 2008 AS CORRECTED. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.**

**20. Comments from Committee Members or Chair**

Mr. Campana thanked the committee for their hard work. For the Atypical Antipsychotics, the PA requirement for Clozapine will be dropped. Recently a bill went through Congress regarding Medicaid changes. CMS can once again issue federal upper limits for drugs. Due to that change, we have some changes that need to be made on our preferred drug list. For drugs covered under the federal upper limits, the pharmacists are put in a bad position when they get “medically necessary” for a preferred drug that happens to be a brand name, and then we pay them the federal upper limit. To make the process smoother, we will remove the brand name drugs that are subject to the federal upper limit and update the PDL to prefer the generic versions. This does not affect the prescriber, but makes it easier for the pharmacist and ensures that their reimbursement for branded drugs prescribed under the medically necessary clause will not be subject to the federal upper limit. The committee further discussed the federal upper limit issue.

Mr. Campana said the next meeting would be January 16, 2009.

**21. Adjourn**

**DR. DEMAIN MOVED ADJOURN THE MEETING. SECONDED BY DR. GALE. THE MOTION PASSED UNANIMOUSLY.**

The meeting adjourned at 11:56 a.m.