

**Pharmacy and Therapeutics (P&T) Committee Meeting Record**

**Date:** August 27, 2010    **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; Dennis Tofteland, RPh; John Mahan, M.D.; Mark Johnston, RPh; Elaine Ladd, PharmD; Scott Malm, PA-C; Tami Eide, PharmD; William Woodhouse, M.D.; Perry Brown, M.D.; Mark Turner, M.D.; Catherine Hitt-Piechowski, PharmD

**Others Present:** Steve Liles, PharmD; Melinda Sater, PharmD; Jane Gennrich, PharmD.; Cody Scrivner CPhT; Rachel Strutton

**Committee Members Absent:**

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Phil Petersen, M.D.	Dr. Petersen called the meeting to order.
<b>Committee Business</b>		
➤ <i>Roll Call</i>	Phil Petersen, M.D.	Dr. Petersen completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➤ <i>Reading of Mission Statement</i>	Phil Petersen, M.D.	Dr. Petersen read the Mission Statement.
➤ <i>Approval of Minutes from July 16, 2010 Meeting</i>	Phil Petersen, M.D.	The July 16, 2010 meeting minutes were accepted with one correction. The dates for the future meetings were listed for the year 2010; the minutes will be changed to reflect the year 2011 instead.
➤ <i>DERP Update and Key Questions</i>	Tami E. PharmD	Dr. Eide presented the following DERP (Drug Effectiveness Review Project) Key Questions: Drugs for Neuropathic Pain – complex neuropathic pain will be added; drugs will include anticonvulsants, tricyclic antidepressants, SNRIs but not SSRIs, and topical analgesics including Lidoderm. Newer Antiplatelets – Effient and Pletol will be added to the drugs covered; duration of therapy will be added; suggestion made to include information on the drug-drug interaction between Plavix and PPIs. Comparative Effectiveness of Typical and Atypical Antipsychotics – This review will be done by AHRQ but will be supported by DERP. The University of Alberta will be doing the actual work. It will include

		<p>pediatrics, adults (subdivided into age ranges 18-36, 36-54, 54-65), and geriatrics. Individual drugs will be compared, not typical vs atypical classes. At this time, the plan is to only look at oral agents but the suggestion was made to include injectable antipsychotics as well. Core illness symptoms and adverse effects will be compared.</p>
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<p><b>Public Comment Period</b></p>	<p>Phil Petersen, M.D. Cody Scrivner, CPhT</p>	<p>Twelve (12) people signed up to speak during the public comment period. Only ten (10) people were actually present when their name was called. Public testimony was received from the following speakers:</p> <table border="1"> <thead> <tr> <th>Speaker</th> <th>Representing</th> <th>Affiliation</th> <th>Agent</th> <th>Class</th> </tr> </thead> <tbody> <tr> <td>Dr. Alan Olmstead</td> <td>Self – Idaho Medicaid physician</td> <td>Abbott Labs Centocor</td> <td>Humira</td> <td>Cytokine and CAM Antagonists</td> </tr> <tr> <td>Dr. Stephen Denagy</td> <td>Self – Idaho Medicaid physician</td> <td>Eli Lilly Forrest</td> <td>Lexapro, Antipsychotics</td> <td>Antidepressant, SSRIs Atypical Antipsychotics</td> </tr> <tr> <td>Dr. Charlie Novak</td> <td>Self – Idaho Medicaid physician, Idaho Psychiatric Association</td> <td>Eli Lilly</td> <td>Antipsychotics</td> <td>Atypical Antipsychotics</td> </tr> <tr> <td>Mary Seroski</td> <td>Self, National Fibromyalgia Assn (Boise chapter)</td> <td>Eli Lilly</td> <td>All fibromyalgia agents</td> <td>Fibromyalgia Agents</td> </tr> <tr> <td>Barbara Valdez</td> <td>Self, NAMI (National Alliance on Mental Illness)</td> <td>NAMI has multiple pharmaceutical corporate sponsors</td> <td>Antipsychotics</td> <td>Atypical Antipsychotics</td> </tr> <tr> <td>Sandra Jensen</td> <td>Self, Idaho Arthritis in Motion</td> <td></td> <td>All rheumatoid arthritis agents</td> <td>Cytokine and CAM Antagonists</td> </tr> <tr> <td>Phyllis Reff</td> <td>Self (parent of 5 children with psychiatric issues)</td> <td></td> <td>Antipsychotics, Antidepressants, ADHD medications</td> <td>Atypical Antipsychotics, Antidepressants, ADHD medications</td> </tr> <tr> <td>Jane Pace</td> <td>Self – Idaho Medicaid participant</td> <td></td> <td>Antipsychotics</td> <td>Atypical Antipsychotics</td> </tr> <tr> <td>Lisa Wilson for Bhumik Parikh</td> <td>Employee of Centocor Ortho Biotech</td> <td>Centocor Ortho Biotech</td> <td>Stelara, Simponi</td> <td>Targeted Immune Modulators</td> </tr> <tr> <td>Laura Litzenberg</td> <td>Employee of Janssen</td> <td>Janssen</td> <td>Invega Sustenna, Invega tablets</td> <td>Atypical Antipsychotics</td> </tr> </tbody> </table>	Speaker	Representing	Affiliation	Agent	Class	Dr. Alan Olmstead	Self – Idaho Medicaid physician	Abbott Labs Centocor	Humira	Cytokine and CAM Antagonists	Dr. Stephen Denagy	Self – Idaho Medicaid physician	Eli Lilly Forrest	Lexapro, Antipsychotics	Antidepressant, SSRIs Atypical Antipsychotics	Dr. Charlie Novak	Self – Idaho Medicaid physician, Idaho Psychiatric Association	Eli Lilly	Antipsychotics	Atypical Antipsychotics	Mary Seroski	Self, National Fibromyalgia Assn (Boise chapter)	Eli Lilly	All fibromyalgia agents	Fibromyalgia Agents	Barbara Valdez	Self, NAMI (National Alliance on Mental Illness)	NAMI has multiple pharmaceutical corporate sponsors	Antipsychotics	Atypical Antipsychotics	Sandra Jensen	Self, Idaho Arthritis in Motion		All rheumatoid arthritis agents	Cytokine and CAM Antagonists	Phyllis Reff	Self (parent of 5 children with psychiatric issues)		Antipsychotics, Antidepressants, ADHD medications	Atypical Antipsychotics, Antidepressants, ADHD medications	Jane Pace	Self – Idaho Medicaid participant		Antipsychotics	Atypical Antipsychotics	Lisa Wilson for Bhumik Parikh	Employee of Centocor Ortho Biotech	Centocor Ortho Biotech	Stelara, Simponi	Targeted Immune Modulators	Laura Litzenberg	Employee of Janssen	Janssen	Invega Sustenna, Invega tablets	Atypical Antipsychotics
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<p><b>Drug Class Reviews and Committee Recommendations</b></p>		
<p>Androgenic Agents</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Androgenic Agents</u> There was no new clinical data to share with the Committee.</p> <p><b>Committee Recommendations</b> The Committee felt there were no evidence based differences to support any changes to this class, but had no issues with any changes due to cost effectiveness.</p>
<p>Pancreatic Enzymes</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Pancreatic Enzymes</u> Dr. Liles explained that the FDA required all of the pancreatic enzymes that had been on the market previously to go through the FDA approval process. As a result, there have been multiple products that voluntarily left the market and new products that have become available. The main change has been to standardize the manufacturing processes so that there is more consistency in the amount of enzymes in the products. Due to this unique situation, Idaho Medicaid has been preferring any pancreatic enzyme that received FDA approval since this class of medications was last reviewed by the P&amp;T Committee.</p> <p><b>Committee Recommendations:</b> The Committee endorsed approval of all currently FDA approved products as there have been so many changes to what is available and most patients have needed to switch products in the last 12 months.</p>
<p>Analgesics/Anesthetics, Topical</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Analgesics/Anesthetics, Topical</u> Dr. Liles provided a review of new drugs in this class, Qutenza (capsaicin 8% patch), Pennsaid (diclofenac 1.5% topical solution) and Capsaicin OTC. He also provided a review of eight new clinical trials.</p> <p><b>Committee Recommendations</b> Quetenza is only administered in a prescriber’s office and therefore should not be covered under the outpatient prescription drug program. The Committee recommended a utilization review of Lidoderm Patches (lidocaine) due to the high volume of use. The Committee recommended that Capsaicin OTC continue to not be covered under the outpatient prescription drug program. The Committee recommended that Pennsaid be non-preferred and that Flector Patch and Voltaren gel continue to be non-preferred with the same therapeutic criteria.</p>

<p>Targeted Immune Modulators (Cytokine/ CAM Antagonists)</p>	<p>Gerald Gartlehner, MD, MPH, DERP Investigator</p>	<p><u>Targeted Immune Modulators (Cytokine/ CAM Antagonists)</u>                  In addition to Dr. Gartlehner’s DERP review, Dr. Liles also reviewed three (3) new drugs for this class, golimumab (Simponi) – TNF blocker, tocilizumab (Actemra) – IL-6 receptor inhibitor, and ustekinumab (Stelara) - IL-12 AND IL-23 inhibitor, which were approved by the FDA after the DERP cutoff for new data. The Committee reviewed three (3) clinical trials for Actemra, six (6) clinical trials for Simponi and three (3) clinical studies for Stelara.</p> <p><b>Committee Recommendations</b>                  The Committee would like to see longer term safety data and additional head-to-head trials for the three new agents (Simponi, Actemra, and Stelara) before considering them for preferred status. Based on efficacy and safety data, the Committee also recommended that Kineret (anakinra) be switched from preferred to non-preferred status. The Committee recommended that Cimzia (certolizumab), Enbrel (etanercept), and Humira (adalimumab) remain preferred agents.</p>
<p>Bone Resorption &amp; Suppression Agents</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Bone Resorption &amp; Suppression Agents</u>                  Dr. Liles provided a review of the Guidelines from NAMS (north American Menopause Society) 2010 and a clinical trial comparing Forteo vs. alendronate for glucocorticoid-induced osteoporosis.</p> <p><b>Committee Recommendations</b>                  The Committee recommended Forteo be made preferred for glucocorticoid-induced osteoporosis but remain non-preferred for other indications. The Committee considers alendronate, Actonel, and Boniva to be therapeutically equivalent medications, but recommended grandfathering if any of these currently preferred medications were switched to non-preferred status.</p>
<p>Platelet Aggregation Inhibitors</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Platelet Aggregation Inhibitors</u>                  Dr. Liles presented data on the new agent Effient which has good efficacy data but an increased risk of bleeding as compared to Plavix. Dr. Liles also presented the labeling changes for Plavix with respect to drug-drug interactions with PPIs.</p> <p><b>Committee Recommendations</b>                  The Committee recommended that Effient be non-preferred due to safety issues. The Committee concluded that there was no evidence to support preferring any of the other agents over any other.</p>
<p>Antiemetics (Newer)</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Antiemetics (Newer)</u>                  Dr. Liles provided a review of the NCCN (National Comprehensive cancer Network) 2010 Guidelines. Granisetron is now available generically. There was no other new clinical data to share with the Committee.</p>

<p>Hypoglycemics, Insulins and Related Agents</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><b>Committee Recommendations</b> The Committee did not feel there were evidence-based differences in safety or effectiveness between the agents. They also recommended removing therapeutic criteria on ondansetron if it would not be cost-prohibitive. Dr. Liles stated that he could provide utilization data from other states who had discontinued therapeutic criteria.</p> <p><u>Hypoglycemics, Insulins and Related Agents</u> Dr. Liles provided a review of the updated ADA (American Diabetes Association) 2010 Guidelines. He also reviewed clinical trials on Lantus vs Levemir and Lantus vs. Novolog Mix.</p> <p><b>Committee Recommendations</b> The Committee felt there were no evidence based differences to support any changes to this class.</p>
<p>Hypoglycemics, Incretin Mimetics/Enhancers</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Hypoglycemics, Incretin Mimetics/Enhancers</u> Dr. Liles provided a review of the updated ADA (American Diabetes Association) 2010 and the AACE/ACE (American Association of Clinical Endocrinologists/American college of Endocrinology) 2009 Guidelines. Two (2) new products were reviewed - Onglyza (saxaglipton) and Victoza (liraglutide).</p> <p><b>Committee Recommendations</b> The Committee recommended having either Januvia or Onglyza available as an add-on agent, but not as a first line agent. There were no other recommendations from the Committee.</p>
<p>Antiparkinson’s Agents</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Antiparkinson’s Agents</u> Mirapex is now available generically as pramipexole. Mirapex ER is a new extended release formulation that is now available – it only has FDA approval for Parkinson’s disease and not for restless leg syndrome.</p> <p><b>Committee Recommendations</b> The Committee felt there were no evidence based differences to support any changes to this class.</p>
<p>Drugs to Treat ADHD</p>	<p>Marian McDonagh, PharmD, DERP Principle Investigator OHSU EPC</p>	<p><u>Drugs to Treat ADHD</u> Intuniv (guanfacine ER) was not included in the DERP report as it did not receive FDA approval prior to the DERP data cutoff date. Dr. McDonagh reviewed new studies added to the DERP review on ADHD treatment.</p> <p><b>Committee Recommendations</b> The Committee stated that the different stimulant medications are therapeutically equivalent. The Committee recommended that for Strattera, the timeframe of having failed at least one stimulant within the past two months be removed and be changed to just failure of at least one stimulant anytime in the</p>

<p>NSAIDS</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p>past. The Committee did endorse Strattera remaining a non-preferred agent. The Committee also recommended that generic guanfacine IR be a preferred agent and Intuniv (guanfacine ER) be a non-preferred agent requiring trial and failure of IR guanfacine. The Committee acknowledges that Intuniv is FDA approved for the treatment of ADHD in children while guanfacine IR does not have FDA approval for this indication, but the Committee stated that there is sufficient evidence in the medical literature that guanfacine IR is safe and effective for this indication.</p> <p><u>NSAIDS</u> Dr. Liles provided a review of one (1) new product - Vimovo (naproxen/esomeprazole). There is no data that this medication is superior to the two components given separately.</p> <p><b>Committee Recommendations</b> The Committee felt there were no evidence based differences to support any changes to this class. Vimovo should only be preferred if the combination product is more cost effective than the components administered separately.</p>
<p>Antibiotics, Inhaled</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Antibiotics, Inhaled</u> This is a new drug class review. Dr. Lilies provided a review of the two (2) products listed in this class, Tobi (tobramycin) and Cayston (aztreonam). They are both FDA approved for Cystic Fibrosis patients.</p> <p><b>Committee Recommendations</b> The Committee recommended diagnostic criteria of Cystic Fibrosis. Other than the diagnosis criteria the Committee felt this was a class that required the clinical expertise of specialists and that both medications should be preferred.</p>
<p>Tetracyclines</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Tetracyclines</u> This is a new drug class review done because of the high cost of some of the agents in this class. There was no clinical data to share with the Committee.</p> <p><b>Committee Recommendations</b> The Committee recommended generic tetracycline, minocycline and doxycycline as preferred agents. The committee endorsed choosing products based on cost as the different dosage forms and brand name agents are therapeutically equivalent to generic formulations.</p>

<p>Epinephrine, self-injected</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Epinephrine, self-injected</u> This is also a new drug class review done because of the high cost of some of the agents in this class. There was no clinical data to share with the Committee.</p> <p><b>Committee Recommendations</b> The Committee endorsed choosing cost-effective products as long both pediatric and adult dosage strength are available as preferred agents.</p>
<p>Alzheimer’s Drugs</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Alzheimer’s Drugs</u> There is a new Aricept 23mg tablet strength available which is FDA approved for moderate to severe dementia. Aricept 5mg tablets are FDA approved for mild to moderate dementia and 10mg tablets are FDA approved for moderate to and severe dementia.</p> <p><b>Committee Recommendations</b> The Committee felt there were no evidence based differences to support any changes to this class.</p>
<p>Antipsychotics, Typical and Atypical</p>	<p>Marian McDonagh, PharmD, DERP Prin. Investigator OHSU EPC and Steve Liles, PharmD Provider Synergies</p>	<p><u>Antipsychotics, Typical and Atypical</u> Dr. McDonagh discussed the most recent DERP update on this topic. Dr. Liles then discussed the APA (American Psychological Association) 2009 Schizophrenia guideline watch. Dr. Liles stated that the superiority of atypicals as compared to typical antipsychotics is being questioned by multiple national psychiatric organizations, as the very clinically significant metabolic side effects of the atypicals are more widely recognized.</p> <p><b>Committee Recommendations</b> Dr. Phil Girling (psychiatrist) recommended open access to any antipsychotic medication for patients with a schizophrenia or psychotic diagnosis. Dr. Petersen questioned whether every antipsychotic would be appropriate as a first agent for a newly diagnosed patient. For patients prescribed antipsychotics for mood disorders including bipolar disease, Dr. Girling stated that step therapy would be reasonable. The Committee recommended that Dr. Eide and Dr. Girling work together to create a list by antipsychotic medication of FDA approved indications and evidence-based indications. The target deadline for the first draft is 10-15-2010 at which time it will be sent to all committee members for review. Dr. Eide will collate the reviewers’ responses and arrange for further discussion. Dr. Girling also expressed concern about the accuracy of diagnosis for patients and proposed at least an annual psychiatric evaluation by a specialist for Idaho Medicaid participants receiving antipsychotic medications. Dr. Brown expressed concern that there are not enough psychiatric specialists in Idaho for an annual consult to be feasible. The Committee also expressed concern over the large number of pediatric patients receiving these medications. Dr. Girling stated that for autism and disruptive behavior disorders, Abilify and/or risperidone should be the first-line agents based on the evidence. All Committee members agreed that regardless of what changes occur in the future; currently stable patients should be grandfathered on their current antipsychotic therapy.</p>

<p>Antidepressants, SSRI</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Antidepressants, SSRI</u> Dr. Liles reviewed the Guidelines Update – APA (American Psychological Association) 2009 for Panic Disorder. He also provided a review of clinical trials for Lexapro which has gotten FDA approval for adolescent depression since the last P&amp;T Committee review. Paroxetine is non-preferred because of safety issues not because of cost issues.</p> <p><b>Committee Recommendations</b> Dr. Girling (psychiatrist) stated that there was no difference in efficacy for adolescent depression between the different SSRIs, including Lexapro and the currently preferred generic SSRIs. The Committee felt there were no evidence based differences to support any changes to this class</p>
<p>Antidepressants, Other</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Antidepressants, Other</u> Dr. Liles provided an explanation of new formulations of venlafaxine that are now available. Venlafaxine ER tablets are a generic formulation of branded Venlafaxine ER tablets and venlafaxine ER capsules are a generic formulation for branded Effexor XR capsules. There was no new clinical data to share with the Committee.</p> <p><b>Committee Recommendations</b> The Committee felt there were no evidence based differences to support any changes to this class.</p>

**Pharmacy and Therapeutics Committee  
Public Comment  
August 27, 2010**

Dr. Alan Olmstead

Thank you, I'm very honored to be number one on this distinguished list today, for sure. I'm Alan Olmstead. I'm a private dermatologist in solo practice in Twin Falls. I've been in practice for 26 years now, and I have something of an interest and expertise in psoriasis, and I'm here speaking as a private citizen as well as a practicing dermatologist today, but I have to disclose that I am on the speakers bureau for Abbott Labs, so I do speak for Humira, and I also have some connections with Centocor as well. I'm not on their speakers bureau, however. Psoriasis is a chronic disease that has just a tremendous number of co-morbidities associated with it. It's probably a genetic disease and it's been the bane of a lot of dermatologists' existence for many, many years. This new class of drugs called Biologics came out, starting realistically about ten years ago, and it has tremendously changed the scope of how we can practice dermatology. One of the biggest problems with psoriasis in addition to all of the co-morbidities that we now associate with it, is quality of life issues. We can sacrifice a lot in our lives. I think as we mature, we all realize we have to sacrifice a lot in our lives, but the quality of life is not one of those things that I would ever like anybody to sacrifice as long as there are some changes that we can make in the medical system. So I'd really like to ask the Committee to maintain the present PDL that we have right now. Humira certainly is my go-to drug in that class of drugs, and I use it because I find that I have the best experience with it. I really think that between 75% and 80% of the patients that I start on Humira do exceptionally well, not only in the short-term, but in the long-term, and again the long-term treatment is something that we always have to look at in psoriasis because it's not a disease we have any cures for, nor do I see any cures coming up in the near future at all. So I would really like to maintain the status quo and in closing, really, I just wanted to give one example of how Humira especially changed a patient's life. I saw a patient, this was actually about a year ago that I saw the patient, and, you know, he, you know, was throwing flowers at my feet. "Thank you doctor, for changing my life like you have", and all I did was wrote a prescription basically for a drug that works, and I left the room and the nurse chatted with him for a second longer, and she said he had one more question to ask, so I walked back into the room and the patient said "Doc, my sex life is great". I think that's a realistic example of what patients with psoriasis actually do deal with, that this is a terrible chronic disease that we can now impact. It's just so wonderful to be able to have these drugs available for us. Thank you.

Dr. Stephen Denagy

I'm Dr. Steve Denagy. I'm an internist and psychopharmacologist from Idaho Falls. I teach for Idaho State University, and I do consult and speak for the speaker's bureaus for several pharmaceutical companies, a very long list, including relevantly Eli Lilly (Cymbalta), and I speak for Forrest on Savella, but I've spoken for about another half dozen or more companies. I'm here to talk probably about the two things today that are close to my heart because you have a very busy agenda. I'll try not to take up too much more of your time. That is, we have Lexapro approved for adolescent depression, so I'm hopeful that the Committee will give good access to that. In our office, we have child psychiatrists also in our office and we use an enormous amount of Lexapro. There are rational reasons for that: number one, because it has no drug-drug interactions that are relevant, which is important for the safety of our clients. Two, it is far more efficacious on a molar basis compared to the supposed generic which is Celexa or citalopram. There is a 4:1 difference that's well defined in the clinical literature between the two drugs. That makes a big difference because sometimes with, not so much with Medicaid I think you guys are pretty good, but when I try to get a molar equivalent dose of citalopram, most of the Part D plans complain to me that 80 mg of citalopram is too much, even when the equivalent dose or the available dose of Lexapro. So I'm hoping that we have good access to that. I don't know how you will define that, but it is approved for adolescents. We already had been using it in adolescents and kids before the approval came through

Rachel Strutton-Draft

because it's a very useful drug. Second that's very close to my heart is atypical antipsychotics, which I understand you're discussing today, and I don't know how you guys will manage this, I know it's an expensive and difficult issue for the State, and I'm sensitive to that. The only suggestions I have, if I were to sit in your shoes, is probably that polypharmacy is one of the big things that I would look at that you should look at. I prefer not to, if you look at my profile, I'm sure you know somehow what I do, but we don't do too many dual, I have a few who are on two atypicals, but I prefer to use typicals if I'm going to add another one. Unfortunately, some of them are going off the market; Mobar just disappeared to my dismay, but anyway, so somehow looking at that and perhaps low doses of some of the drugs, particularly, we only have one really useful parenteral drug which is Sustenna. We only have one drug which is metabolically controlled, which is Geodon. We have some drugs like Seroquel which are very sedating. Don't take my Zyprexa away, because that's the only one that I can give in a crisis reliably and keep people out of the hospital because it has no relevant cardiac side effects, so I can dose it without worrying about knocking some of our clients off. So those are the important things to think about from my safety perspective, so open access if at all possible, or perhaps if you have to save some dollars, looking at the polypharmacy issue and perhaps a little bit more scrutiny streamlining the prior authorization process would be great. So these are currently things that are close to my heart because I lost an hour and a half in my office yesterday in prior authorizations with a couple of crisis patients, one of whom would have probably been hospitalized, had she not gotten her parenteral drug, so making it as easy as possible, understanding the fiduciary constraints that you guys are under, would be really, really good, and maybe enlisting some of our suggestions from the community. I know I have fifteen seconds left, but not in this kind of encapsulated setting, but also in a perhaps questionnaire setting, like "Guys, how would you like us to do this?", I think you would find that more physicians than you would expect would be receptive to that kind of feedback, so that's what I have to say. Any questions?

#### Committee

First, I appreciate your comment that you had less trouble from us than private insurance.

#### Dr. Stephen Denagy

Yeah, I have never spent 90 minutes on the phone with you guys, so that is impressive.

#### Committee

If you were going to plug a list of "You absolutely have to have these available to start somebody", what would be on that list?

#### Dr. Stephen Denagy

Zyprexa would have to be my first one, not because it's cheap. I know sometimes, well I'm not going into, you guys know the fiduciary issues, but I can safely give it without worry. That one drug has probably helped me keep more people out of the hospital than any other drug I can think of. Before these drugs came to market, the atypicals, because I've been doing this for almost 30 years now, we, at any given time, had in our big practice, probably about eight patients in the hospital, about 2/3 of them children. Hospitals would, you know, throw parties for us because they said we represented about three or four million dollars of annual hospital revenue for them. Now, it's rare that we have patients in the hospital. It's true, Craig Denny, who is a child psychiatrist, has a lot of hospital patients, but he takes them off of the streets, so he takes crisis patients in. So the advent of the atypical era really has changed the game. You know, if you've not been in practice that long, you might not feel that, but those of you who have been around long enough, I think you know what I'm talking about. Zyprexa would be number one. Number two are parenteral atypicals. I think Sustenna is a bit of a game changer because it's a monthly shot. Unfortunately, Consta is a good drug, but some people have had it run out. As far as the other atypicals, Geodon stands out because its metabolic, you know, parameter, it really does. I saw a patient last night in full remission of bipolar disorder, who is at a BMI of 22, and she was a BMI of 35 two years ago, so that's a remarkable improvement. The other drugs all have advantages. You have Risperdal which is approved for autism, Abilify has been approved for autism, but the differences are a little bit different. Those are probably the most critical things that I'd like listed there in order that have absolute stand outs, uniqueness. Geodon's a little bit harder to dose. The night issue is a problem with it, but no drugs are perfect. I know you've addressed this before. It's really hard to make a priority list, because I have people who do great on Seroquel and that's their go-to drug, so it's a tough problem. I don't envy you trying to figure this out, but probably Zyprexa is the one I need for my knockout punch, if I can say it that way, it sounds crass, but our acute manic patients need to sleep and sleep is absolutely essential, and that's what I give them to sleep. Thank you.

Rachel Strutton-Draft

Dr. Charlie Novak

Charlie Novak, I'm a psychiatrist in Boise, Idaho. I'm President Elect at St. Alphonsus Medical Center, I'm Clinical Chief at Intermountain Hospital. I'm here representing the Idaho Psychiatric Association, I'm their Public & Government Relations Representative, and I was asked to speak on behalf of atypicals and open access. I have one speaker's bureau affiliation, and that's with Eli Lilly. Efficient, cost-effective care of people with schizophrenia and chronic psychotic illnesses, as you know, is extremely difficult. It's our cancer, diabetes, very difficult to treat seizure disorders; it's a very similar, chronic illness, and we need all the weapons we can have available. I've been sitting on the Governor's task force for two years, so I can tell you how much it does cost when people end up in the hospitals, in the ER, in the jails, in the prisons, and the emergency rooms and crisis centers. That's really what you're talking about here. I think you need to sit down and as you think about how you're going to try to manage this, if you really think that limiting access to these medications will save the taxpayer money, I'm hoping you'll put together an explanation of that for the taxpayer, for the Idaho Psychiatric Association, and for the Alliance for the Mentally Ill, because it probably won't. If you just look at how much it cost, in 2008 it cost \$60,000-\$80,000 to put somebody in the State Hospital, and you only have to go, let's see, if 100 people statewide in the course of the year end up in the State Hospital, that's 6 million dollars minimum just in State Hospital care. We know right now in the ER since we've limited access over the last couple of years to the community mental health center care to access to psychiatrists and access to medications and access to psychosocial treatments, that our involuntary holds in the ER in Boise are up fourfold. That, in 2008, cost the County Taxpayers about 2 million bucks, so you can see there's a few million dollars right there, just limiting access at that level. So you start limiting access to medications at this particular time, you can just add a few million more on there, so from the taxpayer's perspective, I think it's important that you all take a look at that very closely and think about what you're really doing if you decide to limit. We do, and I do believe, you have to manage and you have to utilization manage the Medicaid dollar, but for this particular population and this group, I think it's going to cost the taxpayer money in the long run and it's not going to be good for the patients in the long run, to try to limit access to this particular group of medications. I stand for any questions? Yes?

Committee

Now, did they breakdown that 2008 data with regards to how many of those were on medications and had recent changes in medications related to utilization parameters. Did they break it down with regards to access to providers in the state. I'm a little concerned when you use data like that, that there's no connection made there to any specific changes in the Medicaid formulary.

Dr. Charlie Novak

No, in this state, there is no data. I can tell you from working in the ER what percentage of people come in because they've had access to care difficulties and I can tell you that's really quite high, very, very high, and that is how this ties in right now, here and now, to why it's not a good idea to try to limit access.

Committee

My questions are more specifically because I see patients getting admitted that don't have access to any provider or any medicines. Heck, I keep using Stelazine, you know, I mean an old warhorse, because they're on nothing, and that's really the issue rather than they are not on a specific drug.

Dr. Charlie Novak

What you can do there, in regard to that argument, you can get 60% of your patients better with Stelazine or with Invega or with Zyprexa. It's that other 30%-40% that is the problem. So all you have to do is take those numbers and say "Well 30%-40% is if the right drug at the right time, and the right medication, if you can keep them out of the hospital or out of jail, or out of prison or all the places that cost us a lot more money in the long run", so, but that 30%-40% is still a lot of people, and it's a lot of people who have a very serious illness. You can't get specific data, although if you look at utilization companies, insurance companies, Kaiser, the number of people that have looked at this, most of them don't limit access to the medications. They realize the right provider, the right medication, the right psychosocial treatments in a timely fashion, is what really saves you money down the line.

Rachel Strutton-Draft

Question

Let me ask you the same question I asked Dr. Denagy. If you were going to make a list of things that absolutely had to be available for a starting medicine.

Dr. Charlie Novak

Well, again, the reality is, my list representing the chronic and severely mentally ill and representing community treatment, would be all of the long-acting intramuscular medications. We've got Haldol, Prolixin and Risperdal and now we have two more, Invega and Zyprexa. They are the most expensive. They are the ones you want to utilization manage, but on the bottom line, we've got to have them. Those are the ones that really keep people out of the hospital in that population that I'm talking, so that's my go-to list if I had to say "What do I need?" and then, of course in the ER's, we need all the options IM-wise because in the ER's, if you can really get somebody stable in the ER back on a medication, so you have your, you know, all of the medications that are available IM, that's what the ER's need because you do need a variety. We work in a psych hospital setting, and in that setting, we use Haldol and we use Prolixin, we use the old fashioned ones, thorazine, but we also have Zyprexa, Geodon, and we have all the IM preparations for acute treatment, which again in the ER's does keep some people out of the hospital.

Committee

So the essence that we're looking at, the ER stuff doesn't come under us. That comes from the hospital stock. I'm looking at you starting a new patient in your office on a medication, what has to be there. So assuming that if whatever you give works, you've got free access to, your own pick list.

Dr. Charlie Novak

Again, that is why I think open access is so important. What you realize is that the pharmaceutical companies do give you statistics that say "This is what percentage of people the drugs work with". In the field you find out pretty early on, certain medicines work for certain kinds of patients, certain kinds of patients who aren't sleeping or who are agitated respond to certain other medications, and it's very individualistic. Somebody has morbid acute dystonic side effects or tardive dyskinesia type side effects is going to go on a different set of medications, and if you don't have really all the options available to you, you really do things sometimes over and over again giving you the same side effect or the same issue, so I don't think it's a lot different than seizure medicines. There are some people that respond to seizure medicines and if you don't have an armamentarium of seizure medicines, there are some people who are not going to get better, and you do have to look at all the options in that regard. So, it's dang hard for me to say "Well, I can get by without this medicine or that medicine" because there are so options.

Committee

We're talking about getting by without a medicine as your first choice, when you first see a patient. You talk about side effect management, we all know what the side effects are. So if a first medicine, where you don't know what the side effects are, is there a list that you have, are there medications that you rarely or never give as the first medicine that is given in your office?

Dr. Charlie Novak

There are, from my clinical experience, there are medicines that I don't give as a first option, and a few want those and you can have those, but I think that's one psychiatrist's view and experience on what's happened. The Psychiatric Association in general would not have a consistent list of medications that each psychiatrist, all of us, would never say "We never use Geodon" or "We never use Zyprexa" or "We never use Seroquel" or "We never use Invega", I can't represent the Psychiatric Association in that regard.

Mary Seroski

Hi there. I'm the director of the fibromyalgia support group here in Boise, and we are concerned about any removal of any of the FDA approved drugs for fibromyalgia. Also, it would improve the quality of life of the fibromyalgia sufferers, who I call "fibromates", because I suffer from fibromyalgia too.

## Rachel Strutton-Draft

Doctors also prescribe off label for medications for fibromyalgia and what I'm kind of concerned about is that any medications that they prescribe, to let the fibromyalgia patients have those too, because every person is different, every symptom, they react to every medication differently, and fibromates have chronic pain and they find themselves limited to bed rest. This chronic pain reduces their quality of life to such a point that some of them even have suicidal thoughts because it causes fatigue, it causes muscle pains, it causes memory loss, cognitive problems, and such poor quality of sleep that they never reach the healing delta stage. Doctors need the freedom to provide quality care and proper medications to fibromates so they can improve their quality of life, then patients can provide for their family as they need to and want to do. Each fibromate is different and has different reactions to medications, and doctors will need to try different medications to find the right combinations that help the people get to their highest quality of life, so we urge the Idaho Medicaid Department to accept the doctors' prescriptions. The patients are victims of not only of no or low income, but also of the inability to find a good job that would have the benefits because of their illness, a good job with benefits that will help their illnesses, so they can get the insurance to help their illness as well and get off Medicaid. So basically, let the doctors have freedom to try different medications until they get the right combinations. And that's what I ask.

## Barbara Valdez

I am a family member, a member of NAMI, and a caregiver of a client of Region IV Mental Health with schizophrenia, and this letter was written in response to a perceived threat of the cutting of atypical antipsychotics from the Region IV Mental Health Center because of budget cuts. Given the complex range of psychiatric illnesses and the diversity of responses by individual patients with mental illness, I believe that Health & Welfare physicians should be able to exercise full professional judgement, choosing from a complete array of medications for any one patient, just as they do in the private sector. This belief is rooted in our experience with the family member's illness of schizophrenia. Had newer generation medications not been prescribed for him, we believe he would have required further and repeated hospitalizations. As it was, following the illness-related accident in which he lost two fingers, an increased dosage of Risperdal enabled him to return to school part-time and to increase his work hours at McDonald's. In as much as he's prediabetic, other medications could not be prescribed for him. Also, the frequent blood tests required for some older medications could not be administered, given the symptoms he manifested. Later, the consensus of doctors and nurse practitioners with Seroquel, a medication he willingly took, and it would avoid several side effects that had developed with Risperdal. These medications have been essential for his daily work and school life, and to avoid hospitalization. Had such life-saving drugs not been available to him, he probably would not be able to live in the community, and might become a ward of the State. The day will probably come when he will require further change in medications, and we hope he can be given the most effective ones, including newer ones. It is shocking enough that the 600 clients of the Adult Mental Health Center have no psychiatrist. To also deprive them of any medications available in the psychiatric community which are essential to their well being and very existence violates, I think, even rudimentary medical care for brain disorders. Were the citizens of Idaho aware of these issues, I believe they would support the compassionate choice of funding a full spectrum of medications for this most vulnerable population who depend upon them for their very lives. Thank you.

## Sandra Jensen

I am Sandra Jensen. I'm here in two capacities, as a co-director of Idaho Arthritis in Motion, and as a 35 year patient with rheumatoid arthritis. When I first recognized arthritis as a disease, my grandfather had it. I was probably about ten years old and he would ask me to go get his pills. I'd say "How many do you want, Grandpa?", and he said "Bring me eight aspirin and just as many prednisone". When I was diagnosed at age 16, this is what the world I was, that's what I took, aspirin and prednisone for 25 years. They tried me on every NSAID over the years that became available, as it became available, and none of them really worked. I was looking at complete disability and life in a wheelchair. When I was talking to my future husband in my early 20s about getting married, I told him that I expected to be in a wheelchair by the time I was 65. Because of the biologics that came into existence in 1999, I no longer feel like that's going to be my life. I've had numerous joint replacements, and because of the biologics, I plan on living a full and productive life. All arthritises are considered to be the #1 cause of disability in the United States. This is per the CDC. Idaho is expected to, the number of cases of arthritis is expected to double. If you are looking at not supplying these patients with the new biologics, you are going to cost the State more money in disability payments than it would cost to prescribe these drugs when they are first diagnosed. If you do that, then these people can live a full

Rachel Strutton-Draft

and productive life, instead of looking at a life in a wheelchair and not being able to do anything. So please consider continuing to fund the biologics in the future.

Committee

Thank you.

Phyllis Reff

My name is Phyllis Reff and I'm a parent of five children, and I'm going to be discussing antipsychotics, antidepressants, and ADHD medications. These are my five children. They are all on one or more of those medications. My two youngest are adopted. I adopted them knowing they had fetal alcohol and drug exposure, and I will begin by reading something that my daughter wrote last night. She is my 20-year-old with schizophrenia, autism, and depression, etc., and I corrected it, so it's going to be hard for me to see it, but I'm going to read what she wrote pretty much. I'm titling it "I'm Almost 21". "I was born October 26, 1989. Soon after, my mother noticed I was having some developmental issues. After ten years of searching, I was diagnosed with autism. In my junior year of high school, I finally had friends and was getting good grades, but things were about to change. In late 2007, I went up to my mother's room, closed the door, and explained my pain, but only through tears. My mom thought I was joking at first, but when the tears continued to flow, they tried me on some medications after that, but nothing worked. During winter break in 2007, the pain I was in was unbearable." She couldn't describe the pain, partially due to her autism, and it was mental pain, but it affected her whole body. "My parents were in contact with my psychiatric provider practically every day while we were supposed to be enjoying our Florida vacation. I had two hospitalizations and one emergency room trip my freshman year of college. It was a miracle I survived." I have to say that I don't believe that there's a psychiatric patient in Idaho who wants to be in the hospital. They didn't ask to have schizophrenia, bipolar disorder or anything. They want to live and have as full a life as they can have. "During my sophomore year, after lots of medicinal changes, we found a medication combination that worked. Two of my medicines are without a generic. They are the Invega Sustenna monthly shot and Abilify. These are my antipsychotic medications. Without them, I'm as good as dead." I'm going to point out that we, as her parents, never wanted any of our children on medication at all, so we pushed for one medication that would take care of what was happening to her. "My parents were always against medication, actually. When they agreed to provide me with medication, they tried to keep it to a single drug. Unfortunately, we had to change medicines, dosages and medicines, etc., for well over a year. Now I take 6-7 medications just to keep me alive. Without them, life would not be worth living." It's clear to me, and this is from just one of my children, that if she didn't have the medications, she would take her own life because it would be unbearable. We need access to all these medications so that all children, all adults, can live a life worth living. Why bother? Why should they spend their life in a psychiatric hospital, a State psychiatric hospital. That's not life. My oldest son, he has schizoaffective disorder. He's been hospitalized numerous times, however he was hospitalized in another state before he came here. One time was about two months he was in the hospital. He's a brilliant guy. He's got a lot to offer this world, but he's not getting the opportunity until he can re-establish himself through the use of medications. Without them, he doesn't have a life either. He has been hospitalized in Idaho. I can't remember if it's one or two times, because I had two children in the hospital at the same time for psychiatric issues. For my son, Jonathan, here who's much taller now, he has autism and he also has depression and anxiety disorders. He's on Abilify right now. I know things will change for him. He may need additional medications in the future and he may not, and we're working with him to try to keep it to this one medication at this point, but there is no generic for Abilify. My two youngest who were born with fetal alcohol and drug exposure, they have many diagnoses, I won't list them for you, but my daughter, she is on Vyvanse right now for ADHD. We've tried numerous medications, generic and otherwise. When you find a medication that works, if you don't stick to it, they're going to fail and we're going to revert back. My son is also on a medication for ADHD and I don't believe they have a generic available for that, so I hope you'll consider things like step therapy for these kinds of medications, but if a practitioner says to you that this is the only thing that has worked, I think they need to be able to offer it to families.

Committee

Thank you.

Rachel Strutton-Draft

Jane Pace

Hi. My name is Jane Pace, and I'm a patient of Dr. Peppersack's. When I had met her, she was the most, the nicest and very most concerned person I had ever met. She gave me the strength to go forward with my divorce and get rid of my depression and my racing thoughts. Now, all this was done under medication. Without the medication, I would not be able to function. I still do suffer through depression and racing thoughts, but like I said without the Zyprexa, Lamictal, Adderall, Cymbalta; I take all those medications to keep everything under control. I also suffer from rheumatoid arthritis and also short-term memory loss, depression and post traumatic syndrome, and without the medications I wouldn't be able to function, so that's basically all I have to say. Thank you.

Committee

Thank you.

Lisa Wilson for Bhunik Parikh

Good morning, I'm not Bhunik Parikh, just in case you were wondering. I'm Lisa Wilson with Centocor Ortho Biotech and, unfortunately the representative, our PharmD, was not able to make it; Fred Sego. I understand that his public testimony has been made available to you, and I just wanted to have an opportunity to respond, or for him to have an opportunity to respond to any questions that may come up, so I can share his name with Tami Eide or whoever, and if there's any questions that are unanswered today, we can make sure that we get back with you. Thank you.

Laura Litzenberg

Good morning, thank you for the opportunity to provide additional information that's not available to the Committee through the DERP report. I'm here, and I will be speaking about two medications offered from Janssen. I am Laura Litzenberg, and I am a clinical pharmacist with the Health Economics & Outcomes Research Group. The first medication is Invega Sustenna. As we've heard, Invega Sustenna is an injectable medication that is approved for the treatment of both acute and maintenance schizophrenia. The acute indication was based on four clinical trials that showed an onset of action within four days and a difference from placebo at eight days. This was maintained throughout the 13-week period for the acute indication. As far as the maintenance indication, the Invega Sustenna was compared to placebo and, during this time, what we looked at was time to relapse, and there was an independent committee looking at the event of relapses with a blinded study. At the interim analysis, the study was stopped because the difference in relapse was so much greater in the patients receiving placebo than in Invega Sustenna. At the time that the study was stopped, the average length of time for people taking Invega Sustenna was about 230 days. The average length of time that people stayed on placebo was about 100 days. When we looked at the long-term open maintenance in this trial, the patients that were receiving placebo during the double blind portion that were then transferred over to Invega Sustenna had a decrease in hospitalizations from 0.27 to 0.06.

Committee

Can I stop you for just a sec? The studies that we were the most interested in were the head-to-heads versus the other medications. Could you skip to those?

Laura Litzenberg

This is Invega Sustenna as opposed to Invega Oral. So there was a significant difference in the number of people that were hospitalized and the hospitalization rate from the time that people were on placebo to when they were switched to Invega Sustenna, if you look at the people that were on Invega Sustenna for the whole trial and you compared their hospitalization rates prior to being on Invega Sustenna, the rate of hospitalizations decreased from 0.35 to 0.04 patient years. Now, are there any questions on Invega Sustenna, which is the 30-day long-acting injection?

Rachel Strutton-Draft

Okay, then I'll switch over to Invega Oral. This is a once-a-day oral tablet. I'll go into the head-to-head trials with Invega Oral. There was a trial comparing Invega Oral to risperidone looking at patient satisfaction. This was the primary end point of the trial, was patient satisfaction, with the idea that if patients aren't satisfied with their medication, then they become non-adherent to that medication. So in this particular trial, patients that were on risperidone taking a dose of 4 mg or 6 mg that their physicians deemed them at need for a new medication, either because they were noncompliant or because they were not getting the efficacy with the medication, those patients were then randomized to Invega Oral. The randomization was either immediate or delayed. The delayed people continued to receive Risperdal for two weeks. At that point of time, then their satisfaction was looked at, and compared to, the people that were transferred over to Invega, and then all of the people continued to take Invega after that point. What we found is, at that two-week period where some people continued to be on Risperdal, that there was a decrease in their satisfaction, or the number of people that were satisfied completely was 45% with risperidone and 70% with paliperidone.

The next thing I'd like to talk about is comparing Invega to olanzapine with regard to metabolic side effects. In this study, the primary end point was the ratio of triglyceride to HDL, and what we found is that there was a significantly worse ratio in the patients taking olanzapine compared with those taking paliperidone. The paliperidone patients had no difference in their triglyceride/HDL ratio from baseline to end point, and the patients on olanzapine had a significantly worse triglyceride to HDL ratio.

Finally, I'd like to go over the Invega clinical trial in patients with bipolar-1 depression, where the drug was compared to placebo and quetiapine. In this particular trial, patients had a manic or mixed episode, an acute episode. They were randomized to one of those three treatments. What we found is that there was a significant difference between the active treatments and placebo. When we looked at a non-inferiority analysis, there was a non-inferiority between quetiapine and Risperdal. I'd like to ask the Committee to look at the prescribing information on the websites, where they can find the safety and the warnings for these two products. Are there any questions?

Committee

Thank you. Is that the last speaker we have? Okay.

Committee

I'd like to say a couple of things. Some misconceptions I think on how Medicaid works versus other insurances. For Medicaid patients, every drug is available, and when we talk about the preferred drug list, we're talking about starting agents. The other thing is, in regards to mental health drugs, Idaho Medicaid has never, and never has any plans to, of taking someone off of a medication that they are stabilized on. We will never do that, and I think there was some information out there that was a little misleading, and I just wanted to clarify that.

Committee

Yeah, we're not stupid (joking and laughter).