Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: November 16, 2012 **Time:** 9:00 a.m. – 3:00 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Perry Brown, M.D.

Committee Members Present: Perry Brown, M.D.-Chair; Elaine Ladd, PharmD.; David Calley, PharmD.; Tami Eide, PharmD.; Kevin Ellis, PharmD.; Mark Turner, M.D.; Troy Geyman, M.D.; Jeffrey Johnson, PA-C, PharmD.; Leigh Morse, M.D.; Hamilton Warren-Sutton, M.D.

Others Present: Paula Townsend, PharmD, Magellan Health Services; Mark England PharmD, Magellan Medicaid Administration; Jane Gennrich, PharmD., Division of Medicaid; Chris Johnson, PharmD., Division of Medicaid; Cody Scrivner, Division of Medicaid; Teresa Martin, Division of Medicaid

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Perry Brown, M.D.	Dr. Brown called the meeting to order.
Committee Business		
➢ *Roll Call*	*Perry Brown, M.D.*	Dr. Brown completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➢ *Reading of Mission Statement*	*Perry Brown, M.D.*	Dr. Brown read the Mission Statement.
➢ *Approval of Minutes from October 19, 2012 Meeting*	*Perry Brown, M.D.*	The October 19, 2012 meeting minutes were reviewed. Dr. Johnson made a motion to accept the minutes, Dr. Morse seconded and the Motion passed. The minutes were accepted as proposed.
➢ High Dose Citalopram Drug Utilization Review	Mark England, PharmD	**High Dose Citalopram Drug Utilization Review** Dr. England provided an overview on high dose citalopram. In August of 2011, the FDA released a Safety Announcement addressing high doses of citalopram and potential adverse effects it can have on the heart. The maximum daily dose is now recommended to be 40 mg per day when it was previously 60 mg per day. Letters were sent to 186 prescribers with a list of

		their patients who were currently prescribed more than 40mg daily along with the FDA Safety Announcement and a Survey Response form. As of January 3, 2012, 59 responses had been received and reviewed. At the January DUR meeting it was recommended that the maximum daily dose allowed for Idaho Medicaid participants be decreased to the FDA recommended 40 mg and to require a quantity override prior authorization for any claims with a dose greater than 40 mg per day. On March 28, 2012 the FDA sent out a revised Drug Safety Communication reducing the maximum citalopram dose for patients 60 years or older from 40mg to 20mg. At the August DUR meeting, it was recommended to place an edit in the system to require prior authorization for patients 60 years or older who were prescribed more than 20mg daily.
➢ DUR Board Update Topiramate Indication	Chris Johnson, PharmD	**DUR Board Updates - Topiramate Study** Dr. Johnson presented a DUR report completed to evaluate evidence based use of topiramate in Medicaid clients. Monthly topiramate claims have increased from January 2011 of 700 claims to August 2012 of about 900 claims. This increase in claims prompted a drug utilization review to determine if topiramate was being prescribed for FDA approved uses of migraine prophylaxis or epilepsy disorder. Dr. Johnson stated the increase in use may be a response to the recent approval of a weight loss drug that contained topiramate and phenterimine or the non-FDA approved use for bipolar disorder. Dr. Johnson reviewed previous studies from DERP reviews which concluded that there were no statistically significant differences between topiramate and placebo or with divalproex montotherapy for bipolar disorder and therefore topiramate is neither FDA approved nor appropriate for off-label use in bipolar disorder. The DUR evaluated 1,222 topiramate clients from 1/1/2012 thru 6/30/2012. Participants were separated into two groups based upon topiramate daily dosing; doses greater than 100mg/day (519 patients) and doses less than 100mg/day (703 patients). Stratification by dose was utilized because higher doses suggest topiramate use for epilepsy disorders and lower topiramate doses suggest use for migraine prophylaxis. Participant's medical records were evaluated for ICD-9 diagnosis codes for FDA approved indications of migraine prophylaxis and epilepsy disorder and non-FDA approved use for bipolar disorder or obesity. A majority of participants were being treated for migraine prophylaxis with higher doses correlating with treatment for epilepsy disorders. Many participants had more than one ICD-9 diagnosis including bipolar/migraine, bipolar/epilepsy, and other combinations of diagnoses studied. Many of the patients who are using topiramate for migraines are on higher dosages than are FDA approved for migraine prophylaxis (maximum of 100mg/day) and do not have a history of paid claims for rescue medications for migraines (e.g. triptans). Health care providers with patients who have multiple diagnosis of bipolar/migraine/epilepsy/obesity may be treating non-FDA approved indications. It was noted by Dr. Johnson that 7 patients who had multiple ICD-9 diagnosis were also being

		treated with phentermine (not paid for by Mediciad).
➢ Targeted Immune Modulators (Cytokine/CAM Antagonists)	Kylie Tyler, MD, MPH RTI-UNC Evidence-based Practice C enter	**Targeted Immune Modulators** The review of Targeted Immune Modulators was given by Kylie Tyler, MD via audio recording. The report was completed in December 2011 and was the third update of the original report completed in December 2005. This comparitive effectiveness review compared efficacy, long-term effectiveness and incidence and severity of harms. It also evaluated differences in effectiveness and harms in subpopulations. Diseases evaluated included rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's diseas, ulcerative colitis and plague psoriasis. This update added three new drugs goliumab (Simponi), tocilizumab (Actemra) and astickinumab (Stelara). The update included 68 new trials since the last review. Most of the evidence was ruled as having a low strenghth of evidence. The evidence is currently insufficient to reliably determine the comparative effectiveness and safety for most diagnoses. .
➢ Drugs to treat ADHD	Marian McDonagh, PharmD DERP Prin. Investigator PNW EPC	**Drugs to treat ADHD** Dr. McDonagh presented telephonically an overview of Update # 4 of the Drug Class Review on Pharmacologic Treatemtns in Attention Deficit Hyperactivity Disorder. The report was completed in October 2011. In addition, she present a literature scan of published studies between October 2011 and October 2012. There was a change in the key questions from the last review to include comparisons with any pharmacologic treatment, stimulants and nonstimulants as well as immediate-release vs intermediate-release vs long-acting formulations. New drugs in this review included clonidine IR, clonidine ER, guanfacine IR and guanfacine ER. Evidence in children and adolescents and in adults on the comparative effectiveness of drugs to treat ADHD was insufficient. Extended-release formulations of clonidine and guanfacine did not have comparative evidence. Immediate-release clonidne was similar to immediate-release methylphenidate. The newest scan of the literature revealed a new oral suspension formulation of methlyphenidate. Vyvanse (lisdexamfetamine) is now approved for maintenance treatment of adult ADHD. There are new warnings and precautions for Focalin, Focalin XR and Strattera. Only 16 potentially relevant trials were identified.
Public Comment Period	Perry Brown, M.D. Cody Scrivner	**Public Comment Period** Six (6) people signed up to speak during the public comment period. Public testimony was received from the following speakers. Please see the transcription at the end of the minutes.

Speaker	Representing	Agent	Class
Heidi Brown	Self	Strattera	ADHD Drugs
Robert Wechsler	Self	Anticonvulsants	Anticonvulsants

		including Onfi (clobazam)	
Jeanne VanderZanden	Lundbeck	Onfi (clobazam)	Anticonvulsants
Mark Meier, MD	Self	Celebrex	NSAIDS
Kathie Barrett	NAMI Idaho	Antipsychotics	Antipsychotics
Roy Palmer, PhD	Pfizer	Lyrica Celebrex	Anticonvulsants NSAIDS

Drug Class Reviews and Committee Recommendations

Drug Class Reviews and Committee Recommendations

- Cytokine and Cam Antagonists

Paula Townsend, PharmD
Magellan Health Services

Cytokine and Cam Antagonists

Dr. Townsend reviewed two new indications for drugs in this class.: ocilizumag (Actrema) is now indicated for systemic juvenile idiopathic arthrisis in children ages 2 and older and adalimumab (Humira) is now indicated to induce sustained clinical remission in adults with moderate to severe active ulcerative colitis in patients with an inadequate response to immunosuppressives.

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 all of the diagnoses have at least one preferred drug available.

- Anticonvulsants

Paula Townsend, PharmD

Anticonvulsants

Dr. Townsend reviewed two new drugs in this class. Onfi (clobazam), which is a benzodiazepine indicated as adjunctive therapy in the treatment of Lennox-Gastaut syndrome in adults and children >2 yrs and Potiga (ezogabine), which is a potassium channel opener indicated as adjunctive therapy in the treatment of partial-onset seizures in adults > 18 yrs.

Committee Recommendations

The committee recommended that Onfi be listed as preferred with criteria for use continued. The Committee had specific recommendations on topirimate based on what appears to be some inappropriate prescribing. The DUR Board is directed to do an educational intervention on evidence-based vs non-substantiated off-label use. Patterns of use by specific providers should be evaluated. Adjustment of the criteria for migraine prophylaxis to include a review of prior use of

		ablative mecation (mostly triptans) was recommended. The committee also felt that the pharmacy program should follow up with health care providers with participants who were prescribed phentermine and topiramate. In additiona education to providers on existance of an auto prior authroization for brand name drugs for patients with an epilepsy diagnosis was suggested.
➢ Antihyperurecemics, Oral	Paula Townsend, PharmD	**<u>Antihyperurecemics, Oral</u>** Dr. Townsend indicated that there was no new clinical data to share with the committee. Dr. Eide stated that the comment on the Preferred Drug List (PDL) that Colcrys will be limited to three tablets per prescription for acute gout attacks should be three days of therapy not three tablets. **Committee Recommendations** The committee recommended that Uloric remain non-preferred and that the current therapeutic criteria should continue for this class of drugs.
➢ NSAIDS	Paula Townsend, PharmD	**<u>NSAIDS</u>** Dr. Townsend announced a change to this class. Topical NSAIDS have been moved into this class (they were formerly in "Analgesics/Anesthetics, Topical"). She reviewed one new drug, Duexis (ibuprofen/famotidine), which is indicated for the treatment of signs and symptoms of rheumatoid arthritis (RA) and osteoarthritis (OA) **Committee Recommendations** The committee did not feel that the evidence supported any of these drugs in either the oral or topical groups being superior in effectiveness or safety to any other. The committee did not feel Duexis (ibuprofen/famotidine) offered any clinical advantage and recommended it be made non-preferred as the individual components can be prescribed without prior authorization. The committee recommended that the Department review the DERP evaluation of the study provided by Dr. Meier on Celebrex and consider allowing an acute short-term use of 8 weeks or 2 fills without prior authroization. The committee recommended reviewing Celebrex utilization in 6-12 months as a DUR project.
➢ Pain Drugs, Other	Paula Townsend, PharmD	**<u>Pain Drugs, Other</u>** This is a new drug class grouping and brings together drugs in the anticonvulsant, antidepressant and fibromyalgia groups which are used to treat pain. Dr. Townsend provided a review of new product gabapentin enacarbil (Horizant)which is a prodrug of gabapentin. Horizant is an

		extended-release tablet designed to improve oral bioaviaability. It is FDA approved for the treatment of restless leg syndrome and postherpetic neuralgia.Dr. Townsend discussed a new indication for pregabalin (Lyrica), which is neuropathic pain associated with spinal cord injury. **Committee Recommendations** The committee concluded that there were no evidence-based differences in effectiveness or safety to support preferring any agent over another in this class. The committee felt Horizant provided no advantages and recommended designating gabapentin enacarbil (Horizant) as non-preferred on the PDL.
➢ Antiparkinson Agents	Paula Townsend, PharmD	**Antiparkinson Agents** Dr. Townsend provided a review of Neupro (rotigotine) patch, which has reentered the market -, and is indicated for the signs and symptoms of early-state idiopathic Parkinson's disease. She announced three new generics for this drug class; entacapone for Comtan, carbidopa/levodopa/entacapone for Stalevo and ropinirole ER for Requip XL. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. They stated that Neupro, specifically did not appear to offer any advantages and should be non-preferrred.
➢ Alzheimer's Agents	Paula Townsend, PharmD	**Alzheimer's Agents** Dr. Townsend announced that Exelon patches are now available in additional strengths. **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 continuing the current therapeutic criteria for this class of drugs.
➢ Stimulants and Related Drugs	Paula Townsend, PharmD	**Stimulants and Related Drugs** Dr. Townsend announced new generics - methylphenidate ER capule for Ritalin LA, methylphenidate OROS forConcerta and methylphenidate CD for Metadate CD. She reviewed

➢ Antipsychotics, Atypical	Paula Townsend, PharmD	the 2011 American Academy of Pediatrics (AAP) guidelines which state that extended release formulations of guanfacine (Intuniv) or clonidine (Kapvay) may be helpful when used concurrently with a stimulant in patients who cannot tolerate usual doses of stimulants, particularly those with tics. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. The committee recommended relooking at the prior authorization criteria for Strattera. The requirement for a stimulant trial should be considered for removal. Dr. Townsend will provide utilization comparisons with other states that have no restrictions on use. The state is asked to make sure the system will not edit for an additional prior authorization for dose changes if a PA is currently in place. **<u>Antipsychotics, Atypical</u>** Dr. Townsend announced that there are four new generics: quetiapine for Seroquel, olanzapine for Zyprexa, ziprasidone for Geodon and olanzapine/fluoxetine for Symbyax. She gave an overview of the Cochrane Database Systematic review of studies on aripiprazole for autism spectrum disorders. **Committee Recommendations** The committee concluded that there was no evidence-based differences to support preferring any agent over another in this class. The committee recommended limiting total daily dose by drug not by dosage form. The committee recommended not allowing quetiapine for insomnia. The committee endorsed the DUR project evaluating drugs by diagnosis, age, and dosage prescribed as well as thereapeutic duplication. The Committee asked that the final recommendations for indication, age and dosage be brought back to the P&T Committee.
➢ Antipsychotics, Typical	Paula Townsend, PharmD	**<u>Antipsychotics, Typical</u>** Dr. Townsend announced no new significant clinical information in this class. **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 some typical antipsychotics to require prior authorization in children < 18 years (ORAP, perphenazine, perphenazine/amitriptyline).

➢ Antidepressants, SSRI	Paula Townsend, PharmD Magellan Health Services	**Antidepressants, SSRI** Dr. Townsend announced two new generics -. escitalopram for Lexapro and fluoxetine 60 mg tablet (available as generic only) **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. The committee recommended that the Department consider making paroxetine preferred for patients sixteen years and older.
➢ Antidepressants, Other	Paula Townsend, PharmD Magellan Health Services	**Antidepressants, Other** Dr. Townsend announced one new product: Forfivo XL (buproprion HCL ER, available as 450mg strength only) and a new indication for Aplenzin ER (buproprion HBr) for prevention of seasonal affective disorder. Dr. Townsend reviewed an AHRQ 2011 comparative effectiveness review of 2nd generation antidepressants for adult depression and a systematic review of vilazodone trial data for major depressive disorder. . Pristiq lacks comparative data to other antidepressants. **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 adding trazodone to the list of other antidepressants as a preferred agent. The committee recommended removing the therarapeutic criteria that patients must failed TWO antidepressants before Viibryd will be approved.
➢ Sedative Hypnotics	Paula Townsend, PharmD Magellan Health Services	**Sedative Hypnotics** Dr. Townsend announced the availability of a new product Intermezzo (zolpidem tartrate SL), for treating patients with insomnia characterized by waking in the middle of the night with difficulty or inability to return to sleep. There was also a discussion that chloral hydrate, currently listed as preferred on the PDL, is actually not FDA approved and is therefore not covered by Idaho Medicaid at this time under CMS regulations. **Committee Recommendations** The committee recommended that the state consider using state only funds to cover chloral hydrate as a cost effective, safe alternate to anesthesiologist administered pre-procedure sedation in children. The committee recommended that Intermezzo be non-preferred. The committee also suggested that a DUR project look at longterm use of sedative-hypnotic agents for drugs that

➢ Other Committee Business	Tami Eide, PharmD	are only FDA approved for short-term usage. **Other Committee Business** The next P&T Committee meeting is scheduled for April 19th, 2013. There was no other committee business. The meeting adjourned at 3:00 p.m.

Pharmacy and Therapeutics Committee
Public Comment
November 19, 2012

Heidi Brown
My name is Heidi Brown, and I'm a psychiatric PA. I practice in multiple outpatient clinics in both Idaho and Oregon. I work with Dr. Si Steinberg. I wanted to actually discuss a recommendation that was made a year ago for Strattera to become a preferred agent, yet we've continued to have to do prior authorizations on the medication and we've continued to have to do prior authorizations for every single dose change. This becomes rather cumbersome with a medication that has to be titrated so much because its weight based. This creates difficulties if there are ever any issues between the titrating and getting the medication approved. Above and beyond, I'm more than happy to be compliant with any of the recommendations made by the Board, but I'm hoping that those would be consistent with what I'm expected to do when prescribing this medication. That's all.

Question from Unknown Participant
Thank you. I actually have a question, partially of you and partially of Medicaid pharmacy folks: Is there a reason that we require approval of a dose change if we've approved the agent?

Committee
I thought we had it fixed actually so that we didn't.

Heidi Brown
No, it's been a year and I keep crossing my fingers that I don't have to keep doing them.

Committee
Okay, so we can work with Magellan and we should be able to do that. I'm pretty sure we did it on the stimulants but we may have missed Strattera, so we can work on that, that if there's a dose change, as long as it doesn't go over the maximum daily dose....

Heidi Brown
What about for the initial dosing of the dose, since it's...

Committee
That's something that we'll need to discuss. I mean we appreciate your feedback, but I would really appreciate your feedback if you're still finding that as you change doses, you're still running into prior authorization issues, because, again, the purpose of this is that we need to make some decisions in terms of preferred versus not for a variety of reasons, but it should not be to the point that it is really, truly getting in the way. We should be trying to have minimal impact in terms of your practice, and if it's creating more paperwork than seems reasonable, please provide us the feedback and we'll try to get that fixed.

Heidi Brown
Thank you.

Committee
Yeah, thank you.

Robert Wechsler MD
Hello everyone, I'm Rob Wechsler, I run the Epilepsy Center here in Idaho, and I'm in private practice. I'm not here representing any particular company or product. I'm here representing my patients, the Epilepsy Center, and the Epilepsy Foundation. You've heard me say that every time I come, and I come every time you talk about the epilepsy drugs. You know, every time I come to you guys, I tell you about the fact that I do see a lot of Medicaid patients, even though I'm in private practice, but I've never really been able to tell you how many until now. Because I've gone to a new electronic health record to qualify for meaningful use, and I was trying to decide if I declare under Medicaid or Medicare. Under Medicaid you get more money, but you have to have 30% of your patient volume for Medicaid and, unfortunately, I did not qualify because my Medicaid

volume is 29.4%. But it does highlight the fact that even though I don't qualify for that bonus under Medicaid, a large part of my practice are the patients that we all serve. I feel that I've done a pretty good job for them. I've shared with you guys in past years data that we collected at the Idaho State School, where we dropped seizure emergencies and use of expensive rescue strategies by 80%, just by using good clinical practice and good epilepsy care. What makes that possible is the relationship that I have with Idaho Medicaid, and as I talk to my colleagues in other places in other parts of the country, they are all very, very jealous that we're able to do as well as we are. We're not inundated with a ton of phone calls and barriers to care, and it really allows us to be able to provide that care. What really it comes down to, I think, is shots on goal. Every time I come here, I ask you to keep giving me access to all the drugs for epilepsy in all their formulations, because when you're that patient who defies the odds and becomes seizure free with the seventh or eighth drug that you've tried, you don't really care what happened to the other ninety-nine people. Whatever happens to you is 100% for you, and as an epilepsy center, we have an obligation to provide all the therapies to the patients that may benefit from them. I had a pharmacy student with me the last two weeks, shadowing me, and at one point I pointed out something to her, and she said "I'm noticing a recurring theme". The theme was, patients who have had terrible epilepsy, poorly controlled, who were determined not to be surgical candidates, had tried 8, 9 and 10 different treatments over the past 10-20 years, who are now seizure free on a two-drug combo or a three-drug combo of this or that. It really comes down to shots on goal, it really does, so I value the access to these agents. I encourage you to keep them accessible for us. I noticed on the website that the two that got approved this year were highlighted in blue, and I'm hoping that just means there's going to be more detailed discussion of them; clobazam and ezogabine. I've used both, I've had great successes with some patients with both. If there are any specific questions that you guys have about those or any other agents, I'm happy to answer them. I'm not going to lecture if you don't need it. Okay.

Committee
The highlight just means that theyare new drugs.

Robert Wechsler
That's good to know, thank you.

Jeanne VanderZanden, PharmD
People usually stumble over "VanderZanden". Good morning, I'm Jeanne VanderZanden. I'm with Lundbeck [Pharmaceuticals] in Medical Affairs, and we are the manufacturer of one of the newer anti-epileptics that Rob just mentioned; clobazam or Onfi. Onfi was approved last year for the treatment of seizures associated with Lennox-Gastaut syndrome, which, of course, is a rare and relatively difficult to treat form of epilepsy. As such, clobazam received approval as an orphan drug after having been available in Europe for over 30 years. The monograph written by Magellan, I think, speaks eloquently to the efficacy of clobazam, particularly in drop seizures, which are the type of seizures that have been associated to the greatest extent with rising health care costs, because of injury and difficulty in controlling them. Although Onfi is classified as a benzodiazepine, it is a 1,5-, hence the name "Onfi" versus a 1,4-diazepine, and that structural difference seems to account for some differences in preclinical studies, including preferential binding to alpha-2 versus alpha-1 subunits of the GABA receptor, as well as its partial agonist activity. Now, honestly, we don't know what the precise clinical significance of that difference is, but it may, indeed, account for the decrease in sedation

and tolerance that are seen with clobazam versus other benzodiazepines, and that was also was addressed in the Magellan monograph. With that, I guess, we'd like to thank you for making Onfi available to patients in the state of Idaho, and I'm available for any questions you may have.

Committee
Just a clarification. This was supposed to be the time for practitioners. All pharmaceutical representation required prior approval to speak.

Jeanne VanderZanden
Okay

Committee
You apparently signed in under the wrong place

Jeanne VanderZanden
We apologize for that.

Mark Meier, MD
Hi, I'm Dr. Mark Meier. I'm an orthopedist here in town, and I'm here to speak on my own accord to support the addition, if we can, of Celebrex to the pharmacy for Medicaid. There have been some recent studies that came out of the orthopedic community. I've got a copy of it here. A large, randomized, double-blind, prospective study, where people were given Celebrex during their hospital stay. We all know that it reduces pain, but they were randomized into a six-week period of Celebrex after surgery versus a placebo, and to the amount of narcotic use and amount of pain, and then their function at the end of the period. The people who, when the code was broken, the people who had taken Celebrex had a much greater range of motion in their knee, they took much less narcotics during the rehab period, and that range of motion was maintained for over a year, and these people had the same surgery. The only difference was that they were on Celebrex postoperatively for six weeks, and the outcomes for these patients were better on all of the scales, not only in terms of pain management in the postoperative period, but also in the range of motion and function at the end of the year, than the people who weren't on it. The reason I think this particular anti-inflammatory, you can make the case that, well maybe all anti-inflammatories (Naprosyn and such) can work, but the benefit of the cox-2 inhibitors is that you can, more safely, I think, give anticoagulants for blood clot prevention with Cox-2 inhibitors than you can with regular anti-inflammatories because of the effects on platelets of the other anti-inflammatories, so if we could talk about that later, that's my statement.

Committee
I'd just ask a quick one about the study? That was six weeks of active therapy, then stop and then the results of range of motion where your.....

Mark Meier, MD
Yeah, they followed them the whole time, and the whole time the people on the Cox-2 inhibitor seemed to do better than the ones who weren't.

The side effects were basically the same in terms of the placebo too.

Committee
Okay, so it was placebo controlled.

Mark Meier, MD
It was placebo controlled.

Committee
If we were able to get that study from you sometime that would be good.

Mark Meier, MD
Right here.

Committee
Oh, great.

Mark Meier, MD
Thank you very much.

Committee
Okay, the next category is Private Citizens. Kathie Garrett?

Kathie Barrett
Hi, my name is Kathie Garrett. I'm a board member of NAMI Idaho. I'm kind of one of those annual people that come to testify. NAMI Idaho is the State organization of the National Alliance on Mental Illness, and we are a 501(c)(3). NAMI has not received any compensation or gratuities from drug manufacturers, but we do occasionally receive grants for our educational programs that we put on. We want to thank you for the opportunity to submit testimony today on access to psychiatric medications. We urge the Committee to continue its position of open access to psychiatric medications. We support the full and open access to psychiatric medications for all persons living with mental illness, whether they obtain their treatment services via health insurance, Medicare or Medicaid. For many consumers of mental health services, access to a full range of effective medications is a critical component to a successful treatment and recovery. Although NAMI Idaho is very aware of the critical component of cost, a factor that comes with treating with mental health drugs, the treatment far outweighs the cost factor of the illness, and should be made on health care decisions rather than on cost decisions. Limiting psychiatric medications, whether through prior authorizations or fail first policies and restricted, preferred drug lists, can delay treatment to the point where people will need to use more expensive... It will impair their

recovery, increase hospitalizations, increase office visits, increase the risks of suicide, increase the risk of relapse, and ultimately could lead to irreversible clinical deterioration. Policies regarding pharmacy decisions related to psychotropic medications should be made, and driven by, good health care decisions and not primarily by cost reduction. Idaho strongly supports the position that the doctor and his or her patient should be the one that makes those decisions. Just an overview of what's happening in our public mental health system right now: Over the past few years, budget cuts have strained our public mental health system. Idaho has seen an increase in court-ordered commitments, we've seen an increase in hospitalization, we have seen an increase in the prison population with mental illness diagnoses. We have seen the difficulty of people finding timely access to treatment because of a provider shortage. Idaho needs the Medicaid Pharmacy Program to be our partner in our treatment of mental health and helping people reach recovery. We appreciate the hard work you do. Thank you.

Committee
Okay, drug industry representative, Roy Palmer.

Roy Palmer, PhD
Good morning everyone, my name is Dr. Roy Palmer. I'm a PhD Medical Director with Pfizer and wanted to comment on two drugs that you will reviewing today. First of all, I was going to talk about Celebrex and then I was going to talk about the article which you just heard from Dr. Meier, so I don't think I need to repeat that. I think he did a very nice job of summarizing it, but just to point out that, actually, the letter that I submitted, I think is in your packets and it has a brief summary of it if you want to see that before you get the chance to look at the reprint itself. The other thing I wanted to comment on was about Lyrica or pregabalin. In June of this year, we received a new indication for pregabalin, and that is for the treatment of neuropathic pain associated with spinal cord injury, and this is an indication that hasn't been granted to any other medications prior. Pregabalin is the only agent that has received this indication, and it was based upon two pivotal, double-blind, placebo-controlled, randomized clinical studies, and so I just wanted to very briefly go over the data that supported this because I think it's an important population. So we know, spinal cord injury isn't that common, but the pain associated with spinal cord injury can be debilitating. 40% of patients with spinal cord injury have some kind of neuropathic pain, and in over 60% of people, it can be described as "excruciating" So we did two studies: In one study, it was purely traumatic spinal cord injury, and in the other study it could be traumatic or non-traumatic. The first was a 12-week study with 137 patients. That was the traumatic one. The second was a 16-week study, so these were very robust and the largest spinal cord injury studies that I'm aware of. We specifically had the question for you as to what was the outcome data for that, so I wanted to present that if you're looking at pain of over 30% reduction, that in the first study, 42% of patients reached that level of reduction in the pregabalin arm versus 16% with placebo. That was statistically significant. In the second study, it was 46% versus 31%. So I think that these are not only statistically significant, but also clinically meaningful reductions in what is an extremely difficult patient population to treat. So, as you're considering agents for neuropathic pain, I would ask you to consider this new Lyrica indication and the data that supports it, in what's an important patient population. Thank you for your time.

Committee
So those percentages were for the patients that obtained 30% reduction in their pain index?

Roy Palmer, PhD
That's right. Yes. Thank you.

Committee
That's all we have, so, that concludes it. Since we started early, is there anyone who wishes to speak who arrived late and was unable to sign in? Okay. Great. Thank you.