Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: August 21, 2009 **Time:** 9:00 a.m. – 4:30 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Conference Room D

Moderator: Phil Petersen, M.D.

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

Others Present: Bryan Amick, PharmD; Bob Faller; Rachel Strutton

Committee Members Absent: Mark Johnston, RPh

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Phil Petersen, M.D.	Dr. Petersen called the meeting to order.
Committee Business		
➢ *Roll Call*	Phil Petersen, M.D.	Dr. Petersen completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➢ *Mission Statement*	Phil Petersen, M.D.	Dr. Petersen referred to the Department of Health and Welfare and the Pharmacy Unit's Mission Statements, and described how the P&T Committee objectives coincided with those of the Department.
➢ *Reading of Confidentiality Statement*	Phil Petersen, M.D.	Dr. Petersen read the Confidentiality Statement.
➢ *Approval of Minutes from July 17, 2009 Meeting*	Phil Petersen, M.D.	There were no corrections. The July 17, 2009 meeting minutes were accepted as proposed.

➢ *Key Questions*	Tami Eide. PharmD	Dr. Eide provided an update on the DERP project: Previous DERP reports were scanned to determine need for updates. The project will delay the update of the long-acting opioids. Nasal corticosteroids and the Multiple Sclerosis reviews will not be updated at this time. Dr. Eide presented the following Key Questions: Direct Renin Inhibitors, Angiotension Converting Enzyme Inhibitors and Angiotensin II Receptor Blockers. Newer Antihistamines Atypical Antipsychotics
Public Comment Period	Phil Petersen, M.D. Bob Faller, Medical Program Specialist	Thirty nine (39) people signed up to speak during the public comment period. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
Lynn-Marie Peashka, N.P		All	Antipsychotics
Toni Sparks, N.P.	All Together Now	All	Antipsychotics
Grant Belnap, M.D.	Self	Lexapro	2nd Generation Antidepressants
Allen Olmstead, M.D.	Self		Cytokine/CAM Antagonists (Targeted Immune Modulators)
Shannon Gardiner, P.A.		Celebrex	NSAIDS
Deo Peppersack, N.P.		All	Antipsychotics
Allen Frisk, RPh	Heartland Pharmacy	All	Alzheimer's Drugs
Scott Eliason, M.D.	DHW-Division of Behavioral Health	All	Antipsychotics
Camille LaCroix, M.D.	ID Psychiatric Association	All	Antipsychotics
Jeralyn Jones, M.D.	UW Psychiatric Residency	All	Antipsychotics
Charles Novack, M.D.	Self	All	Antipsychotics

Continued:

Speaker	Representing	Agent	Class
Roseanne Hardin	Self/NAMI	All	Antipsychotics
Paula Campbell	Self/family	All	Antipsychotics
Madeline Wyatt	Self	All	Antipsychotics
Kathy Garrett		All	Antipsychotics
Martha Ekhoff	Self	All	Antipsychotics
William Thompson	Self	All	Antipsychotics
Larry Thompson	Family	All	Antipsychotics
Karla Thompson	Family	All	Antipsychotics
Courtney Santillan	ID Federation for Families with Children with MH	All	Antipsychotics
Kent Sullivan	Family		Antipsychotics
Mary Ward	Family	All	Antipsychotics
Linda Duffy	Self	All	Antipsychotics
Emily Ryan	Self	All	Antipsychotics
Katie Priddy	Self	All	Antipsychotics
Robyn Ringkamp	Self	All	Antipsychotics
Stephen Cheng	Ely Lilly	Zyprexa	Antipsychotics/Stimulants
Jenn Kammerer	AstraZeneca	All	Atypical Antipsychotics
Laura Litzenberger	Ortho McNeal / Johnson & Johnson	Seroquel/Seroquel XR	Atypical Antipsychotics
Lois Maston	Forest Pharmaceuticals	escitalopram	Second generation Antidepressants
Pamala Sardo	Abbott Labs	Humira	Cytokine/CAM Antagonists (Targeted Immune Modulators)
Olivia Whealon	UCB Pharma		Cytokine/CAM Antagonists (Targeted Immune Modulators)
Rick Realson	Merck	Januvia	Hypoglycemics
John Shepski	Shire	Vyvance	Stimulants

Dr. Peterson reviewed the new criteria for public testimony of pharmaceutical liaisons and specified what fit the criteria for new information. Any items not meeting these criteria will be returned.

DUR Review		Dr. Petersen requested a statement be added to the meeting record clarifying the fact that the P&T Committee has never recommended and the Department has never taken a Medicaid participant off of a mental health drug that they are currently using.
➢ Atypical Antipsychotics In Idaho Medicaid children and adults	Kathy Eroschenko, PharmD	<u>Atypical Antipsychotics</u> Dr. Eroschenko provided a descriptive overview characterizing the use and prescribing patterns of atypical atipsychotics in the Idaho Medicaid program including dosing and use of multiple agents.
Drug Class Reviews and Committee Recommendations ➢ Second Generation Antidepressants	Gerald Gartlehner, MD, MPH, DERP Investigator	<u>Second Generation Antidepressants</u> Dr. Gartlehner presented the 4th DERP Drug Class Review on Second Generation Antidepressants. This report was completed in August 2008. The review was expanded to include the indications of seasonal affective disorder and subsyndronal (minor) depression. For major Depressive Disorder in adults, the new evidence did not change the previous report conclusions that no substantial differences in efficacy exist. The overall grade of comparative evidence of most other indications was fair to poor. Dr Gartlehner reported on an analysis of FDA data that confirmed a higher risk of seizures for bupropion. The newer medication desvenlafaxine (Pristiq) was approved based on four placebo-controlled trials and no head-to-head trials exist. **Committee Recommendation** The Committee concluded there was not evidence to support differences in efficacy, effectiveness or safety among the agents. They did not feel it was necessary to single out paroxetine for safety issues. <u>Antidepressants, SSRIs:</u> The Committee recommended paroxetine be added as a preferred agent, if cost effective. <u>Antidepressants ,Other:</u> The Committee recommended no specific changes to the preferred drug list for this drug class.
➢ Stimulants & Related Agents	Bryan Amick, PharmD. First Health	<u>Stimulants & Related Agents</u> Dr. Amick presented an update for this drug class. There have been (2) new products marketed since the last review, Procentra (dextroamphetamine oral solution) and Nuvigil (armodafinil). There is a new indication for Vyvance for ADHD in adults. Dr. Amick reviewed three (3) clinical

		trials for Nuvigil and one (1) for lisdexamfetamine as well as the NICE 2008 ADHD guidelines. **Committee Recommendation** The Committee did not find evidence to support changes to the preferred drug list at this time. They felt there should be representatives from both the amphetamine and methyphenidate-like classes. Because of high utilization, they felt Concerta should remain preferred. The Committee felt that because of place in therapy and black box warnings that Strattera should remain non-preferred. They would like to see data on number of Idaho Medicaid recipients receiving Strattera in combination with a stimulant. They recommended that the criteria for Provigil be extended to Nuvigil and once that criteria was met, the least costly agent would be preferred over the other.
➢ Hypoglycemics, Insulins	Bryan Amick, PharmD. First Health	<u>Hypoglycemics, Insulins</u> Dr. Amick provided information on new indications for insulin glulisine (Apidra) for children over the age of four (4) years of age. He also provided information on new dosage forms for insulin glulisine (Apidra), insulin detemir (Levemir) and FlexPen redesign. Dr. Amick also reviewed one (1) new clinical trial comparing Lantus to Humalog in Type 2 Diabetics and one (1) Meta-Analysis comparing premixed analogues with long acting insulin analogues. **Committee Recommendation** The Committee recommended all agents be preferred for this class, as long as they are cost effective. The Committee felt it imperative that both long and short acting agents be available as preferred agents.
➢ Pancreatic Enzymes	Bryan Amick, PharmD. First Health	<u>Pancreatic Enzymes</u> Dr. Amick shared that Creon is the first pancreatic enzyme combination approved by the FDA per their new guidelines. All other agents will require approval of ANDAs by April 2010. **Committee Recommendation** The Committee concluded there were no efficacy or safety differences among the agents. They recommended Viokase (oral) be removed from the preferred drug list and be restricted to use in continuous enteral nutrition.
➢ Bone Resorption & Suppression Agents	Bryan Amick, PharmD. First Health	<u>Bone Resorption & Suppression Agents</u> Dr. Amick reviewed two (2) new products, calcitonin-salmon (generic Miaclalcin) and Actonel 75mg and 150 mg tablets. He reviewed the National Osteoporosis Foundation (NOF) 2008 Guidelines, one (1) clinical trial comparing ibandronate to alendronate and an adherence study of daily vs. weekly vs. monthly bisphosphonate.

		Committee Recommendation The Committee felt there were no evidence-based differences that supported making any changes to the PDL for this drug class.
➢ Alzheimer's Drugs	Bryan Amick, PharmD. First Health	<u>Alzheimer's Drugs</u> Dr. Amick reviewed the ACCP/AAFP guidelines for treatment of dementia. There was no other new clinical data available to review with the Committee. **Committee Recommendation** The Committee felt there were no evidence based differences to make any changes to this drug class. They felt both Aricept and Namenda should be preferred and Cognex should be non-preferred.
➢ Androgenic Agents	Bryan Amick, PharmD. First Health	<u>Androgenic Agents</u> Dr. Amick reviewed the boxed warning for testosterone gel products, as well as the American Association of Clinical Endocrinologists (AACE) Guidelines. The boxed warning resulted from reports of eight (8) adverse events occurring in children after unintended exposure through contact with an individual being treated. **Committee Recommendation** The Committee felt there were no evidence-based differences to support any changes to this drug class.
➢ Newer Antiemetics	Kim Petersen, MS, Research Assoc., OHSU EPC	<u>Newer Anitemetics</u> Ms. Petersen presented the January 2009 update of the Newer Antiemetics. The evidence showed no consistent, statistically significant differences between dolasetron, granisetron, or ondansetron. Aprepitant was noninferior to superior for complete response to ondansetron. Paronsetron compared with ondansetron in highly emetogenic chemotherapy was non inferior in adults; possibly superior in children. There were no consistent, significant differences in direct comparisons for adverse affects overall between the agents. **Committee Recommendation** The Committee concluded there was no new evidence-based rationale for preferring any 5HT over another. They recommended that brand Zofran ODT be available because of reports of problems of dissolution in the generic. All agents will retain the need for clinical criteria approval and the criteria will be updated for Emend.

➢ Newer Drugs for Treatment of Diabetes	Nancy Lee, PharmD, Fellow OHSU EPC	<u>Newer Drugs for Treatment of Diabetes</u> Dr. Lee presented the drug review for newer drugs for diabetes treatment. The population for the studies was adults and children with type 1 and type 2 diabetes mellitus. Health outcomes were all-cause mortality, micro- or macrovascular diseases and quality of life. Intermediate outcomes were glycemic control, change in weight and time to treatment failure. Harms-related outcomes included overall adverse events, major adverse events, and withdrawals due to adverse events. For all drugs in this report, there is no evidence available on children or on long-term outcomes beyond 52 weeks. There was a slight improvement in A1c for patients with DM1 when pramlintide was used with fixed-dose insulin. For patients with DM2 there was a light improvement when the agent was used with flexible or fixed dose insulin. When used in monotherapy or combination therapy, sitagliptin resulted in moderate improvement in both fasting and post prandial BG compared to placebo. **Committee Recommendation** The Committee felt there were no evidence based differences to make any changes to this drug class. Janumet and Januvia should remain second-line drugs and Byetta and Symlin should continue to require prior authorization for therapeutic use.
➢ Atypical Antipsychotics	Marian McDonagh, PharmD, DERP Principal Investigator OHSU EPC	<u>Atypical Antipsychotics</u> Dr. McDonagh reported on the second update of the Drug Class Review of Atypical Antipsychotics. Because of the extent of the review she focused on the main findings and the best evidence. In effectiveness trials relapse occurred less often with olanzapine than quetiapine. Risk of hospitalization was lower with olanzapine that quetiapine, riperidone or ziprasidone. Quality of life did not differ among olanzapine, quetiapine, risperidone or ziprasidone. The rate of discontinuation of drug was lower with olanzapine and Clozapine that aripiprazole, quetiapine, risperidone or ziprasidone. Paliperidone did not have enough evidence for conclusions. Olanzapine and Clozapine were associated with more negative changes in serum lipids. For bipolar disorder there were limited numbers of head-to-head trials. Improvement in efficacy in acute, manic or mixed symptoms was found with olanzapine, quetiapine and risperidone compared to placebo. Aripiprazole and olanzapine showed better efficacy that placebo in bipolar maintenance. For weight gain : olanzapine > Clozapine >quetiapine >ziprasidone. Data on weight gain for aripiprazole and paliperidone were too limited for conclusions. **Committee Recommendation** Because of patient to patient variability the Committee did not have a consensus recommendation on preferred vs non-preferred agents and recommended that all agents be preferred for new patients. They recommended that all new starts be limited to FDA and evidence-based appropriate

		off-label indications and that current patients be grandfathered. The Committee would like to see any available outcome data from other state Medicaid programs that have made some agents non-preferred. The Department will, with the consultation of Dr. Girling, develop an appropriate indication/diagnosis list for each agent.
➢ Antipsychotics, Typical	Bryan Amick, PharmD. First Health	<u>Antipsychotics, Typical (Conventional)</u> This was the first review for this drug class. There was no clinical comparative evidence to share with the Committee. **Committee Recommendation** The Committee felt there was no reason to make any of these agents non-preferred except thioridazine. The Committee felt it should be second-line due to safety issues.
➢ Cytokine/CAM Antagonists (Targeted Immune Modulators)	Bryan Amick, PharmD. First Health	<u>Cytokine/CAM Antagonists (Targeted Immune Modulators)</u> Dr. Amick shared one (1) new product, Cimzia (certolizumab) as well as it's indications and warnings. He also shared the withdrawal of Raptiva (efalizumab) from the market, the treatment guidelines for RA (American Collge of Rheumatology) and Psoriasis/Psoriatic arthritis (American Academy of Dermatology). Dr. Amick also reviewed six (6) new clinical trials, three (3) systematic reviews and two (2) Meta-Analysis for Crohn's and Psoriasis. **Committee Recommendation** The Committee felt there were no evidence based differences to make any changes to this drug class at this time, other than to remove Raptiva.
➢ Platelet Aggregation Inhibitors	Bryan Amick, PharmD. First Health	<u>Platelet Aggregation Inhibitors</u> Dr. Amick reviewed resistance issues with clopidogrel, a FDA safety review for increased cardiovascular events with clopidogrel and PPIs, the ACCP 2008 Guidelines for ischemic stroke, STEMI, ACS and stents, plus one (1) clinical trial for secondary stroke prevention. **Committee Recommendation** The Committee felt that the evidence re-enforced the current PDL with the less safe ticlopidine remaining as non-preferred.

➢ Antiparkinson's Agents	Bryan Amick, PharmD. First Health	Antiparkinson's Agents Dr. Amick reviewed the new warnings for Stalevo for increased uncontrolled urges and one (1) new clinical trial comparing Azilect, Comtan and placebo. **Committee Recommendation** The Committee felt there were no evidence based differences supporting any changes to this drug class.
➢ Analgesics/Anesthetics, Topical	Bryan Amick, PharmD First Health	Analgesics/Anesthetics, Topical There was no new clinical data to share with the Committee. **Committee Recommendation** The Committee felt there were no evidence based differences to make any changes to this drug class at this time.
➢ NSAIDS	Bryan Amick, PharmD. First Health	NSAIDS Dr. Amick reviewed the guidelines for ACC/ACG/AHA for prophylaxis of NSAID and ASA-associated gastric injury. There was no other new clinical data to share with the Committee. **Committee Recommendation** The Committee did not feel the evidence supported any superiority of Celebrex. The Committee felt there were no evidence based differences to support making any changes to this drug class at this time. They asked that the Department ensure appropriate quantity limits for ketorolac.
➢ Ophthalmics, Antibiotics	Bryan Amick, PharmD. First Health	Ophthalmics, Antibiotics This drug class review has been expanded from Ophthalmic Fluoroquinolones to include all ophthalmic antibiotics. Dr. Amick reviewed one (1) new product Besivance (besifloxacin) and one (1) clinical trial comparing polymyxin B/trimethoprim to moxifloxacin. **Committee Recommendation** The Committee recommended having at least one agent from each class and at least one non-stinging agent.

➢ Ophthalmics, Glaucoma Agents	Bryan Amick, PharmD. First Health	<u>Ophthalmics, Glaucoma Agents</u> Dr. Amick reviewed one (1) new clinical trial between two (2) strengths of brimonidine. There was no other new clinical data to share with the Committee. **Committee Recommendation** The Committee felt there were no evidence- based differences to support any changes to this drug class at this time. As a specialty drug class they felt appropriate use was being maintained.
➢ Ophthalmics, Anti-Inflammatories	Bryan Amick, Pharm.D First Health	<u>Ophthalmics, Anti-Inflammatories</u> This drug class has been expanded from Ophthalmic NSAIDs to include all anti-inflammatories (ie: steroids). Dr. Amick presented information on two (2) new products Durezol (difluprednate 0.05% solution) and Triesence (triamcinolone acetonide intravitreal), as well as the indications for both. It was noted that Triesence has a pregnancy category D rating, whereas the others are rated a category C. **Committee Recommendation** The Committee felt that there was no evidence supporting designating any of the agents preferred or non-preferred . They asked that ophthalmic steroid use be evaluated for possible educational or face-to-face interventions.

Pharmacy and Therapeutics Committee
Public Comment
August 21, 2009

Committee
We have 39 speakers, so I would say that if you could keep it at 1.5 minutes, we'll be good. I should mention that if any of you have a hard copy of your presentations you want to turn in, you can do that when you come up to the podium. We'll start with the practitioners, and the first person on the list is Lynn-Marie Peashka. Thank you.

Lynn-Marie Peashka, N.P.
I talk pretty fast, but I don't know about a minute and a half, I'll give it my best. My name is Lynn-Marie Peashka. I've been in the field of psychiatry for about ten years. I started in Washington State. I've been practicing as a psychiatric nurse practitioner in Idaho for about three years, and I want to point out that my specialty is psychiatry; I'm not a family nurse practitioner who practices psychiatry. Given I just learned about this meeting, I didn't bring any facts and figures. I would say, however, that it doesn't surprise me that I recently learned that NPs are prescribing a lot of psychotropics in the state of Idaho for Medicaid patients. It may be because NPs see more Medicaid patients than psychiatrists; at least empirically that's been my experience. I want to; there are just four major points I want to make. I'm guessing, first of all, that most people in this room do not actually practice psychiatry, so here's what I want to say. First of all, who's most likely to need an antipsychotic? It's going to be someone with a more serious manifestation of mental illness, and of course this is more likely to be a Medicaid recipient because of his or her mental illness. Who is most likely to need a low-dose antipsychotic or low-dose antidepressant? First, it's going to be someone who has a co-occurring mental health and medical condition, a situation we very, very often see in the Medicaid population, and second, someone who has a disabling panic or anxiety disorder, for example secondary to post traumatic stress disorder. With these people, the old adage of "start low and go slow" holds true and proves to be of most value to them for a number of reasons we don't have time to go into right now. The third point that I would like to make is that the population we serve is not a one-size-fits-all group. In order to effectively administer to their mental health needs, we must have access to a wide variety of medications, atypical antipsychotics included.

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

Lynn-Marie Peashka, N.P.
Oh no, the last point was the best one.

Committee
You can entertain questions if you'd like to.

Lynn-Marie Peashka, N.P.
No, I'd rather have the people be able to speak.

Committee
Toni Sparks?

Toni Sparks, N.P.
Hi, I just want to quickly let you all know that the atypical antipsychotics are a passion of mine, because they are the core to the stability to these clients. As far as the diagnosis kinds of things, when billing goes in, not always do all of their diagnoses get included by billers, so I think that for the majority of these people, they are treated because they do have the diagnosis that qualifies for the atypicals. If you restrict this formulary, you will destabilize that stability. These medicines really hold true for their mood stabilizer, for psychotic symptoms, for behavioral impulsive symptoms for our autistic kids and other autistic spectrums, and all of these disorders are a spectrum, and she's right, it's not a one-size-fits-all kind of modality. I will end by just saying that I welcome anyone in this room to hang with me for a day and look at the complications and how we go in and, and we look at the external factors of these folks, and try to help them with the best medicines possible, with the least side effects so that they can tolerate them and they'll stay on their medicines.

Committee
Your practice is?

Toni Sparks, N.P.
I've done both public mental health with Region IV and the Department and I do a case management with a psychosocial rehab agency with Altogether Now.

Grant Belnap, M.D.
Thank you, I'll try and be brief. My name is Grant Belnap, I am a board-certified psychiatrist. The current formulary status for Lexapro as citalopram requires two failures with generic SRIs before prior authorization be given. While I've argued in the past that I wish for less restriction for this, I do deal with reality and I have come to accept that when it comes to adults, however in the adolescent population, I would argue for unrestricted status. As you know, Lexapro has recently been FDA approved for the treatment of major depressive disorder in adolescents in age 12-17. The results of the clinical trials that led to this FDA approval were published in the Orange Journal in July of 2009. I had the fortunate opportunity to be one of the principal investigators on that study, and I believe that my first-hand involvement and my clinical experience qualifies me to make the request, that is the availability of Lexapro on this population as a first-line agent. The only other antidepressant approved for this population is Prozac. One could argue that the logical step would be a failure of Prozac before allowing Lexapro to be used. I think this would be considered outside the norm of care. As you all know, there is a black box warning on antidepressants of the class for suicidality and the emergence of suicidal ideation and behavior in adolescents, children and young adults. The clinical trials with Lexapro showed that the emergent suicidal behavior was equal in the active drug as was found in placebo, thus it seems that it does not increase the risk of suicidal behavior in this population. Prozac does not have that data. In addition, as you are aware, about 12% of anybody who is diagnosed with major depression will eventually be given a diagnosis of bipolar disorder. That is higher in the adolescent population. If you must withdraw medication quickly, you're in trouble if you use Prozac. The half life of Prozac is 2-3 days. The half life of its major metabolite and more active metabolite, norfluoxetine, is 79 days, so effectively you have Prozac in you for six weeks if you discontinue it.

Committee
Time's up sir. Thank you.

Allen Olmstead, M.D.
Thank you for allowing me to participate. I'm Allen Olmstead, I'm a dermatologist in Twin Falls and not a psychiatrist. I want to talk to you today about psoriasis. Psoriasis is a disease that somewhere around 2-3% of the population has and, until very recently, it's been an absolute nightmare to treat. Along about five years ago, there was a new class of drugs that started coming online, drugs called "the biologics" and we actually continue to have new drugs being developed with that line. I've practiced dermatology for 25 years. I've known how it has been to treat psoriasis without these new drugs, with these new drugs, specifically the CAM alpha antagonists, it has just revolutionized the treatment of psoriasis. I would like to share one anecdote with the crew; I recently saw a patient who's been on a drug called Humira, and he'd been on the drug for about 3-4 months and came in just for follow up. When I saw him, he was doing wonderful, basically he was clear. I mean, this is a disease that can cover your body. It's not just a skin disease, it really is a systemic disease. I saw him and he was doing great. I said, "I'll let my nurse come in and talk to you a little bit about how the financial end of things is going from your standpoint" because these are very expensive drugs, and she came out and said "He has one more question for you, why don't you go in and just see what it is.", so I went in and he said "Doc, you've changed my life" and I thought that was always pretty good, getting patted on the back, and then he said "My sex life is great". So I would like to encourage the Committee to maintain our ability to prescribe these wonderful medicines that we just can't live without. It's like once you have them, to take them away would just be a total disaster. Thank you very much.

Shannon Gardiner, P.A.
Thank you. My name is Shannon Gardiner and I'm a physician assistant for an orthopedic spine practice, and I'm here to actually address anti-inflammatories, specifically Celebrex and the prior authorization process required. Postoperatively, we like to use Celebrex to control both inflammation and pain. This tends to be a very effective medication for our patients. We use it to decrease narcotic intake and also getting off their medications more quickly. This has also been proven in the research studies, as well as I've seen it hands on in my own practice. We're able to get a two-week supply of Celebrex through most insurance companies without a preauthorization process. Also, we [illeglibe] especially practice where patients have generally tried several classes of anti-inflammatories or have other complicating medical factors that would preclude them from using typical NSAIDs. As you can see, in our practice, Celebrex is something that we widely use and encompasses a large portion of our population. Having to fill out prior authorization forms is time consuming, can sometimes take 7-10 days, depending on the influx that we receive. This further delays patient care and particularly in a case of postoperative patients, the therapeutic effect is long gone after 7-10 days. I'm asking you to remove this preauthorization process and make it a step-edit process at the pharmacy, to where if a specialty provider prescribes this medication, the patient can obtain the medication without having to go through the prior authorization process.

Deo Peppersack, N.P.
I don't think I need a microphone, and I think you've all probably heard my name, as I've sent several emails and letters to you all, so I'm not going to belabor a point, other than I have patients with me today who are going to testify later on the usefulness and effectiveness of our atypical antipsychotics. I think in a trend in psychiatry where we're trying to reach remission and rehabilitation, I'm appalled at the concept of limiting the access to these medications. We have new ones on the horizon, Seroquel-XR, we have a new one that was just approved with the FDA, we are in a time where we can improve the quality of life in patients, and I don't want to see my patients in the hospital. The rate of hospitalizations, completed suicides and jail time have already increased with the cuts you've already made, and I think it's going to continue to increase. Thank you.

Committee Chair
Could you please state the name of your practice?

Deo Peppersack, N.P.
I actually am a psychiatric nurse practitioner and a family nurse practitioner, and I own my own practice in Nampa. Thank you.

Allen Frisk, RPh
Hi, my name is Allen Frisk, I'm a clinical pharmacist who has been providing MTM (medication treatment management) to about 1,000 patients for Heartland Floto Pharmacy at the assisted living level. I have patients at 76 facilities out of the 120 that are in Boise valley. About 60% have a diagnosis of dementia. About 70% of those have a diagnosis of Alzheimer's, and I'd just like to make a comment about Alzheimer's today. I've seen all levels of all medications used, including the three

drugs for anti-acetylcholinesterase, donepezil (Aricept), galantamine which is now available generically, and rivastigmine (Exelon). Our major goal is to keep them at the assisted living facility level rather than at the skilled nursing care. The average cost per month at an assisted living facility is $3,600 and skilled nursing care now goes for about $7,000, so you can realize about $35,000 a year if you can keep them out of the skilled nursing care level. Donepezil (Aricept) has 90% of the market share right now for good reason. It's been proven effective at all levels of Alzheimer's, mild, moderate and severe, it's been given in combination with Namenda until the end with excellent results in regards to behavioral control and less need for antipsychotics and behavioral medications, and also an attempt to titrate patients up to the full 24 mg dose of galantamine-ER, you usually get nausea and vomiting, and rather than leave them at the level of 16 mg, or whatever, they will just discontinue the drug, so I think it's a major impact on those people trying to control them on an anti-acetylcholinesterase.

Committee
Thank you sir, your time's up.

Scott Eliason, M.D.
Hi, I'm a psychiatrist, I run the Region IV Clinic and I'm the State Medical Director at the Department of Health & Welfare Behavioral Health. I just wanted to talk about a couple of things real quick. First, these patients are just extremely difficult to stabilize, so any change or any restriction can really limit the ability to be able to stabilize them. Just as a quick example, Trilafon is a drug that I never really liked, and I got here and I had a couple of people on Trilafon, and because of funding problems, we had to switch them to other medications, and a lot of them destabilized and have been really difficult. When I say destabilized, they ended up in the hospital, maybe after a suicide attempt or often times getting violent, and to restrict those medications, you're running the risk of a lot of bad things happening. Then another point real quick is to limit away from Depo injections would just be a horrible idea, because of a lot of the people with these illnesses don't take medications the way they're supposed to, right? And to limit those would really cause a lot of destabilization.

Camille LaCroix, M.D.
My name's Camille LaCroix, I'm a board-certified adult and forensic psychiatrist, and I'm the president of Idaho Psychiatric Association and assistant training director for our new psychiatry residency track here in Idaho, and I'm clinically practicing at the VA, but I represent as the president of the Psychiatric Association, the whole state and all its providers. The American Psychiatric Association and, by relationship, the Idaho Psychiatric Association, doesn't advocate preferred drug lists, especially for antipsychotics. They are, in terms of how we use them and what we use them for, the patients with severe mental illness, schizophrenia, severe bipolar disorder, when you aren't given access to all of those medications and the patients are destabilized, the cost of hospitalizing them is far, far greater than the cost of having access to what limited medications we have already. You know, an unstable bipolar patient or schizophrenic patient doesn't take a week or two to stabilize in the hospital. It can take on the order of weeks to months. I've had two patients recently that we had to switch medications on that ended up at the State Hospital for three and four months each. That cost far outweighs the cost of having access to atypical antipsychotics. One in ten schizophrenics will commit suicide. Having an unstable patient that we don't have access to the medications that we need to keep them stable, really puts them at risk, makes our jobs more difficult, and just shuffles them in the system to different areas instead of outpatient, involved in the community and involved with their families. So some of the drive with these changes come from some recent papers regarding the efficacy of atypicals versus typicals. You know, you can't for clinical practice, base what you do on a study. The studies aren't perfect. They don't select for the entire population we see clinically. Usual drug company studies, or this was a nationally funded study, select certain types of patients specifically that aren't the typical kind of patient that you see in, especially, a public sector like Health & Welfare. So these folks do shuffle around the community. We end up seeing them in a variety of settings, and the cost would be much higher. The APA and IPA support more practice guidelines, more education of providers in terms of what the needs are for prescribing these kind of medications. It's not uncommon to have to prescribe one or two, sometimes even three, antipsychotics and mood stabilizers to get these folks better, so we'd much rather have education up front and a full array of medications to choose from. Yes?

Committee Member
We have a lot of comments here weekly about people who are on relatively complex antipsychotic regimens, people who have been on drugs probably for several years, but no comments about any relative efficacy or choice as far as an initial agent. So what really, what is being affected here is a lot of decisions, as far as an initial agent for an antipsychotic. So I'm having a little trouble understanding, because really once people have been on two or three of these things, there are very few places you can go and I even look on the list here and it looks like they're all preferred. Am I wrong?

Camille LaCroix, M.D.
You're correct.

Committee Member
Okay.

Camille LaCroix, M.D.
If you look at the American Psychiatric Association website, it has a section called Practice Guidelines for Clinicians, so it's a consensus and expert panel of practitioners who put out recommendations for what would be the standard of care for treatment of a certain diagnosis. If you look under the schizophrenia practice guidelines, all the recommendations for first-line agents are the atypicals, and they spell out, they have a graph spelling out which agents to start with and then other considerations in terms of medical conditions and side effects that the person may already be having from something as to which agent, but none of them are recommending first-line typicals. It's first-line atypicals, and typicals come in later when you have no other options.

Committee Member
Question. Just in terms of, are there situations where you actually, for a long period of time, manage patients on two different antipsychotics given concurrently?

Camille LaCroix, M.D.
Yes, most definitely. Most of my severe schizophrenics are not on a single agent. We've tried to manage them that way and what happens is that they get stabilized, they lose housing, they end up in the hospital, and it becomes a rotating spiral of decompensation and the two patients I just mentioned to you that have been in the State Hospital on one agent, the first one destabilized, we put him on two agents, an atypical and a typical, and that didn't quite work. We went to clozapine, that didn't work by itself, so it's very common to have most severe bipolar and schizophrenic patients on two atypical antipsychotics. Thank you.

Jeralyn Jones, M.D.
Hi, I'm Jeralyn Jones. I'm a psychiatrist and I've been in practice in Boise for seventeen years, and I'm the current Director of the Psychiatry Residency that was started in 2006 out of the need to bring psychiatrists into Idaho. I just wanted to share with you a story. I practice at the Family Medicine Residency of Idaho, where we see many psychiatric patients, and just this week a woman delivered who, a 26-year-old woman, who was pregnant and had given her first child up for adoption, had been hospitalized sixteen times, and we were able through using an atypical antipsychotic to keep her out of the hospital during her entire pregnancy. Back when I trained, I graduated from training in 1991, the standard practice for pregnant women was to hospitalize them for months, so from three months onward or whenever we could get them in, and the cost difference is tremendous for that, and it's about cost and quality of life, and so many other things, but the cost of an atypical antipsychotic prescribed for a year is less than the cost of one week of psychiatric hospitalization, so that's something to really think about, and other things have spoken to the bad things that can happen, and I don't envy your position now, having to think about the cost of everything, but I would argue for an unrestricted formulary and lots of education, especially to those practitioners who are over-utilizing.

Charles Novock, M.D.
I'm Charlie Novock, I'm a psychiatrist in Boise, been here about 24 years. I just want to highlight two things. You've heard why the atypicals and having a preferred list that doesn't allow access to all of them is the wrong idea. I think the other thing you have to take into account, it's the wrong time. Right now, there's been such a limit in all the other things that we can do to try to help people with severe and persistent mental illness. We have less access to doctors because of cutbacks, we have less access to clinic time, there's less access to case management, so you cut access to medicines, the key element and one of many elements that are key, you're just contributing to the problems, and I just want to highlight the fact that what you've heard already, psychotic illnesses are not illnesses that we get away with no treating. Not only do they have consequences to patients and their families and cause problems, but they also cost us as taxpayers money, because when somebody has a psychotic episode, they don't just go away. They end up in jail or they end up in the hospital, or they end up in prison and they end up in the legal system, and problems

happen because when people get psychotic they either get very irrational and have major behavioral problems or they can get suicidal. So I just wanted to highlight those two things. Any questions? Thank you.

Roseanne Hardin

Good morning everyone and thank you for letting me speak. I'm not a practitioner, I'm a member of NAMI obviously, I've got my T-shirt on today, but I'm here speaking as a family member, a friend, and a colleague of persons with mental illness, probably like the vast majority of the people in this room. Most of you know people, or work with people, or have family members with mental illness. My concern is that there is not open access to the medications that those persons who have been diagnosed need. We're going to have a failure, whether it is the failure that the prescribing physician or caregiver really anticipates is going to be there because they don't have an open choice of which medications would be most effective, or it's a failure because the medication didn't work. I think what failure is has been described pretty graphically, and if you're a family member, it's very graphic. There's the quiet, kind of silent failure, which means your family members withdraws, they're not productive, they don't have any motivation, they're not doing anything, they're just barely there, and then you have the issues with regards to suicide, or you have the noisy failure, the ones that end up in jail with the police coming, with the neighbors being outraged and rightly so, and you being frightened. All of those things happen. Those are just two of the varieties of failures, and sometimes you have a combination of both of them. A system that plans for failure isn't the best kind of system. As a taxpayer, I know I've paid for those failures, and you all do too, so if we have a better way, I think we can't afford to do it the best way. If we can exercise the best clinical judgment with regard to what's going to be most effective for the individual patient, I think we're obligated to do that. Thank you.

Paula Campbell

Good morning, I'm also a member of NAMI, but I'm here as a family member. My name is Paula Campbell and I live in Boise. My 23-year-old son, Jason, has been diagnosed with schizophrenia for nearly five years. Instead of being at a senior prom, he was in a four-door lockdown unit at Intermountain Hospital. Today, I'd like to take a few minutes to tell you his story and the role medications have played in his recovery. Jason was an honor roll student on the championship state football team at Eagle High. He was accepted and on his way to the University of Idaho, when his life took a fateful turn. A series of stressful events sent him into a psychotic episode. My beautiful son was no longer engaged in reality, but responding to demons neither one of us could see or understand. He was in intensive care for 23 days and we all tried to understand, educate ourselves, and learn about how to move forward. He was with me 24/7 for a year and a half. It took two years, though, and multiple trials of medications to get a combination that stabilized him. He's been on Zyprexa, Prolixin, Geodon, Abilify, Prolixin-DC, Risperdal, Cogentin, Artane, and Effexor-XR to name a few. The doses and the combination were both staggering and complex. My son believed in his doctor and together they made progress. With the right medications in place, Jason is now driving, working at a part-time job, and participating in group programs provided by NAMI. To experience their own recovery, many people living with mental illness will need access to treatment including medications. Like my son, many will need to try a wide variety before they find the right medications that allow them to live the life they dream of. Today, I ask that you help countless Idahoans experience recovery by preserving access to a full array of needed psychiatric medications. The cost to the community without them is great. Increased police involvement leading to incarceration, emergency room visits, and increased illicit drug use due to self medication. Open access to all medications for all Idahoans must remain. Thank you for your compassionate consideration.

Madeline Wyatt

Panel, Chair, and Committee members, my name is Madeline Wyatt and I'm a mental health consumer and NAMI member. Excuse me for being... I've lived with this disease unknown to me for 42 years and functioned relatively well as a registered nurse and a mother for the first half of my life, and my life took a distinct turn after my divorce. After 23 years of marriage, I experienced a psychotic break, at which time I was hospitalized for 30 days. I did not understand the warning signs prior to my mental health crisis, even though I'd been an educated nurse, or lack of educated nurse, I required hospitalization for that 30 days. Unable to care for myself upon discharge, I stayed with a friend for three months' time and slowly resolved my agoraphobia and learned to perform duties; shopping and food preparation, and I had to find a job and a place to live. I had to leave my son behind and I was forced to locate to a community out of state and establish a new psychiatrist and a new physician and, at which time I became healthier looked for a job and a place to live. Needless to say, these obstacles are challenging, even without the issue of mental illness. I experienced a second hospitalization when I had a medication change to Abilify when I moved back to Idaho and my Washington psychiatrist graduated me from his care to the care of an Idaho physician, and the physician that I had selected, the mood stabilizer was not added as was recommended by the Washington physician in a timely manner, and I escalated to that crisis of mania, and I again experienced another 30-day hospitalization. As I age, I find that I require a greater time to heal from

my mental health crises and the decisions that are made between me and my physicians, I just feel that it's very crucial that there not be any um, pardon me, these "ums" are pitiful, that it's contraindicated to my progress when there's a third party that isn't familiar with my care, involved in the decision-making process.

Committee
I'm going to have to stop you, sorry.

Madeline Wyatt
Okay, I have a copy.

Kathy Garrett
In 2003, I served in the Idaho House of Representatives and the Speaker of the House and the pro-temp appointed me as Co-Chairman of the Joint Task Force to review prescription drug management efforts. The task was charged to implement and give advice into the forming of the Pharmacy & Therapeutics Committee. The following agreements were part of the task and the recommendations that were high on our list, of course, number one was to make sure that all Idahoans had access to the right medical treatment and prescription drugs. The other thing we said is we wanted adequate opportunity for public input and, as you can see today, it's very challenging. We also asked that a psychiatrist always serve as a member on the committee, and then we had a letter from then Director Kurtz that said the department would not implement prior authorization to atypical antipsychotics. If I had more time, I'd read you the paragraph. In 2006, Governor Kempthorne asked me to chair an interagency work group to meet Idaho's efforts on the role of Medicare Part-D. The participation of all state agencies in this made Idaho the lead in the nation on the implementation of this program. Medicare Part-D studied, so I was really interested when I got the data on those 65 and older, but also those Medicaid clients that were eligible, that they found the following consequences with problems accessing needed medications, 21%, or one in five, responded an increase or reported an increase in suicidal thoughts and behavior, one-fifth required emergency room treatment visits, and one in ten required hospitalization. Finally, one more point. I currently serve as the Co-Chair of the Governor's Suicide Prevention Counsel. Idaho ranks seventh highest in the nation for suicide. Preliminary data shows that in 2008, 248 Idaho citizens have died by suicide. Idaho citizens, that's a 12% increase. More than 90% of suicides in the United States are associated with mental illness or substance use disorder, between 25% to 50% of people with schizophrenia attempt suicide and 10% complete suicide.

Committee
Thank you.

Martha Ekhoff
This might be a challenge, a minute and a half. Hello, my name is Martha Epcott, and I had the great opportunity to represent and be the voice for mental health consumers in the State of Idaho in the role that I play in my job. I'd like to tell you that I qualified for this job because of my history with a psychiatric disorder, and I just want to bring out the quality of life context. I think the physicians here and the practitioners have done a great job. For me, I lost myself in my mental illness. I had been gainfully employed, quite successfully, and became ill really quickly. What ended up happening was I had 16 hospitalizations in a very short time, and I know our hope is that people will be stabilized, I know the hope is that we won't have a lot of people going in the hospital, and they will dictate the numbers of people who have lived successfully in the community, but for me, I never thought about hospitalization as a way for recovery. I never thought about stabilization. I thought about "I want to reconnect with my family, I want to be with my children and laugh with them." I couldn't. I wanted to read a book again, which I didn't for ten years. I wanted to be employed again, which I wasn't for ten years. I want to have a quality of life. I want to be engaged in my community again. I want to be involved with the things that are important in my life. That's quality of life and I think any time that we begin to restrict opportunities for people to join that journey of recovery and really live the quality of life that everyone hopes and dreams for, um.

Committee
Thank you. I didn't catch who you were with.

Martha Ekoff
I'm a consumer.

William Thompson
I'm William Thompson, um, I just came on to tell you my story real quick. I was very successful in school. I'm 24 years old now. I went on to U of I and I had a psychotic break. Well, I came home, was hospitalized because of homicidal behavior and another four years went by without a diagnosis, on all kinds of typical and atypical drugs, and none of them worked. Then I was hospitalized again for homicidal behavior. Well, I got on Risperdal and I am now going back to college, I have a 3.7 GPA, I'm doing well, I'm getting my life back together, and if you take that away, I'm going to be square-one. I don't think I have to tell you how it will affect my life, as well as the lives of others in negative ways. Thank you.

Larry Thompson
My name's Larry Thompson, I'm Bill's father, and that's kind of a tough act to follow. Bill did a good job. He's been on medications for about the last four years. He went to Idaho, like he said, he was in high school, was very, very active, a good athlete, a good basketball player, we had high hopes for him, just like we did for the rest of our family, our other kids that have done very well too, and I'm so proud of Bill for having the courage to face his illness. You know, I've got to thank a lot of people and I'd like to thank everybody in this room, I'd like to thank the people that sell the drugs, I'd like to thank Roseanne at NAMI, she helped our family considerably, and Bill has just struggled with pills for five years. It's just gone up and down. Maybe out of a month, he'd have a week that he was doing well and uh, Deo got him on Risperdal Consta, started about a year ago, and it's just turned his life around. He's able to function, he's able to go to school, 3.7 GPA, I wished I'd have done that, but he's really doing well and we've got a lot of people to thank. I've never met Deo. Deo, I hope to meet you and you might get a hug before this is over.

Committee
Thank you sir.

Karla Thompson
Are you sure you want me to speak? I'm Bill's mom and I just found out about this yesterday. So what I have for you is a very simple visual aid and it goes like this. We're all born and we have a life. This rectangular shape represents a life. We're born and we live. Well, my son had a life, a wonderful, awesome kid, couldn't ask for a better boy. He went to Moscow and suddenly his life as he knew it and we knew it ended, and it became a cycle of medication, feeling better but still not able to work, but feeling somewhat better, and he would become sick and eventually become hospitalized. No longer was his life this white rectangle that you see, but it became a cycle of medication, feeling somewhat better, becoming sick, and being hospitalized. Well, September of this last year, he was given Risperdal Consta. He took one class. He had never been able to take a class before and pass it since high school. He took one class and got an A. Yay! We were so proud of him that he was able to do that. Then with spring semester, he took three classes. We were a little bit nervous about this, afraid he was going to stress himself out. He got two As and a B. This summer, he worked part-time, successfully. He wasn't fired, nothing bad happened, he worked part-time and he took a class and got an A. This spring, he's registered, or this fall, excuse me, he's registered for four classes. So what this Risperdal Consta has done for me, is it's given me my son. What it's done for all of you, is he is a contributor to society and he can be, and will be, a contributor to society, but what it's done for him, is it's given him his life. That's all I have to say.

Committee
Thank you.

Courtney Santillan
My name is Courtney Santillan. I'm the Administrative Director of the Idaho Federation of Families for Children with Mental Health. We are a statewide children's mental health advocacy organization. I wanted to read a letter on behalf of a parent: "As a parent of a child with multiple mental health diagnoses, it is quite evident to me, after eight years of different medications, that open access to all mental health pharmaceuticals is essential. My son has Tourette syndrome. There are currently no medications developed specifically for Tourette's. Doctors prescribe other medications to diminish the motor and vocal tics brought on by Tourette's. Some of these

medications are actually for high blood pressure. Others are neuroleptics and atypical neuroleptics, some of which are antipsychotics. Selective prescription medications are based on one symptom, not on the person's diagnostic label. Since there is no drug for Tourette's syndrome and every Tourette's patient has his or her own unique set of symptoms, a variety of medications are tried at various doses until one that seems to work is found. This takes a toll on the patient and his family. If open access to drugs are not available, this process would take longer than it already does, all to the detriment of the family or individual in this family." For time, I won't read the second paragraph, but I do know Ryan and one comment I want to make about this young man and other youth who are experiencing mental health issues, is that we don't have time to waste playing around with medications, especially for kids. Most children will not qualify as adults in the adult system, they kind of drop off the face of the earth when they turn 18, so if you can't qualify them in one of the adult diagnosis, the serious and persistent mental illnesses, we have until the age of 18 for youth and to get their medications figured out.

Committee
Thank you. I'm real sorry, I cannot read this. I'm going to guess Luther as the last name. Randy Luther? Randy. Okay, I don't know who this is. That's why we ask people to print. I'm really sorry, but if we get to the end of the private citizens and you've signed up and I didn't call your name, let me know…..Kent Pillar?

Kent Sullivan
My name is Kent Sullivan and I'm here basically as was mentioned before, to thank the State of Idaho and Region IV Mental Health professionals for where we are today with my son. This drawl is due to my first 26 years of my life in Oklahoma, and not the last 38 years I've been in Idaho. But he, too, graduated with a better GPA than I did from Boise State University. In 1984, after a series of episodes, he was diagnosed as schizoaffective. We went through, oh golly, we've been in hospitals, we've been forced incarceration and the whole bit for fifteen years because they didn't recognize the fact, and I guess it's pretty typical, that he was mentally ill. Finally, he became compliant with the help of many professionals, and for the last ten years, he's been free of hospitalization. He's able to lead a pretty productive life during the day, thanks to I think mainly Risperdal. Realize, it's a very expensive drug, but by the same token, the cost of incarceration or hospitalization should be weighed against the cost of these medications. I would venture to say it would probably be very close to a pair of sixes. Thank you.

Committee
Thank you sir. Dujane? It starts with a "D"? Anybody whose first name starts with a "D"? Last name starts with an "S". Sorry. Marney Ward? Mary? Okay.

Mary Ward
My name is Mary Ward, and I am the assistant to psychiatric nurse practitioner, Deo Peppersack, and I work at Acacia Mental Health Wellness Center. I have witnessed the failures and successes of hundreds of patients who have been on the proper medications, as well as have family members (my brother and sister-in-law) who suffer from severe mental illness, and I have watched them struggle over the years. Most of their adult lives have been spent in institutions and several suicide attempts. They now have been without hospitalization for the first time in their adult lives for six months. This is due to being on the proper medications, so I really encourage everyone to think about that because the money that's been spent on their hospitalizations outweighs the money that's spent on their medications. Thank you.

Linda Duffy
My name is Linda Duffy. I guess you would call me a consumer. My current diagnosis is schizoid affective disorder, PTSD, and ADHD. About half of my adult life, I've been on typical medications, such as thorazine, Prolixin and Haldol. They were prescribed by psychiatrists. These medications really did not help and left me with side effects that caused physical dysfunction, leading to many hospitalizations and suicide attempts, and also led to financial, social and legal problems in my life. Since then, I've been working with psychiatric nurse practitioners, consulting with psychiatrists who prescribe atypical medications. These medications have less intrusive side effects, they've helped me progress in therapy and manage my psychiatric symptoms, I am not living independently, have had no hospitalizations or suicidal attempts in more than five years. My socialization has improved. I'm even able to participate in different support groups. I'm thankful to these nurse practitioners for putting me back on track with my mental wellness.

Committee
Thank you ma'am.

Emily Ryan
I'm a patient of Deo's and I've lived here for about six years, and it's taken me that long and ten hospitalizations to become stable. I've been stable since December, almost a year now, because I'm on Geodon. So I just don't want my medications taken away because I'd promptly go back in the hospital. Thank you.

Katie Priddy
Hi, I'm Katie Priddy. I'm a patient of Deo's. I've never been hospitalized, but I've been really close to it. It's been really hard for me, I've had a really difficult life. I used to be a self, what's it called, self mutilation? And I have actually stopped self mutilation for about four or five months now, thanks to Deo and the medications she has put me on. I have had several different medications, and I finally found the ones that have worked for me. I've been stable for about over a year, and if you guys take away my medications, I probably will go into the hospital.

Robin Ringkamp
I've been a patient of Deo's for a long time, and before I started my medication, I was self medicating and I was in and out of jail a lot. I have a 14-year-old son that got the brunt of most of that. Since I started medication, my world has completely changed and I don't want my medication taken away or changed.

Committee
Charles? Charles N-O-R-D. Charles? Okay, there's another name here that, I'm sorry, I can't read, "W" first initial, first name, "S-E-S-H" last name. No? Okay. Anybody sign up that we didn't talk to or didn't have an opportunity to speak? Okay. We'll move on to the drug industry approved presentations. Stephen Cheng. As you can see, we're running out of time here, and we have seven people to speak.

Stephen Cheng
Good morning, my name is Stephen Cheng, I'm a Health Outcome liaison with Eli Lilly & Company. I would like to share with you, some new information regarding Zyprexa. First, Zyprexa has a new FDA indication as of March of this year. This indication is for Zyprexa and fluoxetine in combination for the acute treatment of treatment-resistant depression in adults. Second, there have been two new meta-analyses published in the Lancet earlier this year comparing antipsychotics in the treatment of persons with schizophrenia. The first meta-analysis was funded by the NIMH to compare first- and second-generation antipsychotics in the treatment of schizophrenia. This study found that only four of the nine second-generation antipsychotics were more than the first-generation antipsychotics. These include Clozaril, Zyprexa and Risperdal. The second meta-analysis compared nine second-generation antipsychotics head to head. This study found that overall efficacy for Zyprexa proved superior to Abilify, Seroquel, Risperdal and Geodon, but was not significantly different from Clozaril. Zyprexa also proved superior to Seroquel, Risperdal and Geodon on drop-out rates, due to lack of medication efficacy. Thank you.

Jenn Kammerer
Good morning, I'm Jenn Kammerer with AstraZeneca Neurosciences. On behalf of AstraZeneca, we express our support for open access. We also acknowledge the need for additional comparative effectiveness research, particularly bipolar disorder, to detect differences in the individual agents within this class. Seroquel-XR and Seroquel are both indicated similarly for acute bipolar depression, acute bipolar-1 manic episodes as an adjunct to mood stabilizers in maintenance treatment of bipolar disorder, and for acute schizophrenia. Where they are different and what is new in the past year, is Seroquel-XR is also approved for acute bipolar-1 mixed episodes and maintenance treatment of schizophrenia. Seroquel-XR and Seroquel are the only atypical antipsychotic agents with proven and consistent efficacy across bipolar studies as monotherapy. The Seroquel extended-release formulation offers a once-a-day dosing across all approved indications, and an easier, more rapid titration schedule. The XR formulation also continuously allows the drug...

Committee
Just a minute? Could I have you just present your new data please?

Jenn Kammerer
Those are new indications and I believe that you also asked for comparative studies and there are no direct comparative studies between the extended-release and the immediate release.

Committee
Okay, thank you. Laura Litzenberger? You may want to give your new data first and we're going to have to move pretty quick here.

Laura Litzenberger
Okay. My name is Laura Litzenberger, I'm with Ortho-McNeil-Janssen and Johnson & Johnson, and first I'd like to say that Johnson & Johnson and Ortho-McNeil-Janssen support uninterrupted patient and health care professional relationships, and believe that the health care professional and the patient and their caregivers are the best to decide any types of therapy for those patients. Chairman asked that we provide comparative information for Invega. There has been a recent study looking at acutely ill patient, comparing Invega to quetiapine. Doses of Invega were 9-12 mg, with a mean dose of 10 mg. The dose of quetiapine were doses of 600-800 mg with a mean dose of 700 mg, and in those patients, there was a difference in overall PANSS scores, significant at five days and continued for the fourteen days' of monotherapy. Moving on to Risperdal Consta, there have been comparative information with Risperdal Consta and oral quetiapine showing that the time to relapse and the number of days that people maintain therapy is longer with Risperdal Consta than with oral quetiapine.

Lois Maston
Good morning. I'm Lois Maston, I'm a pharmacist and clinical specialist representing Forest Research Institute. Escitalopram (or Lexapro) was recently approved for the acute and maintenance treatment of major depressive disorder in adolescents age 12-17 years. It's only the second antidepressant to have this claim. Escitalopram is not approved for the treatment of major depressive disorder in children under twelve. In an acute treatment study, escitalopram 10-20 mg per day was significantly superior to placebo on the Children's Depression Rating Scale - Revised beginning at week-4 and through the end of the study. An extension study showed that continued treatment with escitalopram resulted in significant and clinically meaningful superiority over placebo at week-24, demonstrating sustainability of effect. Escitalopram was well tolerated, with an adverse event profile similar to that seen in adults. The most commonly recorded treatment emergent adverse events were headache, menstrual cramps, nausea and insomnia, however only nausea and insomnia were reported with an incidence greater than placebo. Unlike other SSRIs, escitalopram has low potential for pharmacokinetic drug interactions due to its minimal impact on the CYP450 system and no dosage adjustments are required in special populations. Escitalopram did not have any suicides in its trials, however patients taking antidepressants should be monitored for clinical worsening and suicidality, especially during the first few months of treatment and at times of dosage change.

Pamela Sardo
Good morning. Thank you for the opportunity to come before you today. I'm Pam Sardo, Government Regional Clinical Executive with Abbott Laboratories. There are six conditions for which Humira has been given FDA approval; rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, and polyarticular juvenile idiopathic arthritis. I've been asked today to limit my comments to the new indication and new data regarding the juvenile idiopathic arthritis. Published in the New England Journal of Medicine in August of 2008, polyarticular JIA study was stratified into two groups: methotrexate treated and non-methotrexate treated. At the end of week-16, there was then an open label lead-in phase in which all patients received Humira, and so 94% of those patients in the Humira plus methotrexate group, and 74% of the patients in the non-methotrexate group were pediatric ACR30 responders, which I can define that later, and so at 32 weeks or until disease flare in the double blind phase, fewer patients who received Humira experienced a disease flare in this debilitating condition compared to placebo. Additionally, more patients treated with Humira continued to show pediatric ACR and not just 30, but also 50 and 70 response at week-48 compared to patients treated with placebo. After 32 weeks or at the time of disease flare, there was an open label phase, and I just want to conclude by saying that the pediatric ACR responses were maintained for up to two years in this population. I encourage the Committee to refer to the full prescribing literature for comprehensive safety and efficacy, and also Abbott is going to adhere to the FDA's guidance regarding labeling changes in the anti-TNF class and update the label accordingly, and will continue to monitor the data to ensure patients and physicians have information they need. I'll be happy to take any questions, I know you're out of time. Thank you very much.

Olivia Whealon
Hi, my name is Olivia Whealon, I'm a PharmD Medical Science Liaison for UCB, presenting new information on Cimzia (certolizimab pegol) and its approval in RA. Initially approved in Crohn's disease in 2008, approved in RA in 2009. Approved for the treatment of adult patients with moderate to severely active disease, it is available in a new, pre-filled syringe and it continues to be available as a lyophilized product. It's the only pegolated anti-TNF medication that offers stable dosing as a significant benefit is observed with increasing dosing, it can be used with or without methotrexate, the maintenance dose can be dosed 200 mg subcutaneously every two weeks or 400 mg monthly. It's shown to improve signs and symptoms of RA, as well as inhibit the progression of structural damage. Treatment has also shown to have rapid improvement in physical function, fatigue, arthritis pain, and has been shown to increase work productivity. Please see full prescribing information for important safety. Thank you.

Rick Realson
Hi, I'm Rick Realson, I'm a pharmacist, I work for Merck as a Health Science Consultant, and today I'd like to present some new data on Januvia and Janumet, and I'll refer you to the product circular for indications and contraindications which have not changed since last year. Study 079 is a new study that was designed, is a randomized, double-blind study with 1,200 patients with Januvia, or I'm sorry, Janumet and metformin, and to see what the differences would be with the combination versus metformin alone. In about 621 patients per group, the average A1c was about 9.9 in the study, and at the conclusion of the study, the reduction of A1c was about 1.8% in the metformin group, but 2.4% in the Janumet group, a difference of 0.6%. In addition, they divided the group into folks above and below the mean, which is 9.7% A1c. Those that fell below the mean of 9.7% A1c, reduction of A1c was 1.5% with Janumet and 1.1% with metformin. The group above the mean had an average A1c of 11.4%. Reduction with Janumet was 9, or I'm sorry, 3.3%, and the reduction with metformin was 2.4%, so a relatively large difference there as well with the large, the higher A1c group. Also, I'd like to talk about the study protocol 53, which is a study in which the randomized patients to Januvia versus placebo who were already on metformin and their A1c was 9.2-9.3% on average.

Committee
Okay, we're going to have to stop you, I'm sorry.

Rick Realson
Thank you. The request was that Janumet should be maintained on the PDL without restriction. Thank you very much.

John Shepski
Hi, I'm John Shepski, I'm a Senior Medical Science Liaison with Shire Pharmaceuticals. I wanted to tell you about some new information regarding Vyvanse. Vyvanse, of course, is the only prodrug, long-acting stimulant available. There's a new indication for 13-hour duration in children ages 6-12. This was shown in an analog classroom study, where they monitor behavior and attention to math problems. First sign of efficacy was seen at 1.5 hours, which was the first measured time point. The last measured time point was 13 hours and statistical significance was retained, as well as at all points in between. There is also a new study looking at nasal inhalation versus oral administration, and the finding was that if you put Vyvanse into a liquid and snort it, the blood levels of dextroamphetamine are exactly the same, oral versus nasal, so the point is, you can't overcome the long-acting properties of the drug by putting it into solution. Similar studies have shown the same thing with IV administration. So the point is that you can't cheat the long-acting properties of the drug in order to abuse it. The last point I wanted to make was regarding daily consumption or DACON units. DACON is obtained by looking at a national database of prescriptions. After five million prescriptions, the DACON or daily consumption for Vyvanse is 1.0, which means that it's truly a once-a-day drug, patients aren't taking more than one a day. For a class of long-acting stimulants, that tends to be at around 1.2. That's all I wanted to say. Thank you.

Committee Chair
There's a couple of comments. I have something to say about our scientific testimony. The new requirements for public testimony regarding scientific data [inaudible] and specifically this data is restricted to information new enough to not be included in the [inaudible] available to us, and that we require data to be submitted for review prior to the meeting. As a result, we ended up getting all kinds of information submitted for review, including [inaudible] graphs, studies dating back fifteen years or

more, package inserts, and Medicaid [inaudible]. Some of the documents we received were in excess of 150 pages. This is all on the P&T website for anybody who's interested in looking at it. I personally went through all of this information to see what would actually fit criteria of the testimony, so to clarify our policy, I will restate: The data will be required to be submitted for review 30 days prior to the meeting. I will add that we don't want anything more submitted [inaudible] to present. Virtually all of the [inaudible] material is already available to us. If you have an important new study, send us that, but nothing more. I have asked the staff to politely return any submissions containing more data than [inaudible]. So take that back and we'll send that out to you, all of our pharmaceutical people. Now a second comment. I was curious about how many people got up and said "Don't take away our meds", because to my knowledge, we have never required somebody to change meds they were stabilized on. Is that correct?

Tami Eide
That is correct.

Committee Chair
Okay, so if I could just put that at the end of the public comment that we don't take away medicines people are stabilized on with a psychiatric diagnosis. Make sure that's in the minutes.