Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: 8/15/08 **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; Stan Eisele, M.D.; Catherine Hitt, PharmD; Michelle Miles, PA-C; Tim Rambur, PharmD; Mark Johnston, RPh; William Woodhouse, M.D.; Andrew Olnes, M.D.; Dennis Tofteland, RPh; Tami Eide, PharmD

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

Committee Members Absent: Donald Norris, M.D.

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Dr. Petersen	Dr. Petersen called the meeting to order.
Committee Business		
➢ *Roll Call and introduction of new P&T member*	Phil Petersen, M.D.	Dr. Petersen completed the Roll Call and welcomed Dennis Tofteland, RPh as a new member of the P&T Committee. Dr. Petersen announced Dr. Andrew Olnes resignation from the Committee. The P&T Committee thanked Dr. Olnes for his time and contributions to the Committee.
➢ *Richard M. Armstrong, Director Division of Health and Welfare*	Richard M. Armstrong	Mr. Armstrong expressed his appreciation to the P&T Committee for its hard work meeting the needs of Idahoans, by making sure appropriate clinical medication is available and provided as efficiently as possible.
➢ *Reading of Confidentiality Statement*	Phil Petersen, M.D.	Dr. Petersen read the Confidentiality Statement
➢ *Approval of Minutes from July 18, 2008 Meeting*	Phil Petersen, M.D.	There were no corrections. Minutes were approved as proposed.

<table>
<tr><td>➢ Key Questions</td><td>Tami Eide, PharmD</td><td>Dr. Eide announced that through the DERP literature scan process it has been determined the following drug classes will not be updated this year:

<u>Skeletal Muscle Relaxants</u>
<u>ACE Inhibitors</u>
<u>Oral Hypoglycemic Agents</u>
<u>Antiplatelets</u>
<u>Angiotensin Receptor Antagonists</u>
<u>Antihistamines</u>
<u>Hepatitis C drugs</u>
<u>Alzheimer’s Agents</u>
<u>Multiple Sclerosis Agents</u>

Dr. Eide presented the following Key Questions from the Drug Effectiveness Review Project:

<u>Proton Pump Inhibitors</u>
<u>Triptans</u></td></tr>
<tr><td>Public Comment Period</td><td>Phil Petersen, M.D.
Bob Faller, Medical Program Specialist</td><td>Public Comment Period
Twenty one (21) people signed up to speak during the public comment period. Public comment was received from the following speakers:

<table>
<tr><th>Speaker</th><th>Representing</th><th>Agent</th><th>Class</th></tr>
<tr><td>Dr. Stephen DeNagy</td><td>Self</td><td></td><td>Antidepressants & Stimulants and related agents</td></tr>
<tr><td>Dr. Brian McNeel</td><td>Allergan Pharmaceuticals</td><td>Alphagan P</td><td>Ophthalmics, Glaucoma Agents</td></tr>
<tr><td>Dr. Richard Radnovich</td><td>Self</td><td>Cymbalta and Lyrica</td><td>Antidepressants, Other & Anticonvulsants</td></tr>
<tr><td>Dr. J.T. Leavell</td><td>Self</td><td>Concerta</td><td>Stimulants and related agents</td></tr>
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Public Comment Period (Continued)

Public Comment Period (Continued)

Speaker	Representing	Agent	Class
Dr. J.T. Jaccard	Self	Strattera	Stimulants and related agents
Dr. Grant Belnap	Forest Pharmaceuticals	Lexapro	Antidepressants, SSRIs
Wahiba Estergard	Eli Lilly	Cymbalta	Antidepressants, Other
Wahiba Estergard	Eli Lilly	Strattera	Stimulants and related agents
Elson Kim	Forest Pharmaceuticals	Lexapro	Antidepressants, SSRIs
Elson Kim	Forest Pharmaceuticals	Namenda	Alzheimer's Agents
Annie Ogostalick	Abbott	Humira	Cytokine and CAM Antagonists
Ned Masin	Alpharma Pharmaceuticals	Flector Patch	Analgesics/Anesthetics, Topical
Jay Lovin	Wyeth Pharmaceuticals	Pristiq	Antidepressants, other
Joann Ginas	Bristol Myer Squib/Sanofi	Plavix	Platelet Aggregation Inhibitors
Noam Frey	Shire	Vyvanse	Stimulants and related agents
William Schmidt	Glaxo Smith Kline	Requip XL	Antiparkinson's Agents
Gary Lo	Novartis	Focalin XR	Stimulants and related agents
Adam Sosa	Ortho McNeil Jannsen	Concerta	Stimulants and related agents
Jon Beaty	Boehinger Ingelheim	Aggrenox	Platelet Aggregation Inhibitors
Ann Corbin	Boehringer Ingelheim	Mirapex	Antiparkinson's Agents
Leigh Plettts	Astella	tacrolimus	Atopic Dermatitis

DERP Review of Drug Class: Stimulants and Related Agents	Kim Petersen, MS, OHSU EPC	Ms. Petersen reviewed the results of a September 2007 update to the drug class review on Pharmacologic treatments in ADHD. Methylphenidate transdermal, methamphetamine, hydrochloride and lisdexamfetamine disnesylate were added to the review. The report was expanded to look at risks for misuse of these agents in patients with previous substance abuse problems or an increase in illicit substance use in patients treated with a stimulant ADHD drug. 108 new publications were included in the review. There are no trials of comparative effectiveness of these drugs and evidence for comparative efficacy and adverse effects is limited by small sample sites and very short durations. Evidence about abuse/diversion is conflicting and evidence in sub-populations is generally not comparative. **Committee Comments** Dr. Eide announced the Department would be implanting a change to no longer require a diagnosis of ADHD for children. **Committee Recommendations** The Committee recommended Desoxyn be removed from PDL. The Committee felt there were no clinical reasons to include or not include any of the agents on the PDL. They recommended having at least one methylphenidate and one amphetamine product on the PDL. The Committee recommended tht Strattera be retained with the current criteria and that Desoxyn be non-preferred.	
Drug Class Reviews and Committee Recommendations			
➢ Platelet Aggregation Inhibitors	Steve Liles, PharmD	<u>Platelet Aggregation Inhibitors</u> This drug class was last reviewed April of 2007. Dr. Liles reviewed the PROFESS clinical trial and a meta-analysis. For prevention of serious vascular events after stroke, the Committee also reviewed the STEMI (ACC/AHA 2007); Stroke and TIA:Early Management (AHA/ASA 2007) and the stroke and TIA: Secondary preventions (AHA/ASA 2008) Guidelines. **Committee Recommendations** The Committee felt there was no compelling evidence to make any changes.	
➢ Antiemetics	Steve Liles, PharmD	<u>Antiemetics</u> This drug class was last reviewed August 2007. Dr. Liles provided an update of two (2) new generic products, granisetron, a generic form of Kytril, and dronabinol a generic form of Marinol. The Committee reviewed one (1) clinical trial for chemotherapy related nausea and vomiting. **Committee Recommendations** The Committee recommended no changes in the current PDL. Based on the dissolvability of generic	

		ondansetron ODT, they recommended brand Zofran ODT also be preferred.	
➢ Pancreatic Enzymes	Steve Liles, PharmD	<u>Pancreatic Enzymes</u> This is a new class of drugs and is under review for the first time by the Committee. Dr. Liles provided an overview of the products included in this class. There were no quality clinical trials available for review for this drug class. **Committee Recommendations** The Committee felt they could not make recommendations due to lack of data on efficacy and safety. The Committee had no specific recommendations for this drug class.	
➢ Hepatitis B Agents	Steve Liles, PharmD	<u>Hepatitis B Agents</u> This drug class was last reviewed August 2007. Dr. Liles shared FDA labeling changes for Hepsera and Baraclude, plus one (1) clinical trial on lamivudine. **Committee Recommendations** The Committee recommends all agents remain on PDL and no changes should be to the formulary at this time.	
➢ Ophthalmics, Fluoroquinolones/Macrolides	Steve Liles, PharmD	<u>Ophthalmics, Fluoroquinolones/Macrolides</u> This drug class was last reviewed August 2007. Dr. Liles provided updates on two (2) new products, azithromycin (Azasite) and a higher concentration levofloxacin (Iquix). Dr. Liles also provided an in-vitro antibacterial activity update, as well as updates on adverse effects, dosage and efficacy. **Committee Recommendations** The Committee felt Iquix should be preferred for corneal ulcers only. The Committee felt the evidence did not support an inclusion or exclusion of any drugs.	
➢ Ophthalmics, Glaucoma Agents	Steve Liles, PharmD	<u>Ophthalmics, Glaucoma Agents</u> This drug class was last review in April 2007. Dr. Liles reviewed five (5) new clinical trials and one (1) new meta-analysis. **Committee Recommendations** The Committee felt there was no reason to designate any agents as non-preferred on the PDL. The Committee recommended making Combigan a preferred agent.	

Drug Class Reviews and Committee Recommendations (Continued)			
➢ Ophthalmics, NSAIDS	Steve Liles, PharmD	Ophthalmics, NSAIDS This drug class was last reviewed in August 2007. Diclofenac solution, the generic version of Voltorin, is now available. The Committee reviewed two (2) clinical trials. **Committee Recommendations** The Committee felt there was no clinical data to support any change of preferred agents in this class. The Committee recommended getting input from ophthalmologists on the irritation from diclofenac generic compared to the brand name.	
➢ Bone Resorption Suppression & Related Agents	Steve Liles, PharmD	Bone Resorption Suppression & Related Agents This drug class was last reviewed April 2007. Dr. Liles provided an update for two (2) new products (Fosamax Plus D and Actonel) for this drug class. Alendronate, the generic form of Fosamax is now available except as an oral solution. Dr. Liles shared the FDA labeling changes for valoxifene and two (2) new clinical trials. Evista is now indicated for a reduction in risk of invasive breast cancer and in post menopausal women who have osteoporosis, or at high risk for invasive breast cancer. **Committee Recommendations** The Committee recommended that one each of daily, weekly and monthly doses be available as preferred agents. They did not feel there was any reason to include or exclude any agent based on the current data. The Committee also recommended Evista (raloxifene) be removed from this drug class and be placed as a hormone agent with in the PDL.	
➢ Androgenic Agents	Steve Liles, PharmD	Androgenic Agents This drug class was last reviewed April 2007. Dr. Liles had no new data to share with the committee with regards to this class. **Committee Recommendations** The Committee felt there was no new clinical data to make any recommendations for change.	
➢ Analgesics/Anesthetics, Topical	Steve Liles, PharmD	Analgesics/Anesthetics, Topical This was the first review of this drug class which includes diclofenac topical patch (Flector), lidocaine patch and diclofenac topical gel. Dr. Liles provided the indications; adverse effects and dosage information. Two (2) clinical trials for Flector and one (1) meta-analysis for Lidoderm patch were	

		reviewed. **Committee Recommendations** The Committee recommended the Flector Patch be placed as a non-preferred agent, but be available for short-term use with the criteria of history of non-steroidal intolerance and only for acute injury for two (2) weeks or less. The Committee recommended keeping all agents in this class as non-preferred until there is more data available for review.	
➢ NSAIDs	Steve Liles, PharmD	<u>NSAIDs</u> This drug class was last reviewed in April 2007. Dr. Liles had no new evidence to share with the Committee. **Committee Recommendations** The Committee felt there was no significant data to make recommendations for change. The Committee recommended no changes to the PDL for this drug class.	
➢ Cytokine and CAM Antagonists	Steve Liles, PharmD	<u>Cytokine and CAM Antagonists</u> This drug class was last reviewed June 2007. Dr. Liles provided an update on the new dosage forms or adalimumab and abatacept. Dr. Liles reviewed new indications for adalimumab and abatacept, as well as the FDA safety investigation on the link between TNF blockers and development of lymphoma in children and young adults. The Committee reviewed 10 clinical trials, a systematic review on rheumatoid arthritis, ECULAR 2008 safety data and the ACR guidelines. **Committee Recommendations** The Committee felt there was no evidence to include, exclude or change the preferred status of any of he agents.	
➢ Atopic Dematitis	Steve Liles, PharmD	<u>Atopic Dematitis</u> This drug class was last reviewed June 2007. The Committee reviewed two (2) new clinical trials for this drug class. **Committee Recommendations** The Committee felt there was no new compelling clinical evidence to make any changes to the PDL.	
➢ Antiparkinson's Agents	Steve Liles, PharmD	<u>Antiparkinson's Agents</u> This drug class was last reviewed April 2007. Dr. Liles reported on the availability of ropinirole generic and the market withdrawal of Kemadrin and Neupro. There was no new clinical data for this drug class	

		available for review. **Committee Recommendations** The Committee felt that there was no new significant data to make any changes to the PDL.	
➢ Alzheimer's Agents	Steve Liles, PharmD	<u>Alzheimer's Agents</u> This drug class was last reviewed April 2007. There was no new clinical evidence to review for this drug class. **Committee Recommendations** There was no evidence to recommend one agent over another in general. For safety reasons the Committee recommended Cognex not be preferred. Exclon was recommended for the PDL only if it was cost comparable to the oral form. The Committee recommendation for the drug class was to remove the PA criteria requirement of a specific MMSE score but to keep the diagnosis of dementia with physician assessment of severity.	
➢ Antidepressants, SSRIs	Steve Liles, PharmD	<u>Antidepressants, SSRIs</u> This drug class was last reviewed August 2007. Dr. Liles provided an update on one (1) new drug (Luvox CR) in this drug class, as well as safety data for birth defects with SSRIs.. The Committee reviewed two (2) new clinical trials and one (1) systematic review. **Committee Recommendations** The Committee felt that there was no new significant clinical data to make any recommendation for change. The Committee recommendation was for no change to the PDL. Tehre was a recommendation with consideration of cost to allow Lexapro as a preferred agent given its equivalence in efficacy, effectiveness and safety in comparison to other agents. For safety reasons they recommended paroxeline remain non-preferred.	
➢ Antidepressants, Other	Steve Liles, PharmD	<u>Antidepressants, Other</u> This drug class was last reviewed February 2007. Dr. Liles provided an update on the new product desvenlafaxine. He also reported there is now a generic bupropion XL available. The new indications for duloxetrin's use in Fibromyalgia were reviewed, as well as six (6) new clinical trials. **Committee Recommendations** The Committee did not have recommendations for changing the current PDL status of any of the agents. For safety reasons they recommended nefazadone, venlafoxine be non-preferred. They recommended that bupropion immediate release and bupropion SR either be non-preferred or have dose limitations placed on them as bupropion XL is a superior product.	

P&T Guideline Review	Paul Leary, Deputy Administrator, Division of Medicaid	**P&T Guideline review** Mr. Leary reviewed the draft document: *Idaho Medicaid Pharmacy and Therapeutics Committee* the Department guidelines for the operation of Idaho's Division of Medicaid's Pharmacy and Therapeutics (P&T) with the Committee members. This was a review of proposed changes to the structure of the P&T Committee meetings. He also cited the section of Administrative Rule that cover guidelines of the Idaho Open Meeting Law (Idaho code §§ 67-2340 through 67-2347), as well as proposed guidelines for public testimony.	

Pharmacy and Therapeutics Committee
Public Comment
August 15, 2008

Dr. Stephen DeNagy

Thank you for the opportunity to speak today. My name is Dr. Steve DeNagy. I'm an internist and clinical psychopharmacologist from Idaho Falls. I also teach continuing education for Idaho State University Department of Counseling, psychopharmacology updates that are required for licensure for various specialties, and I guess what brings me here partly is, since I came halfway across the state to see my daughter's equestrian, she's an eight-year-old in Hailey, I thought I'd make it the rest of the way to visit you all today too. I really appreciate the efforts that you all do. I see we have some Eastern Idahoans here on the Committee, and I think it's a very important task we all have. I would direct everybody to the south wall of this room, to your fourth chart here, Goals of the Department, which really favorably mesh with my Hippocratic Oath also, to improve the health status of Idahoans and increase the safety and self sufficiency of individuals and families, and to enhance the delivery of health and human services. I'll start my brief comments with a case study that shows the importance of this issue of access to drugs and the idea of restricted formulary. The 35-year-old bipolar patient who I see was well treated with Geodon, these are not drugs in this class but it's a very dramatic case, who was begun, unbeknownst to me by her pain specialist on methadone. If you look in the Epocrates, that's listed as a contraindication, however when that drug was started at 20 mg, she did well for a couple of weeks and then suffered syncopal episodes, and when the EMTs arrived for that, she suffered a cardiac arrest in their presence, and she had a shockable rhythm and, thank God that she was resuscitated. The reason for that is that both drugs are associated with QT-prolongation and torsades de pointe, which apparently caused her sudden death. At this point, we don't know if she has an underlying illness that causes the conduction issue or if it's a drug/drug interaction. So it is important and imperative, I don't know if the doctor who started it knew that interaction or not, but I'm not sure that it would have been easy to start another agent, had he known that. Now, the thing that's driving us batty in the clinic is, four drugs in particular that you're looking at today, two in the antidepressant class and two in the stimulant, or at least the attention deficit class, and I would like to at least speak to increase the access to Cymbalta, Lexapro, Vyvanse and Strattera. Cymbalta, because for us in the clinic, especially in my practice, which are refractory patients with difficult-to-treat illnesses, we have antidepressant efficacy and anti-anxiety efficacy, we have two pain indications, a peripheral pain indication which is the diabetic peripheral neuropathy which tests the hypothesis that in a central pain illness which is fibromyalgia which is of course a difficult to understand illness but is a prototype of an illness which is central, non pathologic pain, it is well tolerated and we really, frankly, don't have any other good alternatives when I have a patient who presents with those kinds of illnesses. One could argue that well, we could try a tricyclic antidepressant, but in the case of evidence-based medicine, I don't know that we have double blind, placebo controlled, head-to-head comparisons, non inferiority or superiority studies with tricyclics. In fact, when I see referral patients on tricyclics, we see a wide smattering of dosages. I would refer some of our members on the committee and to my clinician colleagues to look at Sheldon Preskorn's data on the PK's of these drugs. Lexapro, because of its drug/drug interactions, the fact that it has none, makes it extremely safe for my chronically multiply ill patients, and in the case of Vyvanse, lysine amphetamine is an

excellent drug. It is a very long acting drug, it is smooth, it is difficult to divert, and while one of the pharmacies for Medicaid did inform me that the lysine bond is easy to break, in fact you have to work really hard to snort or abuse this drug. Snorting the drug would actually make it less available as an addictive drug, and Strattera of course, I've been to this Committee and advocated it before, it's non divertible, it's an efficacious drug, and I really appreciate it, especially in our atypical populations. Any questions? Did I make it in under three minutes?

Committee: I think you were plus.

Dr. DeNagy: So can I have two more seconds?

Committee: No. I think that's enough.

Dr. DeNagy: Okay, thank you.

Dr. Brian McNeel
Good morning and again, thank you for having me here as well. Mark Twain said at one point "I didn't have time to write you a short speech, so I wrote you a long one instead". Fortunately for you all, I had the time to write you some short notes here. I'm a clinical practitioner here in Boise. I've been with Dr. Mark Hollingshead for eleven years and just recently branched out to my own office. I'm also an assistant professor at Ohio State University. I am speaking on behalf of Allergan Pharmaceuticals today. I have no financial interest in Allergan or neither drug company, and I'm not a paid consultant to them. I'm speaking really specifically to fluoroquinolones and the newer glaucoma medicines. Glaucoma's a very difficult thing to treat, particularly because it's a painless, asymptomatic, and very expensive disease process for most folks. In best case scenarios, glaucoma's typically out of a very, very poorly compliant patient population and I think those of us in clinical practice realize that with Medicaid patients in particular, you get less compliance, and so really the newer medicines here, particularly Lumigan and Combigan in particular, are absolutely wonder drugs for us and particularly again in our Medicaid populations just in and of the fact that Lumigan, particularly, has a tremendously long course of action, a very, very long half life, and for those patients who do occasionally skip doses, which we all know they do, it still does have very good clinical efficacy. Combination systems as well, Combigan has come up in particular here as a combination drug of both a beta blocker and an alpha agonist. It's an absolutely fantastic treatment additive to our armormentarium for glaucoma. It's extraordinarily more comfortable than Cosopt, that also increases compliance, and we found it to be just clinically very, very efficacious, leaving aside clinical studies, but I don't read them either, so, I'm not sure if you guys do. The other thing too with combination medicines and very, very potent drugs like Lumigan, is that it's really simplified our treatment paradigm for glaucoma in that we're not titrating multiple medicines and trying to match one medicine to the other. Essentially, if we have three drug classes in two medicines which is very, very easy for patients to comply with, if that doesn't work, patients just typically go to surgery at this point, so it's really helped from that standpoint. A couple of things that are really nice about drugs like Lumigan in particular are the large sample size, the fact that we don't need to refrigerate like we do some of the other medications. I'm sorry, did you have a comment or question?
Dr. McNeel: Okay then. So, in summary, basically, long acting, easy to administer, safe drugs increase compliance, they decrease the cost to Medicaid because we're getting less patients in surgery at this point, and ultimately benefit patients and help to preserve vision. Okay, now I will exit stage left. Thank you.

Dr. Richard Radnovich
Hi, good morning, I'm Dr. Radnovich. I'm a physician. I'm not here on behalf of any pharmaceutical company, I'm here on behalf of my patients and on behalf of other physicians who treat pain in the state. I'm the founder of Injury Care Medical Center, I'm on faculty at the University of Washington, and clinical faculty at The Family Practice Residency of Idaho just up the street. In my private practice, I see Medicaid patients. About half of my patient population is pain and a large percentage of those folks are fibromyalgia-type chronic pain patients. As I said, I still see Medicaid patients in my private practice and I also see Medicaid patients at The Family Practice Residency and I'm sure that you know that Family Practice Residency is the largest provider of Medicaid services in the state, so I speak from experience when I talk about Medicaid, fibromyalgia specifically, and about the prior authorization process. Let me just say something about the prior authorization process. The pharmaceutical prior authorization process as it's been, has been bad for patients. It's been bad for business, and it's just plain bad medicine. It's particularly bad for our fibromyalgia patients. They're already

suffering, they're already more challenging, and they already use more resources and on my end they use much more resources when we have to apply the prior authorization process. We have very few effective treatments for fibromyalgia patients and only two FDA-approved drugs; Cymbalta (duloxetine) and Lyrica (pregabalin). Those medications have been shown to be safe and effective in large, well controlled trials, they have mechanism of actions that are not usually exclusive; Cymbalta is a norepinephrine serotonin reuptake inhibitor and Lyrica is a neuronal calcium channel blocker, and they therefore can be used concurrently and effectively together. Older medications for fibromyalgia like Neurontin, gabapentin or the tricyclics have not been shown to be consistently safe and effective in large, well controlled trials, they have large side effect profiles with the potential for large side effects, terrible drug/drug interactions potentially, and are not to be used as first-line agents anymore. There are better agents out there. I therefore respectfully urge the P&T Committee to approve Lyrica and Cymbalta as first-line agents in the treatment of fibromyalgia. If you have any questions, I would be happy to answer. Again, thank you for your time and I would urge you to do the right thing medically and approve Lyrica and Cymbalta as first-line agents. Thank you.

Dr. J. T. Leavell

Good morning, my name is Dr. Tim Leavell. I'm a developmental behavioral pediatrician and I work at St. Lukes Children's Hospital. The last twenty years, attention deficit hyperactivity disorder has been my number one managed clinical condition. In our clinic, we have 60% of our patients receiving Medicaid, so I see a lot of Medicaid patients. The treatment of attention deficit hyperactivity disorder has a number of different agents included in this class, and the standard that we use for electing one drug over another is the Multi-Mode Treatment of ADHD Study, a large, randomly controlled trial funded by the Department of Education and MIH, the ruling on the 600 patients. In that study, the single most effective treatment for attention deficit hyperactivity disorder was an intensely, three times a day, at that time they used short-acting methylphenidate, it set the standard that twelve hours of clinical efficacy with the drug needs to be present to achieve the best outcome with kids with attention deficit hyperactivity disorder. Despite the fact that there are a lack of head-to-head studies in this class, it does not mean that the 12-hour drugs that we use are all the same. They have distinct differences and, as a practitioner, I feel it's important that our clinical judgement is recognized and we be able to use that clinical judgement in the selection of the most appropriate drug for the patient. Sometimes it's an OROS methylphenidate drug like Concerta and I have great success with that drug, but sometimes the family has a history of responding to mixed amphetamine salts, another 12-hour drug. Sometimes the family has a positive response with atomoxetine. It's a completely different chemical, although the effect size is less, it can be a very effective drug, and currently atomoxetine requires at least one failure with another drug in the class. My only comment is that I think that we need to endorse and list as preferred agents, all the long-acting medications in this class and allow practitioners the freedom to make the choice of which one will fit the patient best. The other comment I would make is to endorse the time that we waste every day in the prior authorization process, and I suspect that Medicaid also uses a lot of man hours giving us the okay for drugs that are within the indication, and I would urge that we consider streamlining that process or perhaps even eliminating that process. Thank you.

Dr. J.T. Jaccard

Again, thank you for being here. My name is Tad Jaccard, and I am a child psychiatrist who works in Spokane at Sacred Heart Medical Center. My reason for being here is that having worked on this level of committee in the State of Washington, having seen all of this done, I wanted to suggest basically the same thing that Dr. Leavell has suggested, that you all provide each of the providers who are out there who have the clinical skills, the ability to use any medication that they want first line that they feel is appropriate. Right now, as he pointed out atomoxetine (Strattera) is required in terms of some kind of first-line failure. It is demonstrated by the Texas Medication Algorithm Project to be the first drug that should be used when people have anxiety disorders and now that I work in a partial hospital program where I follow children over a five-week period on a daily basis, it's become quite clear to me that that is the right call, that if a child has anxiety disorders, atomoxetine should be the first drug used. Unfortunately, I have also worked for the Juvenile Rehab Administration in a school that we ran in Spokane and watched that medication be effective, and then have children run off for two weeks and then be brought back, have the drug started again, so have seen it be effective, lose its effect while they are gone, and then be effectively re-established after their return. It's also a better drug for Tourette's syndrome, it's a better drug for diversion, all of which people know and for reasons I think it is approved here if you have any of those conditions. However it is an effective drug for children period, with about a 60-70% rate of efficiency, and also there are people who flat don't want to give their children stimulants, and they should have the option to go to a non-stimulant drug if they so desire. I would tell you also that one of the things we struggle with in Washington is using combination drugs such as Strattera with stimulants, and these drugs do, in fact, have some different mechanisms of action and, in fact, also turn out to be useful in combination in certain patients. We are required to get prior authorization to use both, but I think that's an appropriate thing to do.

Dr. Grant Belnap
Thank you for the opportunity to be here. My name is Grant Belnap and I'm a Board Certified General Psychiatrist. I have a practice in Eagle. In addition, I am a contract physician with Affinity, Inc. and Riverside Rehab, two agencies that serve the Medicaid population in the valley, and I'm here on behalf of Forest Pharmaceuticals to discuss the use and hopefully decrease the limited and restricted status of Lexapro or escitalopram. It's been pointed out earlier that escitalopram or Lexapro has significant advantages and benefits in terms of side effect and drug/drug interactions, its profile is safe and effective, and used by psychiatrists as a first-line agent and have more new start prescriptions than any other serotonin reuptake inhibitor. The reason for that is because it's been shown to be very effective and safe, and particularly in terms of polypharmacy, and goodness knows that the patient population we're serving with Medicaid is, unfortunately, a very ill population. I think that actually, it decreases the likelihood of further visits by getting a drug that works safely and effectively the first time, and I would ask that prior authorization, if possible, be removed to allow freer access to the medication. Thank you, any questions?

Wahiba Estergard
Good morning everyone, my name is Wahiba Estergard and I'm a Neuroscience Medical Liaison for Eli Lilly and Company. Thank you so much for the opportunity to be here. Today, I will be talking about Cymbalta in the treatment of fibromyalgia, as well as Strattera in the maintenance therapy for ADHD. As far as fibromyalgia, the indication represents a second FDA-approved use for Cymbalta. The first one being, DPNP or diabetic peripheral neuropathic pain. The analgesic effect of Cymbalta are believed to be independent of the central antidepressant's effects. Cymbalta at 60 mg q.d. has demonstrated efficacy in two randomized, placebo controlled trials in both in patients with fibromyalgia as measured by the Brief Pain Inventory 24-hour Average Scale. Some patients actually experience a decrease in pain in the first week of treatment, which persisted throughout the studies. About 55% of the patients on Cymbalta 60 mg q.d. had clinically meaningful relief as indicated by 30% improvement in the BPI at end point. Now some of the safety and tolerability issues with Cymbalta; like all antidepressants, it has a black box warning for suicidality, so any patient starting on Cymbalta should be monitored closely. Some of the other most common adverse events for Cymbalta are nausea, dry mouth, constipation and somnolence. Now to conclude, fibromyalgia can alter the functional capability of patients and could lead to considerable difficulty carrying out activities of daily living. Cymbalta can significantly improve functioning and decrease the pain associated with fibromyalgia. Now I will move on and talk about Strattera in the maintenance of ADHD. There are three points that I would like to make. First one is Strattera is very unique in that it's a non stimulant. Its FDA indicated and approved for the treatment of ADHD. Strattera is also the first ADHD medication approved for the maintenance treatment of ADHD in children and adolescents. The second point that I would like to make is that not all ADHD patients are the same and the comorbidities are very common. According to some studies, about 65% of patients with ADHD have comorbidities. Third point I would like to make is of diversion of stimulant medications and the subsequent abuse by individuals without ADHD is a very growing concern in the United States. According to the 2006 National Survey of Drug and Health, an estimated about 1.2 million people use prescription stimulants and methamphetamines illicitly in the past year. Unlike stimulants...

Question: You said that Cymbalta patients with the fibromyalgia study, which actually wasn't in our data over here, that they had an decrease in their BPI, but you didn't say how long the study was.

Answer: The studies we have, a short-term study as well as long-term studies, the short-term studies are twelve weeks and then we also have data for six month studies.

Elson Kim
I have two topics, would I have three minutes or six minutes?

Committee: Make it as short as you can, sir.

Okay. My name is Elson Kim and I am employed by Forest Research and I represent both Lexapro and Namenda. The literature that I want to present this morning compares Lexapro to other selective reuptake inhibitors. The information will demonstrate Lexapro's superior tolerability, persistence, and that a patient on this treatment benefitstranslates into cost effective treatment in depressed patients. The HRQ, in their report in January, 2007, demonstrated that Lexapro in comparative trials when

compared with other SSRIs and SNRIs, had the lowest incidence of dizziness, headache, insomnia, nausea and somnolence, and if Lexapro has the lowest incidence of adverse effects, then Lexapro should also have the best persistence. In a study done by Dr. Woo and colleagues, we had a longitudinal database of over 11 million patients, the recruited about 44,000 patients and in that study, they demonstrated 30% more likely to stay on therapy at two months, 42% more likely to stay on therapy after six months. Further testimony to this Committee by this speaker in studies done by Lamb, Moore and _____, Lexapro had better efficacy and lower rates of discontinuation than other brand name or generic antidepressants. Dr. Woo and colleagues further demonstrated in another longitudinal database of 11 million patients with about 38,000 patients for this study, that the data demonstrated Lexapro in patients were more likely to be adherent, less likely to discontinue, and less likely to switch medication. Escitalopram patients also have lower rates of hospitalization, lower hospitalization days per hundred, and lower emergency room days per hundred. In the same study in a six-month analysis, escitalopram patients demonstrated significantly lower total health costs by about $839 per patient, and even when a sensitivity analysis was done, making the other drugs at $0 cost, leads to a $273 savings per patient. Lastly on Lexapro, the company released on May 7th that Lexapro significantly improves symptoms of depression as compared to placebo treatment, and was well tolerated in adolescents age 12-17 with major depressive disorders that could interface the data presented in the 2008 American Psychiatric Association. Escitalopram compared to citalopram, venlafaxine and other antidepressants had fewer reported adverse drug events, increased patient persistence, decreased patient discontinuation and therapy switching, and lower hospital ER utilization, which reduces the total cost of care. Now switching gears to Namenda. Namenda is the only NMDA receptor antagonist approved for treatment of moderate to severe Alzheimer's disease, with proven efficacy in both monotherapy and combination therapy with cholinesterase inhibitors. USP model guidelines for 2008 includes glutamate path remodifiers as a separate class of therapy for anti-dementia agents. In 2002, J.W. Hill demonstrated that ADRD patients had twice the comorbidities, higher utilization rates, 2.5 times rate of hospital admissions, and two days' longer length of stay than age-matched controls without ADRD. Costs related to the care of patients with ADRD may be blended by appropriate drug therapy. Cummings in 2006 demonstrated in a combination trial that treatment with memantine reduced agitation, aggression, irritability, and appetite/eating disturbances. It also reduced agitation and aggression in patients who were agitated at baseline and thru eight emergence in those who were free of agitation at baseline. Gauthier then later showed in monotherapy and combination trials that specific, persistent benefits were observed on the symptoms of delusion and agitation and aggression, which were noted to be associated with rapid disease progression, increased caregiver burden, early institutionalization, and increased hospital care. Dr. Philiate in 2007 did a review of medical charts of 375 residents in 100 nursing homes, and half of the patients were randomized that discontinued therapy and the other half continued therapy on memantine, and what they found was that patients who had treatment discontinued, had a significant increase in the use of psychotropic medications, more specifically, these patients were discontinued with a significant increase of antidepressants, anticonvulsants, and antipsychotics, as well as significant weight loss. The study demonstrates the impact of memantine withdrawal and the use of psychotropic drugs and a change in weight. In closing, patients treated with memantine for moderate to severe Alzheimer's disease have shown improvement in cognition, function, behavior and global measures. Namenda is safe and well tolerated, and can be used effectively as monotherapy or in combination with acetylcholinesterase inhibitors. Thank you.

Annie Ogostalick

Hi there. Thanks for the opportunity to speak with you today about Humira. I'm Dr. Annie Ogostalick and I'm a National Clinical Executive in the Clinical Evidence & Outcomes Group at Abbott, and in the next few minutes, I want to highlight for you, three of the key attributes of Humira. Efficacy across a broad scopes of indications, consistent safety across that broad scope of indications, and finally comparatively efficient maintenance dosing across indications, so first, let's talk about efficacy. Humira's the first fully human, monoclonal antibody targeted against TNF. Currently indicated in rheumatoid arthritis and juvenile idiopathic arthritis, psoriasis, Crohn's disease, psoriatic arthritis and ankylosing spondylitis, so this broad scope of indications encompasses rheumatology, gastroenterology and dermatology. So within this broad scope of indications, key outcomes are as follows: in rheumatoid arthritis, a demonstrated inhibition in randomized control trials of radiographic progression of disease with administration of Humira along with methotrexate which was sustained out to five years in an open-label extension study, sustained efficacy reducing ACR scores by 50% over up to seven years in approximately two-thirds of patients with rheumatoid arthritis from open-label extensions of multiple randomized controlled clinical trials. So now switch to Crohn's disease. In placebo controlled trials of patients with moderately to severely active disease, about a third of patients were in remission after Humira induction therapy within four weeks, and maintained that clinical remission out to 56 weeks. Humira administration resulted in fewer Crohn's disease hospitalizations and all-cause hospitalizations compared with placebo. In a four-week randomized controlled trial of patients who had become intolerant or who had lost response to Remicade, about one in five patients achieved clinical remission of their Crohn's disease versus placebo. Finally, in plaque psoriasis, following sixteen weeks of treatment with Humira, about 70% of patients in a 52-week double blind, placebo controlled trial, had 75% reductions in their disease scores, 45% of patients had a 90% reduction in their disease scores, and fully

one in five had a total clearing of their psoriasis; that's a 100% reduction in their disease scores. This efficacy is unique among the self-injected TNF inhibitors. Let's talk about safely briefly. Within this broad scope of indications, there has been an immense amount of safety data collected in diverse patient populations. Rates of serious infection, tuberculosis and lymphoma rates were all within range of other documented anti-TNF and biologic-naive RA patient incident data. A recently presented analysis of Humira reconfirmed the consistent safety of this product in global clinical trials across all indications. Also in terms of post marketing surveillance, as of June 2005, an estimated 70,500 patient years of exposure has been reported. This consistent safety suggests considerable differences compared with other TNF antagonists. Finally, let's talk about dosing briefly. Recommended maintenance dose of Humira for adult patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and psoriasis is 40 mg administered once every other week as a subcutaneous injection. There's a four-week induction period for patients with Crohn's disease and in patients with psoriasis, there's a brief, one-time initial loading dose, which is in contrast to other self injected TNF inhibitors, where several months' of updosing is required in the treatment of psoriasis. So to conclude, Humira's unique among self injected TNF inhibitors across a broad scope of indications with proven efficacy, in-depth safety data across multiple indications with consistent safety, and efficient maintenance dosing across indications. Please consult the full prescribing information in your packets and we would respectfully ask that you allow parity access on the PDL for self injected TNF inhibitors. Thanks for allowing me to share this information with you.

Ned Mason

Good morning, thank you for allowing me an opportunity to present a brief synopsis of the efficacy and safety of Flector Patch, a diclofenac epolamine topical medication. I am Dr. Mason, a Board Certified Physician and Senior Medical Science liaison within the Medical Affairs Division of Alpharma Pharmaceuticals, the same company that manufactures Kadian extended-release morphine sulfate. As you know, pain is a major health problem in the US today and it's the most common reason that people seek medical care. Acute pain occurs in approximately 20% of adults in the US annually. Sprains, strains and contusions are the most common causes of acute pain, and in a 2004-2005 study of ER patients, sprains and strains accounted for about 18% of the injuries and contusions. Flector Patch is indicated in the United States for the topical treatment of acute pain, due to minor strains, sprains and contusions, and contains 1.3% diclofenac epolamine. The epolamine salt form of diclofenac was chosen over about twenty-three other formulations because of its balanced hydrophilic and lipophilic properties, bipolar properties that allow for a predictable, controlled release of diclofenac directly into the site of injury to alleviate pain and decrease inflammation. Flector Patch is applied to the most painful area twice daily. The patch delivery system provides patients with a convenient dosage form that is easily applied. Additionally, comparative bioavailability studies have shown that Flector Patch when applied twice a day at steady state, has less than 1% of the plasma concentration reached by a single 50 mg oral dose of diclofenac, Voltaren presence. In addition to its efficacy proven in clinical trials, Flector Patch has demonstrated an excellent safety and tolerability profile. It was approved in the US last year and represented the first NSAID to gain FDA approval after the NSAID COX-2 cardiovascular adverse event issues in 2004. In the absence of evidence, like all other NSAIDs, the FDA did require a black box warning reminding professionals and patients of the NSAID potential of cardiovascular and GI adverse events. However, it is important to note that the Flector Patch has been available worldwide since 1993 and has over 175 million patches sold in over six million patients. Worldwide safety experience has shown a very safe profile, with no deaths. The most common adverse events are application site reactions, such as rash and pruritus that did not require additional follow-up, and resolved soon after patch removal. In conclusion, in the face of so many uncertainties, with the long-term risks associated with the use of oral NSAIDs for the treatment of acute pain associated with sprains, strains and contusions, please do not discount the need for anti-inflammatory agents for these conditions. Flector Patch has an important contribution to make in this situation. Access will allow the State of Idaho continue to provide quality care while potentially reducing medical costs associated with adverse events and therapy failures of other alternatives. Any questions? Thank you very much.

Jay Lovin

Hi, my name is Jay Lovin, I'm the District Manager for Wyeth Pharmaceuticals and I live here in Boise, Idaho. I would like to take just a couple of minutes this morning and introduce the new SNRI therapy for adult patients with major depressive disorder. We know that MDD can be a debilitating illness and the more options that are available for patients, the better we can treat this illness. Now Pristiq (desvenlafaxine) 50 mg is the newest option. Pristiq is the first SNRI to be approved by the FDA in approximately five years, the last being duloxetine in about 2003. The efficacy of Pristiq as a treatment for depression was established in four eight-week, randomized, double blind, placebo controlled, fixed dose studies at doses of 50 mg to 400 mg a day in adult outpatients who met the DSM-4 criteria for major depressive disorder. Based on the results of these trials, the recommended therapeutic dose is a single 50 mg tablet once daily. A dosage adjustment for patients with severe renal disease or end stage renal disease is recommended as one 50 mg tablet every other day. It is important to note that all doses were effective in treating MDD, however as the dose increased, so did the side effects

and discontinuation rates. At the 50 mg dose, the discontinuation rate due to adverse events was 4.1% with Pristiq and 3.8% with placebo. The most common adverse events were nausea, dizziness, sweating, constipation, and decreased appetite. The pharmacokinetic profile of Pristiq differs from other SNRIs in the fact that it was not primarily metabolized through the liver. It is, however, primarily metabolized through conjugation, with minor metabolism through the 3A4 pathway. The 2D6 pathway is not involved and, therefore, the drug interactions are low and the drug concentrations are independent of the phenotype of the patient. Pristiq is classified as a pregnancy category C and like all SNRIs, carries a black box warning for suicidality in children, adolescents and young adults. Patients taking Pristiq should not cut, crush or chew the tablets, so as not to change the release profile of the matrix. If there are no questions? Thank you for your time.

Joann Ginal
Members of the P&T Committee, my name is Joann Ginal, PhD. I'm an MSL with Bristol-Myers Squibb. I want to thank you for the opportunity to present clopidogrel, brand name Plavix, on behalf of Bristol-Myers Squibb and Sanofi Aventis. According to Idaho Department of Health & Welfare statistics, CV deaths which include heart disease and stroke, account for one-third of Idaho residents' deaths in 2004. That was the most recent information I could find. Plavix indications are recent MI, recent stroke, or established peripheral arterial disease, and also acute coronary syndrome which includes non ST-elevated MI, unstable angina, and ST-elevated MI. Contraindications are hypersensitivity to any part of the product and active pathological bleeding, such as peptic ulcer or intracranial hemorrhage. PTP has been reported rarely following the use of clopidogrel, usually with less than two weeks' of exposure, and in clinical trials, the most common clinically important side effects were pruritus, diarrhea and rash. The rates of major and minor bleeding were higher in patients that were treated with clopidogrel and aspirin compared to placebo and aspirin in clinical trials. The clinical efficacy of clopidogrel is derived from several pivotal trials involving over 81,000 patients. CAPRI was a three-year, 19,000-patient study comparing aspirin versus clopidogrel in patients with prior MI, prior stroke, established PAD, and the study demonstrated that clopidogrel alone reduced the risk of combined end points of MI, stroke and vascular disease by 8.7%, which was a statistically significant P-value of 0.04. The CURE trial was a one-year study with over 12,000 patients comparing clopidogrel plus aspirin versus aspirin. These patients had acute coronary syndromes and presented within twenty-four hours of onset of chest pain or symptoms consistent with ischemia. Primary outcome was CV death, MI or stroke, and the combination of aspirin and clopidogrel had a 20% relative risk reduction over aspirin alone. In patients with ST segment elevation MI, the safety and efficacy of clopidogrel have been evaluated in two major trials, that would be MIT and CLARITY. Another very important trial is the MATCH trial, an 18-month trial with 7,500 patients with previous ischemic stroke or TIA, within three months of randomization. MATCH compared aspirin plus clopidogrel versus placebo plus clopidogrel. The MATCH trial demonstrated an ischemic stroke or TIA patients at high risk, that adding aspirin to clopidogrel provided no additional benefit than clopidogrel monotherapy. That was a relative risk reduction of 6.4%. In addition, the results showed that adding aspirin to clopidogrel led to an increase in bleeding. Last May, the ProFESS trial results were presented at the European Stroke Conference. This was one of the largest stroke trials, in fact the largest stroke trial to date, with over 20,000 patients. Investigators were seeking to establish that extended-release dipyridamole plus aspirin on a b.i.d. dosing is not inferior to clopidogrel 75 mg once a day.

Committee: Thank you very much. Your time is up.

Joann Ginal Questions? Thank you.

Noam Frey
I'm Dr. Noam Frey, I'm a Senior Medical Liaison for Shire Pharmaceuticals, the manufacturer of Adderall-XR, Vyvanse and Daytrana, and I want to thank you for having me here. I want to talk a little bit about Vyvanse today, mainly because the review that you're going to see soon enough has been last updated about a year ago and in that year, it was our first year at market and we have a lot of information and data to share with you. As you know, Vyvanse is a prodrug which means that it has a new chemical and a new biological delivery system of d-amphetamine for the treatment of ADHD. Basically, what we have is the inactive drug being absorbed rapidly and then being converted to l-lysine and d-amphetamine, which is the active molecule, through an enzymatic process. This process provides the prolonged release of d-amphetamine, which then translates to long efficacy throughout the day for Vyvanse which speaks volumes in patients, when you have ADHD kids who go back home and eat, do homework, or sit down at family time, and not only during their school hours. We have a couple of new data studies to share with you. One of them is a phase-3B study that we've done, showing efficacy up to thirteen hours, and we now have an FDA-approved promotion for thirteen hours post dose, the only ADHD medication that has that. We also did an analysis of a phase-2

study, where we looked at Vyvanse and Adderall-XR in an analog classroom study, and we showed significantly more math problems attempted and solved at twelve hours with Vyvanse versus Adderall-XR, and I think the most compelling evidence for you would be our daily consumption average. After a year in the market and over two million prescriptions, the daily consumption average for Vyvanse is still rock solid at 1.0, if you compare it to Adderall-XR it's about 1.2, and other long-acting medications at 1.1 up to 1.3. In other exciting news for us was that we received an FDA approval for adult indication in April of this year after presenting a phase-3 study with 420 patients that showed a 43% reduction in ADD symptoms for adults using Vyvanse. As you might know, in therapeutic doses, Vyvanse had shown less abuse liability than immediate-release dexamphetamine, and it's the only drug for ADHD that is dissolved in water. Do you have any questions? Thank you very much.

Dr. William Schmidt

Good morning, my name is Dr. Bill Schmidt, I'm a Medical Scientist with GlaxoSmithKline and I would like to thank the Committee for allowing me to briefly discuss with you, a new medication called ReQuip-XL. Now patients with Parkinson's disease, as we all know, frequently take multiple medications which can lead to poor adherence, and that can result in a worsening of their symptoms. For example, a recent study of patients taking three times a day ReQuip immediate-release, showed that fully two-thirds of the patients were actually not adherent, resulting in recurrence of their symptoms. Also, t.i.d. dosing of immediate-release dopamine agonists can result in pulsatile stimulation of dopamine receptors, with increased risk of dyskinesias and motor fluctuations. ReQuip-XL was developed to provide better medication adherence, smoother blood levels of ReQuip, and to reduce this pulsatile stimulation of the dopamine receptors. It was approved by the FDA on June 13th of this year and I point out that you do not have the dossier for that, I guess, since I believe it was not requested. It is, however, the only once-daily dopamine agonist available today because of the withdrawal from the market of the Nupro patch earlier this year. Now time obviously doesn't allow me to discuss all the ReQuip-XL trials, but for example a recent head-to-head study compared adjunctive immediate-release ReQuip to ReQuip-XL in patients not optimally controlled already on levadopa. The patients who were taking ReQuip-XL did maintain significantly greater reduction in so-called "off time", they showed significantly greater improvements in Clinical Global Impression Scores, and significantly greater improvements in so-called "on time" as measured by the PDRS Total Motor Scores. It's available in strengths of 2 mg, 4 mg and 8 mg, and it does offer patients and physicians a much simpler and potentially faster initial titration. Also switching a patient from t.i.d. immediate-release ReQuip to ReQuip-XL can be done immediately and with no titration necessary. The most common adverse reactions in patients with advanced Parkinson's who were taking levadopa were dyskinesias, nausea, dizziness, hallucinations, somnolence, abdominal pain and orthostatic hypotension. In view of its established efficacy, we request that ReQuip-XL be added to the formulary. Thank you. Any questions?

Gary Lo

Good morning, my name is Gary Lo, and I'm a Regional Account Manager with Novartis Pharmaceuticals. Today, I would like to talk to you regarding Focalin-XR. Focalin-XR extended-release capsules are a once-daily, long-acting preparation of dexmethylphenidate. Because this chemically refined form of methylphenidate only contains the active isomer, it provides efficacy at half the dose of the racemic mixture of methylphenidate. Focalin-XR is unique, that it uses SODAS technology, with 50% of the dose being delivered immediately upon ingestion, and 50% of the dose delivered approximately four hours later. As such, it is effective within one hour of ingestion and maintains its efficacy for up to twelve hours. Focalin-XR and Concerta were examined in two multi-center, randomized, double blind crossover studies comparing the efficacy and safety of Focalin-XR 20 mg and 30 mg versus Concerta 36 mg and 54 mg and placebo in children with ADHD. For these two studies, the study designs and end points were identical. The patient population consisted of 82 children in study one, Silva et al, and 84 children in study two, Muniz et al. Study subjects were all between the ages of six and twelve. Primary efficacy was measured by the change from pre-dose SKAMP rating scale combined scores and two hours post dose during a 12-hour laboratory assessment. The efficacy end points were measured in a laboratory classroom setting. Focalin-XR 20 mg a day was significantly more effective than Concerta 36 mg per day, and the primary efficacy are a variable change from pre-dose to two hours post dose in SKAMPs combined score. The SKAMP combined score 0.5 to 5.0 hours post dose were statistically significant in favor of Focalin-XR 20 mg compared with Concerta 36 mg at all time points, with no statistically significant differences between Focalin-XR 20 mg and Concerta 36 mg noted at 7 and 9 hours post dose. Significant differences in favor of Concerta 36 mg compared to Focalin-XR 20 mg were noted at 10-12 hours post dose. A similar trend was detected for Focalin-XR 30 mg and Concerta 54 mg. In general, the authors state that Focalin-XR had an earlier onset of action than Concerta, while Concerta had a stronger effect at 12 hours post dose. Treatment with either agent associated with statistically significant improvements in ADHD symptoms compared to placebo at all igniter points. Focalin-XR is indicated for the treatment of ADHD in patient's ages six years and older. It is the only methylphenidate simulate given once daily with improved indication in adults, adolescents and children. Focalin-XR capsules can be opened and sprinkled over applesauce for those unable to take pills or capsules. Thank you for considering retaining Focalin-XR on the Idaho Medicaid Preferred Drug List.

Adam Sosa

I made some deletions to my initial testimony, so I'll try to be brief. My name's Adam Sosa and I'm a Scientific Affairs Liaison with Ortho McNeil Jannsen, and I do need to comment on the Silva study comparing Focalin-XR versus Concerta. Probably two points of interest I think that were peculiar with the study was to keep the study blinded, Concerta is not, you cannot break it apart, so it did have to be encapsulated, so we don't know what kind of effect it would actually have on the dissipance rate of Concerta, since 22% of the drug is initially released upon ingestion, so that encapsulation may have impacted its initial ability to get into the body. The other point I would point out is that in the Silva study, the authors do note that while we're looking for a true 12-hour drug for treatment of ADHD, there did seem to be that taper-off effect with Focalin-XR in comparison to Concerta at hour points 10 and 12, so again just looking for that true 12-hour drug. Just some points of interest, with regard to the study. It was a smaller study, but I wanted the members to be aware of that. Concerta is a drug indicated for the treatment of ADHD in children, adolescents, and more recently got an indication for adults, so it is a new indication within the last month. Concerta does use an OROS delivery technology system and to not clump all these long-acting stimulants together, there are differences in their technologies. The OROS system has more of an ascending profile, a nice smooth profile over a 12-hour period in releasing the drug, which is an important distinction because this minimizes peak and trough fluctuations that you might see through other bi-modal systems that will have, for example like the initial dose, peak and then four hours later another burst in dose. This is a true ascending profile. The long-term efficacy of Concerta in children and adults has been demonstrated and maintained for up to two years and one year for each of those respective groups, and in a 12-month retrospective study, Concerta was associated with a longer length of therapy and lower switch rate when compared to the studied short- and intermediate-acting methylphenidates, such as Metadate-CD treatments. We do know from research that adolescents and adults with ADHD will engage in aggressive and sometimes risky driving behaviors. In three different studies by Cox, Concerta has significantly improved driving scores and improved driving performance in both simulated and on-road settings. While Concerta cannot be broken apart, crunched or sprinkled, this is important, because this compromise-resistant formulation of Concerta is what helps to potentially decrease the risk for abuse. In fact, the American Academy of Child & Adolescent Psychiatry, in their practice parameters, identify Concerta as being less prone to abuse and diversion than immediate-release methylphenidate tablets. In summary, Concerta has proven to be effective for up to twelve hours in the treatment of ADHD in children, adolescents and adults, the OROS system minimizes dose peaks and trough fluctuations that you can see with other methylphenidate products, and finally the hospitalization visit rate, and the greater adherence and persistence rates, are greater compared to immediate-release methylphenidate. Thanks for your time, and I would respectfully ask that there be no restrictions placed on Concerta for the preferred drug list. Thank you.

Committee: Okay, we have three more speakers and we have five minutes. We could probably go a little bit over.

Jon Beaty

Good morning, my name is Jon Beaty. I'm with the Medical Affairs Department for Boehinger Ingelheim, and I'd like to speak to you about stroke this morning, which is the third leading cause of death in the United States, a leading cause of disability. Aggrenox, or extended-release dipyridamole plus aspirin, one capsule b.i.d. is indicated for the reduction of risk of current stroke in patients who have had a previous ischemic stroke or TIA. It's a novel formulation. The capsule contains 25 mg of aspirin and 200 mg of dipyridamole pellets. Each dipyridamole pellet has an extended-release coating and a core of tartaric acid for increased absorption. In individuals with low gastric acid, this is important because the extended-released coating and core of tartaric acid increases the bioavailability. Aggrenox is not interchangeable with the individual components of aspirin and Persantine tablets as noted earlier. It inhibits thrombosis through the combined actions of both the aspirin and the dipyridamole, it's been shown to be twice as effective for secondary stroke reduction as low-dose aspirin alone. In the ESPS 2 trial, Aggrenox showed a statistically significant 22% relative risk reduction for stroke P-value of .008 compared to low dose aspirin. There is an increased risk of headache associated with dipyridamole compared to placebo. The studies with extended-release dipyridamole show that headache is generally mild and transient, and is the most common side effect of Aggrenox in ESPS-2. Because it contains aspirin, Aggrenox should be avoided in the third trimester of pregnancy. Patients who consume more than three alcoholic drinks every day should be counseled about the bleeding risks involved with chronic heavy alcohol use while taking aspirin. In the ESPS-2, Aggrenox had similar bleeding rates to low dose aspirin. The incidence of intracranial hemorrhage was 0.6%; that's nine patients, compared with 0.4% in the placebo group. As noted earlier by Dr. Lyles, the extended-release dipyridamole and aspirin is recommended as a first-line therapy option for prevention of non-cardioembolic cerebral ischemic events in the ASA 2008 stroke guidelines update. I'm happy to take any questions. Thanks.

Leigh Plattes

Good morning, I'm Leigh Plattes, I'm a Scientific Liaison from Astellas, and I'm here today to talk about Protopic (tacrolimus) for atopic dermatitis. Tacrolimus is indicated for second-line therapy for short-term or non contiguous long-term treatment of moderate to severe atopic dermatitis now in immunocompromised patients who have failed the first line of therapy. It is not indicated for children under the age of two, the dose for children is 0.03% and the dose for adults is 0.1%. It's estimated that about 10% of the population suffers from atopic dermatitis. There is extensive clinical experience in the United States with over 2.1 million patients who have used this compound, and worldwide about 5.4 million. Extensively studied in about 20,000 patients, of which 8,000 or more were children, in 8,700 long-term treatments. In the early studies versus vehicle, the active drug was five times as efficacious in reducing itch and achieving a 90% clear or almost clear in patients, usually within the first week. In studies up to three years, there was no loss of effectiveness. In three studies against pimecrolimus, tacrolimus was found to be more effective, had a faster onset of action, had more itch relief, and a similar safety profile. In three long-term quality of life studies, it was proven to show increased improvement of quality of life, even in children. There are no reports of malignancies in twenty-three comparative clinical trials, however there is a black box warning on this compound. In twelve years of clinical development and post marketing in 5.4 million patients, there were 46 cases of lymphoma and non melanoma skin cancers, however this is less than the US population according to the SEER database and the Physicians Health Study. So in summary, tacrolimus is an important addition in the treatment option for patients with atopic dermatitis, it's safe and effective if used according to the label, and there are ongoing safety studies to assess the safety and malignancy. Are there any questions? Thank you very much.

Ann Corbin

Good morning. I'm Ann Corbin, I'm a National Medical Scientist with Boehinger Ingelheim Pharmaceuticals. I'm here to speak with you today about pramipexole or Mirapex, for the treatment of Parkinson's disease. Mirapex was approved since 1997 and it's now recently been approved for restless leg syndrome. Parkinson's disease is a progressive, neurodegenerative disease with debilitating and devastating motor complications and non motor complications. In clinical trials, Mirapex is a non-ergot dopamine agonist which is rapidly absorbed. Urinary excretion is a major route of metabolism. It has flexible dosing with ease of titration. Rapid titration may be achieved to an effective dose which is up to 4.5 mg per day within three weeks in patients with normal renal function. Mirapex as monotherapy in early Parkinson's disease helped to improve motor function and activities of daily living, helped to delay the onset of motor complication, and helped to delay the need for levadopa. In the CALM-PD trial, which was a four-year, randomized, controlled trial comparing Mirapex with levadopa as the initial dopaminergic treatment for Parkinson's, it showed that dyskinesias were reduced with Mirapex therapy? Mirapex as adjunctive therapy in Parkinson's disease helped to increase the quality of "on time" and the duration of "on time", helped to reduce the duration and the severity of "off time", and helped to improve tremor. It also helped to improve with the levadopa dose in advanced Parkinson's patients. The most commonly reported adverse events in early and late disease were dizziness, dyskinesia, extrapyramidal syndrome, hallucinations, headache, insomnia, and nausea. Patients have reported falling asleep during activities of daily living, including operation of a motor vehicle, which sometimes resulted in accidents. Patients and caregivers should also be informed that impulse control disorders and compulsive behaviors may occur while taking medicines, including pramipexole, to treat Parkinson's disease. Mirapex is well tolerated in early and late Parkinson's disease, Mirapex is renally cleared (the half life is 8-12 hours), the bioavailability is over 90%. There are no predicted P450 interactions with Mirapex. It is the only non-ergot dopamine agonist which is not metabolized through the P450 system. In summary, we are asking that you place Mirapex on the Preferred Drug List for Parkinson's disease because Mirapex has been shown to be efficacious and help treat the symptoms of early and advanced Parkinson's disease, help improve the activities of daily living, help dely the onset of motor complications, and also to reserve the use of levadopa until patients need it most. All dopamine agonist treatment options should remain available for people suffering from Parkinson's disease. Any questions? Thank you kindly.