Rachel Strutton-Draft

Pharmacy and Therapeutics Committee Meeting Record

Date: February 20, 2009 **Time:** 9:00 a.m. – 3:30 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, M.D.-Chair; Stan Eisele, M.D.; Perry Brown, M.D.; Catherine Hitt PharmD; Tim Rambur, PharmD; Mark Johnston, RPh; Dennis Tofteland, RPh; Philip Girling, M.D.; Michelle Miles, PA-C; Tami Eide, PharmD

Others Present: Steve Liles, PharmD; Bob Faller; Rachel Strutton

Committee Members Absent: William Woodhouse, M.D.; Mark Turner, M.D.

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Dr. Petersen	Dr. Petersen called the meeting to order.
Committee Business		
➢ *Roll Call*	Phil Petersen, M.D.	Dr. Petersen completed the Roll Call and welcomed the P&T Committee members.
➢ *Introduction of new Committee*	Phil Petersen, M.D.	Dr. Petersen introduced and provided a brief biography on new Committee member Dr. Philip Girling, whose term began February 2009. Dr. Girling serves as the P&T Committee's advisor on mental health drugs.
➢ *Committee member term expiration*	Phil Petersen, M.D.	Dr. Petersen announced the expiration of Dr. Eisele's term on the P&T Committee and thanked him for his service.
➢ *Reading of Confidentiality Statement*	Phil Petersen, M.D.	Dr. Petersen read the Confidentiality Statement.

➢ *Approval of Minutes from January 16, 2009 Meeting*	Phil Petersen, M.D.	There were no corrections and the minutes were accepted as proposed.
➢ *Announcements*	Phil Petersen, M.D.	Dr. Petersen announced a change to the agenda. A new drug class, GI Antibiotics, listed on today's agenda would not be reviewed, and if there was anyone who had signed up to provide public testimony for this drug class, the Committee would still hear their testimony.
➢ *Key Questions*	Tami E. PharmD	Dr. Eide presented the following Key Questions from the Drug Effectiveness Review Project: Proton Pump Inhibitors Beta Adreneric Blockers Targeted Immune Modulators Direct Renin Inhibitors, Angiotensin Converting Enzyme Inhibitors and Angiotensin II Receptor Blockers HMG-Co-A Reductase Inhibitors (Statins) Pharmacologic Treatments in ADHD Dr. Eide also reported on recent DERP literature update scans on previous reports. The DERP project will update reviews on ADHD, Statins and Beta Blockers. They will not update the Constipation, Neuropathic Pain, NSAID, Angiotensin Receptor Blocker or ACE reports.

Public Comment Period	Phil Petersen, M.D. Bob Faller, Medical Program Specialist	Twenty three (23) people signed up to speak during the public comment period. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
Dr. Robert Wechsler	Self/Epilepsy Society	Not Specified	Anticonvulsants
Dr. David Bettis	Self	Not Specified	Anticonvulsants
Michael Vallez	BSU/HCU	Not Specified	Hepatitis C Agents
Dr. Steven Vincent	Self	All	Multiple Sclerosis Agents
Dr. Ellen Hunter	Self	Not Specified	Hepatitis C Agents
Tracy Young, NP	Self	Not Specified	Hepatitis C Agents
Gordon Myre	Self/MS Support group	All	Multiple Sclerosis Agents
Kimberly Escavedo	Self/MS Support group	All	Multiple Sclerosis Agents
Mary Seroski	Self	Lyrica	Anticonvulsants/Fibromyalgia
Caleb Simpson	Self	All	Multiple Sclerosis Agents
Jennifer Brzana	GlaxoSmithKline	Treximet	Antimigraine Agents, Triptans
Shawn Murphy	EMD Serona	Rebif	Multiple Sclerosis Agents
Sharon Cahoon-Metzger	Biogen Idec	Avonex	Multiple Sclerosis Agents
Elaine Thomas	Bayer	Betaseron	Multiple Sclerosis Agents
Juanita McDonough	GlaxoSmithKline	Altabax	Impetigo Drugs, Topical
Rick Swartwout	Pfizer	Genotropin	Growth Hormone
Linda Burkett	Novo Nordisk	Norditropin	Growth Hormone
Vincent Yan	UCB Pharmaceuticals	Keppra XR	Anticonvulsants
Vandana Slatter	Roche	Pegasys	Hepatitis C Agents
Sue Heineman	Pfizer	Lyrica	Anticonvulsants
Isaac Lloyd	Schering Plough	Peg-Intron	Hepatitis C Agents
Pam Sardo	Abbott Laboratories	Depakote & Depakote ER	Anticonvulsants
Tom Rambow, PA	Self	Lyrica	Anticonvulsants

Drug Class Reviews and Committee Recommendations		
➢ *Antiepileptic Drugs for Nonepilepsy Conditions*	Marian McDonagh, PharmD OHSU EPC	Antiepileptic Drugs for Nonepilepsy Conditions This update added the indications of migraine prophylaxis and chronic pain as well as a review of new citations since the last review. Treatment of neuropathic pain was dropped from the review since it is included in a separate review that looks at treatment across drug classes. **Committee Recommendations** The Committees recommended no change to the Prior Authorization (PA) criteria for this drug class including the step therapy requirement for gabapentin failure prior to Lyrica use for neuropathic pain.
➢ *Newer Insomnia Drugs*	Susan Carson, MPH OHSU EPC	Newer Insomnia Drugs The review included twelve (12) new placebo-controlled trials, and an adjusted indirect meta-analysis which included 22 placebo-controlled studies. When manufacturer recommended initial doses were compared, the newer insomnia drugs were similar for subjective sleep outcomes. There is no comparative evidence for Zolpidem extended release and no long-term comparative evidence for the group as a whole. No evidence in children was idenditified. **Committee Recommendations** The Committee concluded that there was no new evidence to support differences in efficacy, effectiveness or safety. They recommended adding generic Zalplon to the PDL, if it was cost effective. The Committee also recommended Idaho Medicaid do an analysis to determine if quantity or duration of therapy restrictions should be implemented.
➢ *Opioids for Chronic Non-Cancer Pain*	Roger Chou, MD OHSU EPC	Opioids for Chronic Non-Cancer Pain Dr. Chou reviewed the fifth update to this drug class, which was finalized May 2008. There were no changes to the key questions, included populations or products added to this update. The included outcomes did not change. Dr. Chou provided an overview of the literature searches conducted through September 2007. The Committee reviewed three (3) new head-to-head clinical trials and their results, as well as six (6) placebo-controlled trials. Evidence was added for long-acting Morphine vs. Oxycodone, Oxymorphine vs. placebo and transdermal fentanyl vs. placebo. The overall evidence for this drug class is poor to fair and no differences in efficacy or adverse events can be identified for this body of evidence. **Committee Recommendations** The Committee felt there was no significant data to support any differences in efficacy or effectiveness. The Committee recommended no change to the current PDL for this class. The Committee made a

		recommendation for Idaho Medicaid to monitor use patterns and do interventions on multi-drug use and multi-prescribers. The Committee also recommended Idaho Medicaid take additional steps to inform prescribers of the Division of Medicaid, Pharmacy Unit's "Lock-in" program.
➢ *Anticonvulsants*	Steve Liles, PharmD	Anticonvulsants Dr. Liles announced the availability of generic products for Depakote Sprinkles and Depakote ER, generic levetiracetam as well as Stavzor (valproic acid DR) and Keppra XR. The Committee reviewed the FDA warnings on suicidality. **Committee Recommendations** The Committee recommended no changes to the current PDL for this drug class. The Committee also recommended that current epileptic patients stable on one product be grandfathered. The Committee would like to review available data on epileptic patients changing anticonvulsant products from branded to generic, as well as changing to different manufacture, if any becomes available.
➢ *Analgesics, Narcotics, Short-Acting*	Steve Liles, PharmD	Analgesics, Narcotics, Short-Acting Dr. Liles announced availability of one new product (oxycodone/ibuprofen – generic Combunox) for this drug class. There was no new significant clinical data to provide to the Committee. **Committee Recommendations** The Committee had no recommendation for changes to the current PDL for this class. They recommended the same analysis and deterrents of abuse as with the long-acting agents be undertaken.
➢ *Antimigraine Agents, Triptans*	Steve Liles, PharmD	Antimigraine Agents, Triptans This drug class was last reviewed October 2007. Dr. Liles announced the availability of generic sumatriptan. The Committee reviewed one (1) new clinical trial for the new combination product Treximet. **Committee Recommendations** The Committee concluded there was no new evidence for differences in efficacy, effectiveness or safety, to favor one product over another. They recommended only adding Treximet if it was more cost effective that the individual components as clinical evidence did not support including or excluding it. The Committee recommended continuing grandfathering for stable patients.

Drug Class Reviews and Committee Recommendations (Continued)		
➢ *Skeletal Muscle Relaxants*	Steve Liles, PharmD	Skeletal Muscle Relaxants The Committee reviewed three (3) new clinical trials. **Committee Recommendations** The Committee recommended no changes to the PDL for this drug class and to maintain the clinical restrictions on Carisoprodol, for safety and abuse avoidance reasons.
➢ *Multiple Sclerosis Agents*	Steve Liles, PharmD	Multiple Sclerosis Agents This drug class was last reviewed October 2007. The Committee reviewed three (3) new clinical trails, BEYOND, PRECISE, and REGARD. **Committee Recommendations** The Committee recommended that all agents remain preferred on the PDL, and that prescribers have open access to the best agents for their particular patient.
➢ *Growth Hormone*	Steve Liles, PharmD	Growth Hormone Dr. Liles provided an overview of label changes (New indications: Humatrope – hypopituitarism in adults and Norditropin – Turner syndrome, small gestational age (SGA). New dosage forms: Omnitrope – available in cartridges) for this drug class. There was no other new clinical data available for review. **Committee Recommendations** The Committee recommended no changes to the current PDL for this drug class. They felt that indications on one drug could be inferred to the others. The Committee felt it should continue to require PA for indications and be used for actual deficiency and metabolic syndromes, not for SMA or intrauterine delay.
➢ *Hepatitis C Agents*	Steve Liles, PharmD	Hepatitis C Agents This drug class was last reviewed October 2007. Dr. Liles provided label changes (New Indications: PEG-Intron – in combination with riboviran for patients as young as three (3) years. New warning: Suicidal ideation or attempts – during treatment), for this drug class. The Committee reviewed one (1) new clinical trial (IDEAL) and one (1) Meta-analysis. **Committee Recommendations** The Committee recommended no changes to the current PDL for this drug class.

➢ *Otic Fluoroquinolones*	Steve Liles, PharmD	Otic Fluoroquinolones The Committee reviewed one (1) new clinical trial for Ciprofluxacin with hydrocortisone. **Committee Recommendations** The Committee had no recommendation for preferred status based on the evidence. They recommended Idaho Medicaid evaluate education vs. restriction to encourage non-quinolone antibiotics as first line.
➢ *Impetigo Agents, topical*	Steve Liles, PharmD	Impetigo Agents, topical There was no new significant clinical data available for the Committee to review. **Committee Recommendations** The Committee made a recommendation that Altabax, five (5) G tube only, be added as a preferred agent to the PDL, if determined to be cost effective.
➢ *GI Antibiotics*	Steve Liles, PharmD	GI Antibiotics This drug class was on the agenda, but was not reviewed by the Committee due to low utililization.
➢ *Ulcerative Colitis Agents*	Steve Liles, PharmD	Ulcerative Colitis Agents There was no new significant clinical data available for review. Balsalazide, generic agent for Colazaz is now available. One (1) correction was made to the PDL: Sulfasalazine showed as non-preferred and should have been classed as a preferred agent. **Committee Recommendations** The Committee recommended no changes to current PDL for this drug class, based on clinical evidence.
➢ *Antihistamines, Minimally Sedating*	Steve Liles, PharmD	Antihistamines, Minimally Sedating This drug class was last reviewed October 2007. Dr. Liles provided an overview of two (2) new products (cetirizine OTC and Rx – generic Zyrtec and Allegra ODT – for children six (6) – eleven (11) years of age) for this drug class. **Committee Recommendations** The Committee had no recommendations based on clinical evidence to prefer one (1) drug over another. The Committee recommended to have all agents containing pseudoephedrine placed as non-preferred on the PDL for this drug class, based on lack of evidence supporting effectiveness and safety concerns.

Pharmacy and Therapeutics Committee
Public Comment
February 20, 2009

Robert Wechsler, MD

Good morning. Thank you for this opportunity. My name is Robert Wechsler, I'm the Medical Director of the Idaho Comprehensive Epilepsy Center at St. Lukes. I chair the professional advisory board for the Epilepsy Foundation of Idaho, and I'm here representing all patients with epilepsy. I'm not representing any individual company or product. I see all patients regardless of insurance, and have a large proportion of Medicaid patients in my practice. 1 in 100 people has epilepsy. Epilepsy medications are not all the same. They vary in their mechanisms of action and tolerability. Some work better for certain epilepsy types, some can exacerbate seizures in certain patients. The best drug for one patient can be the worst for another. This is the third time that I have addressed you. You have given me access to all medications and I would like to share with you, the results of that. Use of rectal diazepam rescue for seizure emergencies: At the Idaho State School and at the Boise Group Homes, at a cost of $300 per dose has been dramatically reduced. Idaho State School has gone from an average of eight rescue doses per month to one per month. We have had no ER visits and no hospitalizations for seizure emergencies in over a year. We have also minimized use of enzyme-inducing drugs and their long term health consequences. We now face new challenges. Several new drugs are coming out and many of our current drugs are going generic. Generic formulations can pose dangers in epilepsy more so than other disease states. Subtle variations that may yield unnoticeable changes in other disease states can cause life threatening seizures in epilepsy. I have seen seventeen patients who have had adverse reactions to generic substitution in the past few months, a 75-year-old woman, seizure free for eight months on brand name lamotrigine went into status epilepticus within weeks of being switched to generic. She spent Christmas in the Intensive Care Unit. A young man, seizure free for eighteen months, had a breakthrough seizure within days of a switch. This happened while he was driving and he ran head on into a truck. While not all generic formulations are bad, and while many patients can tolerate switch to generics, the decision of whether or not to switch needs to rest with the treating physician, not the pharmacist, and not a benefits manager. I urge you not to restrict access to therapies for patients with epilepsy. The access you have already provided has saved the State of Idaho thousands of dollars and has helped to improve the quality of life for many of my patients. Please keep all anti-epileptic medications, all formulations, including brand name agents and new emerging therapies, on formulary for our Medicaid patients. Thank you.

David Bettis, MD

Good morning, I am Dr. David Bettis, a pediatric neurologist. I've also addressed you before. I can keep my remarks short because of how much I agree with Dr. Wechsler and he is, as you can imagine, a very tough act to follow. But I would endorse a couple of points that I think justify revisiting. Generic anti-epileptic drugs is an increasing subject in our field of epilepsy. Dr. Wechsler is a full-time epileptologist and it's about 2/3 of my practice. I think between the two of us, we have more epilepsy in our practices than any other physicians in the state. I am not universally opposed to generic drugs. I think we all need to be cost conscious, that's really not a decision anymore, and I also like to think of myself as a good steward of funds in the public sector, which are becoming increasingly scarce, but substitution of a generic medication in the field of epilepsy can result in a seizure, which is a complication of greater concern and impact on patients than many other medical conditions where the condition may be uncontrolled for a short period of time. A seizure can cause physical injury, it can cause social restrictions in terms of loss of independence or a driver's license, and in a worse case scenario, even death. I am not opposed to the use of generic drugs universally, but in patients who have been very difficult to control, where Dr. Wechsler and I have spent years achieving control, I certainly am not pleased when a generic substitution occurs without my knowledge or participation, and I don't think it's in the patient's best interest to save a few dollars and perhaps have a seizure. I'm going to be careful about not over-using brand name only, but it remains to be seen, and there are some emerging events that are more common with certain medications that we need to keep a careful eye on. Thank you.

Michael Vallez

Good morning and thank you for giving me this opportunity to address you. This is the first time I've ever addressed this committee and that is because I'm new to Boise, Idaho. I'm an Assistant Clinical Professor at Boise State University. I'm also a Nurse Practitioner who specializes in hepatitis-C treatment and liver care. I came specifically to Idaho

because you do not have a very dedicated liver care; there is no liver transplantation unit here in Idaho, so my motto of care is to prevent cirrhosis, thereby preventing any need for liver transplantation. Though I'm new to Idaho, I've been treating hepatitis-C for over ten years, and I was lucky enough to be awarded a National Fellowship from the American Association of the Study of Liver Disease. As a provider, though, I might prefer one drug over another, whether it's the Schering product or the Roche product. I would urge this committee to allow the providers to make that decision based on their individual patients' needs. I cannot emphasize enough that there are times that one product will be more effective than the other product for the patient, and I ask the committee to just allow both products to be on your formulary. Thank you very much for your time and I appreciate your patience. Thanks.

Dr. Steven Vincent
Thank you for allowing me to meet with you today. I also would like to, before I talk about what I've come to talk about today, say thank you to Dr. Wechsler and Dr. Bettis as a person who practice general neurology, although I have a special emphasis on MS. I, too, take care of Medicaid patients with anti-epileptic drugs and a switch is occasionally dangerous, and I have had two recent cases. Luckily, no one was hurt as a result, but people with low frequency seizure rate suddenly developed high frequency. I have been practicing in Idaho Falls for just over 15 years. I'm the current Chair of the General Neurology Section of the American Academy of Neurology. I'm an Associate Clinical Professor of Neurology at the University of Washington. I'm the Medical Director of the Idaho Falls Multiple Sclerosis Center. We have approximately 400 patients with multiple sclerosis in Eastern Idaho. Some do travel from Boise and some from Twin Falls. We have many patients with Medicaid; I can't tell you the exact number, but if we don't treat our patients properly, unfortunately, they can develop disability, which sometimes brings them to Medicaid ultimately. We are actively involved in Phase-3 drug studies in our center, and we take care of Medicaid patients when, as you may know, many neurologists in the state will not. When we talk about attack rate when we're discussing drugs, I want everyone to remember it involves disability often with a real person and I want to make sure that is remembered. I'm concerned about a tiered system requiring additional paperwork and step therapy. I don't think this is appropriate for multiple sclerosis. It may be for other disease states, but I believe strongly that it's not the case with this.

Committee: Doctor, your time's up.

Dr. Steven Vincent
Really? Okay, thanks.

Ellen Hunter, MD
Good morning, I'm Dr. Ellen Hunter and I'm a gastroenterologist and hepatologist practicing in Boise. I do see Medicaid patients. I've specialized in the area of liver disease and have treated numerous patients with chronic viral hepatitis over the past twenty years. Currently, the standard treatment for chronic hepatitis-C is combination therapy with pegylated interferon and ribavirin, with the goal of completely and permanently clearing the virus, which we call a sustained virological response, or SVR. There are two pegylated interferon products available; PEG-Intron and Pegasys, and in scientific, well-designed publications, the two products have similar efficacy in their ability to achieve an SVR and a similar side effect profile. I use both therapies in my practice and have found the SVRs to be similar, and overall I have found the side effects to be similar as well. However, I have had patients who have intolerable side effects with one or the other product, such as severe headaches, and then I've had to switch them over to the other product in order to help them continue the therapy and to successfully complete therapy. This need to change from one product to the other has not been with one particular product, it's gone both ways. So I recommend to this committee to keep both PEG-Intron and Pegasys available to providers for the treatment of chronic hepatitis-C.

Tracy Young, NP
Hi, I'm a Nurse Practitioner, having been practicing for about nine years, and in the last four years have treated a fair amount of hepatitis-C. I would like to reiterate what Dr. Hunter says, that it's imperative that we be allowed to continue with both medications; PEG-Intron and Pegasys, because for her reasons, when we need to switch, it's helpful to have something switch to, but also I tend to use PEG-Intron more because in practice, as well as what I've been able to glean from literature, there appears to be more neutropenia with Pegasys, which is particularly an issue in the patients I have with advanced cirrosis. Currently, I have 34 patients on treatment, and eight of those have stage-3 or stage-4 cirrosis, so that neutropenia is a big issue. Thank you.

Gordon Myre
Good morning everyone, my name is Gordon Myre. I am here to speak for myself and the members of my support group, of which we have about 25-30 members, all of which benefit from the different types of therapies. I was diagnosed with MS in 1989. The first medication to slow the progression of MS was introduced in approximately 1997. I started the treatment right away. Now they start patients as soon as possible, as soon as they're diagnosed. I wish that would have been possible for me because I wasted eight years before medication was available. I understand now that being and staying on your medication is very important. One thing that MS caused for me, was that I had to retire from my employment because I don't get around so good anymore. I worked for 15 years after being diagnosed. I've been on four different types of treatments, all of which work in different ways. I changed from one to another because of the different side effects. I am not currently on any type of medication because I'm taking part in a, I've actually reached secondary progressive MS and there's no proven treatment for secondary progressive MS, so I'm taking part in a blind study that's taking place in Portland, Oregon, to try to find a medication for secondary progressive MS. I believe that everyone should have equal and accessible ability to all the different types of medications. Thank you very much.

Kimberly Escavedo
Hi, my name is Kimberly Escavedo, and I came here for myself and my support group. I'm the MS support group leader in the Nampa and Canyon County area, and I have about 60 members in my group that I hear from and support, and with all their different stories and so forth, and with my experience, the different medications out there to help us in MS, you know, they're very important to help slow the progression of our illnesses down, so we have to have access to all of them because one might help me, and then it may not help somebody else in my group. Listening to all of the different stories from the people in my group, you know, one works for them and one doesn't work for the other, and with all the different therapies, and you know, our doctors are the ones that, you know, we know about the drugs, but we have to use all the ones that we can relate to, so, you know, it's very important for us to have all the different therapies available to us so we can use. You know, it might help us today, but it may not help us tomorrow, so we have to change, so all of our options need to be open, so I would like consideration of that. Thank you very much.

Mary Seroski
Good morning everybody. I don't have a whole book to read to you, I promise. Mary Seroski. I am the leader of the Boise Fibromyalgia support group and I have members who take many kinds of medications for their fibromyalgia, you know, amitriptyline, Cymbalta, Lyrica, Soma, Flexeril, Klonopin, Norco, Vicodin, Zoloft, Provigil, Lunesta and Ambien. The only drugs so far that are approved by the FDA are Cymbalta, Lyrica and now Savella, which is coming out next month, and that's been working quite well in Europe for over 50 years. Savella and Cymbalta are basically antidepressants that work with pain and depression, but Lyrica, you know, attacks the neuron for sensory pains like pins and needles. My husband is currently on Lyrica and it works great for him, and he's tried other things, and sometimes he has to resort to Norco, but Lyrica is what keeps him going from day to day, so he doesn't have to, he can get up and do things. He's doing a lot more than I can. Pain is maybe the first sign for fibromyalgia. I believe the lack of delta sleep triggers it. I've gone through a sleep study and was found to have never reached delta level, and that's where the body comes and regenerates hormones and heals itself. A spinal tap also showed high levels of substance-B, proving the patient is in a high level of pain, and studies have shown that if pain is not under control, the brain literally shrinks. These studies have compared normal, healthy people's brains with those under constant pain, and they have found that the hypothalamus actually shrinks, and that is probably because of the bombardment of pain signals, so medicines like Lyrica and Cymbalta, etc., are essential in reducing, if not temporarily stopping the pain signals, so we have to get pain under control and I, you know, it's essential to keep these medications available for people who have fibromyalgia. The quality of life is at stake here. I used to pride myself in computer capability, programming and such. Now, more often than not, I get lost with what I am doing. Right now, I have no insurance whatsoever, so I have to go on these programs, these assistance programs, to get any kind of medication. When I was on insurance, I was trying to get Provigil to keep me awake in the mornings, and my insurance company wouldn't allow me to have it. They wanted me to try the generic, cheaper stuff, but what they failed to do is look at my record and see that I already tried those and they didn't work, and I needed Provigil. They even made my doctor write this long letter of why I needed Provigil and they still denied it. I figured, "I am paying premiums and they're supposed to be working for me, not I work for them". They should have given me Provigil.

Committee
I'm sorry, your time's up. I appreciate your testimony.

Mary Seroski
So, um, don't let this happen to fibromyalgia patients, please. Thanks.

Caleb Simpson

Hi, I'm Caleb Simpson. I work for United Health Care in their Secure Horizons Division, which is for people on Medicare or people on Medicare and Medicaid, but they haven't asked me to be here. I'm not here representing them, I have not been assigned this task or been requested presence at this meeting. I'm here because I have MS and I have tried several medications and, as several people have said, including Vincent, step therapy, while cost effective, is not necessarily the best and most effective way, well it's definitely not the most effective way, to get patients the most appropriate medication for them. I was on a few prescription drugs, two or three, prescription drugs for the first ten years of my MS, and in the summer of 2005, I was actually in a wheelchair or using forearm crutches to get around because my gait was quite awkward and it was very difficult to walk, especially distance. In the summer of 2005, I switched medications to Novantrone, which is a chemotherapeutic drug that's approved for MS, and the difference is astounding. Three years later, I feel fantastic, and I would hate for somebody to miss out on an opportunity for a drug that works for them, simply because they have to try some cheaper ones first. The cheaper ones work for some people, but they don't work for others. But I would appeal to leave it up to the doctor, which drug is the right one for the patient and why. I hear that Tysabri is going be on the list today, if I heard that right, and Tysabri would be another one that is successful in reducing the severity and the frequency of MS attacks so much better than some of the other drugs, and if a doctor thinks that it is a better drug for a patient, and if the patient is willing to put up with some of the risks associated with the drug, I would hate for them to be denied the right to choose that drug. I'll let the rest of the doctors that are going to be speaking on that and the representatives speak. Thank you very much.

Jennifer Brzana

Good morning, I'm Jennifer Brzana, Regional Medical Scientist with GlaxoSmithKline, and I'm going to speak about Treximet, a single tablet containing 85 mg of sumatriptan in rapid-release technology, and 500 mg of Naproxen sodium. I have three main points today: Treximet treats the multiple mechanisms of migraine, which sets it apart from all the other drugs in the triptan class. Point two, Treximet has proven superiority to Imitrex, the gold standard for treating migraine. Point three, I will address the question "Why not simply get this as two separate prescriptions?". Early in migraine, neurochemicals such as CGRP, substance P and kinins are released from the activated trigeminal nerves. CGRP results in vasodilation, kinins progress to result in the release of prostaglandins, and as the migraine progresses, further prostaglandins are produced by activated structures along the pain path in the CNS. These pathophysiologic steps represent the early and later phases of migraine. Triptans address the early phase and NSAIDs address the later phase, and this is the justification for "Why Treximet?". Point number two, in the pivotal trials of this product, the FDA required Treximet to meet six co-primary endpoints in the treatment of moderate to severe pain. It had to prove superiority over sumatriptan and naproxen sodium, not only at two hours post dose, but through 24 hours post dose. Treximet was superior to both components at providing pain freedom at two hours and sustained pain freedom through 24 hours. In the patients who were treated with Treximet, the use of rescue medications, including opiates and butalbital-containing medications was significantly reduced. Now why now simply give this as two prescriptions? Many headache specialists have been combining NSAIDs and triptans for years, and this is because migraine patients simply aren't satisfied with current therapy. A survey of 425 patients showed that 71% reported using multiple medications to treat their migraine headaches, and over half of them reported using a step care approach. In managed care database of over 1,500 patients who had previously treated their attack with a triptan and NSAID simultaneously, only 10% repeated that behavior with their next attack. 23% utilized step care; they took the nonspecific medication first and the triptan only after it failed. The bottom line is, data shows that many patients with access to multiple migraine medications practice step care with an attack, taking a triptan only after failing a nonspecific medication. This may delay the onset of pain relief and lead patients to use additional analgesics, such as opiates and other rescue, predisposing them to medication over use. Thank you.

Shawn Murphy

My name is Shawn Murphy, and I'm the Medical Science Liaison for EMD Serono, and I would like to thank the committee for the opportunity to speak on behalf of the inclusion of Rebif on the Idaho State Medicaid Formulary. The Therapeutics & Technology Assessment subcommittee of the American Academy of Neurology, is responsible for the article "Disease Modifying Therapies in MS". Reporters review the published data of each DMT, with an emphasis on the product's pivotal trials and class-1 evidence. One of the opening remarks of the review states "The most important therapeutic aim of any disease-modifying therapy is to prevent or postpone long term disability". The article defined the three key efficacy parameters in MS trials as delaying confirmed progression of disability as measured by EDSS, relapse rate reduction, and T2 volume change on MRI. In looking at each of the drugs' pivotal trials, only Rebif had a statistically significant effect on all three efficacy parameters. While Rebif was approved outside of the United States in 1998, it was not allowed to enter the US marketplace because Avonex held orphan drug status. Thus, to gain entrance in the US, Serono undertook the EVIDENCE trial. Based on the results of the EVIDENCE trial, Rebif was allowed to overturn the orphan drug status held by Avonex. It was the first in the over 20-year history of the Orphan Drug Act that protection was overturned based on clinical superiority as defined by the FDA. In the head-to-head trial with Avonex, Rebif was shown to be clinically superior in reducing relapses and MRI activity at 24, 48 and 64 weeks. The side effects, severe adverse events, and drug discontinuations were comparable between both Rebif and Avonex. Next I would like to highlight data regarding Rebif and Betaseron as is outlined in the Drug Effectiveness Review Project at Oregon Health Sciences University. In an effort to compare the efficacy of Rebif and

Betaseron, the OHSC drug report reviewed two studies, neither of which found a significant difference in efficacy. However, the document states that both on table 2, page 16 and table 5, page 21, that Rebif had superior tolerability as measured by fewer injection site reactions, fewer flu-like syndromes, and less depression when compared to Betaseron. Finally, I'd like to point out that Rebif is the only DMT with two FDA-approved dosages, both of which were indicated for delaying confirmed progression of disability. Thank you for your time.

Sharon Cahoon-Metzger

I'm Sharon Cahoon-Metzger. I'm a PhD Medical Science Liasion with Biogen Idec. I'm here today to speak to you on behalf of Avonex. First off, I'd like to point out that Biogen Idec strongly advocates open and equal access to all agents for MS. MS is a heterogenous group of disorders classified as one disease. Patients don't present the same, they don't progress the same, there's a lot of variation in physical versus cognitive dysfunction related to MS, and really MS is one of those fields that really does require the art of medicine. Physicians see a patient, and they know they've seen that type of patient before, and they have a feeling about the drug that might work best in that patient. We support the ability of the physician to practice the art of medicine with their MS patients. Having said that, I'm here to support Avonex, so I'm going to give you a little bit of information about Avonex. Avonex is the only one of the injectables that had disability progress as its primary outcome in a phase-III study and we agree completely with what was said and with the AAN statement that prevention or slowing down of disability ought to be the primary objective of MS treatment. It's the only MS treatment that currently has disability progression, reduction of relapse rates, and treatment for CIS patients in the label as its indication. It has the lowest rate of neutralizing antibodies among the interferons, the lowest rate of injection site reactions among the injectables, and the highest rate of compliance. It's a once-weekly injection as opposed to the more frequent injections. Patients don't glean benefit from a drug that they don't take, so compliance is an issue with that. We now have safety data for patients out to 15 years, so Avonex clearly is a reasonable option but, again, we as a company strongly advocate open and equal access so that physicians have that choice. Thank you

Elaine Thomas

Good morning and thank you for your time to listen to my request to keep Betaseron, as well as the other three disease-modifying therapies, on your formulary. I am Elaine Thomas, Medical Science Liasion for Bayer Health Care Pharmaceuticals. So first, I'd like to say that Betaseron is the oldest drug on the market. It's the work horse. It's been there and approved since 1993. There's greater than a million patient years of experience with this drug, both here and in Europe, it has proven its excellent tolerability and efficacy in four clinical studies that are actually in the package insert, and these studies span relaxing-remitting MS as the pivotal study and then a study in the very earliest form of not even diagnosed as MS yet, clinically isolated syndrome, and there are two secondary progressive MS studies in this package insert, so I encourage you to look at that. So, what are the AAN guidelines? Does dose matter? Dose does matter. The AAN guidelines suggest that higher dose and higher frequency are more efficacious than lower dose and lower frequency, and they state that it could be the dose, but it could also be the frequency of administration of the drugs that make the difference. So what's new? I want to tell you about the BENEFIT study, which is the study that actually led the FDA to approve Betaseron for the clinically isolated syndrome, the first clinical indication that you have MS, followed also by a constellation of MRI lesions that look like MS. So in the study, which is the only prospectively planned, five-year (it's the longest class-I data study out there) showed that Betaseron significantly delayed the onset of clinically definite MS (that means having your second attack) or McDonald MS with highly statistically significant values (37% and 45% respectively with P-values less than 0.001). Cognition was also looked at in this early patient population, and at five years, there was a significant improvement, in other words, the pSTAT scores did not go down, in those treated early with Betaseron from their very first clinical event, and this is over five years. So Betaseron is the only high-dose, high-frequency drug that is indicated in this earliest population, the CIS group. So therefore, we have both early- and late-stage relaxing-remitting disease data that is very significantly showing a decrease in relapse rate and improvement of the health of your MS population. So two other new things: There's just been introduced a 30-gauge needle, which is the thinnest needle in MS. It may help overcome some needle phobia and patient's compliance. The other really important point is that it's refrigeration-free. So not all of your patients have access every day to a refrigerator, and if you can keep your drug out of the refrigerator; if you're a long haul truck driver where you don't always have access to your home refrigerator, I think it's an important consideration. So please keep all of the disease-modifying therapies available for these patients because they're all different. Thank you.

Juanita McDonough

Members of the committee, my name is Juanita McDonough. I'm a registered nurse with GlaxoSmithKline Pharmaceuticals. I want you to know that Dr. Woodhouse's comments were not wasted on me. At the January review, he stated that the most helpful public testimony is that which succinctly highlights new and differentiating data. I'm here today to ask the committee to consider adding Altabax to the PDL without restriction. Altabax is indicated for the treatment of impetigo due to Staph or Strep. I want to emphasize three key points which will differentiate Altabax from other agents on the market: First, Altabax is unique. Altabax is the first and only in a new class of topical antibacterials called pleuromutilins. Altabax works by interfering with multiple aspects of protein synthesis. As a result, has excellent efficacy and a low propensity for the development of resistance.

Altabax was shown to be 32 times more potent that generic Mupiricin against Staph in vitro, and this is key. Altabax consistently demonstrates lower MICs against drug-resistant Staph pathogens. Now, my second point expands on this a little bit more. In an in vitro, multi-passage study, 100% of the isolates remained susceptible to Altabax at day-20. Now this compares to 17% of the isolates remaining susceptible to Mupiricin, and may I emphasize that these isolates were our worst case scenario and contained many of the common drug-resistant isolates, and Altabax remained susceptible to 100% of the isolates at day-20. Lastly, Altabax has a very simple, five-day b.i.d. dosing. This shorter course of treatment and b.i.d. (twice a day) dosing, will increase the likelihood that your patients will receive a full course of treatment. A quick safety update: The most common drug related adverse reaction was application site irritation which was demonstrated in 1.4% of patients. Altabax is available in two sizes: The 5 gm tube and the 15 gm tube. The 5 gm tube offers the best value and our pediatricians tell me that the 5 gm tube is more than adequate for a full course of treatment. So let me close by asking the committee to add Altabax to the PDL without restriction. Thank you for your time, and do you have any questions of me? Thank you.

Rick Swartwout

I would like to thank the committee for allowing me to speak today. My name is Rick Swartwout and I'm the District Manager with Pfizer's Endocrine Care Division. I wanted to start out by recognizing with the committee that somatotropins, which I'm going to talk about today, growth hormone, is for a milligram per milligram basis, all of them are the same, I realize that. However, when you start to look at the differences among the products that are out there, the way that the product is delivered often differentiates how likely a patient is to take the medication. My product is Genotropin. Genotropin does have a pen delivery system which most other companies do have, which is certainly an advantage over the old, original, two-vial system and had to be mixed. However, I did want to mention that with Genotropin, we do have a unit dose system called MINIQUICK. MINIQUICK is a product that is preservative-free. It can be stored for up to three months at room temperature in the patient's home prior to reconstitution and delivery. It is one of the easiest to add mix and deliver. Simply put a pin needle on the top of the syringe, you screw the plunger down until it stops, take the cover off and inject your drug. Although you may think of unit dose as being a product that's going to have a premium price, it does not, so it's priced out equivalent to our multi-dose type of Genotropin. It's been a huge benefit to patients that have families that are mechanically challenged and cannot put intricate systems together, they just don't understand how to do that and don't do that properly. It's been a big benefit to temporary caregivers, such as a summer camp nurse or a grandparent temporarily taking over for parents while they're gone, and in more dramatic cases, we've even had patients that were blind and one that only had one hand that could assemble the MINIQUICK device and found that that was the only system they could work with. Additionally, with Genotropin, we do have the Bridge program which is a patient processing center that helps facilitate getting the patient up and running on their medication. They provide a starter kit which is loaded with instructional materials, as well as ancillary supplies to be able to get that patient started on their product. Also, the Bridge program does have the ability to send out a nurse to train that patient free of charge, and this can be done either at the patient's home or in the prescriber's office, depending on what their preference is. Genotropin does have indications, five of them for growth and one of them for adult growth hormone deficiency. I bring this up because of the fact that as a company, Pfizer can supply educational materials to patients about the disease itself, diagnosis and treatment, and other companies that don't have those indications can't supply those materials. Because of these benefits, Pfizer respectfully requests that you add Genotropin, include that on the Idaho PDL. Thank you.

Linda Burkett

Good morning. My name is Linda Burkett. I appreciate the opportunity to be here. I am a Medical Liaison at Novo Nordisk and I support Norditropin which is another growth hormone product. On 10/31/08, Norditropin got another indication for treatment of short stature related to small for gestational age children who do not catch up their growth by the age of 2-4 years, and that's in addition to four other indications that we have. Pediatric growth hormone deficiency, adult growth hormone deficiency and the treatment of short stature related to Noonan syndrome, as well as Turner syndrome, and we do have documentation and educational materials for each of those. Norditropin is the only growth hormone that is indicated for the treatment of short stature related to Noonan syndrome, and about 83% of those children will be short and need therapy. It's also important to note that the preservative in our product is phenol, so that's available to be able to use in the Neonate or the infants, and it's available in our Nordiflex pen. The Nordiflex pen is the only pre-mixed, pre-filled, multi-dose disposable growth hormone device with dosage flexibility, and our 5 mg and 10 mg pen also have room temperature stability up to 77° for 21 days, which is extremely helpful. It's a very easy product to learn and to teach for patients. Our pen goes together really simply; you put on a needle, you dial up your dose, you give your injection, and this happens to be a 10 mg pen, so the patient can actually leave this on the counter, not forget to put in the refrigerator, and thereby decrease wastage of product. We do have a support service for our patients, where education can occur in the home or the physician's office for teaching and product availability for patients that might be between insurance or Medicaid or whatever. I would like to thank you for allowing us to be here to present and we encourage you to keep Norditropin on the Idaho Medicaid PDL. Thank you.

Vincent Yan
Good morning everyone, my name is Vincent Yan, I am a PharmD representative of UCB Pharmaceuticals and Keppra-XR. The goal of my brief presentation this morning is to respectfully request that we consider adding Keppra-XR onto your preferred drug list for your epilepsy patients. Despite the availability of several anti-epileptic drugs, nearly one in three epilepsy patients will suffer through breakthrough seizures. Non adherence is prevalent and has consequences such as increased breakthrough seizures, auto accidents, falls, fractures, hospitalization, and even higher rates of death. Keppra-XR is indicated for the adjunctive therapy in treatment of partial-onset seizures in patients sixteen years of age and older with epilepsy. It employs a matrix technology and is dosed once a day, with an effective starting dose of 1000 mg, and may be increased by 1000 mg every two weeks, to a maximum dose of 3000 mg q.d. Keppra-XR is available as 500 mg tablets and it has similar bio-availability to the immediate-release levetiracetam, but the duration per 24 hours that blood levels are within 75% of peak plasma levels is 7.8 hours for Keppra-XR versus 3.4 hours for the immediate-release levetiracetam. Keppra-XR has no known clinically significant drug-drug interactions. In a recent, well-controlled clinical trial, Keppra-XR demonstrated efficacy when added to 1-3 concomitant anti-epileptic drug medications in adults with refractory epilepsy who were experiencing partial-onset seizures, one or more per week. Treatment with 1000 mg of Keppra-XR dosed once a day without titration, significantly reduced seizure frequency from baseline compared to the placebo. 10.1% of patients treated with Keppra-XR achieved seizure freedom on their first dose throughout the entire twelve-week treatment period versus only one patient (1.3%) in the placebo arm. 24% of Keppra-XR patients had their seizure frequency reduced by 75% or more versus only 11% in the placebo arm. The most frequently reported adverse events in patients receiving Keppra-XR in this clinical trial, seen at a frequency of 5% or higher compared to placebo, were irritability and somnolence. Additionally, no patient discontinued treatment due to adverse events. Keppra-XR is effective as adjunctive therapy in refractory adult epilepsy patients with partial-onset seizures and is generally well tolerated. These factors, along with once-daily dosing regimen, can help patients attain seizure control and may help them adhere to their treatment regimen. As seen with the immediate-release Keppra, Keppra-XR will be promoted only to neurologists and epileptologists. According to IMS data from 08/2008, 93% of Keppra use was in epilepsy.

Committee: Thank you very much, we appreciate your comment.

Vincent Yan
Thank you.

Vandana Slatter, PharmD
Good morning. My name is Vandana Slatter, currently a Medical Liaison with Roche. Thank you for the opportunity to testify on behalf of PEGASYS for chronic hepatitis-C. PEGASYS in 2009 remains the most commonly prescribed interferon for hepatitis-C in the United States, and is either preferred or at parody on state drug lists. There are six main reasons why PEGASYS is the most commonly prescribed interferon for chronic hepatitis-C. First, PEGASYS has the broadest range of FDA indications, and those which are unique to PEGASYS include compensated cirrhosis, HIV/HCV co-infection, and as monotherapy for chronic hepatitis-B. Second, a wealth of clinical data supports the PEGASYS label. PEGASYS COPEGUS or ribavirin therapy has achieved the highest recorded FDA registrational trial SVRs in patients overall (63%), in the most common genotype-1 (52%), and in genotype-1 (high viral load, very difficult to treat patients) 41-47%. As prior package insert, relapse rates are 19-20%. PEGASYS offers predictability and durability of response. Genotype-1 patients who are virus free by weeks 4-12 have a high probability of achieving SVR and 87% are 68% respectively. Those who do not reduce by two logs, a two-log drop in viral load or are virus free by week-12 have very little chance and can consider stopping therapy. Greater than 99% of patients who achieve an SVR remain virus negative long term. Four: PEGASYS offers demonstrated tolerability and safety. 89% of chronic hepatitis-C monoinfected patients can complete therapy. Safety is detailed in PEGASYS COPEGUS package inserts which were updated in June of 2007. A “Dear Healthcare Professional” letter containing important drug warning update to PEGASYS and COPEGUS was mailed in January, 2008. Fifth: PEGASYS is easy to use. It does not need to be dosed by weight, due to its small volume at distribution; one standard dose for all patients. It’s easy to teach. Packages are ready to use, pre-filled syringe, and easy to dose reduce if needed. Sixth: Roche is committed to optimizing therapy for all HCV patients. The largest trial of Latino patients, the LATINO study, was just published in January in the New England Journal of Medicine. SVR and Genotype-1 Latinos were 34% versus 49% Latino-Caucasians. Finally, the majority of registration trials for small molecules in development are being done with PEGASYS. Thank you.

Sue Heineman
Good morning, I’m Sue Heineman, a pharmacist here in Boise, and I work for Pfizer as a Medical Outcomes specialist. Thank you for letting me speak this month with the rest of the public instead of afterwards when everyone has left, so I do appreciate that. But I’m going to talk in support of pregabalin, or Lyrica, today. You guys have the 600+ pages of data and I’m not going to talk about that, but what I do want to revisit are the questions that have come up over the last two years as we had talked about pregabalin. One, the

concern about is there a dose creep that was seen with the gabapentin and, no, we're not seeing that. You guys can look at your own data, I pulled it up, you know, the CMS data is available. The majority of your patients are on either that starting dose for most of our indications at 75 mg b.i.d., or the therapeutic, the higher dose, the 300 mg b.i.d. dose, that's where the majority of where your patients are. With gabapentin, you remember, you've got to go high to get the efficacy, which is ironic because you really don't get better efficacy with the higher doses. So I just wanted you to revisit that, that we're not seeing the dose creep, we're not seeing the indications off label. We are committed to being on label with pregabalin, which, you know, if you remember one of the discussions last year was the fact that a patient had to fail gabapentin for DPN, an indication it does not have, and I would just ask that you revisit that and lift that criteria for a doctor who wants to start pregabalin on a patient, not to have them forced to use a product (gabapentin) that's not approved for DPN. That's it, so thank you for your time and thank you for what you're doing.

Isaac Lloyd

Thank you. Good morning, my name's Isaac Lloyd and I'm a Medical Science Liaison with Schering-Plough. I'm here to talk to you today about PEG-Intron. Apparently, both products are available for Medicaid patients in Idaho; PEG-Intron and PEGASYS, and with such a limited drug category, two drugs available, I think patients and providers both appreciate the ability to choose. First of all, I'd like to point out recent unique indications for PEG-Intron. As of 12/12/08, PEG-Intron is the first and only approved pegylated interferon combination with ribavirin for untreated children ages three and older with chronic hepatitis-C. PEG-Intron's dosed by body surface area in children, 60 $\mu g/m^2$/week, with 15 mg/kg/day of treatment of ribavirin in two divided doses. Currently, there are no published head-to-head studies with parent pegylated interferons, however it is important for the committee to know the results of the IDEAL study, which compares the two pegylated interferons. The IDEAL study was presented at the EASL meeting in 2008 and is available in abstract form. Top line for the results from the IDEAL trial, which is a prospective study of over 3,000 US genotype-1 patients, the most difficult to treat patients, overall sustained virological responses were similar through the three treatment regimens, PEG-Intron 1.5 was 40%, PEG-Intron of 1.0 was 38% and the PEGASYS regimen was 41% SVR. However, a lower percentage of patients in the PEG-Intron 1.5 arm had experienced relapse after the end of treatment. 24% for 1.5, 20% for 1.0, and 32% for the PEGASYS regimen. Analysis of the 52% of patients that actually received the same dose of ribavirin revealed the following: sustained virological responses were 40% for PEG-Intron 1.5, 38% for 1.0, and 38% for the PEGASYS regimen. However, again, there was a difference in relapse rates. For PEG-Intron 1.5, it was 22%, 1.0 20%, and for the PEGASYS regimen, 35%. There are just two unique benefits that I'd like to talk to you a little bit about PEG-Intron. First of all is the ability to weight-base dose. Since 1960, the average weight for both US men and women has increased by almost 25 lbs. According to the Idaho State Behavioral Risk Factor Surveillance System from 2007, 63% of Idaho adults are overweight, with a BMI of >25, and approximately 25% being obese at >30. Patients weighing more than 165 lbs or 75 kg, have lower SVR rates when given flat-dose interferon therapy. PEG-Intron is the only pegylated interferon to offer individualized, weight-based therapy at 1.5 µg/kg. In published studies, weight-based PEG-Intron and ribavirin demonstrated similar response rates regardless of weight. The second thing I'd like to talk to you about is our support services, which is a BMI chart, which is a free service of Schering-Plough for patients getting interferon therapy. All Medicaid patients have agents who they can talk to in multiple languages, a live nurse, 24/7. That's all I have for you this morning. Thank you..

Pam Sardo

I know you want to move on and you've heard a lot of good information this morning. Good morning, my name is Pam Sardo. I'm a Government Regional Clinical Executive PharmD with Abbott Laboratories and I want to thank you for the opportunity to come before you today to speak about two products that are currently available for the patients in Idaho, and those two products are Depakote-ER and Depakote. Depakote and -ER are very well known to this committee. They are FDA approved for treatment of acute manic or mixed episodes associated with bipolar disorder with or without psychotic features, prophylaxis of migraine, monotherapy and adjunctive therapy in the treatment of complex partial seizures, either in isolation or associated with other types of seizures, and also as monotherapy and adjunctive therapy in the treatment of simple and complex absence seizures, and this can also be adjunctively with multiple seizure types that include absence seizures. The efficacy of Depakote-ER in reducing incidence of complex partial seizures has been published in the Journal of Neurology and revealed that patients had statistically significant reduction in the complex partial seizures at eight weeks. Regarding treatment guidelines and consensus statements for epilepsy, the 2005 Expert Consensus Guidelines did recommend both Depakote and Depakote-ER among the first-line monotherapy drugs of choice for a variety of generalized seizures that include absence, generalized tonic-clonic and myoclonic seizures, and regarding mania, the American Psychiatric Association in 2002 did recommend Depakote-ER and Depakote as first-line in acute mania associated with bipolar. In 2004, another Expert Consensus Guideline set described the use of Depakote for treatment of mania without psychosis, mania with psychosis, dysphoric mania or true mixed mania, and classic euphoric mania. Also, the American Academy of Neurology has recommended Depakote and Depakote-ER for migraine prophylaxis. The prescribing literature does discuss potential adverse events which could include hepatic failure, teratogenic effects and pancreatitis. I do encourage you to review the prescribing information and wish to thank you for your continued consideration of Depakote and Depakote-ER for the appropriate patients in Idaho. Thank you very much.

Committee
Yes sir?

Tom Rambow, PA
I wasn't on the list. Can I just make a quick point about Lyrica? Would that be okay?

Committee
Sure, I need you to sign in, though, please.

Tom Rambow, PA
Thank you sir. I'll only be thirty seconds. Thank you for having me, my name's Tom Rambow, I'm a physician's assistant and I work at the Idaho Pain Center. I just want to make a quick point about Lyrica and the use of it with post herpetic neuralgia. If we're able to get these patients early enough, from a clinical standpoint, when you're trying to make a choice as to what you're going to use for treatment, you've got very little time with these patients before they could develop cephalization of pain. If I have a choice on what medication I'm going to use, I'd rather go with something that I know is going to be more effective, at least clinically and with data. So if I have a patient like that and I'm trying to treat them aggressively, I would like to have the opportunity to use Lyrica if they have not used it. It's important, like I said, if we can catch these patients early, sometimes we can prevent a chronic pain problem, rather than, you know, being able to get them under control. So that was really the only point I wanted to make. With the current rules, we have to try gabapentin and sometimes it's just not good for the patient. So I appreciate your time. Thank you.