Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: November 18, 2011 **Time:** 9:00 a.m. – 3:45 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, M.D.-Chair; Perry Brown, M.D.; William Woodhouse, M.D.; Dennis Tofteland, RPh; John Mahan, M.D.; Catherine Hitt-Piechowski, PharmD; Elaine Ladd, PharmD; Tami Eide, PharmD; Mark Turner, M.D., Hamilton Warren-Sutton M.D., Jeffrey Johnson, PharmD, PA-C
Others Present: Steve Liles, PharmD; Mark England PharmD, Magellan; Jane Gennrich, PharmD.; Cody Scrivner, CPhT; Rachel Strutton, Division of Medicaid
Committee Members Excused: Mark Johnston, RPh;

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Phil Petersen, M.D.	Dr. Petersen called the meeting to order.
Committee Business		
➢ *Roll Call*	Phil Petersen, M.D.	Dr. Petersen completed the roll call, welcomed the P&T Committee members and called the meeting to order. He also introduced two new Committee members Jeffrey Johnson, PharmD, PA-C and Hamilton Warren-Sutton M.D., and provided a brief background on each.
➢ *Reading of Mission Statement*	Phil Petersen, M.D.	Dr. Petersen read the Mission Statement.
➢ *Approval of Minutes from the October 21, 2011 Meeting*	Phil Petersen, M.D.	There were no corrections. The October 21, 2011 meeting minutes were accepted as proposed.
Drug Class Reviews and Committee Recommendations		**Drug Class Reviews and Committee Recommendations**
➢ Hepatitis C-Protease Inhibitors	Steve Liles, PharmD Provider Synergies	**Hepatitis C-Protease Inhibitors** Dr. Liles provided review of two new products in this class boceprevir (Victerelis) and telaprevir (Incivek). The Committee reviewed the indications, contra-indications, warnings and four clinical trials for these new products. Differences between the two agents and their place in therapy for Hepatitis C were emphasized. Dr. Liles also stressed that there is only one try of these agents per lifetime as resistance develops.

		Committee Recommendations The Committee recommended preferring both agents and monitoring appropriateness of their use through retrospective review.
➢ Antihyperurecemics	Steve Liles, PharmD Provider Synergies	**Antihyperurecemics** No new clinical data was presented. **Committee Recommendations** Results of a recent DUR study on colchicine use were discussed with the Committee. The Committee recommended modifying the prior authorization requirements for Colcrys (colchicine) to prevent delay in treatment of an acute gout attack. They recommended that a maximum quantity be established for an acute attach. Quantities over that should be considered chronic use and the current criteria should be applied for prior authorization The Committee also made a request of the Department to continue to monitor the use of Colcrys (colchicine).
➢ Cytokine and CAM Antagonists	Steve Liles, PharmD Provider Synergies	**Cytokine and CAM Antagonists** Dr. Liles discussed that abatacept (Orencia) was now available for SQ administration and that tocilizumab (Actemra) was now FDA approved for treatment in juvenile idiopathic arthritis (JIA) in children two years old and older. He also discussed two new clinical trials and one meta-analysis. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class.
Public Comment Period	Phil Petersen, M.D. Cody Scrivner	**Public Comment Period** Dr. Petersen made an announcement that the Department of Health and Welfare made a revision to the recent changes to the public comment guidelines recommended by the Committee and determined pharmaceutical companies can present pre-approved testimony on new information. The Committee urged the speakers testifying on behalf of the pharmaceutical companies to restrict their testimony to new clinical data only. Ten people signed up to speak during the public comment period. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
Rob Wechsler, M.D.	Idaho Comprehensive Epilepsy Center	All	Anticonvulsants
Ellen Hunter, M.D.	Self	telaprevir	Hepatitis C-Protease Inhibitors

Drug Class Reviews and Committee Recommendations		**Drug Class Reviews and Committee Recommendations**
NSAIDS	Kim Peterson, MS, DERP Investigator OHS EPC (audiotape)	**NSAIDS** Ms. Peterson provided the DERP updated review of NSAIDS completed November 2010. The review did not show any clear differences in pain reduction across all included drugs. This update included the topical NSAIDs, for which there are no head-to head trials between the various agents and dosage forms.
	Steve Liles, PharmD Provider Synergies	Dr. Liles provided a review of a new product Sprix (ketorolac) nasal spray and one clinical trial on this new product. **Committee Recommendations** The Committee concluded that the new product Sprix (ketorolac) was a niche drug and should be available as a one time prescription with a five day quantity limitation. They requested the Department monitor the use of this product. The Committee also recommended eliminating diagnosis criteria for Celebrex, but stated that there was no evidence to support that Celebrex was more effective than other NSAIDs. The Committee concluded that there were no evidence-based differences among any of the other agents to support preferring any agent over another in this class.
Neuropathic Pain Drug Class Review	Shelley Selph, MD Investigator OHS EPC (audiotape)	**Neuropathic Pain Drug Class Review** Dr. Selph presented the updated DERP drug class review on neuropathic pain. This update was completed in July 2011. The review concluded that that gabapentin, pregabalin, and lamotrigine were comparable to tricyclics for pain relief in diabetic neuropathy and postherpetic neuralgia. Duloxetine, pregabalin, and gabapentin were superior to lacosamide and lamotrigine for pain relief. Lidocaine patch has been shown to be comparable to pregabalin for pain relief, but pregabalin is associated with significantly more withdrawals due to adverse events. For other types of neuropathic pain, evidence was insufficient to draw conclusions about comparative

Stephen Carlson, RPh	Intermountain Hospital	All	Antipsychotics
Shannon Gardiner, PA	Self	Celebrex	NSAIDS
Michael O'Brien, M.D.	Self	Lyrica	Fibromyalgia Agents
Kathie Garrett	NAMI Idaho	All	Antipsychotics
Paula Campbell	NAMI Idaho	All	Antipsychotics
Kathleen Karnik, PharmD	Ortho-McNeil Janssen	Invega Sustenna/ Risperidal Consta	Antipsychotics
Roy Palmer, PhD	Pfizer	Celebrex	NSAIDS
Rajesh Patel, PharmD	Bristol Myers Squibb	Orencia	Cytokine & CAM Antagonists

		effectiveness and safety. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class.
Anticonvulsants	Steve Liles, PharmD Provider Synergies	**Anticonvulsants** Dr. Liles reviewed the American Academy of Neurology (AAN) Treatment Guidelines for diabetic peripheral neuropathy. He reported that topiramate is now classified as pregnancy category D and is associated with cleft lip and palate in exposed infants. He provided a review of one new product, Gralise (gabapentin ER) which is indicated for post-herpetic neuralgia. He presented dosage and administration recommendations and one clinical trial for this new agent. **Committee Recommendations** The Committee recommended making Vimpat (locasamide) a preferred agent. They also recommended that vigabatrin (Sabril) and felbamate (Felbatol) remain non-preferred agents.
Fibromyalgia Agents	Steve Liles, PharmD Provider Synergies	**Fibromyalgia Agents** Dr. Liles provided a review of one new clinical trial for milnacipran (Savella). It was noted that there are non head-to-head trials comparing the three agents that are FDA approved for treatment of fibromyalgia- Cymbalta, Lyrica, and Savella. **Committee Recommendations** The Committee concluded that there is no evidence to support one agent over another. The Committee recommended that patients not be approved for Cymbalta and Savella concurrently, but that a patient could be on Lyrica and either Cymbalta or Savella concomitantly for separate diagnoses.
Stimulants and Related Agents	Steve Liles, PharmD Provider Synergies	**Stimulants and Related Agents** Dr. Liles presented a review of one new product clonidine ER (Kapvay) including its dosage and administration and clinical trials supporting its FDA approval. He also reviewed results of the FDA observational study that compared cardiovascular events in prevalent users vs nonusers of ADHD medications. He also updated the Committee on the newest American Academy of Pediatrics (AAP) practice guidelines on ADHD. **Committee Recommendations** The Committee recommended the PA criteria be removed from Strattera (atomoxetine). The Committee recommended continuing to require the therapeutic criteria for stimulants that include past or present drug abuse with amphetamines, opioids, hallucinogens, and other drugs of abuse

		as contraindications. The Committee also recommended that both Intuniv (guanfacine ER) and Kapvay (clonidine ER) be non-preferred agents with the immediate release formulations of guanfacine and clonidine being preferred agents. The Committee recommended expanding the therapeutic criteria for Daytrana from patient's unable to take oral stimulants to also including patients who do not tolerate an oral stimulant.
Antipsychotics, Atypical and Typical	Steve Liles, PharmD Provider Synergies	**Antipsychotics, Atypical and Typical** Dr. Liles provided a review of one new product lurasidone (Latuda) which is now approved for the treatment of schizophrenia only in patients 12-17 years old. He also updated the Committee on the labeling changes for Invega (paliperidone) which now indicates it for treatment in adolescents 12 years and older. A new clinical comparative trial of ziprasidone and olanzapine was reviewed. An announcement that Zyprexa is now available generically as olanzapine and that Seroquel will be available generically in March 2012 was made. **Committee Recommendations** The Committee felt there was no data to prefer one agent over another. They felt it was important to not switch stable patients for continuity of care. The Committee recommended Invega Sustenna (paliperidone) as a preferred agent. They re-endorsed their previous recommendation to develop and implement guidelines for evidence-based appropriate indications and dosage. Dr. Warren-Sutton and Dr. Eide will work together on development of these criteria. The Committee also recommended that the Department provide educational materials to health care facility discharge planners regarding accessibility of the preferred products after the completion of inpatient treatment and the prior authorization process and therapeutic criteria requirements. The Committee also stated that these drugs should not be used as sedative/hypnotics for sleep.
Antidepressants, SSRI	Steve Liles, PharmD Provider Synergies	**Antidepressants, SSRI** Dr. Liles provided a review on the new labeling changes for citalopram which restricts dosing to 40 mg daily (was previously approved for 60 mg). It was noted that the DUR Board is currently conducting a DUR intervention on patients receiving more than 40 mg daily. Prescribers of these patients have received a letter and replies will be analyzed and reviewed by the DUR Board in January 2012. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class. The Committee recommended that paroxetine remain a non-preferred agent due to its adverse effect profile. Antidepressants, Other

Antidepressants, Other	Steve Liles, PharmD Provider Synergies	Dr. Liles provided a review of the new product Viibryd (vilazodone) which is a SSRI and 5HT1A receptor partial agonist indicated for treatment of major depressive disorder. He reviewed the indications, dosage/administration, adverse effects and two double blind randomized control trials on this new product. He also announced the new FDA approved indication of chronic pain for Cymbalta. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class. The Committee concluded that there was no evidence supporting Viibryd as first line and recommended PA criteria of a failure of two preferred agents (SSRI and/or other antidepressants).
Sedative Hypnotics	Steve Liles, PharmD Provider Synergies	<u>Sedative Hypnotics</u> Dr. Liles provided a review of two new products Silenor (doxepin) and Zolpimist (zolpidem) nasal spray, including their indications, dosage/administration and one double blind randomized control trial for Silenor. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class. The Committee recommended limiting all the agents in this class to short term intermittent use (no longer than 15 days per month). An exception should be made for any diagnosis of major psychiatric disorder. In order to make this more manageable, it was suggested that the 15 day restriction be implemented initially for new starts only. Prescribers should be given a six month warning to allow them to taper chronic users off of the drugs.
Antiparkinson Agents	Steve Liles, PharmD Provider Synergies	**<u>Antiparkinson Agents</u>** There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class.
Alzheimer's Drugs	Steve Liles, PharmD Provider Synergies	**<u>Alzheimer's Drugs</u>** Dr. Liles provided review of one new double blind randomized control trial. **Committee Recommendations** The Committee concluded that there were no evidence-based differences to support preferring any agent over another in this class. The Committee did recommend removing the requirement of a Mini-Mental State Exam (MMSE) from the PA criteria, but continuing to require a diagnosis

		of dementia.
➢ *Other Committee Business*	Tami Eide, PharmD	At the end of the meeting Dr. Eide announced that Chairman Dr. Phillip Peterson and Dr. William Woodhouse will be leaving the Committee and that this would be the last meeting they would be in attendance. Dr. Eide thanked both the Committee members for their time and the expertise they brought to the Committee. The other Committee members also thanked Dr. Petersen and Dr. Woodhouse as well.
	Perry Brown, MD	Dr. Brown asked that the Department explore methods of allowing a fill for omeprazole 28 caps/14 days specifically for H. pylori infections to pay at point of sale without a need for a manual prior authorization. This would improve compliance, particularly in the refugee population. Dr. Eide took this as an action item.

Pharmacy and Therapeutics Committee
Public Comment
November 18, 2011

Rob Wechsler, M.D.

Thank you, my name is Robert Wechsler, and I am the Medical Director of the Idaho Comprehensive Epilepsy Center. I have a solo private practice, but also work for St. Luke's in terms of running the epilepsy center there. I'm Chair of the Professional Advisory Board for the Epilepsy Foundation of Idaho. I do participate in a number of clinical trials, and do work with a number of the companies, but when I come to this meeting every year or two; I make a point of emphasizing that I am not representing any one company or product. I am here representing my patients and the clients of the Epilepsy Foundation of Idaho. Epilepsy is a really common disease; one out of a hundred people, and most of the time we can achieve seizure freedom with medication, probably about two-thirds of the time. The key to that success is access to therapies, and every time I come and speak to you all, I thank you for the access that you have given me to the anti-epileptic drugs, because we've had a lot of success with them. I've shared over the years with you a number of anecdotes. I do the seizure clinic at the Idaho State School. I see a lot of Medicaid patients in my private practice. I'm probably one of the only private practice neurologists left in the state that sees all patients without any kinds of restrictions on access. At the State School, we've seen about an 80% drop in seizure emergencies and the use of DIASTAT since I took over that clinic. A lot of that comes back to minimizing polypharmacy and picking the right drugs for the right epilepsy types. I really do appreciate the access to these agents. Every year, I bring you an interesting anecdote. I saw a patient a few days ago that I thought I needed to share with you. He is on three drugs plus a vagus nerve stimulator, and he is actually seizure free. He has been seizure free for over a year and he's starting to work and it's a success, but it's a success that came from trying a lot of different things along the way. We have a lot of new drugs that have come out and that are about to come out. There are two new drugs that will be coming out early next year. We have Ezogabine, which is going to be a first ever NMDA receptor blocker, so it's a novel way of attacking seizures. Then we have clobazam, which is a novel version of a benzodiazepine. It's a 1,5- as opposed to a 1,6-benzodiazepine, and it's

thought to have less tachyphylaxis and less sedation than the other benzodiazepines. Ezogabine is going to be for partial onset, and clobazam is going to be coming out for drop seizures and Lennox-Gastaut syndrome. The last time I spoke, I addressed the generics issue with you guys a little bit, and somewhere along the way, I got a little bit misquoted. I do think that there are circumstances where generics are perfectly appropriate. For example, initiating a new therapy as an add-on, but there are also circumstances where having the brand name available is important, because of our drugs often having a narrower therapeutic window, and because epilepsy is just that much more fragile, we do see problems when we make those switches. There was a great study that came out of Canada a couple of years ago. I cite it a lot because the lead author's name was Duh, D-U-H, and I thought it made such a great point. They made a comparison of three groups of patients followed for a year in Canada. They were epilepsy patients who were either on brand name topiramate, generic topiramate, same manufacturer for twelve months, or generic topiramate with manufacturer substitutions allowed, and the brand name people did the best, the generic single manufacturer did okay; it was not as good, but it was not statistically different, and the multiple manufacturers group did significantly worse than the other two groups. So we have seen this a lot. We all, as neurologists, see patients that end up in the emergency room when they've had a substitution. We try to track that. We did get a law passed in 2010 in Idaho that says that if a pharmacy is going to make a substitution, even if it is one generic manufacturer to another, the patient and the provider need to be notified. That is sometimes happening, it's still not happening all the time, but it is an important issue. So, yes, there are circumstances where the generics are perfectly appropriate, but there are also circumstances where the brands are necessary and that should be the prescriber's decision. The American Academy of Neurology and the American Epilepsy Society have come out and said, for example, that if a patient has achieved seizure freedom on a brand name agent that they should not be substituted. That's a scenario where the substitution could lead to seizure breakthrough and it may not be possible to get that control back all that easily. I think that's about all that I have to say today, unless anyone has any questions. I've never had an opportunity to answer questions before.

Question from Committee Member: One question to you is, as things are, right now with the Medicaid formulary, are there any that you wish you could go to first line that are not available to you? That you have to get prior authorization for?

Rob Wechsler, M.D.
Well, you know, my answer to this is going to be different from my staff's answer. We have a really good relationship with you guys. We really have a good relationship with the Prior Authorization Department. When they see something odd, they've gotten to know me well enough that they can say, "Gosh, that doesn't sound like Dr. Wechsler, can we call him up and find out what's going on?", and that's been very valuable for us. So, we do typically have to do a first round of prior authorizations, but rarely do we have to get into a big fight, but that comes from me and my practice, and the relationship that we've built with you guys. So I'm not seeing a big problem in terms of access. If you were to ask me which ones would I put myself or my family on first, I think my top three at this point are probably levetiracetam, lamotrigine and lacosamide. Those are the ones that I've had the best luck with in terms of tolerability and efficacy in combination. I will say that if I look at the brand versus generic issue, when we run into problems with patients having either tolerability issues or seizure breakthrough, it seems to be more often with the generic lamotrigine than with any of the other products that have gone generic recently. That's the one that's given us the most headaches.

Ellen Hunter, M.D.
Good morning, my name is Dr. Ellen Hunter, and I'm in private practice. I'm a gastroenterology and hepatologist here in Boise, and I appreciate the opportunity to speak in front of the P&T Committee for the Idaho Medicaid Program. I am on the speaker's program for the two protease inhibitors that you've heard about this morning. I'm not being sponsored by either company at this meeting for this talk or this presentation. I'm here on behalf of the patients that I see with chronic hepatitis-C. Hepatitis-C is an important and serious medical condition that affects about four million persons in the United States. It can cause permanent scarring that we call cirrhosis, and it may also cause liver failure and liver cancer. I've been treating hepatitis-C patients since 1986, when hepatitis-C was known at that time as non-A/non-B hepatitis because the virus was not identified until 1989. I have treated a large number of patients with chronic hepatitis-C and have seen the improvements over the years in the treatment and the efficacy. However, this is a difficult disease to treat because of the side effects of the medications, and there are some types of hepatitis-C that do not respond as well to treatment. So, recently, a significant breakthrough in treatment has occurred, with the development of the protease inhibitors that

we've heard about previously this morning, and they can directly inhibit the virus and lead to clearance and subsequent cure of hepatitis-C virus in patients with the most common type of hepatitis-C known as genotype-1. The response rates have gone from approximately 50% and now are up to 80% even with some subgroups, even higher with the addition of the protease inhibitor, and this was added to the pegolated interferon and ribavirin. As you have heard, there are two oral protease inhibitors that have been recently approved for the treatment of hepatitis-C: boceprevir (or Victrelis) and telaprevir (or Incivek). They are not used together. One of them is used in combination with pegolated interferon and ribavirin. Treating hepatitis-C is complicated and adding a protease inhibitor to the regimen has only added to the complexity for both the patient and the treating providers. The protease inhibitors have to be taken about every eight hours around the clock. Patients are taking two telaprevir every eight hours or four boceprevir every eight hours each time. This is on top of taking pegolated interferon injections once weekly and ribavirin pills daily. I see pros and cons to both protease inhibitors and in my practice it is important for me to have both products available. The treatment regimens between the two medications are very different. An advantage of using telaprevir is that the treatment regimen is relatively straightforward. The patient is started on all three drugs, so-called "triple therapy" on day-1 and the duration of telaprevir, the protease inhibitor, is twelve weeks in all patients. After that, the patients are only on two drugs; the pegolated interferon and ribavirin somewhere from 24 to 48 weeks, depending on their response. In contrast, with boceprevir, patients are started on pegolated interferon and ribavirin for a so-called "lead in" period for four weeks and then after that, the protease inhibitor boceprevir is added. Then patients are on triple therapy with boceprevir, pegolated interferon and ribavirin from anywhere from 24-44 weeks, depending on the patient's response. The treatment algorithm for using boceprevir is more complicated, so compliance can be a significant issue. Compliance is important to improve the chances of clearing the hepatitis-C virus and to avoid the development of mutations. The pill burden is somewhat less with telaprevir, which also helps with the compliance. As you've heard, the treatment of hepatitis-C is an expensive proposition. Dual therapy with pegolated interferon and ribavirin is already expensive, and both protease inhibitors are adding a significant cost on top of that. A potential advantage to boceprevir is its lower cost. This may be true, if patients are taking triple therapy for a minimum of 24 weeks; however, once the duration of boceprevir is extended to 36 or 44 weeks, the costs are similar to twelve weeks' of telaprevir. My goal for the hepatitis-C patients of Idaho is to clear the virus in as many patients as possible to avoid the latter complications and treatments, such as liver transplantation that carry an enormous cost. In my practice, I am using telaprevir for my patients with hepatitis-C who need triple therapy, because of the more straightforward regimen, the lower pill burden, the shorter duration of treatment, and the potential for improved compliance. I definitely would recommend that both agents be available and that telaprevir be available to me to prescribe to my patients with hepatitis-C. I will take any questions and I want to thank you for the opportunity of talking to the Committee today.

Stephen Carlson

Good morning, I'm Stephen Carlson. I work at Intermountain Hospital, Boise Idaho. I am the Director of Pharmacy there. I currently practice in a position that is uniquely on the front lines of behavioral health in our state. I see some of the most acute patients at probably some of their toughest times that they are in need of our services. I believe that decreasing re-hospitalization and the opportunity to have access to all the uniquely used medications is a must for our state, due to reducing that number of re-hospitalization and that overall cost of putting them back in and recycling them through hospitals. So I am here to urge you that you keep an open formulary, but I did want to mention one medication that we are having really good luck with. Since last April, we have had more than forty patients start on Invega Sustenna and, to this date, I have not seen any of them readmit to our hospital. Since the majority of them were from the Treasure Valley, I have to think that's playing a role. It's nice that the medication does actually have the potential for the patient to go out the door with thirty days of medications on board and, like I said, they are not readmitting. While they're in house, they're brought up to therapeutic level relatively quickly, so we're able to see where they're at and able to actually have discharge planning that happens while they are actively participating in what their plan is upon leaving our facility. So I do consider behavioral medications once where we don't want to handcuff our providers to a restricted formulary, because we're still trying to figure out what unique medications will fit for any particular patient. I have nothing to disclose. I'm a member of ASHP, CPNP and also Kappa Psi. Do you have questions?

Question from Committee Member:
The readmissions, how many of those do you think are from patients just quitting their medications because they think they're better, or other reasons?

Stephen Carlson
Here at Intermountain, my perception is that there are quite a few frequent fliers, and yes, a lot of it is associated with "I felt good, I was doing really good for 2-3 weeks, I had some good times with my friends, I didn't need these meds", and that's truly what these people think, is that they don't need their medications. So any opportunity that we can get them set up with partial hospitalization or programs that allow them to be more successful as far as their medication management, I think we need to do what we can. Thank you for the opportunity.

Shannon Gardiner, P.A.
I have to say this morning that I'm very grateful for the microphone, so I apologize, I don't know what's going to be worse; the point that I'm trying to make, or listening to my voice. My name is Shannon Gardiner and I'm a Physician's Assistant, and I've been practicing in this community for over ten years now. I've worked in several speciality practices, including OB/GYN, as well as General Orthopedics with an emphasis in hand and upper extremity, and currently I've been employed in a Spine and Pain Management practice for the last seven years. Since I've always been in speciality practices, I'm very familiar with some of the obstacles that we face, and one of these obstacles can be prior authorization for medications, in our practice, particularly, Celebrex. By the time the patient reaches our office, generally they've been around their primary care physicians, urgent cares, emergency rooms, and have generally had multiple conservative treatments, including traditional anti-inflammatories. When we choose an effective and well-tolerated medication like Celebrex, we run into some obstacles when we try to get that prescribed, and the prior authorization process happens to be a big delay in patient care. Once the pharmacist identifies the need for prior authorization and gets that faxed to our office and we track down the chart and fill out the paperwork, sometimes 3-5 days can go by, and for our patients that are in pain, 3-5 days can feel like a lifetime. Additionally, in our practice, a large patient population for us is postoperative, and several studies have demonstrated that using Celebrex in the postoperative period, and the biggest benefit that I've personally seen, is a decreased use in narcotic medications, both in the number of narcotic medications that are taken, as well as the length of time that those narcotics are taken. As a practitioner that deals with chronic pain and the difficulty with prescribing narcotics, if I can use a medication that will decrease their overall narcotic use, I think that is the best thing that I can do for a patient. I would advocate today that you help me provide better patient care by allowing Celebrex to bypass the prior authorization process when it comes from a speciality practice. At the very least, I would ask that you consider allowing us to write for Celebrex in that postoperative period. Thank you and I appreciate your time.

Question from Committee Member:
So instead of spending all this time with prior authorizations, why don't you write for generic meloxicam?

Shannon Gardiner, P.A.
Again, most of the time, when patients have come through our office, we've gone through the gambit of meloxicam, Relafen.

Question from Committee Member:
So you have evidence that Celebrex is superior to meloxicam?

Shannon Gardiner, P.A.
I do.

Question from Committee Member:
Would you share that with the Committee?

Shannon Gardiner, P.A.
Well, I don't have anything off the top of my head, other than what I've seen in my practice, and again, when it comes to patient tolerability, I have just found that most patients tolerate Celebrex far better than they tolerated the meloxicam.

Question from Committee Member:
So you've tried patients on generic meloxicam first? We're just interested in the data.

Shannon Gardiner, P.A.
Yes, sure. Thank you.

Michael O'Brien, M.D.
My name is Michael O'Brien, M.D. I practice neurology and I guess I'm one of the veterans around here. I started in medicine probably almost fifty years ago, so I've been here in Boise for 40 years, and, unfortunately, I'm the one who has to take care of a lot of the Medicaid patients and Medicare patients. My experience in dealing with one of these entities that is fibromyalgia is extensive. Unfortunately, we don't have a whole lot that we can do for these patients. The people that come around and talk to us about fibromyalgia, we can't give them pain medication because they'll have rebound, so the medications that we can use in these patients are very limited. We do have the drug, Lyrica, which I think is excellent. My approach to treating these problems has to do with the role of serotonin and norepinephrine. You may find that these neurotransmitters are also used in pain and are also used in depression, but now recently Lyrica came out and it does have an effect on norepinephrine, so we have that. We just need a drug that is easy to use that the patients can tolerate, and we have the ability with this drug, Lyrica, to increase the dosage without increasing the cost of the medicine, which I think is a tremendous benefit. I would like to say that in the meetings that I go to with the other neurologists, we often ask "What is the chief reason for using a drug?" and I have to tell you what the other guys are doing. This might seem surprising to you. It probably far outstrips the other reasons, such as the effect of the drug, the cost of the drug, but what the other guys are doing, they all appear to look at Lyrica as the drug of choice for such things as fibromyalgia. It also has other uses, but that's the point I would like to make at this time. Thank you. Any questions? Okay, thank you for allowing me to talk.

Committee
Okay, we've finished up with the medical providers. I would like to go with the private citizens. Next is Kathie Garrett.

Kathie Garrett

Good morning, my name is Kathie Garrett and I serve as a volunteer for a number of organizations from the Chair of the Governor's Council on suicide prevention to the Idaho State Planning Council on Mental Health. Today, I am here on behalf as a volunteer board member of NAMI Idaho. NAMI Idaho is the state organization of the National Alliance on Mental Illness, the largest grass root organization in the US devoted to improving the lives of people with mental illness and their families. Within NAMI Idaho, we have nine affiliates in our communities from Bonner's Ferry to Pocatello, who are there to help at the grass roots level, to help people whose lives have been touched by mental illness. As an organization, NAMI Idaho has not received compensation or gratuities from drug manufacturers, but has received some money to support their educational programs, and I believe in your letter in your packet from Doug McKnight, that is fully disclosed there. Our members, whether family or consumers, know first hand the effects of not having the right medication has on their lives. Our members know the struggle that many people with mental illness have to reach recovery. This is why we thought it was so important to share our thoughts and concerns with you. NAMI supports full and open access to psychiatric medications for people, all people, with mental illness. The treatment of mental illness differs from many other illnesses in one critically important way, and that is finding the correct medication is often the most difficult part and challenging part of treating a patient with mental illness, and can take many years. Medications are a powerful tool that, with appropriate treatment, people with mental illness do recover, from 60-80%, exceeding the treatment success of heart disease. We know one size does not fit all. Effectiveness and side effects from one medication to another varies significantly from patient to patient. Finding the most helpful medication and the dosages can take multiple trials and should be based on the clinician's judgment and informed consumer choice. Safety and health should be the driving concern when treating people with mental illness. Without the appropriate medication, people with mental illness may even experience the inability and high cost of hospitalization, emergency rooms, interface with our court systems or our police. There are so many outcomes, and yet we know that treatment works, and treatment can provide a life of recovery. We hope that you support an open access to medications for Medicaid clients. Thank you.

Question from Committee Chairperson:
There were two letters from your organization, one from the organization and one from a member. Both of those letters said "We support open formularies, we oppose restrictions based on copays, and that we want lower prices for people that have to pay themselves". The letter from the individual actually described her son, who basically was doing okay until he lost insurance and then suddenly he couldn't afford anything and now he's in prison. So you're here to say "We want open access", but if you look at the access follow-ups and stand back, all of it is driven by the astronomical price of these individuals, and I'm curious how much your organization pressures the producers of these medications to try to have more reasonable prices?

Kathie Garrett
Alright, thank you. I didn't see the second letter, so I can't really address what they...

Comment from Committee Chairperson:
It actually says most of the same stuff as the first letter.

Kathie Garrett
Those are NAMI National standards and NAMI National is very engaged in those issues and promotes those issues, so that's where we kind of began our discussion as far as, you know, we understand, very personally understand, how the right medication for people with mental illness is necessary to bring about that recovery, to get the symptoms under control so you can use the other methods of treatment. When your symptoms aren't under control, it's very difficult to have good therapy, so we support that, we encourage that, we're concerned, we're just, you know, on the cusp of some very great breakthroughs, giving the physicians the tools they need to maybe better treatment of mental illness, so we want to continue that innovation, we want the best possible drugs. We realize the cost is critical, but the cost on the other hand is critical. I just heard a county commissioner yesterday tell Health & Welfare, or the Health Care Task Force, about the increase in cost that they're seeing in Bonneville County because of untreated mental illness. So we know the cost, you know, is going to show up somewhere else, so while the drugs are expensive and we're going to continue to encourage pharmaceutical companies to find better treatment, but also realizing that we needs drugs that are more affordable, in the meantime, that's the best we have. Thank you.

Paula Campbell

Hi, good morning, and I am the second letter, so I do want to clarify. My son was not in prison, he was just five days in jail, so I hope I don't ever have to go down that road. Anyway, my name is Paula Campbell.

Committee Chairperson:
So you know we read your letter.

Paula Campbell
Yes, that's a good thing! I live in Boise. My 25-year-old son, Jason, has been diagnosed with schizophrenia for seven years. We've had a life of ups and downs. I've received support and education from NAMI Boise, and have served on their board for five years. My son has had multiple trials of medications to get a combination that stabilized him. He has been on Zyprexa, Prolixin, Geodon, Abilify, Prolixin-DEC, Risperdal, Cogentin, Artane, and Effexor-XR to name a few. The doses and the combinations were both staggering and complex. For three years, he and his doctor worked, and seemed to have the combination right. Jason got his own apartment, had a full-time job, and was happy to be functioning well. In February, he was dropped from Medicaid, due to his income. He lost his PSR services, he then lost his psychiatrist who decided to do hospital only, no office visits, and it took three months to find someone who would take Medicare only. In addition, a computer glitch at the pharmacy stopped filling his antipsychotic medications, and Jason took a severe turn for the worst. He self medicated and has now been in the Ada County Jail. Lack of the correct medications, for any reason, creates increased cost to the community, families and consumers. To experience their own recovery, many people living with mental illness will need access to treatment, including medications. Like my son, many will need to try a wide variety before they find the right medications that allow them to live the life they dream of. Today, I ask that you help countless Idahoans experience recovery by preserving access to a full array of needed psychiatric medications. The cost to the community without them is great. Increased police involvement leading to incarceration, emergency room visits, increased illicit drug use due to self medication. So open access to all medications for all Idahoans must remain. I am supporting both as a family member and an advocate, open access to all psychiatric medication, oral or injectable, provision of written guidance disallowing restrictions on access to psychiatric medications for any services subcontracted by Medicaid or Medicare, increased funding for NIMH research or pharmaceutical research to develop new psychiatric medications, and there also has been, just in regards to your other question, a lot of work being done in genetic therapy now. I am opposing, both as a family member and an advocate, fail first provisions, in state policies, pharmaceutical pricing or rebate reduction making psychiatric medications unaffordable, and standardized medication lists or formularies based on medication cost alone. I don't want another son like mine in jail or hospital in the State of Idaho. Thank you. Any questions? Thanks.

Kathleen Karnik, PharmD
Hi. My name is Kathleen Karnik, and I'm with the Health Economics and Outcomes Research Department for Janssen Pharmaceuticals, and since you last reviewed the antipsychotic class, six studies have been published on our products. I won't go into detail on all of them, just a quick overview. We've had three non-inferiority studies, which have been published comparing Invega Sustenna with Risperdal Consta. A 53-week double blind study used lower initiation doses of paliperidone palmitate using 78 mg injection given in the gluteal muscle. Adequate therapeutic plasma levels for paliperidone palmitate had not been established by day-64, thus the paliperidone palmitate did not demonstrate noninferiority. However, the results from this study helped in the design of subsequent studies, as well as the development of the FDA-approved dosing regimen. The noninferiority was demonstrated in the other two trials; one was a 13-week international, multi-center, randomized, double blind, double dummy, active control study of 1220 adult patients with schizophrenia, and the other was an open-label, rater-blinded study of 413 Chinese patients with acute schizophrenia. Both trials demonstrated that once paliperidone palmitate was initiated with a current FDA-approved dosing regimen of 234 mg on day-1 and 150 mg on day-8 injected into the deltoid muscle, followed by flexible dosing every 28 days, without oral supplementation, was not inferior to Risperdal long-acting injection 25-50 mg given every two weeks with oral Risperdal supplementation. Therapeutically effective plasma levels of paliperidone palmitate were observed from day-4 onwards. The tolerability and safety of paliperidone palmitate was generally similar to Risperdal long-acting injectable, with no safety or tolerability findings. These studies show that paliperidone palmitate does not require oral supplementation, uses a smaller-gauge needle, is administered once monthly, rather than bi-weekly, which may aid in patient compliance, and the formulation does not require refrigeration or reconstitution. Invega extended-release tablet indicated for schizophrenia in adolescents 12-17 years of age, did receive an indication for this age group, based on the study by Singh et al that was

published this year. The PANSS total scores improved significantly from baseline to endpoint in all treatment groups, when compared to placebo. Finally, Risperdal Consta published two open-label studies; one compared to quetiapine, which was an open-label, randomized, active-control trial in patients with schizophrenia or schizo-affective disorder, who were switched from treatment with oral risperidone, olanzapine, or conventional neuroleptics to Risperdal long-acting injectable or quetiapine. The aim of the study was to evaluate symptom or relapse intolerability. The authors concluded that the switch to Risperdal long-acting injectable was associated with longer time to symptom relapse than was the switch to quetiapine. That was 16.5% versus 31.3%. A larger portion of patients receiving the Risperdal Consta completed treatment than those who received quetiapine, and both treatments were safe and well tolerated over the 24-month study. The other compared Risperdal Consta with aripiprazole, comparing safety and efficacy for long-term maintenance of patients with schizophrenia, and the authors concluded that no statistical significant differences were observed between Risperdal long-acting injectable and aripiprazole with regard to time to relapse and time in remission from schizophrenia. Thank you. Any additional questions? I tried to do a quick overview. You have a two-page document as well.

Roy Palmer, PhD
Good morning, my name is Dr. Roy Palmer. I'm with Pfizer. I just wanted to say a few words about a study that hasn't been included in the Provider Synergies Magellan review, and that's the CONDOR study, and I believe in your materials, you should have a one-page summary of that study. I think it's an interesting study. It was published in the Lancet, a premier European Journal, it's a multinational study in thirty different countries. What it set out to look at, was whether the strategy of using Celebrex versus diclofenac plus a PPI, whether there was any difference in GI outcomes with those two strategies. So, the theory behind it is that we know that using a PPI is likely to give gastric protection, but primarily in the stomach and the upper GI, whereas the systemic effects of NSAIDs are such that there may be adverse GI effects throughout the entire GI. So what they used in this study was a primary endpoint, they used all the normal upper GI endpoints, but also tried to look at lower GI and particularly hemoglobin and hematocrit changes that could be identified as either definite or presumed lower GI blood loss. So that's kind of an interesting study. The patients chosen were at high GI risk and low CV risk, so for that reason, aspirin use was excluded from the study, and high GI risk was identified as being over 65 or having a history of ulceration. I won't go through all the details of the study, but it was a six-month study, and the results were that 20 Celebrex patients met the primary end point and there were 81 patients in the diclofenac plus PPI who met the primary endpoint. So in the interests of not giving a lobbying presentation, I'll just read the conclusions of the authors verbatim. They said that "A COX-2 selective NSAID provided significantly better outcomes than a nonselective NSAID plus a PPI when considering significant hemoglobin decreases with a defined or obscured source of GI blood loss." Thank you for the opportunity. I hope you will consider this study along with the other data you have. I can answer any questions.

Question from Committee Member:
Were there actual documented GI bleeds in the study or were they basically looking at certain markers of basic hemoglobin counts?

Roy Palmer, PhD
The majority of the endpoints were hemoglobin changes, but there were, I can give you the numbers, five ulcerations and erosions in the Celebrex group versus twenty in the NSAID group, so that was not significant, but the study was powered to look at those endpoints.

Question from Committee Member:
So five out of twenty and twenty out of eighty.

Roy Palmer, PhD
Eighty-one, yes, that's correct. Thank you.

Rajesh Patel, PharmD
Hello, my name is Raj Patel. I'm a medical liaison with Bristol-Meyers-Squibb in support of Orencia which was talked about in the previous talk from a medical and research standpoint. Thank you for the opportunity to provide public testimony for Orencia for rheumatoid arthritis. I will briefly give a

summary about Orencia and some of the data that has come out of the study that supports a subcutaneous updated label. So intravenous and subcutaneous Orencia are indicated for the treatment of moderate to severe adult rheumatoid arthritis.

Committee Chairperson:
Please just present the study. Thank you.

Rajesh Patel, PharmD
The pivotal study for the subcutaneous indication was a randomized, double-blind, double-dummy, placebo-controlled study comparing the noninferiority of subcutaneous Orencia with IV Orencia. Essentially, the primary endpoint was ACR of 20 at six months, and was essentially looking at a noninferiority comparison between IV and subcutaneous. Essentially, the final efficacy results was ACR 20 at six months was 76% and 75.8%, subcutaneous to IV. So essentially, proving noninferiority of the two formulations. Additional secondary endpoints that were looked at were, of course, ACR 50s, ACR 70s, and those also had overlapping lines with ACR scores at six months. Also, when looking at the safety summary for the subcutaneous formulation, no additional safety indications that were inconsistent with IV were found. Therefore, our summary of important safety information is consistent; subcutaneous is consistent with our IV. Dosing was talked about, so some keys from that pivotal study is there was an IV loading dose given, which is in the weight-based range on day-1, and then on that same day-1, the subcutaneous 125 mg/mL subcutaneous dose, fixed dose, is given weekly from day-1 thereafter. So essentially, that's the comment on the dosing. As far as a second bullet we have as far as dosing, if a patient is unable to receive an IV load, they may receive a subcutaneous dose from day-1 without an IV load. Finally, if a patient is switching from IV to subcutaneous, they may, the next time they're going to receive their IV dose, they may receive a subcutaneous dose weekly from that next IV expected dose. In quick summaries, so as far as the safety experience, just commenting on immunogenicity of course with subcutaneous agents, the safety experience and immunogenicity for Orencia subcutaneous was consistent with the IV formulation. Then when you look at injection site reactions, 2.6% for the subcutaneous Orencia versus 2.5% for the placebo. Mild were 83% in severity, moderate was 17% in severity, and none necessitated drug continuation. With that, I will welcome any questions that you may have. Thank you.