Pharmacy and Therapeutics Committee Meeting Record

Date: 1/20/05 **Time:** 9:00 a.m. – 4:00 p.m. **Location:** 3232 Elder Street, Conference Room D

Moderator: Steve Montamat, M.D.

Committee Members Present: All voting members were present.

Committee Members Absent: Richard Markuson, Rph

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Dr. Tamara Eide	Dr. Eide called the meeting to order and introduced Dr. Steve Montamat as the new chair of the committee.
➢ **Roll Call**	Dr. Steve Montamat	Dr. Montamat called the roll. All voting members were present. One non-voting member was absent.
➢ **Reading of Confidentiality Statement**	Dr. Steve Montamat	Dr. Montamat read the confidentiality statement.
➢ **Committee Business**	Dr. Tamara Eide & Dr. Steve Montamat	Dr. Montatmat introduced the newest member of the Committee, Dr. William Woodhouse.
Approval of Minutes from September 19, 2005 Meeting	Dr. Steve Montamat	The minutes from the November 20, 2005 Committee meeting were approved.
➢ **Discussion of Key Questions**	Dr. Eide & Dr. Montamat	The key questions for the fourth update of the Triptans, initial review of the Inhaled Beta 2-Agonists, and the first update for the Newer Sedative Hypnotics were discussed.
DUR OUTCOME PRESENTATION	Heather Brandt, PharmD	Dr. Brandt presented a review of the findings and outcomes since the implementation of Loratidine OTC as the preferred second generation antihistamine on June 1, 2005.
➢ **Loratidine**		

Utilization in the Idaho Medicaid Population		The purpose of the review was to collect data regarding the clinical and financial outcomes resulting from the PDL implementation. The review indicated that the total cost and number of claims for second generation antihistamines significantly declined beginning in 2003. The data also indicated that the change in market share resulted in a $25 savings per claim. The utilization data indicated a similar rate for procedures, office and hospital visits and an increase in ER visits from 2004 to 2005. Several trends were identified among chronic allergy suffers. This included a decrease in 2nd generation expenditures, and an increase in overall drug and procedure costs. These findings do not correspond with recent published outcomes studies. A need for further study was identified. Dr. Brandt will follow up in 4-6 months with additional information.
Public Comment Period	Dr. Steve Montamat	People signed up to speak during the public comment period. Public comment was received from the following: 1. Libby Neske (Ortho/McNeil/Janssen)—Axert ® 2. Dr. Charles Novak (Sanofi)- Ambien CR®/hypnotics 3. Tyler Sommer (King Pharmaceuticals)—Sonata® 4. Nancy Nadolski (nurse practitioner)—Lunesta® 5. Don Moran (Sanofi-Aventis)—Ambien ® IR/CR 6. Dr. Robert Calder (Merck)—Maxalt® 7. Long Nguyen (Glaxo/Smith/Kline)—Coreg® 8. Lisa Lawrence (nurse practitioner)-Rozerem® 9. Jean Pham (Glaxo/Smith/Kline)- Imitrex®,Amerge® 10, Sylvia Foster (Glaxo/Smith/Kline)—fondaparinux (Arixtra®) 11, Dr. Robert Lee (self)—Coreg® 12. Gary Dawson, PhD (Takeda)—Rozerem® 13. Sue Heineman, PharmD (Pfizer)—Triptans/Relpax® 14. Dr. Mandy Hosford (AstraZeneca)—Toprol ® XL 15. Lawrence Hicks, MD (N/A)—Triptans/Relpax®
Drug Class Review Newer Sedative Hypnotics	Selma Gearhardt, PharmD	Dr. Gearhardt presented a review of the Newer Sedative Hypnotics whose primary indication is for insomnia. Her presentation included

		data on the dosing, pharmacology, interactions, adverse effects, safety, and contraindications. Drugs included : zolpidem zaleplon eszopiclone
Drug Class Review Clinical Data Newer Sedative Hypnotics	Susan Carson, MPH	Ms. Carson attended via conference call and presented the Oregon Health Sciences Evidence-based Practice Center Original Class Review on Newer Sedative Hypnotics. The report was finalized in December 2005. The Committee accessed and reviewed a copy of the report prior to the meeting.
Triptans	Tami Eide, PharmD	Dr. Eide presented a review of the Triptan drug class including indications, pharmacology, drug-drug interactions, availability, and dosing. This was presented in conjunction with the updated Drug Class Review of Triptans from the Oregon Evidence-based Practice Center. The review was completed November 11, 2005. The Committee accessed and reviewed a copy of the report prior to the meeting. Agents included: eletriptan frovatriptan naratriptan rizatriptan sumatriptan zolmitriptan
Review of Clinical Data Injectable Anticoagulants	Steve Liles, PharmD	Dr. Liles presented data on the indications and clinical trials for injectable anticoagulants. The agents reviewed included: dalteparin enoxaparin tinzaparin fondaparinux

Beta Blockers Ulcerative Colitis Agents		Dr. Liles presented data on the indications, adverse effects, beneficial effects and clinical trials for the Beta Blockers. Emphasis was placed on those agents shown to be effective in heart failure. bisoprolol carvedilol metoprolol succinate Other Beta Blockers reviewed included: acebutolol atenolol betaxolol labetalol metoprolol tartrate nadolol pindolol propranolol timolol Dr. Liles presented a review of the indications, pharmacology, dosing availability, clinical trials and adverse events of the following agents: Asacol® Colazal® Dipentum® mesalamine generic enemas/suppositories Pentasa® sulfasalazine oral generics
DUR Board Presentation on Appropriate Use of Sedative-hypnotic Agents	Chris Owens, PharmD	Dr. Owens reviewed results of an educational intervention completed by the DUR Board on the appropriate use of sedative-hypnotic agents. Comparison data, safety concerns, and interactions of these agents were sent in an educational leaflet to specific pharmacist and physician providers.

Committee Clinical Discussions and Conclusions		**Newer Sedative Hypnotics** Based on the evidence that was presented, the Committee consensus was that there is no evidence that any of these drugs are more efficacious than another. The major differences are pharmacokinetic and the agent prescribed often depends on the problems with sleep that the patient is experiencing. **Triptans** The Committee noted that there was no new evidence since the last review to change previous conclusions. Based on the evidence that was presented, the Committee consensus was that there is no evidence that any of these drugs are more efficacious than another, nor do any provide any significant safety advantages. **Injectable Anticoagulants** Based on the evidence that was presented, the Committee consensus was that there is no evidence that any of these drugs are more efficacious than another, nor do any provide any significant safety advantages. **Ulcerative Colitis** Based on the evidence that was presented, the Committee consensus was that there is no evidence that any of these drugs are more efficacious than another, nor do any provide any significant safety advantages. Having dosage forms desirable for children available was discussed. **Beta Blocker** The Committee noted that there was no new evidence since the last

		review to change previous conclusions. Based on the evidence that was presented, the Committee consensus was that there is no evidence that any of these drugs are more efficacious than another, nor do any provide any significant safety advantages. The Committee still felt that Coreg should be restricted to its heart failure indication.
Public Meeting Adjourned		
Closed Executive Session	Randy May, Chief Deputy Administrator	Mr. May presented the financial data on the selected drug classes.
Committee Final Recommendation for Therapeutic Classes	Steve Montamat, MD	**Newer Sedative Hypnotics** The Committee recommended that Ambien® and Lunesta® be designated as preferred agents and that Ambien CR®, Rozerem® and Sonata® be designated as non-preferred agents and require prior authorization. **Triptans** The Committee recommended that Amerge® , Imitrex® (all dosage forms), Maxalt®, Maxalt - MLT® Relpax® Zomig® (oral) and Zomig-ZMT® be designated as preferred agents. The Committee further recommended that Axert®, Frova® and Zomig® (nasal) be designated as non-preferred agents and require prior authorization. **Injectable Anticoagulants** The Committee recommended that Fragmin®, Lovenox®, Innohep®, and Arixtra® all be designated as preferred and that prescriber choice be allowed within this class. **Beta Blockers**

		The Committee recommended that generic formulations of acebutolol, atenolol, betaxolol, bisoprolol , labetalol, metoprolol tartrate, nadolol, pindolol, propranolol, and timolol as well as Inderal LA® and Toprol XL® (metoprolol succinate) be designated as preferred agents. The Committee recommended no changes to the current status of Coreg®. Coreg will be considered a preferred agent for heart failure. The Committee recommended that all other brand name products be designated non-preferred.

Pharmacy and Therapeutics Committee
Public Comment
January 20, 2006

****We encountered intermittent audio technical difficulties during some portions of the public comment period. Therefore, we were not able to include some of the testimonies received in this transcript.****

Libby Meske—Ortho/McNeil/Jensen (Axert)

I will be discussing some of the highlights for Axert and some of the differences between the Triptan drugs. I am not going to go into the pharmacology or the kinetics since I only have five minutes. I don't want to bore you to death with it. I do want to highlight that some of the Triptans are basically very similar, however there are some key differences, some very subtle differences among the Triptans that I would like to discuss. Some of these differences can be very important to the patient. When we asked physicians and patients, there was actually …

Tyler Sommer—King Pharmaceuticals (Sonata)

First of all, I am sure you would all agree that when the decision is made to treat patients with a sedative hypnotic the prescriber needs to consider what favorable attributes an agent should possess that can effectively manage the patients insomnia, as well as keep potential side effects to a minimum. Additionally, the agent should provide the patient some administration options as well. First, I would like to highlight a few things regarding Sonata. Without going into great detail in the PI, which many of you are privy too. Sonata is simply a non-benzodiazepine hypnotic that interacts with the gaba-benzodazapine receptor complex. Sonata's receptor binding profile results in its efficacy, safety profile and tolerability. This includes its reduced potential for psychomotor and memory impairment. What are Sonata's pharmacokinetical advantages? #1, it has a rapid onset of action. Sleep latency studies found that most patients were able to fall asleep within 30 minutes. The safety and efficacy of Sonata has been evaluated in almost 3,300 patients in clinical studies at doses of 5, 10 and 20 milligrams; and 264 patients with transient insomnia at doses of 5 and 10 milligrams. #2, Sonata is rapidly eliminated. Sonata's half life is approximately 1 hour, the shortest of any approved hypnotic currently available. Compared to other newer sedative hypnotics, Lunesta's half life is 6 hours with recommended sleep time of 8 hours. Ambien has a half life of 1.4 to 4.5 hours with sleep time of 7-8 hours. Ambien CR also has a half life of 1.62 to 4.05 hours with a recommended sleep time of 7-8 hours. Roserem has a half life of 1 to 2.6 hours though no recommended sleep time has been indicated. Again, Sonata's half life is around an hour with a recommended sleep time of four hours. This can allow patients certain dosing options, which is unique to Sonata, especially for those who prefer to fall asleep on their own. #3 Due to Sonata's favorable pharmakinetical qualities, the potential for psychomotor impairment and the next day residual hangover can be minimized. One study involving 36 healthy individuals found that 10mg of Sonata was not associated with any residual impairment in word recall or any other memory or psychomotor tests at any time point, even two hours prior to waking. Epidemiological studies, driving simulators and closed road driving studies show that benzodiazepines impair performance to some degree. The magnitude of impairment was based on dose, time of administration and half life of the drug. Sonata was found to have no significant effects on driving performance in the morning following bedtime administration. In fact, driving ability after four hour-middle of the night dosing was not found to be significant with either the 10 or 20mg dose. Next, I would like to address Sonata's use on the elderly. An open label study was conducted on 486 elderly patients with an average age of 72.5 years of age. Self administered Sonata, 5 and 10mg's nightly for six to twelve months. Results of the study revealed statistically significant improvements in all three sleep variables. (Latency to persistent sleep, sleep duration and the number of nocturnal wakenings), No differences were recorded in those patients ages 65-69 versus those patients older than 70. Additionally, the most

frequent adverse reactions associated with discontinuation therapy included pain, somnolence, GI changes, and cardiovascular changes. They are not indicated for long-term use. This study does exemplify the safety and efficacy of Sonata. Over a long-term period, the population is more susceptible to side effects. In summary, Sonata is not new. It was approved in 1999 and post marketing data over the past several years has established Sonata as a safe and efficacious product. #1, it has rapid onset of action, within 30 minutes; a short half-life of 1 hour and a psychomotor impairment window of around four hours. I'm sure we understand that this committee is charged with the judicious use of all medications for its Idaho Medicaid population and this class is no exception. It is obvious that the market for these non-sedative hypnotics is quite crowded. Even with so many new entrants entering the market place. However, we have to take into consideration what is in the best interest of the patient. Will one medication from this class fill the needs of every single patient? Of course not. However, circumstances will arise that will call for other options. I would ask the committee to review the data for Sonata, its unique attributes and consider adding Sonata to the PDL.

Nancy Nedowlski—NP (Lunesta/Ambien CR/Rosera)

I can speak for any of these companies, because I use sleep medications every single day in my practice, because 70-90% of the patients that I see in psychiatry are not sleeping well. Last night, a third of Idahoans did not sleep well. In other words, 450,000 Idahoans did not get to sleep, stay asleep and woke up not feeling well today. I am here because I believe strongly in getting patients to sleep, keeping them asleep and helping them function the next day. Because sleep is supposed to be a third of our lives, if we don't get it, if our patients don't get it—things go south. What we know is that any other co-morbidity that doesn't have good sleep, things get worse. If we look at chronic pain, if we look at COPD, if we look at any of those co-morbidities, if patients don't get sleep those co-morbidities don't get better. The NIH has actually had a lot of discussion about sleep medications and treating sleep appropriately. Last year, the NIH had a symposium to discuss what qualities a good sleep medication should have. It should be able to get in, do its job and get out without causing any problems. Any of you who know about sleep medicine will appreciate that in America, this (bottle of alcohol) is America's #1 sleep aid, including in Idaho. In the studies that were actually done with a sleep in America poll (done last year) showed that 11% of people who don't sleep well use alcohol. Now, alcohol would be great if we could do it IV all night long. However, when people use alcohol they get to sleep, but because of the metabolism it turns into a stimulant later in the night. I am here because Lunesta asked me, but I could also be here because Ambien CR or Roserem asked me. Knowing that all of these medications treat sleep differently than alcohol and knowing that our patients will do whatever it takes to get to sleep. There is a lot of discussion about which method of action should be used. What we want is a clean medication such as the non-benzodiazepines and the melatonin agonists. Which is what Roserem is and they actually have the cleanest/least side effect profile in getting our patients back to work the next day. Marilyn Monroe and Jimmy Hendrix didn't do anything to help us with sleep. Marilyn Monroe actually took a medication which is a barbituturate, called Seconal. Seconal is a shot gun approach to that gaba complex to get patients to sleep. It also depresses respiration. It also does a lot of things. Marilyn didn't just take the barbiturate; she followed it with alcohol as did Jimmy Hendrix. That didn't help us a lot with teaching practitioners and prescribers about treating sleep. If I can leave one thing with you, my hope is that you will understand the importance of treating sleep with a medication that can get in, do its job and get out. I like knowing that we have more information about sleep, sleep architecture and about treating sleep than we ever have in America. It was only about 50 years ago that we put the language around sleep architecture. It has only been 12 years since the AMA recognized sleep as a specialty. So appreciating that, what we know about the non-benzodiazepines today, looking at their safety profile by the FDA and how long they have been tested and how long they have been shown to be effective without any rebound insomnia and without any risk of addiction, I strongly encourage you to take a look at all of the medications that are available in this class.

Don Moran (Aventis)—Lovanox/Ambien and Ambien CR

In addition to being a member of the company and a member of the medical staff, I have the distinction and probably one of the few people in this room that has read the entire 600 plus pages of the Oregon Sedative Hypnotic Report in its entirety front to back. Not once, but actually several times. Now, most of you think that is a cue for me to get a life. I bring this to your attention that in the course of culling through that information, I have learned several pieces of information

which I think will be no secret to anyone at this table. I have also found some pieces that needed to be addressed and I am happy to report that the Oregon group, when presented with facts that I thought needed to be addressed, corrected them before putting out this publication for your review and discussion here today. They didn't come 100% on some of the perspectives that I held, but I am hoping to hear that your discussion today touches on the same points, especially since there are some guidelines and some conclusions reached in the report that are not entirely in concert with conclusions reached by the NIH and even the AHRQ. So, to back up, I notice that Susan Carson is speaking today and I just reviewed her press release from last week announcing the sedative hypnotic report available throughout the country. It is on WebMD and other internet sites and she concludes fairly that head-to-head comparisons of the drugs, I think those will be reiterated today, and all though there are some differences between the sedative hypnotics on some outcomes, no one drug appeared to be consistently superior. I don't think that is a secret to any of us here. Insomnia is not a one-size fits all diagnosis. I think as clinicians, we have identified that patients present with insomnia as a primary complaint or unfortunately sometimes ominously as a co-morbidity with other more ominous chronic illness. For that reason, I think the discussion with Dr. Novak, it is imperative, I believe that physicians have a variety of tools available to be attentive to their different needs of patients presenting with insomnia and the different needs as it relates to their co-morbidity and even the fact that they may be using other medications that may confound and interact with their sedative hypnotic choices. Now, Susan also in her press release, makes another conclusion and here is where I think there is a fork in the road between my philosophy, perhaps yours and maybe what you will hear from the Oregon group today. The Oregon group also compared the newer sedative hypnotics to benzodiazepines. Most of these comparisons found that the newer drugs were as effective as benzodiazepines with similar side effects. See, there is a fork in the road because I believe the NIH and I know the AHRQ have been a little more militant in pointing out that the data says that benzodiazepines have a higher level of risk, a higher level of co morbidity and injuries related to their use/abuse/potential than the newer sedative hypnotics. I guess the informatory on that end point is the Center for Medicaid and Medicare Services, who have now endorsed that thinking by excluding benzodiazepines as anxiolitics and sedative hypnotics entirely from the Part D drug benefit. Now having said that, Ambien was introduced in 1993, that is 13 years ago for the treatment of insomnia. Since that time, they have dispensed over 12 billion doses of medication. It's approved for insomnia. In September of this year, we tried to improve on the product even further and we have developed a controlled release dosage form and I think some important things to keep in mind is that this new product is different from our first generation Ambien, it is approved for the treatment of insomnia. The language around length of therapy has been removed from the label indifference to the wishes of the FDA. Secondly, it is approved for insomnia caused by difficulties in sleep onset and sleep maintenance. So it is a controlled release dosage form. It delivers 60% of its medication within the first 30 minutes, with sustained released for the next 2-6 hours of 90%. The sustained release allows plasma concentration to be maintained, so that the drug has duration of action between 6-8 hours. The half life of the drug is not changed. It is still 2.8 hours, thereby insulating the patient from residual side effects. So based on the safety of 12 billion doses of the Ambien family, the improved labeling, the improved efficacy of this product, I think Ambien CR is a very logical option for patients and physicians in the community who need several tools available for diagnosing and treating insomnia in their population.

Q-Dr. Gearhardt: Why did the company wait 13 years to bring the CR form to market?

R- Well, I think that it is a function of gathering data, finding out how one can improve on an existing legacy product.

Q-Dr. Gearhardt: Does it have anything to do with the patent expiration?

R- I don't doubt that in life cycle management in pharmaceutical companies when you have a successful product why not try to improve and make it even more successful. The point is that this new dosage form which exists when compared even against our own benchmark product measured by terms of benchmarks of latency to persistent sleep, sleep duration, It's even improved over what we consider a gold standard. So, from objective poly-sonography testing we have actually improved the product and we are happy that the end point is actually one that we are proud of and we are confident that it is a safe extension of a very successful product line. 12 billion doses, it has got a nice legacy behind it. It is hard to argue with success.

Q-Dr. Montamat:	I would say that it is pretty disingenuous to use the half-life of Ambien and Ambien CR as a safety point. That half life is the same, but when you have an extended release product, you have more of the product being released later in the sleep cycle. So, I think to say people are going to be as wakeful, and I think there is data to suggest that they are not as wakeful. It is harder to compare when there is not the data for Ambien. There is data, but there is a significant portion of people at the higher dose of Ambien CR, 15% to be exact, that do have some problems with wakefulness.
R--	That is a statistic that I would love to debate with you.
Q-Dr. Montamat:	It is on the FDA website.
R--	I have the data as well on the product labeling. You know, I would say that statistic for somnolence, dizziness are not unique and are not unusual for all sedative hypnotics. The point is the half-life; the calculated pharmokinetic value of the T-one-half is 2.8 hours. It is the change in plasma concentration from the peak to the elimination phase. That is immutable. It is 2.8 hours and the subsequent testing demonstrating changes in cognition as measured by the flicker test, as measured by digit substation test, driving tests is on par with placebo, no difference. I guess what I would do before accepting your comment is, I respect your point of view but I think I would like to debate it further before it gets entered into the record as absolute dogma, if you don't mind.
R-Dr. Montamat	I would say that is fine if you could submit, and hopefully you have here, the paper that you are talking about that is from NIH and AHRQ. I don't know what you are talking about.
R-	I have the papers here, but yea they are technical reports. I would be delighted to provide the information.
R-Dr. Montamat:	I can enter into the record the FDA website.
R-Dr. Eide	I do have one comment. I do think it is a stretch to give CMS a logical reason for excluding the benzodiazepines without being related to side effects. It is historical and goes back to policy and is not anything that they logically thought out as to why they excluded coverage.
R--	The testimony that I read of those minutes is that it is a default to the Beers criteria, which identifies those products as being part of the standard Beers list, the drug list which is contraindicated or strongly advised to not be used in the elderly patients. It is not just sedative hypnotics. It's a variety of substances such as anti-cholinergic, its anti-depressants, so none the less some of those substances, even thought they are on the Beers list will be covered by Part D benefit, sedative hypnotics will not nor will benzodiazepines sedative or benzodiazepines anxiolitics. Again, I am defaulting to the testimony that I have read in the public record about Beers criteria being the clinical basis to defend the policy.
Q-Dr. Eide	I think we have to remember that we use benzodiazepines for more than sleep. We use them for seizures too and that certainly does not go through the Beers criteria.

Dr. Robert Calder (Risotriptan/Maxalt), Merck

Risatriptan/Maxalt is offered in two dosage forms, tablets and orally disintegrating tablets. The studies supporting the tablets, (there were four placebo controlled, multi-center, randomized trials that supported the efficacy for the oral tablets) and I won't belabor the studies and describe them in detail. The primary end point was a change from severe or moderate pain to mild or no pain. That end point was reached in about 70% of patients on 10mgs and about 60% on 5mgs and about 30% on placebo. Also, in addition to the headache pain relief there was also significant relief of the non-pain, the nausea, the vomiting, the photophobia, which is very important in migraine patients. Orally disintegrating tablet formulation, the MLT, was also studied in two randomized trials, two multi-center trials and that showed similar results to the oral tablets. About a 70% response rate at two hours for the 10mgs and about 60% for the 5mgs. The metabolism of riszotriptan is that it is metabolized not by cytochrome-P450, but rather by MAO-A and then only thing to be concerned with there is, if the patient is on propranolol is that the dose of Maxalt should be 5mg, because there is a metabolite of propranolol that is a substrate for MAO-A, so the blood level can go

up if you use the two. I would now like to do something that is a little unusual and this to offer you a few comments/suggestions on reviewing the Triptans. I have attended a lot of the meeting. I think those of you that have seem me before know that. I think that the first thing that I would recommend is to not listen to people like me when it comes to comparing the products, because it is impossible to summarize the Oregon based medicine report, 318 pages, you would have to be a Cicero type orator to summarize that in less than an hour. I mean, the summary itself is 31 pages long. I couldn't summarize that in less than an hour. So, I didn't make comparative statements and I'm not going too. In fact, in this group of drugs, it is so difficult to make comparisons because different studies are doing different patient populations with different efficacy measures. The FDA, I won't read it, but the FDA actually required a bold new statement in the circular for the oral Triptans saying you can't compare non-head-to-head studies with these products. So, what you are doing to compare them, I think, is the best thing to do and I think that is to rely on objective third-party statements, such as the Oregon evidence based medicine report, which I think is terrific. Another comment is I have seen committees spend a lot of time thinking about pharmokinetics with these products. The problem with the pharmokinetic parameters, half-life, T-Max, etc. don't predict clinically what happens with the products. You will see in the Oregon report, I too have an impoverished personal life and actually read the whole report. So, like the previous speaker I have nothing better to do. I can tell you that it's a good sleep aid. In any case, the best sleep aid is reading one of those reports. I can tell you that pharmokinetics do not predict how these things are going to clinically respond. You don't see much about pharmokinetics in the Oregon report for that reason. My last comment is dosage form. A lot of committees get into huge discussions about, oh we've got to have every dosage form, we've got have the IM, we've got to have the intranasal, we've got to have the oral tablets and the disintegrating tablets. As a physician, we started out in neurology before we went into preventive medicine. I can tell you that most people prefer oral tablets or orally disintegrating tablets. That's the vast majority of what people want. In conclusion, I would say that if you have the temerity to read that report, I think you will see that Maxalt compares favorably and that's all that I will say and that I think it is an excellent choice for your PDL.

Long Nguyen (Glaxo/Smith/Kline)—Coreg

Last year, the FDA beta-blocker review committee reexamined the data from the Capricorn trials and additional language to the package insert. It pointed out a significant 40% reduction in re-infarction and a 23% risk reduction in all causes of mortality in the group receiving carvedilol and ACE Inhibitors compared to the ACE Inhibitors alone. To refresh your memory, the Capricorn was the only trial specifically designed to evaluate the safety and efficacy of a Beta Blocker in post-MI patients with left ventricular dysfunction, with or without heart failure symptoms. Although there were a number of post MI trials that demonstrated long-term mortality reductions in patients using Beta Blockers after heart attacks, such as propranalol in the B-hab trial, the Timberlol Norwegian trial and the Metoprolol Lit Trial. All, except Capricorn, were done in the 1970's and '80's. An era before thrombolytics and angioplasty were available and before the introduction of an ACE Inhibitor as a standard of care for patients post MI. In other words, patients in these older trials were not on ACE Inhibitor therapy. They were low risk patients, because all the trials excluded heart failure patients. Most patients were not on Statin therapy and the majority of the patients did not receive aspirin. The study subjects did not receive any form of interventional procedure or clot buster drug for their MI. Therefore, it is not evidence based medicine to use old trial results and apply them to today's medicine. This is why the Capricorn is so unique, because it is the only trial that reflects how we manage our patients today. It is the only Beta-Blocker trial that the FDA gave carvedilol an indication to reduce mortality in post MI patients with left ventricular dysfunctions, especially with an ejection fraction of less than 40%. Carvadalog is a Beta Blocker with unique properties and benefits unlike other Beta Blockers. It is an nonselective Beta Blocker with vasodilating properties. It blocks Beta I and Beta II and Alpha I at the receptors. It has demonstrated its benefit through many randomized trials in all stages of heart failure and post MI. Furthermore, there is evidence to show that Carvadalog improved metabolic and glycemic profiles in the diabetic hypertensive patients on top of Ace Inhibitor therapy compared to Metopolol. In light of this new and not so new evidence, we are asking members of the Idaho P&T Committee to continue to keep Coreg available for heart failure patients. Since there is no evidence for any other Beta Blocker indicated for the use of post MI patients with left ventricular dysfunction and an injection fraction of 40%. Therefore, we ask the committee to consider

restricting any other Beta Blocker to be used for this indication. I would like to thank you, the committee members, for the opportunity to present this testimony and I would be happy to entertain any questions or comments.

Lisa Lawrence (NP)—Rozerem

Approximately half of the patients that I see are Medicaid. I have been very pleased with Rozerem, because so many of my patients have concomitant problems with addictions and so many of them have long histories of trying to self-medicate. I could use the alcohol visual aid here. So, when Rozerem came along it was, I found it to be very helpful, because it was one less thing that I had to worry about as far as addictions were concerned. Whether it was going to work or not, was …