Pharmacy and Therapeutics Committee Meeting Record

Date: 02/16/07 **Time:** 9:00 a.m. – 5:00 p.m. **Location:** 3232 Elder Street, Conference Room D

Moderator: Don Norris, M.D.

Committee Members Present: Bob Comstock, RPh.; Catherine Gundlach, PharmD; Donald Norris, M.D.; Phil Petersen, M.D.; Richard Markuson, RPh.; Stan Eisele, M.D.; Michelle Miles, PA-C; Tami Eide, Pharm.D.; Thomas Rau, M.D.; William Woodhouse, M.D.; Rick Sutton, RPh.

Others Present: Bob Faller, Cindi McGuire , Selma Gearhardt, PharmD; Steve Liles, PharmD,

Committee Members Absent: None

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Don Norris, M.D.	Dr. Norris called the meeting to order.
Committee Business		
➢ *Roll Call*	Don Norris, M.D.	No members were noted absent.
➢ *Reading of Confidentiality Statement*	Don Norris, M.D.	Dr. Norris read the Confidentiality Statement
➢ *Introduction of new P&T member Michelle Miles, PA-C.*	Don Norris, M.D.	Dr. Norris introduced the new P&T member Michelle Miles. Dr. Eide introduced Cindi McGuire as the new administrative support for the Committee.
➢ *Approval of Minutes from October 20, 2006 Meeting*	Don Norris, M.D.	Dr. Eide pointed out on page 4, Committee Clinical Discussion and Conclusions under Statins, it should read "January 2007" instead of "January 2006". Minutes were approved with the noted correction.
➢ *Key Questions*	Tami Eide, PharmD	Four sets of key questions have been finalized for DERP-2: • Drugs for Chronic Constipation • Newer Drugs for Neuropathic Pain • Drug Combination Products for Type 2 Diabetes – The framework will be the same for all of the combinations we will look at.

		• Drug Combination Products for Hyperlipidemia
DERP Update	Tami Eide, PharmD	We are in the DERP II process, which has a different look that DERP I. Dr. Eide reviewed the new process for topic choice. This process will be more objective than previously done in DERP 1 with the use of a decision matrix. Each state or organization will complete an evaluation based on disease burden, therapeutic alternatives, and clinical impacts to their program. The process for deciding on drug updates has also been formalized and includes an overview of new studies, indications, drugs and adverse events.
Public Comment Period	Don Norris, M.D. Bob Faller, Med Program Specialist	Twenty-seven people signed up to speak during the public comment period. Public comment was received from the following speakers:

Speaker	Representing	Agent	Class
Robert Wechler, M.D.	Self		Antiepileptics
Jeff Berlant, M.D.	Self	zolpidem and zolpidem CR	Sedative/Hypnotics
Scott Hoopes, M.D.	Self		Antidepressants
Kathy Werner-Leape, N.P..	Self	Rozerem	Sedative Hypnotics
Steve DeNagy, M.D.	Self	Emsam Cymbalta	Antidepressants - Other
James Herrold, M.D.	Self	Lyrica	Antiepileptics
Rosemarie Kelley	DaiichiSankyo	Floxin Otic	Otic Flouroquinolones
Barb Hair	Merck	Maxalt	Triptans
Bill Schmidt	GSK	Lamictal	Antiepileptics
Shawn Murphy	Serono	Rebif	Multiple Sclerosis Agents
Kathie Garrett	Self		Antidepressants
John Sonoda	Sanofi-Aventis	Ambien CR	Sedative/Hypnotics
Kay Leslie	Genentech	Nutropen and Nutropen AQ	Growth Hormone
Fran Gander	Astra Zeneca	Nexium	PPIs
Carey Crill	self		Antidepressants
Johnna Nelson	Lilly	Cymbalta	Antidepressants - Other
Brendan Hupf	EMD Serono	Saizen	Growth Hormone
Rajiv Dass	Sepracor	Lunesta	Sedative Hypnotics
Bonnie Kolor	Roche	Pegasys	Hepatitis C Agents
Jordan Jensen	Pfizer	Relpax	Triptans

		Gary Dawson | Takeda | Rozerem | Sedative Hypnotics Todd Landweh | Pfizer | Genotropin | Growth Hormone Joseph Ineck | Self | methadone safety | Opioids Sue Heineman | Pfizer | Lyrica | Antiepileptics Jennifer Brzana | GSK | Imitrex | Triptans Diana Lein | Santarus | Zegerid | PPIs Kim Laubmeier | BMS | Emsam | Antidepressants - Other Arina Kuzanofsova | Scherinyo | PegIntron | Hepatitis C
Drug Class Review ➢ Analgesics, Narcotics, Long-Acting ➢ Analgesics, Narcotics Short-Acting ➢ Ulcerative Colitis Agents ➢ MS Agents ➢ Hepatitis C Agents	Steve Liles, PharmD Steve Liles, PharmD Steve Liles, PharmD Steve Liles, PharmD Steve Liles, PharmD	<u>All drug classes reviewed at this meeting were previously reviewed. Presentations focused on updated information since the last review.</u> <u>Analgesics, Narcotics, Long-Acting</u> Dr. Liles stated that there is one new drug in this class that is an extended release form of oxymorphone called Opana ER used for the treatment of moderate to severe pain. Dr. Liles reviewed clinical trial data, warnings, and drug interactions. <u>Analgesics, Narcotics Short-Acting</u> Dr. Liles stated that there is one new drug in this class that is an immediate release form of oxymorphone called Opana used for the treatment of moderate to severe post surgical pain. Dr. Liles reviewed clinical trial data, adverse events and precautions. <u>Ulcerative Colitis Agents</u> Dr. Liles stated that there is no significant new clinical information since this class was last reviewed in January 2006. A newly marketed agent, Lianna, will be reviewed the next time this drug class is reviewed. <u>MS Agents</u> Dr. Liles stated that this class was last reviewed in May 2006. Dr. Liles reviewed new clinical trial data and new pediatric data. <u>Hepatitis C Agents</u> Dr. Liles stated that this class was last reviewed in May 2006. He reviewed recommendations from a technical review published by the American Gastroenterological Association (AGA) in 2006. This review is similar to the 2002 NIH consensus guidelines. Dr. Liles reviewed new clinical trial data.

➢ Growth Hormones ➢ Otic Fluoroquinolones	Steve Liles, PharmD Steve Liles, PharmD	Growth Hormones Dr. Liles stated that this class was last reviewed in May 2006. Dr. Liles reviewed new indications and products. Zorbtive is a new drug in this class approved for short bowel syndrome. Otic Fluoroquinolones Dr. Liles stated that this class was last reviewed in May 2006. Dr. Liles reviewed the AOE: AAO-HFSF Treatment Guidelines and the 2006 Cochrane review of Chronic serous Otitis Media.
➢ Antimigraine Agents, Triptans ➢ Proton Pump Inhibitors ➢ Newer Drugs for Insomnia ➢ Antiepileptic Drugs in Bipolar Mood Disorder, Neuropathic Pain and Fibromyalgia ➢ Anticonvulsants	Steve Liles, PharmD Susan Carson, DERP Susan Carson, DERP Marian McDonagh, DERP Steve Liles, PharmD	Antimigraine Agents, Triptans Dr. Liles stated that this drug class was last reviewed in January 2006. A public health advisory on drug interactions with SSRIs was issued since the last review. Dr. Liles reviewed new clinical trial data and pediatric data. Proton Pump Inhibitors Ms. Carson stated that this class was last reviewed in July 2006. This is the fourth update to the PPI report. There were two changes to the scope of the report. Included populations were expanded to children and non-erosive or empirically-treated GERD. Zegerid was added to this review, but there were no studies that met inclusion criteria. Results of this review do not change previous conclusions. Newer Drugs for Insomnia Ms. Carson stated that this is the first update of this report. The name of the report has been changed. It was formerly known as Newer Sedative Hypnotics. Ramelteon and zolpidem extended release were added to this review. The population included was expanded to children with insomnia. No evidence was found in children. No major changes were made to the previous conclusions of the report. Antiepileptic Drugs in Bipolar Mood Disorder, Neuropathic Pain and Fibromyalgia Dr. McDonagh reviewed this updated report which now includes Fibromyalgia and two new drugs, ethotoin and pregabalin. There were no major new findings and no conclusive evidence of differential treatment effects with this update. Anticonvulsants Dr. Liles stated that there is no new clinical information.

➢ Erythopoiesis Stimulating Proteins	Steve Liles, PharmD	Erythopoiesis Stimulating Proteins Dr. Liles stated that this drug class was last reviewed in May 2006. Dr. Liles stated that there was a manufacturer announcement in January 2007 concerning use of darbepoetin in cancer patients with anemia not caused by chemotherapy.
➢ Antidepressants, Other	Steve Liles, PharmD	Antidepressants, Other Dr. Liles reviewed new clinical trial data, dosages, systematic reviews, guidelines, safety data for pregnancy, suicide, and metabolic effects.
Committee Clinical Discussions and Conclusions	Don Norris, M.D.	Analgesics, Narcotics, Long-Acting The Committee did not feel that there were any significant changes. They felt a need for updated and more extensive education on methadone. Analgesics, Narcotics, Short-Acting The Committee did not feel that there were any significant changes. They felt Opana did not provide any clinical advantage over other agents. Ulcerative Colitis Agents The Committee did not feel any changes were needed at this time. MS Agents The Committee felt that there should not be any restrictions on these agents. Hepatitis C Agents The Committee felt that a weight- based product needed to be available. They felt pegelated products were needed. Growth Hormone The Committee felt there was no new data and did not feel the need to make any changes to their recommendations for this class. Otic Fluoroquinolones The Committee did not feel that there were any significant changes. Proton Pump Inhibitors The Committee would like to have Prevacid solutab available. They felt that at least two agents were needed because of tolerability. Newer Drugs for Insomnia The Committee felt that there was not sufficient data available for Ambien CR and Rozerem to show any advantage over the other agents.

		Antiepileptic Drugs in Bipolar Mood Disorder, Neuropathic Pain and Fibromyalgia The Committee did not feel the need to make any changes to their recommendations for this class. They felt that Lyrica should still be second line after gabapentin for neuropathic pain. Anticonvulsants The Committee did not have any comments. Erythopoiesis Stimulating Proteins The Committee did not have any comments. Antidepressants, Other The Committee felt there may be some advantages in dosing for Cymbalta compared to Effexor. They felt Paxil may not be necessary. Antimigraine Agents, Triptans The Committee felt it was important that prescribers have a choice.
Public Meeting Adjourned	Don Norris, M.D.	Dr. Norris adjourned the public portion of the meeting.
Closed Executive Session	Paul Leary, Medicaid Deputy Administrator	Drug class cost models were reviewed and recommendations made as follows by the committee. **Hypoglycemics, TZD:** • The Committee recommended Avandia®, Actos®, Avandamet®, Avandaryl® Actosplus Met®, and Duetact® be designated as preferred agents. • There were no agents designated as non-preferred. **Hypoglycemics, Meglitinides:** • The Committee recommended Starlix® and Prandin® be designated as preferred agents. • There were no agents designated as non-preferred. **Lipotropics, Other:** • The Committee recommended Niaspan®, gemfibrozil generic, colestipol generic, Tricor®, cholestyramine generic and fenofibrate generic be designated as preferred agents. • The Committee recommended Zetia®, Triglide®, Antara® Omacor® and Welchol® be designated as non-preferred agents that require prior authorization. **Narcotic Analgesics, short-acting:** • The Committee recommended propoxyphene/apap generic, apap/codeine generic,

		tramadol generic, hydrocodone/apap generic, asa/codeine generic, codeine generic, morphine IR generic, oxycodone IR generic, oxycodone/apap generic, pentazocine/naloxone generic, hydromorphone generic, oxycodone/asa generic, and levorphanol generic be designated as preferred agents. • The Committee recommended propoxyphene compound generic, propoxyphene generic, meperidine oral generic, Darvon N®, Combunox®, pentazocine/acetaminophen generic, Panlor DC/SS®, Opana®, fentanyl buccal generic, hydrocodone/ibuprofen generic, tramadol/acetaminophen generic, butalbital compound/codeine generic, and dihydrocodeine/apap/caff generic be designated as non-preferred agents that require prior authorization. **Narcotic Analgesics, Long Acting:** • The Committee recommended methadone generic, Kadian® and morphine extended release generic be designated as preferred agents. • The Committee recommended Duragesic®, fentanyl transdermal generic, Avinza®, Opana ER®, Oxycontin®, and oxycodone extended release generic be designated as non-preferred agents that require prior authorization. • Duragesic® is recommended by the Committee as preferred over generic fentanyl transdermal when the therapeutic prior authorization criteria are met. **Anticonvulsants:** • The Committee recommended methobarbital generic, phenobarbital generic, clonazepam generic, carbamazepine generic, Carbatrol®, Equetro®, phenytoin, , Dilantin®, Mebaral®, primidone generic , valproic acid generic, Depakote® sprinkle, Depakote ER®, Depakote®, Celontin® , Peganone®, Gabitril®, ethosuximide generic, zonisamide generic[2], Trileptal®[2], Lyrica®[2], gabapentin generic[2] , Topamax®[2], Keppra®[2], Lamictal®[2], and Diastat® be designated as preferred agents. • The Committee recommended Phenytek®, Tegretol XR®[1], Felbatol® and lamotrigine generic[2] be designated as non-preferred agents that require prior authorization. • [1] Clients currently receiving Tegetrol XR® will be "grandfathered" and not need to switch to a preferred agent. • [2] These anticonvulsants are recommended as preferred for epilepsy and other seizure orders only. Non-seizure indications will still require that therapeutic prior authorization criteria are met. **Growth Hormone[1]:** • The Committee recommended Saizen®, Tev-Tropin®, Serostim®, Genotropin®, and Nutropin AQ® be designated as preferred agents. • The Committee recommended Nutropin®[2] and Humatrope®[2] and Norditropin®[2] and Zorbtive® be designated as non-preferred agents that require prior authorization.

		• [1] Current therapeutic criteria for growth hormone will continue to be required for all agents. • The Committee recommended that Nutropin®[2], Humatrope®[2] and Norditropin®[2] be "grandfathered" for current patients. These agents will be non-preferred and require prior-authorization for new patients. **Hepatitis C Agents:** • The Committee recommended Pegasys® and ribavirin generic be designated as preferred agents. • The Committee recommended Copegus®, Infergen®, Rebetol® Peg-Intron and Peg-Intron Redipen® as non-preferred agents that require prior authorization. • The Committee recommended that Peg-Intron be "grandfathered" for current patients. These agents will be non-preferred and require prior-authorization for new patients. **Multiple Sclerosis Agents:** • The Committee recommended Betaseron®, Avonex®, Rebif® and Copaxone® be designated as preferred agents. • There are no agents designated as non-preferred. **Erythropoiesis Stimulating Proteins:** • The Committee recommended Aranesp® and Procrit® be designated as preferred agents. • The Committee recommended Epogen® as a non-preferred agent that requires prior authorization. **Otic Fluroquinolone Preparations:** • The Committee recommended Floxin® otic and Ciprodex® otic as preferred agents. • The Committee recommended Cipro®HC otic as a non-preferred agent that requires prior authorization. **Phosphate Binders:** • The Committee recommended PhosLo®, Fosrenol® and Renagel® as preferred agents. • There were no agents designated as non-preferred. **Sedative-Hypnotics:** • The Committee recommended chloral hydrate generic, temazepam generic, triazolam generic , Lunesta® and Ambien® as preferred agents.

		• The Committee recommended flurazepam generic, Rozerem®, Ambien CR® Sonata®, Doral® , estazolam generic, Restoril® 7.5 mg as non-preferred agents that require prior authorization. **Proton Pump Inhibitors :** • The Committee recommended Prilosec® OTC, Nexium® and Prevacid® capsule, Prevacid®solutab and suspension as preferred agents. • The Committee recommended Zegerid®, Aciphex®, Protonix® and omeprazole generic as non-preferred agents that require prior authorization. **Injectable Anticoagulants:** • The Committee recommended Fragmin®, Lovenox®, Arixtra® and as preferred agents. • The Committee recommended Innohep® as a non-preferred agent that requires prior authorization. **ACE Inhibitor/Calcium Channel Blocker Combinations:** • The Committee recommended Tarka® and Lotrel® as preferred agents. • The Committee recommended Lexxel® as a non-preferred agent that requires prior authorization. **Angiotensin-2 Receptor Antagonists:** • The Committee recommended Diovan®, Diovan HCT®, Benicar, Benicar HCT®, Micardis®, Micardis HCT®, Cozaar®, Hyzaar®, Avapro® Avalide® as preferred agents. • The Committee recommended Teveten®, Tevetan HCT®, Atacand® and Atacand HCT® as non-preferred agents that require prior authorization. **Benign Prostatic Hyperplasia Treatment Agents** • The Committee recommended doxazosin generic, terazosin generic, Uroxatril®, Cardura XL®, Flomax®, Avodart®, and finasteride generic as preferred agents. • There are no agents designated as non-preferred. **Bladder Relaxant Preparations:** • The Committee recommended oxybutynin generic, Vesicare®, Oxytrol®transdermal, Enablex®, Sanctura® and Ditropan XL® as preferred agents. • The Committee recommended Detrol® and Detrol LA® as non-preferred agents that require prior authorization. **Lipotropics, Statins:** • The Committee recommended Advicor®, Altoprev®, Lescol/Lescol XL®, Lipitor®, lovostatin generic, pravastatin generic, and simvastatin generic as preferred agents. • The Committee recommended Caduet®, Crestor® and Vytorin® as non-preferred agents

		that require prior authorization. **Calcium Channel Blockers:** • The Committee recommended Dynacirc CR®, verapamil generic, Sular®, Cardizem LA®, Diltiazem®, Verelan PM®, nifedipine ER generic, felodipine ER generic and Norvasc® as preferred agents. • The Committee recommended nifedipine IR generic, nicardipine generic, Cardene SR®, Covera-HS® and isradipine generic as non-preferred agents that require prior authorization. **Beta-Blockers:** • The Committee recommended atenolol generic, metoprolol generic, propranolol generic, sotalol generic, nadolol generic, acebutolol generic, labetalol generic, pindolol generic, timolol generic, bisoprolol generic, betaxolol generic, Toprol XL® and Inderal LA® as preferred agents. • The Committee recommended Levatol®and Innopran XL® as non-preferred agents that require prior authorization. • The Committee recommended that Coreg® continue to require prior authorization for heart failure. **Antimigraine Agents, Triptans:** • The Committee recommended Imitrex (oral)®, Imitrex (nasal)®, Imitrex® SQ ,Amerge® and Maxalt/Maxalt MLT® as preferred agents. • The Committee recommended Relpax®, Axert®, Zomig/ZomigZMT®, Frova®, and Zomig® (nasal) as non-preferred agents that require prior authorization. • The Committee recommends that Zomig/Zomig ZMT® be "grandfathered" for current patients. These agents will be non-preferred and require prior-authorization for new patients. **Minimally Sedating Antihistamines:** • The Committee recommended Semprex-D®, loratadine/loratadine-D generic, and Clarinex® syrup as preferred agents. • The Committee recommended Zyrtec® syrup, Clarinex/Clarinex D®, Zyrtec/Zyrtec-D® oral, Allegra® and fexofenadine generic as non-preferred agents that require prior authorization. • The Committee recommended that the step therapy criteria requiring trial of first generation antihistamines be removed. **Antidepressants, Other:** • The Committee recommended mirtazapine generic, bupropion IR , bupropion SR generic, Wellbutrin XL® and Effexor XR® as preferred agents.

		• The Committee recommended nefazodone generic, venlafaxine generic, Cymbalta® and Emsam® as non-preferred agents that require prior authorization. • The Committee recommended that venlafaxine and Cymbalta® be "grandfathered" for current patients. These agents will be non-preferred and require prior-authorization for new patients. **Ulcerative Colitis Agents:** • The Committee recommended sulfasalazine generic, Colazal®, mesalamine rectal generic, Asacol®, and Canasa® as preferred agents. • The Committee recommended Dipentum® and Pentasa® as non-preferred agents that require prior authorization.

Pharmacy and Therapeutics Committee
Public Comment
February 16, 2007

Robert Wechler, M.D.
Thank you for the opportunity of addressing this committee. I am a board certified neurologist here in Boise and medical director of the Comprehensive Epilepsy Center at St. Lukes. I am here representing the Epilepsy Foundation of Idaho, I am not representing any particular drug and I am not being compensated for my comments. Approximately 1 in a 100 people has epilepsy in the United States. Epilepsy is not a single condition, but a group of many different conditions that manifest in a variety of different ways with a common theme of sudden unprovoked and debilitating seizures. Two thirds of patients with epilepsy can have their seizures completely controlled with medication. These patients, when successfully treated, can have their lives and productivity restored. The epilepsy medications are not all the same. Some medications work better for certain epilepsy types. Some medications may actually exacerbate seizures in certain patients. These agents vary greatly in their mechanism of actions, tolerability and their side effect profiles. Some of the older agents commonly available as generics presently, can lead to chronic health complications after years of use. Examples of this include accelerated osteoporosis, cerebellar atrophy that is not reversible and interactions with a variety of medications through effect on liver function. The best drug for one patient might be the worst for another. For these reasons it is critical that treating physicians have access to all medication options when caring for patients with epilepsy. I would urge you not to restrict access to antiepileptic agents for patients with epilepsy. In the short term, having access to these options ensures patient's well being. In the long term access to appropriate care benefits not only our patients but our community as well. Access to appropriate care enables many disabled epilepsy patients to resume productive lives. Remember two thirds of epilepsy patients can have their seizures completely controlled and their productivity restored with appropriate medication intervention. For those of whom seizures cannot be fully controlled, access to appropriate care reduces the need for subsequent costly emergent interventions. Please keep all antiepileptic medications in all their formulations for our Medicaid patients. Thank you.

Jeff Berlant, M.D.
Hello, I'm Dr. Jeff Berlant. I am a psychiatrist here in Boise. I wanted to just make some observations about some of the managed care accounts around the use of zolpidem and zolpidem CR. I have watched with some befuddlement and amazement how some companies in the private sector have tried to handle this

issue. One of the strengths of the Medicaid program is the availability of zolpidem. Two points about zolpidem CR though are constructive. Number one, it seems to have fewer critical adverse effects that have really troubled some patients with zolpidem, between problems with significant amnesia, vomiting, and visual hallucinations. About five percent of patients on zolpidem will have one of those adverse effects. With Ambien CR and zolpidem CR we don't see those as problems. You may wish to go back to your database and see how many prescriptions for zolpidem have been one time occurrences with no further refills, because of that problem. Those are wasteful funds especially if the patient is unable to take that agent and has to stop it at first dose. The other thing with zolpidem CR that has struck me is that I have had a number of patients that required 20 mg of two zolpidem for sleep to make it through the night before that. Unfortunately they also got sick off the recommended dosage but that is what they needed to have adequate sleep. With a psychiatric practice it is very important that our patients get sleep, so I deal with this problem a lot. The Ambien CR is made so that it last further through the night and actually comes in a lower dose. I have had several patients that have been able to switch from 20 mg of two zolpidem to one zolpidem CR and sleep better through the night, not have next day fatigue, not have memory problems and no depressive affect that sometimes follows. It is striking to me that some of these clients despite the cost of even a single zolpidem CR being lower that regular zolpidem wholesale have fought the urge to use CR. Some have insisted they I prescribe two zolpidem 10 mg at twice the price compared to one zolpidem CR. Thank you.

Scott Hoopes, M.D.

Scott Hoopes, psychiatrist here in Boise. I would like to say a few words with respect to principles, in particular mood disorder and antidepressants. The four pillars of treatment need to be first. We need to be getting people well, that is in all of our interest. We are all stakeholders in this. We do not want people to not be working or not functioning, we want them to be well. The three principles of getting people well, first we have to start with reliable good diagnosis. Unfortunately in Idaho, I have been in places where most of the sickest of the psychiatric patients are treated by people who are not specialists. Bless their heats they are doing the best they can, but they are not trained to start the diagnosis. There are instruments and ways to establish reliable diagnosis. Second, we need to do monitoring and outcome data. We need to know if people are getting well or not. You need to know that in terms of making decisions. In terms of getting people well we need to keep in mind that we are treating individuals, we are not treating clinical studies. In a clinical study we may have 60 people out of 100 get well from an antidepressant. We may have in another study 60 people out of 100 get well from an antidepressant. These studies do not address the question of is that the same 60 people. As a clinician I can tell you that it is not, so we always need to bear in mind that we are treating individuals and to do that we need open formularies to access medications. If anything can be contributory today from what I have said, I hope that we can look at this population, your point of management and the diagnostic point and the outcome point. Then the medications will manage themselves.

Kathy Werner-Leape, N.P..

My name is Kathy Werner-Leape and I am actually a psychiatric nurse practitioner. I am in private practice in Pocatello, Idaho. I am the founding director of Cedar Health Center and that is a 5013C that treats mostly Medicaid and Medicare clients with psychiatric illness. We also provide care for indigent clients. No company is paying me to speak today. Why I have come here is that I would like for you to take special consideration for the new medication Rozerem. The reason that I am here today to talk about Rozerem is that a majority of my clients have issues with substance abuse. Substance abuse takes a huge toll economically and functionally on my clients. Also, there is another issue, I treat children through the geriatric population. A number of the medications on the formularies are becoming very popular at Pharm parties, etc. Rozerem works and it takes a different way to make it work. A lot of the other agents give people the feeling of almost being drunk before they fall asleep and some of the newer agents out there do not do that. The one that I feel the strongest about is Rozerem. Rozerem is different because the first time that you use it is does not always have that same instant ability for someone to fall asleep. After a week or two weeks it starts working better and better. So that it does mean that the provider does have to teach sleep hygiene and teach you that you need to lay down and let this medication work. However, it is very valuable and I ask that you please consider it especially with the huge problem of substance abuse in this community and within this state. Limiting access to this drug really does limit my ability to provide proper care. The generic medications are almost entirely medications that can be abused and addictive. Thank you.

Steve DeNagy, M.D.

Hi. I am Dr. Steve DeNagy and have spoke to this group before and recognize some of your folks. I am board certified and certified in clinical psychopharmacology by the SCD. I also run a non-profit organization in Eastern Idaho called the Family Care Center which is one of the largest providers of psychiatric care services in that part of the State and one of the largest child providers. I am also part of the Idaho State University certification course for therapist and psychologists in psychopharmacology. I want to talk about two things. The first is a cost savings matter. Perhaps you could get a cheaper and better contract that Provider Synergies. I have looked at their report and there are a few outrageous omissions that were disturbing to me. First of all, I would argue that in the case of Emsam, they have completely missed the point of the transdermal because it is not for fast metabolism its saturation of the GI tracts MAO is why it is a super drug. This is a major omission. The second is with Cymbalta. I was disturbed by the findings in the report that there is no difference amongst the antidepressants economic factors. I agree with Dr. Hoopes that we need full access to all of the agents because they are different. With the new agents we have apples and oranges. We have a water soluble drug which is low protein bound which requires more high doses which is more expensive. We have Cymbalta which is a lipid soluble drug, high protein bound and more stable and requires lower doses. We can talk more about that if you have questions, but the drugs are surely different. The most egregious omission was that the pain data in depression was left out. The only drug that has published data showing that there is pain, not neuropathic pain but actually depression pain is Cymbalta. I am for the open formulary and it would make our jobs easier. We see thousands of Medicaid patients and it would make our jobs much easier if we had open access. Someone here already from your committee mentioned compliance. If we send patients to the pharmacy and they don't get their drug, most of the time they won't ever take it and that is a burden to society. Thank you very much.

James Herrold, M.D.

Hi, my name is Jim Herrold and I am a neurologist here in Boise. I have been here about 10 years. I am here to advocate on behalf of my Medicaid patients with neuropathic pain. I see a ton of pain patients whether it be trigeminal neuralgia, migraine, etc. and I am here to advocate that Lyrica be put on the panel or list of uses other than what it is indicated for by the FDA which is post-herpetic neuralgia, diabetic neuropathy, and as a seizure agent. Pain patients are extremely difficult to treat. Many of them end up on multiple therapies, narcotics. I have found that Neurotin and Lyrica are very successful drugs. In regards to that, I have had several patients on Neurotin with refractory neuropathic pain that have switched over to Lyrica and low and behold that are not the same drug. They have different efficacy and so on. I am advocating that Lyrica be put on the list of approved drugs that do not need a prior approval and then secondly it is renally excreted and not a lot of drug interactions. Many of these patients are on polypharmacy and it is an easy drug to add and at least try. Trigeminal neuralgia and neuropathic pain should be indications for this drug. Thanks.

Rosemarie Kelley

I am Rosemarie Kelley, Associate Director for Anti-Infectives in Medical Affairs at DaiichiSankyo in New Jersey. I am speaking regarding Floxin Otic ear drops. Floxin Otic is an otic topical flouroquinolone that exerts its antibacterial activity by inhibiting DNA. Floxin Otic is available in either 5ml or 10ml plastic dropper bottles or single dispensing containers. Each single dispensing container delivers .25ml of Floxin Otic which is equivalent to 5 drops from the 5ml or 10ml bottles. Floxin Otic was the first otic topical antibiotic approved for use. With regard to the important safety information Floxin Otic is contraindicated with patients that have a history of hypersensitivity to Floxin in other forms or other ingredients. Serious and occasionally fatal hypersensitivity has been reported with patients receiving systemic quinolones. Since I can't go through all of the safety information please see the prescribing information. Thank you for giving me the opportunity to speak with you today. Based on its positive attributes I hope that you will make Floxin Otic ear drops available for your Medicaid patients.

Barb Hair

Hi, I am Barb Hair. I am a Senior Executive Specialty Representative for Merck Health. I am here to represent Merck and our product Maxalt. First of all, I want to thank you for including both Maxalt and Maxalt MLT on your prior formulary decisions. I also want to thank you for the opportunity to talk today. The indications for Maxalt are that it is indicated for the acute treatment of migraine headaches, with or without aura. Maxalt is not intended for prophylactic therapy for migraine or for use in the management of hemiplegic/basilar migraine. The safety of Maxalt has not been established in cluster headaches, which is predominately present in an older, predominately male population. The contraindications as you know are that Maxalt should not be given to patients with heart

disease, coronary artery with basil spasm or other significant underlying cardiovascular disease. Because Maxalt may increase blood pressure, it should not be given to patients with uncontrolled hypertension. Maxalt should not be used within 24 hours of an ergotomine or ergot type medications. Concurrent administration of MAO inhibitors or use within two weeks of discontinuation of MAO inhibitive therapy is contraindicated. As far as the clinical studies go, there are four clinical studies cited in our package insert. They are randomized placebo controlled trials, they were 84% female and the mean age was 40 years old. Patients were instructed to treat a moderate to severe headache at two hours post. Our efficacy data was the following: relief was reported in 23-40% of patients taking placebo, 60-63% in patients taking Maxalt 5ml, and 67-77% were Maxalt 10ml. That is the two hour data. The four hour data, pain relief was 80-83% per tablet. In separate studies our MLT data was very similar, 66-74% for two hour data and 80-84% for four hour data. We can show your 64-65% elimination in nausea. That pretty much sums it up. I would also indicate that in each product circular there is a statement saying that basically you cannot compare the other triptans with one another from separate clinical trials and it is highlighted and bolded in everyone's product circular for good reason. There are different patient populations, the investigators have different controls in the trials, etc, etc. I am sure you are all aware of that. For any comparative data I would simply refer you to the well respected Ferrari meta analysis and of course the OSHU triptan report. Thank you so much for your time. We certainly would appreciate if you continue Maxalt and Maxalt MLT on your formulary choice for your Medicaid patients. Thank you. Thank you also for the opportunity to speak.

Bill Schmidt, M.D.

Good morning. I am Dr. Bill Schmidt with GlaxoSmithKline medical affairs. I want to take the next few minutes to update you with new information on Lamictal which is an antiepileptic drug for both seizures and all sorts of bipolar disorders. First thing I want to do is mention that we do have a new indication in epilepsy for Lamictal, that is for primary generalized chronic seizures. This indication was granted about six months ago so it happened following the last meeting of this committee. This new indication therefore makes Lamictal a broad spectrum antiepileptic drug. As you know, Lamictal is also indicated for maintenance treatment for bipolar disorder in order to delay the occurrence of mood disorder for all types. By that I mean mania, hypomania, mixed states as well as depression. That in fact makes Lamictal the only antiepileptic drug with a bipolar long term maintenance indication. I should add that Lamictal is not indicated for acute bipolar mood episodes. In those trials, the most common drug related adverse events during the monotherapy phase were nausea, sleep disturbances, some back pain, fatigue and non-serious rash. In fact the serious rash rate was .08 percent, which equates to 8 in 10,000. Lamictal, in addition to being the only antiepileptic indicator for long term maintenance of bipolar, does offer several real world advantages which actually went beyond what we have seen in the clinical trials. That is the fact that drug global monitoring is not required. Given its effectiveness and its favorable accountability, Lamictal is actually an extremely valuable tool especially in managing bipolar disorder and long term maintenance. Therefore, Lamictal is actually very desirable. Thank you.

Kathie Garrett

Good morning, my name is Kathie Garrett and I appreciate the opportunity to speak to you today. I am here as a private citizen so that I kind of feel like a fish out of water. I did serve four years as a State Representative and gave the opening and welcoming remarks at the first P&T Committee about four years ago. However, I was not successful in my bid for reelection. I have always stated that legislators do not get elected because they know or care anything about mental illness and unfortunately I am living proof of that. I spent four years in the legislature working on issues of health care and working for better services for Idahoans with disabilities. I proudly sponsored and passed legislation that promoted these issues. A report card from the states gave Idaho a grade of "F" for their mental health services. With the past few years, the legislature has grown in their understanding of the need for better mental health services. Last year we passed and funded 13 pieces of mental health and substance abuse legislation. Among my legislative assignments I was Vice Chair of the House Health and Welfare Committee, served on the health care task force, mental health subcommittee and mental health transformation workgroup. I have also worked with Medicaid on a number of task forces. I served as the chairman of the Idaho Outreach and Enrollment for the Medicaid prescription drug program. I was asked by Governor Risch to serve as co-chairman of the newly created Council on Suicide Prevention, despite the hard work of many people in Idaho remains at the bottom of mental health services treatments while we remain at the top rate for suicide. Idaho suicide rate stands 47% higher than the national average. Idaho is consistently among the states, currently ranking at number 8. More than 90% of suicides in the United States are associated with mental illness and substance abuse. As time is short I just want to talk about the fact that while we have come a long way, we know treatment works and that recovery is possible we need to

continue to give Medicaid recipients and physicians who treat them a full range of Medicaid drugs. I will continue to work for better mental health services and more suicide awareness and prevention. Thank you for your time.

John Sonoda
Good morning, my name is John Sonoda and I am actually a medical scientist for Sanofi-Aventis. I am here for AmbienCR. AmbienCR is actually indicated for sleep maintenance unlike regular Ambien that is indicated for short term use. The reason for that is the FDA actually looks at sleep maintenance. We have just completed a six month long term trial. In this trial the patients were able to take tablets three times a week or seven times a week. We found that after six months patients were not taking more tablets. What that meant that there is no tolerance or addictive behavior with AmbienCR. After six months we stopped the drug and looked at a 20 point check list. This check list looked at withdrawal symptoms and WASO data. The patients did not have any withdrawal symptoms that were significant to placebo. There was no withdrawal or rebound after six months of AmbienCR. NIH actually looked at the sleep drugs and insomnia and has a sleep consensus statement. When they looked at it they recommended that the nonbenzo were the most effective sleep aids. They also commented on the use of Trazadone and Tricyclic antidepressants as not having any long term data but also having significant side effects. I think this is important because when you look at a disease state like insomnia it may be one of the few disease states where the recommended first line therapy does not have an FDA approved indication for sleep, does not have a dose and in fact tricyclic antidepressants and Trazadone are rarely used to treat depression because of the lack of efficacy and other adverse affects. We can now say the drugs like non-benzos are probably the best drugs we have to treat chronic insomnia. Thank you.

Kay Leslie
Good morning everyone. My name is Kay Leslie and I am an independent regional clinical coordinator with Genentech and a Registered Nurse. I am here to discuss the advantages of Nutropen and Nutropen AQ, both growth hormones that Genentech makes. We have several approved indications including pediatric growth hormone deficiency, adult growth hormone deficiency, chronic deficiency, Turner Syndrome and short stature. We also have two label extensions that are unique to our company, pivotal dosing and adult patients who are hormone deficient can receive growth hormone to increase bone marrow density. We have the only multi use pen device with a premixed solution that containing non-benzyl alcohol formulation and this can be used in neonates. As you are aware benzyl alcohols cannot be used in neonates. We have the only multi- use pen device that is easy enough for the visually impaired to use on their own and we also have the largest surveillance space for our patients' safety data registry in the United States, with over 8,000 continuing patients and 140,000 patient years. Genentech was the first biotechnology company to develop DNA technology which led to the development of growth hormone in the United States. It was also the first company to begin the safety data registry. Nutropen and Nutropen AQ are included as preferred or co-preferred on 90% of the managed care drug formularies. Currently our Nutropen powder is not included in the PDL here in Idaho, but Nutropen AQ is and I thank you for having Nutropen AQ already cleared for preparation. We would like to ask you to also consider Nutropen powder. It has many advantages which helps to customize the concentration of the dose. We are also the only company that has a patient support compliance program which helps the patient stay on the drug and in that way, compliance leads to better clinical outcomes and effective use of your health dollars in Idaho. For all of these reasons, I am asking you to include Nutropen and Nutropen AQ on your PDL for your patients. I appreciate your time today. Thank you.

Fran Gander
Good morning, I am Dr. Fran Gander. I am a Regional Scientific Manager with Astra Zeneca. I would just like to give you a little bit of an update on Nexium. Over the years there have been 11 different pharmacodynamic studies comparing esomeprazole to the other PPIs. In all of them esomeprazole provided significantly greater acid control than the other PPIs. Acid control being defined as the percent of time the gastric ph remains above four. One of these studies was a large five way crossover study. The new information is that last year in a multi center randomized control trial the relationship between gastric acid control and the curing of erosive esophagitis and well as the systematic control of GERD was evaluated. Using doses of 10 and 40 mg of esomeprazole daily for four weeks in patients with Grade C and D esophagitis or more severe esophagitis complete healing of the esophagitis was demonstrated to be positively associated with greater acid control. So the longer you can keep the gastric acid Ph above four the better the healing at least in the severe patients. Grade C and D esophagitis is estimated to be about 25% of the GERD population. Over the years there have been large trials comparing the efficacy of esomeprazole to the other PPIs in healing symptom relief and all of the studies have shown the same pattern, that when the severe grades of esophagitis C and D esomeprazole heals

more patients in eight weeks and that can be up to 17% more patients than others. Similarly, esomeprazole keeps more patients in remission than studies on the maintenance of human than the comparative PPIs. In the last year, we have received some new indications and there is a new dosage form that has been approved. We now have indications for short term therapy of children and adolescents aged 12-17 and in the long term therapy of pathological hypersecretory conditions such as Zollinger Ellison. We have a new dosage form approved, it is an oral suspension. It is not available yet but should be available by the end of March. It is a 20 or 40 ml enteric coated granules as well as some inactive granules which can be re-suspended in one tablespoon, 15cc's of water and given orally or by gastric tube. Thank you very much for your time.

Carey Crill

Hi I am Carey Crill. I am a psychiatric nurse practitioner at Community Partnerships here in Boise. I just wanted to come and promote that we keep an open formulary. A lot of my clients are the chronically mentally ill and while all of the studies are done in the psychiatric populations that are not chronically mentally ill, they are the higher functioning patients. When you get to my patients they do not work the same and they do not do the same. They need a lot of different medication choices. I am afraid that if we limit these choices I will not be able to get these patients back to functioning levels. A lot of times we can get them back to a functioning level at least where they are able to work part time, volunteer or do something to keep themselves active in the community. That is always my goal, but I do need access to the medications to be able to do that. I just want to back up what Scott Hoopes and Jeff Berlandt had to say that we just need to be able to use all of the medication effectively without a lot of prior authorizations because they take up a lot of my time and energy that I would rather spend using with my clients and giving them the care that they need. That is all I have to say. Thank you.

Johnna Nelson

Good morning, my name is Johnna Nelson and I am a PharmD with the outcomes research department with Eli Lilly and Company. I would like to spend just a few minutes talking about comments around supporting the availability of Cymbalta for Medicaid patients here in Idaho. Cymbalta is a selective serotonin norepinephrine inhibitor, it is indicated for the treatment of major depressive disorder. Remission is the goal of antidepressant therapy and it is important to treat patients to full remission as patients that fail to achieve remission face a higher risk of relapse. In clinical trials with MDD Cymbalta demonstrated remission rates of 43–44% compared to 16-29% for placebo. Cymbalta also demonstrated a record onset as early as one to two weeks and sustained efficacy across a broad range of depressive symptoms. Here is what is known, depressed patients with lingering painful physical symptoms have a higher risk of relapse and the time to achieve remission is longer. Cymbalta demonstrated efficacy in treating painful physical symptoms associated with depression and significant improvements were seen in overall pain severity as early as week two. Efficacy in pain may be important because disease state data demonstrates that depressed patients with lingering painful physical symptoms are also associated with greater total medical costs for depressed patients compared to depressed patients without pain. Regarding safety, Cymbalta carries the antidepressant boxed warning for increase risk in suicidality in children and adolescence and should not be used in those patients. Additionally, Cymbalta should not be used in patients with cardiac insufficiency, chronic liver disease, end stage renal disease or impairment or substantial alcohol abuse. Nor should it be used in combinations with MAOIs. Because of the potential risk for serotonin syndrome Cymbalta has a warning against predominant use with drugs such as triptans. As I wrap up, Cymbalta has a rapid onset of action. It treats both the emotional and physical symptoms of depression and it offers patients and opportunity to achieve remission. Thank you very much. I would be happy to take questions if you have any.

Brendan Hupf

Good morning, my name is Brendan Hupf and I am here to speak with you this morning on behalf of EMD Serono, the manufacturer of Saizen growth hormone. I just wanted to talk to you about two things this morning, our portfolio of devices available for your patient's on Saizen and secondly our patient support network. First our devices, Serono realizes the importance of compliance in dealing with growth hormone. We have two devices available to your patients on Saizen. The first one is the One Click. The One Click is unique because in just one click the hidden needle is automatically inserted and the medicine is administered. This eliminates the patient having to actually manually insert the needle. This is the only true auto-injector pen with a hidden needle. We also have the Cool Click. The Cool Click is unique because the Cool Click is actually a needle free device. The patients enjoy their daily dose of growth hormone without having to administer a needle delivery. Secondly, our patient support network. Each patient on Saizen is given a phone number that 24 hours a day can call a nurse and get information on growth hormone and these nurses are also trained on both devices, the Cool Click and One Click. What that means is that

your providers are not going to receive these routine phone calls, instead they will be calling the nurses. Just as a reminder, EMD Serono is also the manufacturer of Serastim which the only growth hormone indicated for HIV wasting. Thank you for your time this morning.

Rajiv Dass

Good morning, my name is Rajiv and I am a Pharmacist with Sepracor Pharmaceuticals. I am here today to speak on behalf of Lunesta and request that the P&T Committee retain Lunesta on the PDL for the next year here in Idaho. We understand that there are recommendations from other states to possibly remove Lunesta from the PDL. That would mean considering taking off one of the most steady drugs in this class with the greatest level of evidence for its use. Lunesta as many of you know is a non- benzodiazepine product used for sleep onset as well as sleep maintenance. Not all of the drugs in this class can say that. Keeping patients asleep through the night is an extremely important parameter for patients in Medicaid with psychiatric conditions. It can also be used for transit use and with proven safety and efficacy. Not all of the drugs in the class can say this. There is also no rebound insomnia with Lunesta after sudden discontinuation of its use. Lunesta has an extremely low level for abuse potential compared to other agents in the same class. Choosing an agent with a low level of abuse should be an extremely important parameter for Idaho Medicaid as well. Lunesta is well accepted and available on 35 other state PDLs, including Louisiana, Delaware, Maryland and other top states. As a matter of fact it is exclusive in Tennessee, Florida, South Carolina, Ohio, and some of the others. Currently in Idaho Lunesta's Medicaid market share is at a steady 13-14%, over the past several months. Removing Lunesta from the PDL is only going to give up valuable rebates and without a significant decline in market share. Lunesta has an appropriate use within the Medicaid patient and will be a cost negative to the state if it were removed from the PDL. Sepracor actively participated in the rebate process and we feel no reason either financial or clinical to remove Lunesta from the PDL. So with that said we respectfully request that someone on this Board make a motion to keep Lunesta on the state PDL. Thank you.

Jordan Jensen

Good morning, I am Jordan Jensen. I am here today on behalf of Pfizer to provide testimony for eletriptan. There are four key parameters that differentiate eletriptan from the other six triptans out on the market. First and foremost, eletriptan was the last to enter the market and has an improved pharmacology and pharmacokinetic profile over the other six triptans. Eletriptan's quick t-max of 30 minutes and long half life of four hours not only makes eletriptan one of the fastest acting triptans but also one of the longest acting triptans out there. This gives patients quick relief and the sustained response which allows them to return back to their day. Second, it is the only one that has proven superiority over sumatriptan. In two randomized double blind placebo controlled studies comparing eletriptan with sumatriptan and placebo in the acute treatment of migraine, eletriptan 40mg demonstrated efficacy in all clinically relevant parameters, including higher headache and pain free response rates, ability to return to normal functionality and greater reduction in associated symptoms of migraine compared to sumatriptan 100ml. I would like to make just a quick note in regards to the encapsulation of sumatriptan in these studies. Pfizer conducted these test both in vitro and in vivo. That encapsulated sumatriptan dissolves at the same rate as commercially manufactured sumatriptan. When comparing the therapeutic gain with sumatriptan response in 14 separate clinical trials, it is evident that the headache response with encapsulated sumatriptan is consistent with what has been reported in GS case, Imitrex placebo controlled trials. Third is the efficacy and poor responders. Eletriptan has established efficacy in patients who responded poorly to other antimigraine agents including sumatriptan, rizatriptan, Fiorinal, Fioricet, and Excedrin migraine, due to either poor efficacy or poor tolerability. Eletriptan provides the relief in the most difficult patients. Fourth and final is that the favorable and pharmacoeconomic profile of Relpax. Relpax has data to show that it is the best value for your patients and they need the lowest pill count out of any of the triptans out there. Based on the favorable pharmacology profile, the head to head demonstrated superiority, the efficacy and poor responder population, and finally the best value with the lowest pill count Pfizer requests that eletriptan remains one of the preferred agents on the PDL as a choice of treatment for Idaho Medicaid patients that suffer from migraines. Thank you for your time.

Gary Dawson

Good morning, I am Gary Dawson, a Regional Scientific Manager for Takeda Pharmaceuticals in the Neurosciences Division. I also have a PhD in Pharmacology and am a licensed Pharmacist in Idaho and four other states. I am here to speak on behalf of Rozerem. Rozerem is indicated for the treatment of sleep onset insomnia and it is the first prescription insomnia medication that dual mechanism of action in over 35 years. It works specifically by targeting the melatonin 1 and melatonin 2 receptors, which is thought to be the source alerting signal of the central nervous system. It has a several fold higher affinity for those receptors and is thought to regulate sleepiness by attenuating that signal. The melatonin 2 receptor is thought to regulate or reset the circadian clock. It is important to note that Rozerem does not work by CNS depression. It has no affinity for GABA, dopamine, serotonin, histamine, or opiate receptors. It is not a

controlled substance. It is the first and only nonscheduled drug that is FDA approved for the treatment of insomnia. The abuse liability studies using doses of up to 160ml, twenty times the daily recommended dose, did not differ from placebo in subjective drug liking, drug strength, or subjective street value. It has no difference from placebo in the cognitive behavioral assessments with dosages again up to 160 mg. It has shown no evidence of rebound insomnia or withdrawal symptoms upon discontinuation. It is approved for continuous use. In studies up to one year and well in excess of 4,000 patients it is demonstrated clear efficacy and safety in both adult and elderly populations. Thank you for your patience and your time.

Todd Landweh

Good morning, I am Todd Landweh from Pfizer. I would like to thank you letting me take the opportunity to talk to you in regards to Genotropin. I would like to see it be continued to be available to your patients. All of the growth hormones therapeutically are pretty much the same. Indications wise, we have the widest range of indications of all the companies. We have just added Turner Syndrome to our portfolio which is also available for adults with growth hormone deficiency. What really sets the difference from one growth hormone to another is the measurement devices. We have the widest range of devices from a two different types of pen devices and syringes to administer the drug. Most importantly to your patients we also have the first preservative free single unit dose that is available to patients that does not need to be refrigerated. Cost effectiveness, it is the same price to use the preservative free single dose unit as it is to use the pens. Growth hormone is dosed and priced on a per ml charge. Again I would like to ask you to continue to allow Genotropin available for your patients. We also have a wide range of support for your patients, whether it is sending a nurse out to have them talk to the physicians, but we also have one of the largest surveillance studies with over 63,000 patients. Thank you again for the opportunity to talk to you and to allow Genotropin available to your patients. Thank you.

Sue Heineman

Good morning, I am Sue Heineman. I will be real brief. Many of you know me and have seen me here several times. I am a pharmacist here in Boise, I work for Pfizer as a Clinical Education Manager. I am going to talk in support of pregabalin. You may ask why am I up here because you just saw me in May 2006 talking about pregabalin,. What has changed? Really not much. I just want to just bring up four points. It is still considered first line by two societies in using it for postherpetic neuralgia with the American Academy of Neurology and the American Society of Pain Educators. Pregabalin has shown at least a 50% reduction in seizure patients. It is an adjunct agent so it is not a first line agent, however, the criteria for use in Idaho Medicaid as a preferred agent. You must fail two agents before you can have access to it. If you look at the non -preferred agent Feldamate, you only have to fail one drug to have access to this which is associated with aplastic anemia and hepatitis. I would just request that the committee review the prior authorization criteria for Pregabalin and its use as a preferred agent. With the DPN and PHN, there is still predominantly gabapentin usage and I realize that the patients must fail this drug before they get pregabalin. You are still seeing a lot of doses greater than 1800 mg with gabapentin. This is the issue that I brought up in May and it is still cost Idaho Medicaid if you look your own data, at least the data that was accessible through the CMS website. Those doses are still costing you more than what pregabalin would cost the state. Please consider looking at that. Lastly, use of narcotics and lidoderm patches, morphine for these conditions, what has happened to these agents uses since pregabalin has come on the market. Just in looking through the IMS health data system , the usage of narcotics and lidoderm patches has decreased since pregabalin has launched. Look at that and see how much pregabalin can help reduce the amount of agents. Thank you very much.

Jennifer Brzana

Good morning my name is Dr. Jennifer Brzana. I am a Regional Medical Scientist with GlaxoSmithKline Medical Affairs. I thank you for the opportunity to discuss the importance of continuing sumatriptan status on the Idaho State Medicaid Preferred Drug List. Sumatriptan is the most widely studied triptan on the market and therefore possesses a vast library of safety and efficacy data. This data allows me to bring to your attention three pertinent points to remember when reviewing the triptan class. Point one is unsurpassed pain free efficacy. The CARPE study which was published in clinical therapeutics found that patients with ISH diagnosed migraines, who took this drug (100mg) early in a migraine 75% were pain free in two hours. The most common side effects include nausea, vomiting, sedation and fatigue, all occurring in less that five percent of patients. I should remind you that all of the comparative data among the triptans that has been published utilize the conventional tablet formulation. The tablet formulation is no longer commercially available. Point two, sumatriptan is now the most rapidly acting oral triptan on the market. 100mg reformulated sumatriptan now has an onset of migraine relief as early as 20 minutes. This is the first and only triptan to surpass the 30 minute onset point. As always, sumatriptan injectable has an onset of 10 minutes, nasal spray 15 minutes. Point three, sumatriptan is the

only triptan available in three different formulations. This availability of several different formulations allows patients to tailor their therapy to target their specific migraine symptoms. This treatment strategy is unique to sumatriptan because we know co- administration of two different triptans in the same 24 hour period is contraindicated. Since late 2006 sumatriptan injection has also been available in a 4mg stat dose in addition to 6mg, further allowing patients to tailor their therapy to meet their specific needs. As these three points illustrate, sumatriptan offers unsurpassed pain free rates, rapid rate of onset, and multiple formulations allow patients the flexibility to utilize a stratified approach. These three points allow sumatriptan to remain the gold standard for treating migraine headaches and a necessary option for patients on the Idaho State Medicaid plan. Thank you.

Diana Lein

Good morning, my name is Diana Lein and I am a Scientific Affairs Liaison for Santarus. I would like to thank you for the opportunity to present information today about Santarus' product Zegerid. Which is an immediate release formulation of omeprazole. It is available in both a capsule and powder for oral suspension formulation. So as you all know PPIs need to be protected from gastric acidity to prevent degradation and activation. All of the other oral PPIs utilize and inherent coding to protect the drug from degradation by gastric acidity delaying its release until it reaches the small bowel. In contrast Zegerid utilizes and antacid buffer which is administered together with the PPI micron zed omeprazole. This combination of micronized omeprazole together with sodium bicarbonate that leads to the immediate neutralization of gastric acidity and allows for rapid pharmacokinetics so that you have peak plasma levels occurring within 30 minutes. In fact the FDA has reviewed the pharmacokinetic and pharmacodynamic data that we have submitted and has classified Zegerid as the only immediate release PPI on the market. Therefore, making Zegerid not AB rated with any other omeprazole product. The unique pharmacokinetic properties translate into superior pharmacodynamic pH control. In Zegerid's pharmacodynamic trials, 40mg of Zegerid when administered in the morning raised the gastric pH over four for 18.6 hours, demonstrating superior pH control. In a study published in the journal Critical Care Medicine, when Zegerid is administered through an NG tube to a patient once a day it raises the gastric pH well over four and sustained. All 14 days of the trial the median gastric pH was over six in this patient population. This led to the approval of Zegerid for the reduction of risk of upper GI bleeding in a critically ill patient. Finally, in two outpatient studies published by Don Castel and Phillip Katz, these were crossover studies in the nighttime heartburn patient. When Zegerid was administered prior to bedtime there was a significant benefit in the reduction of gastric acidity. In the three way crossover trial by Phil Katz, the total amount of acid produced with Zegerid was seven times lower than with others. In addition to being the only PPI indicated for the reduction of risk of upper GI bleeding in the critically ill patient we are also indicated for the treatment of ulcer, GERD, esophagitis, and treatment of active benign ulcers. So in closing I invite you to consider adding Zegerid to your formulary. Joining other states that have also done so including, Florida and Oregon. Thanks.

Kim Laubmeier

Good morning, my name is Dr. Kim Laubmeier and I am a clinical psychologist and the Medical Science Liaison representing BMS. I would like to thank you for allowing the opportunity to provide testimony on Emsam. Emsam is the first transdermal patch indicated for the treatment of major depressive disorder. It is also the first MAOI with no dietary modifications required with the start of the medication. In this brief presentation I will focus on three points. First, in terms of a rationale for Emsam there is a huge unmet medical need for patients with major depressive disorder. Although there are many new and effective antidepressants available many patients fail to respond and the remission rates are not high. In addition there are high rates of non compliance and significant side effects associated with existing treatments. Despite evidence of a robust efficacy in the treatment of major depressive disorder, older MAOIs have been avoided by most clinicians and psychiatrists in general due to safety issues, primarily due to the dietary modifications required and drug interactions. Emsam provides demonstrated efficacy in the treatment of major depressive disorder and allows for important safety advantages over older MAOIs. Second, Emsam has a unique clinical pharmacology that should be considered. The mechanism of action in Emsam as other MAOIs is thought to be related to the potential relation to three key neurotransmitters located in the treatment of depression, mainly norepinephrine, serotonin, and dopamine. We have a unique transdermal delivery. Emsam provides selgeline which will bypass extensive first pass metabolism and then preserve adequate MAOI in the gut to metabolize entirely. In its entirety the data for Emsam support the recommendation that no dietary modifications are required at the starting and target dose of 6mg per 24 hours. In fair balance there are several safety issues that should be considered when prescribing Emsam. There is a potential for serotonin syndrome, and a risk for hypersensitive crisis as such Emsam should not be prescribed with other antidepressants. Overall the data for the clinical trials indicate that Emsam has a safety profile comparable to placebo with the exception to application site reactions. In conclusion the introduction of Emsam has expanded the range of options for clinicians

treating depression. I hope that you would respectively consider Emsam as a preferred drug on your formulary. I will be available later this afternoon if you have any questions.

Public comment was also received from Shawn Murphy, Bonnie Kolor, Joseph Ineck and Arina Kuzanofsova but due to technical issues their testimony was untranscribable.