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UNOFFICIAL TRANSCRIPT*
WASHINGTON STATE PHARMACY AND THERAPEUTICS COMMITTEE MEETING

October 17, 2007
SeaTac Marriott Hotel
9:00am – 4:00pm

Committee in Attendance:

Angelo Ballasiotes, Pharm D
Robert Bray, MD
Carol Cordy, MD (Vice Chair)
Alvin Goo, Pharm D
Jason Iltz, Pharm D
Janet Kelly, Pharm D
Daniel Lessler, MD (Chair)
T. Vyn Reese, M.D.
Patti Varley, ARNP
Kenneth Wiscomb, PA-C

Due to a technology problem, the first portion of this meeting, including the new review of the drugs to treat constipation and the update review of beta blockers was not recorded.

Dan Lessler: ...number of shorter updates or scans to go through and the first one...the first scan is on the new antihistamines. So we...Kim, we've got your first...your title slide up. So you can take it from there. Thanks.

Susan Carson: Okay. Thank you. Alright. So, yeah, this is a preliminary update scan. Is this the first one of the scans you've done today?

Dan Lessler: Yes. This is the first of the scans.

Susan Carson: Okay. So I'll go into a little more detail about the methods. So this was done in May 2007. The last complete update report was done in April 2006 with searches through August 2005. The next slide shows the inclusion criteria for the report. We included both adults and children with seasonal allergic rhinitis, perennial allergic rhinitis or urticaria. Next slide.

* For copies of the official audio taped record of this meeting,
please contact Regina Chacon at (206)521-2027 pdp@hca.wa.gov.

And then the four newer antihistamines that were included in the report are shown on the sides—Cetirizine, Loratadine, Fexofenadine and Desloratadine. Next slide.

So for this preliminary update scan we searched MEDLINE Daily Update and In-Process and Non-Indexed Citations specifically looking for randomized controlled trials and systematic reviews. As part of our process we also searched the FDA and Health Canada web sites for any new safety alerts and also we looked for any new drugs in the class and any new indications since the last report. So that's the process for preliminary update scan. This slide is actually incorrect. The searches for this update scan were conducted through April 2007, not 2006. So more recent than that.

So this slide shows our results. Searches resulted in 255 citations and of those there were 13 potentially relevant trials including 2 head-to-head trials, 9 active-controlled trials included drug versus another comparator and 3 placebo-controlled trials. We also identified 4 potentially relevant systematic reviews and you should have copies of the abstracts of all of these potentially relevant studies in your handout of the scan report.

I'll just say a little bit about the citations that we identified. The head-to-head trials there were 2 of them and one was desloratadine versus fexofenadine in seasonal allergic rhinitis. That was a two-week study and this is the first head-to-head comparison of these two drugs in that population. The other head-to-head trial was cetirizine versus loratadine for perennial allergic rhinitis and both groups also received pseudo Ephedrine and this was a four-week study. And then the 3 placebo-controlled trials all covered desloratadine and there were no placebo-controlled trials of any of the other drugs.

And then the four systematic reviews one of them was non-comparative. It covered only desloratadine and then another looked at safety in pregnancy, safety of the antihistamine when used during pregnancy and the other two looked at...well, one looked urticaria and the fourth looked at allergic rhinitis and urticaria for all of the drugs.

And then additionally there were some active controlled trials. There were several that looked at combination treatment with more than one antihistamine and there were some that compared and included drug to montelukast. Moving on to the next slide.

New drugs or indications – there were no new drugs or indications since the last report, but there is a new formulation of fexofenadine, an oral suspension formulation and that's been approved for seasonal allergic rhinitis in children 2 to 11 and urticaria in children 6 months to 11 years of age. Next slide.

There really aren't any significant new safety alerts. There is a...some new adverse reactions for desloratadine, some new things added to the list of possible adverse reactions and then there is a new...results of a study in mice that showed no increase in tumors with the use of desloratadine. Other than that no new safety alerts. That's really the new information for that drug class.

Dan Lessler: Great. Thank you. I was going to open it up for P&T Committee Members for any questions for Kim about antihistamines. Bob?

Bob Bray: Regarding the new report of the palpitation, seizures and psychomotor hyper reactivity, was that related to excess dosing or is there any more information about that?

Susan Carson: No. The text of the alert is in the scan report and I don't believe that it was related to excess dosing observed during clinical practice.

Dan Lessler: Other questions? And it looks like there is...we're going to move to stakeholder input here. Kim, are you doing the next two scans or is Marian going to do...

Susan Carson: I'm doing TZDs and then someone from UNC is doing antidepressants.

Dan Lessler: Great. Okay. So there is one person for stakeholder input and that's Russ Fotheringham. Again, we would ask that you identify your affiliation and then limit your comments to three minutes, please.

Russ Fotheringham: Absolutely. My name is Russ Fotheringham, regional account manager with Schering-Plough Pharmaceuticals and would like to briefly share a few points with you regarding Clarinex today. First, Clarinex is a once-a-day non-sedating antihistamine that's approved for seasonal allergic rhinitis and the more difficult to treat perennial allergic rhinitis and chronic idiopathic urticaria. Whereas Claritin only has seasonal allergic rhinitis and chronic idiopathic urticaria indications.

Next, Clarinex is well tolerated and has not been associated with clinically relevant drug interactions when administered with other widely used agents such as Azithromycin, [inaudible] and [inaudible]. Those these have been shown to affect the bioavailability of Allegra. Additionally, Clarinex is not effected by food and does not have a warning regarding use of antacids.

Lastly, Clarinex syrup is the only non-sedating antihistamine approved for perennial allergic rhinitis for pediatric age group 6 months and older. Thanks; appreciate the opportunity to share that information with you.

Dan Lessler: Great. Thank you. Any questions? Okay. So at this point I'm wondering if people could look at our most recent motion, which...actually, can you

scroll down on that most recent one that we...so people can take a look? I think was it Jason that actually...

Jason Iltz: That looks like it's correct. This is Jason. I don't know that the new information we have would really change the motion as I crafted it originally. It's interesting though to me in terms of pregnancy rating that Loratadine is still B and then Desloratadine is pregnancy C even though Desloratadine is the principle metabolite that is active. So that doesn't make a lot of sense to me. I don't know if somebody else has something they can share. Is Miriam still on the line? Is that a correct assessment?

Dan Lessler: It's Kim.

Susan Carson: It's actually Susan.

Dan Lessler: Sorry.

Susan Carson: Yeah, you know, the only new information on that would be that systematic review that was published in 2005. For these scan reports we don't review the whole article or assess the quality. I wouldn't be able to comment on, you know, the...how this information would play into your scan, but the whole text of that article might be something that would be used in your decision making.

Dan Lessler: So I'm wondering, Jason, if you're comfortable with your prior motion...

Jason Iltz: Sure. After considering the updated evidence of safety, efficacy and special...oh, first of all, we need to accept that scan. Is that true? So I move to accept the scan as an adequate review of this drug class.

Dan Lessler: Is there a second? Okay. There's a second. All those in favor say I.

Group: I.

Dan Lessler: Opposed same sign. Okay.

Jason Iltz: I guess we should insert what the actual class is. Okay. After considering the updated evidence of safety, efficacy and special populations on newer antihistamines for the treatment of seasonal allergic rhinitis, perennial allergic rhinitis, and chronic idiopathic urticaria, I move that Cetirizine, Desloratadine, Loratadine and Fexofenadine are safe and efficacious. The Washington Preferred Drug List should contain a product that is non-sedating and FDA approved...and an FDA approved product for pregnancy category B, and must make available an FDA approved product for the special population of patients 6 months to 2 years of age. Newer antihistamines can be subject to therapeutic interchange in the Washington Preferred Drug List for the treatment of seasonal allergic rhinitis, perennial allergic rhinitis and chronic idiopathic urticaria.

Dan Lessler: Is there a second? Okay. Any other discussion?

Ken Wiscomb: This is Ken Wiscomb and this is probably more for Siri and I realize that decongestants are not part of the formulations we've discussed here, but do we need to make a statement about not covering these products when they are attached to a decongestant?

Siri Childs: Well, again, this is Siri and that would be up to you to make that distinction. Currently, we do not have the combination products on the PDL.

Dan Lessler: I think the motion best stands as it is. Any other comment?

Patti Varley: This is Patti Varley. Tell me again the thinking behind if the scan shows and there's that new warning in 2006 about Loratadine why it's not being addressed.

Dan Lessler: Desloratadine.

Patti Varley: I'm sorry, Desloratadine.

Dan Lessler: Anybody want to...my assumption is that that is a reported adverse effect through...and Susan, correct me. Is that through sort of the FDA reporting system?

Susan Carson: Yeah. These adverse events were added to the...possible adverse reactions were added to the list of the existing ones and there may even be similar warnings for the other drugs. So I don't want to make too much of that. There's not a black-box warning or, you know, there wasn't a new FDA alert issued for these adverse reactions.

Patti Varley: Thank you.

Dan Lessler: Thanks for that clarification. Any other? Alright. So the motion is on the table. It's been seconded. All those in favor say I.

Group: I.

Dan Lessler: Oppose, same sign. Okay. And we can move on to the next scan. So Susan you're doing that for TZD?

Susan Carson: I'm doing TZD's, that's right, yeah. Okay. So you have the slide up for that?

Dan Lessler: Actually, we need just a second here. Alright. The cover slide, the title slide.

Susan Carson: Okay. Thank you. Okay. So this is a preliminary scan report, which was...you'll see it was done in May 2007 and the date of the last report

was May 2006 with searches through 2005. Because of this you...I'm sure you're all aware there has been a lot of new safety information that's come out both from the FDA and also in publications about safety of both pioglitazone and rosiglitazone. Because they came out subsequent to this scan report it's not included, but I did just want to...it's not included in this scan report, but I did just want to...okay. The next slide shows the inclusion criteria where um...oh, and I just wanted to say that there is a full update of this topic currently in progress wherein we're at the stage of finalizing the key questions for this report. They are going to be posted this week for public comment.

Dan Lessler:

Do you know when that full update will be available?

Susan Carson:

Well, it should be, I believe, nine months from now. We're just now starting the report. So the inclusion criteria for all our reports were adults with type 2 diabetes and adults with pre-diabetes or metabolic syndrome with the definitions on the slide.

The next slide there are two included drugs, Pioglitazone and Rosiglitazone, Actos and Avandia. So for preliminary update scan...again, our methods...well, for this review we searched the literature through April of 2007 searching specifically for randomized controlled trials and new safety information in the FDA and Health Canada Reports...web sites, I'm sorry. And then we...in the report we include the abstracts of any potentially relevant studies that we found. So the results show that we came up with 181 citations and after review of these citations there were 22 potentially relevant new trials in 24 publications. And for the new drugs and indications there were no new drugs in the class added.

The next slide shows...well, I'm sorry. If we can go back to that slide that says results I can just tell you a little bit about the studies that we found. There were two head-to-head trials that were identified both for a diabetes prevention and one of these is the Dream Trial and some new safety information came out in that study also. In the next slide new safety alerts; the FDA issued in 2006 a safety alert for pioglitazone for an increased risk of macular edema. There was already an alert of the same type for rosiglitazone for possible increased risk in macular edema. We also identified new safety information about increased fracture risk in women and this is for both of the drugs. One comes from a randomized controlled trial of rosiglitazone and GlaxoSmithKline reported that there was an increased risk in fracture in women taking the drug and then the FDA analyzed safety data and found that there was also an increased risk of fracture in females taking pioglitazone. So you'll notice the absence of the newer safety information in this update scan. The FDA in August of 2007 issued an alert that there may be an increased risk of heart failure in patients taking pioglitazone. Previously, I believe in May or late April there was another FDA alert of the increased risk of cardiovascular events

for possible increased risk of cardiovascular events in patients taking rosiglitazone. And that's the new information.

Dan Lessler: Great. Thank you. Are there questions from committee members for Susan?

Vyn Reese: This is Dr. Reese from the committee. Is there any thought about the mechanism that...of action of the glitazones on the bone marrow and why they cause this fracture risk?

Susan Carson: No. I'm sorry; I wouldn't be able to answer that because I haven't seen the full study.

Dan Lessler: Any other questions? Okay. Susan, can you stay on with us just for a few more minutes?

Susan Carson: Sure.

Dan Lessler: We're going to take stakeholder input. First is Dr. Gene Felber from Takeda.

Gene Felber: Hi. Thanks again for allowing me to speak. I want to speak about Actos and my sponsor is Takeda. There's been a lot of discussion as just mentioned from the recent FDA hearing, which was really prompted from an meta analysis published by Nisson and colleagues on rosiglitazone. As such there was some follow up meta analysis by Lago more recently and also by Linkhoff on pioglitazone. In response to this I really just want to make two key points. The first one is that the FDA has reviewed the safety information and you've gotten here from the update as to what that safety information is and the conclusions of that are as it pertains to our label. Number two, the meta analysis, all of them, have been criticized for mythological weaknesses, potential selection bias, and using trials using surrogate outcomes rather than to derive the cardiovascular outcomes. As it pertains to rosiglitazone there's sort of been a mixed signal in that published literature, but what's clear is that the data on pioglitazone are consistent. That's randomized clinical trials, the meta analysis and more recently an outcomes analysis by Garrett and colleagues. Of all of these studies Proactive is the only completed randomized placebo controlled clinical trial that was designed statistically empowered to adequately assess and detect the cardiovascular outcomes. So I just want to spend a few seconds on Proactive. As you recall Proactive was published in Lancet back in 2005. It looked at pioglitazone on secondary prevention of macular vascular events. There was more than 5,000 patients with type 2 diabetes and had a history of macro vascular disease. The primary composite endpoint included seven different macro vascular events of varying clinical importance. The primary outcome was not statistically significant. There was a reduction observed in macro vascular events, about 10% among those using Actos. And then interestingly there was a secondary endpoint that looked at all cause of mortality—heart attack and

stroke, which did show a statistically significant 16% reduction in the c group. There's been some subgroup analysis that have come out of Proactive. One was looking at those who had prior MI. There was a significant risk reduction, 28% of the currents of a second or subsequent MI in the pioglitazone group. Another trial looking at just history of prior stroke...or another subgroup analysis, excuse me, and they also found a significant risk reduction, 47% of those for recurrent stroke of those taking Actos versus placebo. It was mentioned that there was a response to fracture risk that was noted in rosiglitazone. Takeda conducted their own analysis and we found an increase...it's about .8 for 100 patients. We're still investigating what the cause is of that. I think it's worth...it's not clear at this point. And then in summary I really wanted to highlight something that was published in an excerpt that was published by Winklemeier and Solomon. This was published in [inaudible] in September. Now these guys are from Harvard and not affiliated with industry. And what they had concluded was that of the two TZDs currently marketed although both represent the same class of drugs the drugs have strikingly different profiles in their effects of ischemic heart cardiovascular disease. And since much of the morbidity and mortality associated with diabetes is due to macro vascular ischemic complications then small increases or decreases in the relative risks translate into major effects as it pertains to public health. Thank you very much.

Dan Lessler: Thank you. Any questions? No questions. Thank you. Next is Dr. Brad Wallum.

Brad Wallum: Thank you for allowing me to speak. I'm here on behalf of my patients and colleagues on the Eastside and the Bellevue region to try to address any concerns you may have related to TZDs in general. I did my fellowship-training program in endocrinology and nutrition, metabolism and I've been in clinical practice and diabetology for about 20 years currently in Bellevue and have a teaching position at the University of Washington. My basic message is that diabetes is very difficult to treat—one of the most complex disorders to treat because there's multiple mechanisms that cause hyperglycemia in diabetes and we currently need every potential armormentarium that we can get to help to control blood sugars. Clinical trials have clearly shown that one's risk for complications not only from diabetes, but from macro vascular disease such as bio cardial infarctions and strokes are reduced if one lowers blood sugars. So the new American Diabetes Association goals are calling for individual hemoglobin A1Cs of six or less. In order to do that we need to have all available potential help that we can get to treat diabetes.

As it relates to TZDs they basically attack the major path of physiologic cause for hypoglycemia, which is insulin resistance. No other class of drugs currently in the market in the United States addresses that basic path of physiology. So I would like to suggest that we have TZDs available to our patients and both of these agents, both pioglit and rosiglit are excellent drugs. Rosiglit has more clinical research than any other drug ever tested

for treatment of hypoglycemia. So we have a lot of data, a lot of information as it relates to these drugs. In terms of any comparisons between Rosi and Pio we do not have any head-to-head clinical trials to address that issue. Currently as it stands when I see patients in my practice who come in and have questions based on the media attention that's recently been put forth since May of '07 we try to review what the patient's options are and in most cases if we do not have a TZD available to treat our patients we're looking at injectable products or one of the insulin products, which in their own right carries significant risk for insulin reactions and other multiple complications especially for older individuals who need to have good vision, have good agility, have good cognitive function to use injectable products. There are other concerns, as well.

So in summary I personally feel that we need to have available for good patient care drugs that attack insulin resistance. Both TZDs are good drugs. We have lots of data for both of these agents. There's no evidence that one of these two TZDs is better than another at this time. There's no head-to-head trials that address that issue. One cannot rely on meta analysis or observational studies to make good clinical judgment for patient care.

I'd like to finish early in case there's any questions or any controversy as it relates to this. Certainly I get phone calls every day from doctors, insurance companies and patients on this subject. I'd be happy to address any questions you have.

Dan Lessler: Are there any questions? No. Okay. Thank you.

Brad Wallum: You're welcome.

Dan Lessler: Next is Dr. Rick Pham.

Rick Pham: Hi. My name is Rick Pham and I'm a medical scientist speaking on behalf of GlaxoSmithKline and thank you for allowing me to speak today. As Dr. Wallum stated I think the cornerstone of treatment for type 2 diabetes is aggressive lowering of A1C and blood sugars and with Avandia we actually have a head-to-head study comparing durability of glycemic control between Avandia, Metformin and Sulfonylurea where Avandia has been shown to be superior in controlling blood sugars out to almost five years versus Metformin and Sulfonylurea. In light of the recent events surrounding this meta analysis the only association that's been made as far as increased myocardial ischemic risk with Avandia is the meta analysis published in the New England Journal and as Dr. Wallum stated meta analysis can actually have many potential problems and limitations as did the New England Journal meta analysis where the author himself actually states that because of the small, short-term trials and because of the small numbers of events that [inaudible] were very wide and there were considerable uncertainty in the magnitude of the hazards.

Since then GlaxoSmithKline has actually come forth with a lot of cardiovascular data from long-term prospective randomized clinical trials like the Adopt Study, the Dream and the Record Interim Analysis, which is a cardiovascular outcome study scheduled to end in December of 2008 and within these studies there has been no association or risk found between the Avandia treated patients versus the control arm. And also in fact when we commissioned three observational studies of three different [inaudible] databases consisting of over 1.3 million diabetic patients there has been no association or risks found between the Avandia treated patients versus Actos versus insulin versus Metformin and Sulfonylureas.

And also currently there are four large on-going clinical trials involving Avandia. The Record Study, the Accord, the [inaudible] 2D and the VA Diabetes Trial. All these trials consist of over 18,000 patients and has been ongoing for the last three to five years and the data, the safety and monitoring board of these trials have not found any safety signal and have confirmed that these trials should continue. So with the robust evidence that has been brought forward that has not shown any association of any risk of myocardial infarction with Avandia I think that, you know, we can be assured that [end of Side A]

[Side B]

Robert Bray: This is Dr. Bray. Is your company pursuing any other indications currently than the current FDA approved indications for the drug?

Rick Pham: I'm not aware that we are. I don't think that we are.

Dan Lessler: Other questions? And while we have Susan on the phone I'm wondering if there are questions...further questions for Susan?

Vyn Reese: This is Dr. Reese. Susan, as I look at the literature I still have safety concerns about the TZDs. Cardiovascular risk is unclear and there are conflicting studies. I'm concerned about congestive heart failure, which is clearly a risk for both of these drugs across all studies and also the risk of fracture, which is a risk for both of these drugs across studies. We have safer drugs that are out there and I'm just wondering if you'd comment on those risks and there are warnings on them by the FDA.

Susan Carson: Um, yeah, both of the drugs have warnings about increased risk of heart failure and then there's this new information, you know, that hasn't been fully reviewed, but there is some concern. Our report was...the focus was the comparative efficacy, effectiveness and safety of the two drugs and we concluded that there was no evidence for any differences in those...for either efficacy or safety for the two drugs.

Dan Lessler: Other questions or comments? Susan, thank you. We can let you go and I guess just...somebody will be calling in from you UNC then?

Woman: Yeah, right. Okay. Thanks. Bye, bye.

Dan Lessler: Bye, bye.

Patricia Thieda: Patricia [inaudible] from UNC.

Dan Lessler: Oh, hi, Patricia. This is Dan Lessler. I'm the chair of the committee. Actually, you're welcome to stay on the line with us. We're just...we're just sort of entering into our deliberations around the TZDs and...

Patricia Thieda: That's fine. I just wanted to let you know that I was available for when you were ready.

Dan Lessler: Okay. Do you want to maybe...if you'd like maybe call us back at about 25 of the hour.

Patricia Thieda: It would be my pleasure.

Dan Lessler: Okay. Thank you.

Patricia Thieda: Alright. Goodbye.

Dan Lessler: Okay. So folks can see our previous motion regarding this class of medication and I'm wondering if there is any general comment at this point?

Ken Wiscomb: This is Ken Wiscomb. Given the fact that this scan didn't include the new FDA warnings I'm wondering if it wouldn't be best just to put off any deliberations for the nine months that it's going to take for a new report and just leave things as they are. I would be concerned that we...because of the timing if we made a new statement about safety and efficacy it might appear that we hadn't taken the new data...or we had taken the data into account when in fact we're not.

Dan Lessler: Other...Bob, do you want to comment?

Bob Bray: I agree with Ken. I think that that's a good point.

Dan Lessler: Janet, was this your motion from...

Janet Kelly: I don't have a problem with it. I agree, I think we want to keep it the way it is until we get that data in. It implies if we make a motion that we reviewed it. So it seems reasonable.

Dan Lessler: So would someone want to make a motion to this then? Actually...we need to accept the scan. I apologize formally. So first is there a motion to accept the scan?

Bob Bray: I move that we accept the scan.

Dan Lessler: Thank you. And a second? Okay. Angelo, a second. So all those in favor please say I.

Group: I.

Dan Lessler: Oppose, same sign. Okay. So next is whether or not somebody would want to make a motion just about deferring consideration until there's a more comprehensive review of this class, which would be in nine months.

Ken Wiscomb: I would move that we defer consideration of this class until such time as the new data is available and included in the scan.

Dan Lessler: Actually, it will be a full update—such time as a full update. That's been seconded by Janet. Alright. All those in favor say I.

Group: I.

Dan Lessler: Opposed, same sign. Okay. So the motion passes. Duane?

Duane Thurman: [inaudible]

Dan Lessler: Yeah, we're not changing it. We're just going to leave everything as it is. So I probably should have had the folks from UNC stay on the line a little bit longer, but...do you have her phone number? Yeah. Thanks. Are you there?

Patricia Thieda: I'm here. This is Patricia [inaudible].

Dan Lessler: Patricia, hi, this is Dan Lessler. I'm the chair of the committee.

Patricia Thieda: Hello, Dan.

Dan Lessler: Nice to meet you here by phone. So you're going to be doing the scan on the antidepressants?

Patricia Thieda: Correct. The drug class review on second-generation antidepressants.

Dan Lessler: Right. So we have...we've got your title slide up and you can take it from there.

Patricia Thieda: Thank you. Good afternoon everyone. This is actually a preliminary scan report following update three and the last update we did on this report was as of September 2006, with searches through April of 2006. So for this report we have searches through August 2007...or excuse me, July. So for the drug class review the populations that we included on the next slide are populations including adult outpatients with depression, anxiety, premenstrual disorders, and children with major depressive disorder. The

interventions that we looked at...there were 11 with no new ones being applicable at this time including fluoxetine, sertraline, paroxetine, citalopram, escitalopram, venlafaxine, fluvoxamine, mirtazapine, duloxetine, bupropion, and nefazodone. And these are the 11 treatments used in the United States. The literature search that we conducted was the MEDLINE, Ovid MEDLINE, Ovid MEDLINE Daily Update, In-Process and other Non-Index Citations from April 2006 through August 16, 2007 using terms that included the drugs and the indications as discussed in previous slides. We did limit it to humans in the English language and randomized controlled trials. Then actually I went into the FDA web site for cedar and the FDA, as well as Health Canada to look for additional alerts concerning new drugs and indications and safety alerts.

We then exported all the new citations into endnotes and duplicate citations were removed. Basically what we found overall is I found 258 new citations. Once I reviewed these I found 90 new potentially relevant studies that fell into the criteria as established by our previous reports and these are included in Appendix A. And there's also a table that shows there's...the conditions...when I went through I broke it out by the conditions being treated because this is a fairly complex report because of the number of drugs and indications and in 7 of the 20 studies in pediatric major depressive disorder our results from the treatment of adolescent depression study, a fairly large study that was conducted. So in addition to those 20 pediatric MDD studies there were 3 new studies in OCD or obsessive compulsive disorder. Major depressive disorder in adults there were 30. Social anxiety disorder was 1. Generalized anxiety disorder there were 6 new studies. Premenopausal dysphoric disorder there were 3. Post-traumatic stress disorder there were 8. Panic disorder there were 6 and additionally there were 13 other articles of interest for background or perhaps observational studies that looked at safety outcome.

So concerning the new safety alerts...oh, I'm sorry. Does anybody have any questions at this point?

Dan Lessler: There is a question.

Patti Varley: Is that premenopausal disorder or premenstrual?

Patricia Thieda: Premenopausal dysphoric disorder was the term that we used for the search.

Patti Varley: I've never seen it described that way.

Patricia Thieda: Well, our librarian who we rely on for this type of thing uses that basically, from what I understand, as a mesh term and it covers both of those as indicated by the PUB MED, which is the NHI.

Dan Lessler: I think probably it is premenstrual, but why don't we...it's okay. It's a fine point.

Patricia Thieda: Oh, you're right. I'm sorry. I'm just nervous.

Dan Lessler: That's okay.

Patricia Thieda: Now that you say that I'm like, "Oh, premenopausal. That doesn't work." It is premenstrual dysphoric disorder and I apologize, ma'am. Any other questions before I continue?

Dan Lessler: No.

Patricia Thieda: Okay. Some of the more interesting things is that there was a plethora of new safety alerts that were found. I thought to be a plethora. There were five distinct new safety alerts. The first one was concerning triptans. The selective serotonin reuptake inhibitors and selective serotonin/norepinephrine reuptake inhibitors and serotonin syndrome and the concern there is combining the triptans with any of the other two drugs can lead to an increased change of serotonin syndrome according to the FDA alert. The second alert was concerning the use of SSRIs in treatment of depression during pregnancy. There were two parts to this morning; one which said that when patient's come off of their drugs according to the FDA they can experience relapse. The other one is a possibility of some...a minor chance, I guess, of increased problems following pregnancy with...during treatment with depression.

The next one was concerning Effexor or venlafaxine extended release capsules and that particular one was concerning the possibilities of problems with overdose. The fourth was unsafe misrepresented drugs purchased over the internet, which included escitalopram and the fifth one was a fairly important one I believe or some would say it's important is the anti-depressant medications. All have this new black label warning concerning the use of this drug in young adults from 18 to 24 with increased chances of suicide. This was a warning issued by the FDA. That was [inaudible] at the FDA. When I looked at Health Canada I did not see any new alerts posted there and that is what I found in the scan. Questions, please?

Dan Lessler: Yeah. Thank you. Are there any questions for Patricia?

Vyn Reese: This is Dr. Reese. I understand there's a population study that's looking at suicide rates in young adults and if that rate has increased since the warnings on anti-depressants in young adults. Would you comment on that or do you have any other knowledge about that?

Patricia Thieda: I have not heard of that study that you...this is a new study that's come out?

Vyn Reese: Yes.

Carol Cordy: It's actually a study that recently was published showing that since the FDA warning and the decreased use of antidepressants that there had been a decline over time in adolescent suicides and now it's going back up. On the other hand in some of the studies like the TADS study that you referenced there is risk without CBT with fluoxetine alone that you have increased risk. So, you know, I think the data says they need treatment, but they need more than just the meds and that is my interpretation as a child person.

Patricia Thieda: I would suggest that there are many factors involved.

Dan Lessler: Other questions for Patricia? So Patricia can you stay on the line just a few minutes while we take stakeholder input because sometimes there are questions that arise from that input that is helpful to have you available to comment on?

Patricia Thieda: It would be my pleasure.

Dan Lessler: Thank you. First is Mark Shigihara.

Mark Shigihara: Thank you very much. I'm Mark Shigihara and I am an employee of Wyeth, but actually the reason why I'm standing here before you is the second hat I wear. I'm a card-carrying employee of the University of Washington and I'm an affiliate assistant professor with their school of pharmacy and just to show that I play no favoritism I'm also on the affiliate faculty for WSU also. What I specialize in is evidence-based medicine review and formulary management and part of what the University asked me to do is take final year Pharm-D students and discuss evidence based medicine and formerly management with them and included in that is they do a four- to six-week therapeutic class review of various drug classes including antidepressants. So every year we have a new refresh regarding the evidence on the antidepressants. So I'd like to share with you some of that data and in the discussion because I am connected to Wyeth I'll do my best to refer to Effexor or Effexor XR so that you get the fair balance on which...where the data is either for best of the products or for only one of the products.

Dan Lessler: I just want to remind you your comments are limited to about three minutes.

Mark Shigihara: Yeah. So moving first to the review of the material last year I was also asked to present and the formulary committee should be commended in terms of their data analysis and Effexor and Effexor XR were both added to the formulary based upon the evidence and when we look at efficacy still Effexor and Effexor XR have robust remission data and the APA (American Psychiatric Association) has...seem set to make remission their gold standard of patient care. So both products are working towards that area.

Also what's unique to Effexor XR is the data that was developed for...in a span of two years for prevention of recurrence of depression for very important...or looking out beyond a short term acute coverage and so the Effexor XR has this two-year unique data and what's significant about this is beyond the result for prevention of recurrence the fact that it was done as monotherapy and so if the state is looking for preferences for monotherapy then this drug based upon [inaudible] that prevents studies of that area.

Another efficacy point is that Effexor XR has the unique data for all the [inaudible] when it comes to depression coverage plus an anxiety spectrum where GAD, FAD and panic disorder is included and given what providers have indicated was...they see depression stand alone patients, but comorbidity with depression is common and anxiety is a common component of that.

Finally, moving to safety – what we need to examine is that some of Dr. Bray's earlier comments...Effexor and Effexor XR are on the market for 12 years. Over 20 million patients and finally it's looking for a comparison between the XR versus the IR...the XR in that time has demonstrated less propensity for the blood pressure increase. Thank you very much.

Dan Lessler:

Thank you. Are there any questions? Thanks. Next is Dr. Matt Trifilo.

Matt Trifilo:

Good morning ladies and gentlemen. My name is Matt Trifilo and I'm here today representing Forest Pharmaceuticals. The purpose of my being here is to provide you with an update and some key findings concerning escitalopram Lexapro that have appeared in literature over the last 24 months. As you know, Lexapro is a member of the SSRI class currently indicated for both major depression and generalized anxiety disorder. In March 2005 Moore and colleagues published one of the first head-to-head comparisons of Citalopram versus escitalopram. The results demonstrated that patients with escitalopram had a significantly greater mean reduction on the [inaudible] and a statistically higher percentage of both responders and remitters at end point compared to citalopram. A study published in 2006 by Lamb and Anderson a meta analysis was conducted comparing escitalopram to both citalopram and placebo. The study designed and examined data from three clinical trials and involved over 1,200 patients. The results found that as the severity of depression increased so did escitalopram's effectiveness. In contrast citalopram's efficacy dropped to placebo levels as the degrees of severity progressed. When compared to other SSRIs or SNRIs for major depression or general anxiety Lexapro demonstrates the equivalent or enhanced efficacy is noted in numerous clinical trials. A recently published article by Kohn and colleagues earlier this year compared escitalopram 10 to 20 mg to duloxetine 60 mg per day. The authors concluded that escitalopram had equivalent or greater efficacy compared to duloxetine as demonstrated by higher response intermission rates for the lower rate of discontinuations due to adverse events. The

published data found that 87% of those receiving escitalopram compared the study compared to only 67% of the duloxetine treated patients. Adverse events were the leading reason for discontinuation at a rate of 2% for escitalopram compared to 13% for duloxetine.

As treatment adherence is a critical factor in achieving successful outcomes and that adverse events are the most frequent reasons for premature treatment and discontinuation it's been recently reported that the economic costs and managed care organizations for duloxetine treated patients discontinuing such treatment produces an additional \$373 in health care costs per patients. Lexapro is dosed once a day without regard to food, no adjustment is needed for mild to moderate renal insufficiency or hepatic failure. [inaudible] is the narrowest in the class with only one step titration if needed. These characteristics contribute to Lexapro's outstanding efficacy, excellent tolerability and safety and may lead to improved compliance and successful outcomes for all patients especially those with complex, multiple drug regimens. Lexapro is a cost effective treatment for patients with both major depression and generalized anxiety disorder. Thank you.

Dan Lessler: Thank you. Any questions? No. Thanks. Next is Dr. Christian Nguyen.

Christian Nguyen: Good morning. My name is Christian Nguyen and I'm with the Outcomes Research and Medical Divisions of Eli Lilly and Company. Thank you for the opportunity to make some brief comments today supporting the availability of Cymbalta for Medicaid patients in Washington. Cymbalta is a selective serotonin and norepinephrine reuptake inhibitor indicated for the treatment of major depressive disorder or MDD, generalized anxiety disorder or GAD, and diabetic peripheral neuropathic pain or DPNP. The approved dosage ranges are 40 to 60 mg for MDD and 60 to 100 mg a day for GAD and DPNP. Remission should be the goal of antidepressant therapy and it's important to treat patients to full remission as patients that fail to achieve remission face a higher rate of relapse. In clinical trials for MDD Cymbalta demonstrated remission rates of 43 to 44% as compared to 16 and 29% for placebo. Cymbalta demonstrated a rapid onset of activity as early as one to two weeks and sustained efficacy across a wide range of depression symptoms in clinical trials. However, according to APA antidepressants efficacy may take up to four to six weeks or more in some patients.

Depressed patients with lingering painful physical symptoms have a high risk of relapse and a time to achieving remission is longer. Cymbalta demonstrated efficacy in treating the painful physical symptoms associated with depression with significant improvement in overall pain severity seen as early as week two.

Efficacy of Cymbalta and the treatment of generalized anxiety disorder was established in one nine-week six dose and two 10-week flexible dose trials in adults. In all three studies Cymbalta demonstrated superiority

over placebo as measured by the greater improvement in the Hamilton anxiety rating scale total score.

In clinical trials for DPNP Cymbalta 60 mg once and twice daily had a significantly greater improvement in average pain severity compared to placebo.

Cymbalta carries the antidepressant box warning for increased risk of...increased [inaudible] in children and adolescents although it is not indicated for treatment in these patients. Additionally, Cymbalta should not be used in any patients with hepatic insufficiency, chronic liver disease, N stage renal disease, renal impairment or substantial alcohol abuse. Nor should Cymbalta be used in combination with MAOs. Because of a potential risk of serotonin syndrome, Cymbalta has a warning against [inaudible] use with serotonergic drugs including triptan and serotonin pre-cursors such as tryptophan.

In conclusion, Cymbalta is a balance and potent dual acting antidepressant. It offers high remission rates as well as broad and rapid relief of both emotional and physical symptoms of depression. It also offers reduction of GAD and DPNP symptoms and a favorable safety and [inaudible] profile. Thank you.

Dan Lessler: Thank you. Any questions? No. Okay. And finally Kathleen Potter.

Kathleen Potter: Hi. I'm Kathleen Potter. I'm a psychiatric nurse practitioner. I'm the founder and director of Mountainside Mental Health, which is a private practice in Pierce County serving approximately 3,000 Medicaid and Medicare recipients. I'm here to talk about Lexapro and it's value in my practice. There are low side effects, easy to use and it works fast. Let me illustrate that with one brief patient profile. Sally, major depressive disorder, generalized anxiety disorder, mid 50s, came to me poly pharmacy—list of drugs. None of them were working effectively. She was calling the crisis line. She was in and out of [inaudible] triage, brief stays in the ER, a few longer hospital stays. We decided to clean up her med list and currently she's on Lexapro 20 mg. In the past three years that she's been on that no crisis line calls, no trips to crisis triage, and no hospitalizations. She's living a life again. She wasn't doing that before. So I would really encourage you to think about Lexapro. I depend heavily on samples, patient assistant programs, but there's nothing like being able to give a patient a prescription, have them go to the pharmacy and have it filled. Thank you.

Dan Lessler: Thank you. Any questions? Okay. And in light of the comment are there any questions for Patricia from committee members? No. So Patricia we can let you go. Thank you very much.

Patricia Thieda: Thank you. Have a good afternoon.

Dan Lessler: Is there a motion to accept the scan?

Patti Varley: This is Patti. I move that we accept the scan.

Dan Lessler: Okay. And a second.

Man: Second.

Dan Lessler: Okay. All those in favor say I.

Group: I.

Dan Lessler: Oppose, same sign. Okay. And next if people on the committee could just turn to the previous motion from April of 2006 and actually Bob...this was a motion you had made and seconded by Patti. Wonder if you want to take a look at that or if people want to have any comments on the previous motion in light of the scan.

Vyn Reese: This is Dr. Reese. I do have concerns about fluoxetine in the elderly. It has multiple drug interactions and my experience has been it's a difficult drug to use on patient's who are on multiple medications. I think it's an important drug and it's reasonable beyond the PDL, but in that subgroup I don't think it's as safe as some of the other drugs that don't have drug interactions. That's my view on fluoxetine.

Bob Bray: I think the reason that drove that particular comment is being included is because of the pediatric evidence.

Patti Varley: That's correct because it is the one that's been approved.

Vyn Reese: Right. But what's good for kids might not be great for seniors.

Bob Bray: Yeah. I agree with you. I think that's why we're saying that we need to have more than just that choice.

Dan Lessler: Bob, are there any changes that you would make to this?

Bob Bray: I would suggest we make no change to that motion.

Dan Lessler: Any other comments? Do you want to just put this...your previous motion forward again and we can vote on it.

Vyn Reese: Could I ask a question first? What drugs are on the PDL at this time? Are they the ones that have the flat markings to them?

Bob Bray: Are we ready for the motion?

Dan Lessler: That would be great.

Bob Bray: Dr. Bray – the motion reads after considering the evidence of safety, efficacy and special populations for the treatment of major depressive disorder, I move that bupropion, citalopram, duloxetine, escitalopram, fluoxetine, sertraline, fluvoxamine, mirtazapine, paroxetine, and venlafaxine are safe and efficacious. The Washington Preferred Drug List must include at least two SSRIs one of which must be fluoxetine, at least one SNRI, mirtazapine, and bupropion. The second-generation antidepressants cannot be subject to therapeutic interchange in the Washington Preferred Drug List.

Dan Lessler: Is there a second?

Patti Varley: This is Patti Varley. I'll second.

Dan Lessler: Any other comment?

Man: I have a question. As I remember the wording about the, "Must include at least two SSRIs, one of which must be paroxetine was because paroxetine was the first one to go generic with the advent of..."

Dan Lessler: Actually, I think it was because it was addressing the pediatric population.

Man: Oh, okay.

Dan Lessler: Yeah. Any other? Okay. All those in favor say I?

Group: I.

Dan Lessler: Oppose, same sign. Okay. So I think that's it and we're right on time and we'll reconvene at 1:00 is the DUR. Thank you.

Siri Childs: Okay. We're going to do three presentations this afternoon and I'm going to do two of them and then Jeff is going to give us a wonderful ending of the day with his presentation. Mine are really very short. The first one that I'm going to do is on the drug utilization review activity for the federal fiscal year 2007 and you all probably should be keenly interested in this one because I'm going to have to ask you to write the DUR annual report this year. We got off last year...ASC actually wrote that report for us, but this next year you'll be getting your assignment again and this information is pretty helpful in completing those different attachments that you write for the annual DUR report.

So again as you know each year we are required by CMS and a federal mandate to report what this committee does in an annual DUR report to CMS and that report is due in June each year so I'll be giving you your assignments in February because we are not going to have a December meeting this year and then we'll have our first draft to you in April and our final draft will be due in May and then we'll submit it to the...a Regence hand of CMS. So without further ado here we go.

As you know in the past we've had our contracted agencies affiliated computer services have been here at this meeting the last couple of years to present what they've done for us in the previous year. We terminated that contract with ACS on July 1st this year so I'm here to tell you what they did in the nine months that we had contracted with them in this federal fiscal year.

The retrospective drug utilization review for Washington Medicaid was contracted out to Affiliated Computer Services for the last five years. We started with them in February of 2002, but we did terminate their contract and so we have just a nine-month in this federal fiscal year. The intensive benefits management program abbreviated as IBM was directed by HRSA by us to look at the top 1,000 clients each month in targeted drug reviews. Along with that retrospective review we sent two contracted ACS clinical pharmacists out to visit face-to-face the top prescribers for each of those drug initiatives in the state. We had one person over in the Spokane area and one person in the Seattle area. So basically what I'm going to do is just show you what we did each month in each of those nine months.

So the first month of the federal fiscal year is October and we had two new drug classes—the atypical antipsychotics and the nasal corticosteroids...oh, excuse me and the TZDs that we went out on the street as you might say to promote the use of the preferred drugs in those new drug classes. We also had an update to the second-generation antidepressant class and so in this review those currently...we did a data poll and identified those clients that were on non-preferred drugs in these drug classes and we targeted those clients. There 1,019 clients on non-preferred drugs involving 740 prescribers and we sent out patient profiles to those prescribers and we asked them if they would please change to a preferred drug. We had a 43% response rate, 29% of those responding indicated that they would switch to a preferred drug.

In November we did a targeted review on atypical antipsychotics and Medicaid clients over the age of 60 possibly being treated for dementia related symptoms. The data poll that we had didn't definitively produce data on clients over 60 that exclusively were on an atypical for dementia related symptoms. That's a little too sophisticated for our system. So we had to do a little broader sweep and just poll all those clients that were over 60 and on an atypical. We sent out a cover letter and I'd like to read the one paragraph of that cover letter. We told them...or they received this letter: The atypical antipsychotics have been commonly used in recent years to sooth agitation, aggression and psychosis in people with dementia related behaviors including those present in Alzheimer disease. An FDA black box warning has been issued for this class of medication in relation to its use on patients over 60 years old with dementia related psychosis. As a result, safety guidelines for the prescribing of atypical antipsychotics have been established. And then we included in the black box warning. So they saw the information from the FDA specifically for

the client...or the patient that they had prescribed an atypical antipsychotic on.

So we had 359 prescribers, 572 clients that received the patient profiles, a fact sheet called Treating Dementia and we do have that included in your binder if you wanted to take a look at that and a request to re-evaluate their patient's therapy. We had a 47% response rate and 17% of those responding plans on re-evaluating the therapy.

In December we had another preferred drug class targeted review. We had a new drug class; the macrolides and we had updates on the long-acting opioids and the newer antihistamines. And again basically we sent out faxes to all of those folks that were on non-preferred in those three drug classes and that involved 317 prescribers of 317 Medicaid clients. Again, we had about a 42% response with 25% of those responding planning to switch to a preferred drug.

In January we looked at proton pump inhibitor use with a duration longer than 90 days. And I'll read to you the paragraph that was in the letter, the cover letter to those folks. According to submitted pharmacy claims data your patient has been receiving a proton pump inhibitor for more than 90 days and may be a candidate for step down or intermittent therapy. Please consider stepping down to an H2RA or discontinuing the PPI to see if symptoms reoccur in clients with GURD with negative findings on an endoscopy. If the PPI agent is required for symptomatic relief please consider using a preferred drug, Prilosec OTC or Prevacid. For further details please refer to the process guidelines in the article, "Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease" in the 2005 edition of the American Journal of Gastroenterology. So we gave them a little bit of information about extended use versus intermittent use.

So in February we targeted polyprescribers and we looked at those clients that had five or more prescribers and we had a little blurb that I'd like to read to you about that. It said: In an effort to help improve the quality of life for your clients, reduce duplication of therapy, reduce polyprescribing and assist prescribers in complex clinical decision making HRSA has identified clients with five or more unique prescribers. This information is provided to inform the provider of potential client narcotic and other medication misuse to highlight multiple prescribing and to offer a tool for coordination of care. 225 clients had 949 prescribers and each of them received this information and this was intended to be an educational intervention. We actually got a 46% response rate with 12% of those responding planning to re-evaluate the drug therapy for those clients.

In March we had another new preferred drug class that we were implementing and that was the inhaled beta-agonist. And then we had an update to the Statins class and an update to the ADHD drug and we again did a data sort and found clients that were on non-preferred drugs in each

of these drug classes and their prescribers received a letter asking them if they could please switch to a preferred drug in those drug classes. 772 prescribers of 1,049 clients on non-preferred drugs received the faxes. In this particular review we had a 58% response rate and 46% of those responding said that they would switch to the preferred drug.

In April we put together a toolkit to help providers address drug and alcohol issues. You may remember that in, I think, February last year we brought our folks here to do a presentation on the information...the contact information that we were ruling out to prescribing to help them enroll...I see Angelo is nodding that he remembers that. It was to try to help connect these folks that we could highly suspect from their increased utilization of ER visits, hospitalization and their medication profiles that they could possibly need some chemical dependency treatment. And so we did roll this one out and remember that it was in two targeted counties—Yakima and Clark County and this is what we said in the cover letter: The Department of Social and Health Services has developed the HRSA toolkit to help you address drug and alcohol issues with your patients. The enclosed information includes a cover letter further summarizing this intervention, the toolkit and comprehensive client profiles for each of your patients who have complex medical issues based on ER, hospital services, drug services and other services. Please consider using this information to address your patient's needs. Included in your packet we gave you a copy of the toolkit, the information sheet and the contact information, and the links to treatment opportunities. There were 135 prescribers of 153 clients that received that information in April and this was a very disappointing response rate. We only had 17% of those prescribers that we contacted respond to this initiative, which was really low for what our average response rate has been and of those only 14% indicated that the information was useful and that they would consider using the services for their patients.

In May we highlighted the opioid dosing guidelines for non-cancer pain and I'm going to read that briefly to you also. We said the number of deaths associated with narcotic prescriptions is rising both nationally and in Washington State. These deaths are related to an increasing number of clients receiving very high doses of narcotics from many providers, from too many different types of narcotics and for very high doses without related functional benefit. In March 2007 the Agency Medical Director's Group released a two-part guideline for opioids used to treat chronic non-cancer pain. Part one included recommendations for initiating and monitoring therapy in addition to threshold doses at which a pain specialist could be sought for assistance. Part two described the management of pain in patients already above the higher-than-recommended doses. The Department of Social and Health Services has identified patients who do not have a history of cancer, but are prescribed opioids above these threshold doses. Please evaluate your patient's current opioid therapy and consider pain management consultation if appropriate. You may find the complete guidelines and opioid dosing

calculator, frequently asked questions and a list of pain management specialists at a web site that we gave them. That information is also included in your binder. There were 877 prescribers of 954 clients that we identified as receiving more than 120 morphine equivalent dosing per day and each of them received the packet of information that I described to you. This also was a very poor response rate. We only had a 10% response rate and 10% of those responding indicated that they planned on re-evaluating the patient's therapy.

Okay. The very last month that we did this year was the program that we started on the erythropoiesis-stimulating agents. Maybe you remember that in June we also brought the two drug manufacturers of the agents Amgen and Orthobiotek to you and they basically endorsed the prior authorization criteria that UMPs...UMP worked with us to develop, which were basically the FDA labeling for these agents. And what we said in this particular letter was: The FDA recently issued a public health advisory that included new safety information for the erythropoiesis-stimulating agents (ESAs). Studies with ESA agents have reported a higher chance of serious and life-threatening side effects and greater number of deaths in certain populations treated with these agents. Based on these reports the manufacturers of these products have agreed to revise their respective product labeling that includes updating warnings and new box warnings and modifications to the dosing instructions. Please monitor your patient's hemoglobin levels to ensure that they do not exceed 12 and adjust the ESA dose to maintain the lowest hemoglobin level necessary to avoid transfusions. Also, please prescribe ESAs only for those indications indicated in the product labeling. Additional information on this topic is available at, and then the FDA web site for that. And this was a very small targeted review, but we felt that because CMS had come out with these guidelines and the FDA had come out with these guidelines that we were really obligated to act on that and so we...on the point of sale side we only had 69...we only had 80 clients and 69 prescribers that we sent this information to. These clients were receiving Epogen, Procrit, Aranesp and we did fax that information to them and we had a 38% response rate and 9% of those indicated that they would re-evaluate the patient's therapy.

Now what I really didn't mention on a case-by-case basis, month-by-month was all the work that our academic detailing pharmacists did. They targeted the top prescribers in each of those monthly initiatives and each month they visited face-to-face with between 134 to 183 prescribers and generally the comments back to us were very, very positive. Prescribers that were visited even though they were the highest users in any particular category seemed to really appreciate the face-to-face visit, the direct contact from DSHS and these folks really did serve as our eyes and ears across the state and, you know, it was a very welcomed part of our program and the prescribers especially appreciated the opportunity to provide feedback to us. And that's it. That's what we did last year.

Carol Cordy: I have a couple of questions and then we can open it up if others do. My first question is, why was the contract terminated at this time and is there something that's going to replace that service?

Siri Childs: Jeff, do you want to response to that?

Jeff Thompson: The major reason was that we had an administrative funding shortfall and we had to look at opportunities to decrease our administrative budget. So in addition to other contracts as well as a layoff at DSHS we are...actually at Medicaid this was one of the things that we had to budget out. One of the issues was that it's been a very good program for communication and it was very difficult to tease out the four brand [inaudible] versus academic detailing versus the IBM portion versus the PDL as far as what contributed to savings and so this was one that got the budget axe. I do hear that there may be a comeback on academic detailing at a legislative level coming up. So stay tuned.

Carol Cordy: And then...I know you've explained this, but when you look at the response rate and then those people that indicated that they would reassess. That really is the percentage of the percentage?

Siri Childs: Yes.

Carol Cordy: Is that right? Because it looks like at least on the toolkit that was like three people responding?

Siri Childs: Very low. Very low. We really were disappointed. Would you say, Jeff, that we really thought we had covered that issue so strongly in those two counties and there is not...there's not indication that there was, you know, a return on our investment and we're kind of puzzled by that because it seems like it's a very needed service that we were trying to perform.

Jeff Thompson: So for instance if you want to get a 12-month prescription history that tool is there. If you want to put somebody on restriction because they are abusing emergency room or narcotic prescriptions that tool is there, but, you know, I just think physicians are too busy. The medical people are too busy to, you know, sort of use those types of tools even though they know that there is abuse out there. And even more disappointing is that the medical providers represent an incredibly small amount of referrals to substance and alcohol abuse treatment. The literature says only 5% of referrals for substance and alcohol abuse treatment come from medical providers and that's both psychiatry and medical, which, you know, is really disappointing. So that's probably, you know, just a reflection of everybody is busy.

Angelo Ballasiotes: I have a complete of comments on this. I kind of wondered if you may have not targeted the right...or...well, not necessarily not targeted the right people with your information, but you might have been a little bit

more inclusive and I know pharmacies get a lot of that information from...and I don't think they were encouraged or talked to or...

Jeff Thompson: We've talked to the Pharmacy Association about putting up red flags for cash payments and other things and while they might have their own little book across their own little pharmacy system, but they don't talk to each other and they can't.

Angelo Ballasiotes: I know, but I just, you know, with regards to...when I was in the system we'd get repeaters and we'd see different doctors and things of this nature so, you know, if I was in that situation I think I would use that program. Number two, the other comment that I have because I work with people who are duly diagnosed and we tried to use that pretty extensively and I think maybe we over-burdened the system because we were told they weren't going to give us any more of these profiles, patient profiles.

Siri Childs: Yeah. Angelo sent us emails, Jeff, telling us the snag that he ran into and we had hoped that we had resolved that for you.

Angelo Ballasiotes: I never got a comment back and then the person that I put in charge of that called up again after my email to you and she was told, "Well, I'll do it this one more time." We have a lot of high utilizers there.

Jeff Thompson: So if you email Siri and I and Steve and let us know where the barriers and we can try and...because that's the first time I've heard that. I can't fix what I don't know.

Angelo Ballasiotes: So what should I do again?

Siri Childs: Send me an email and I'll forward it on to everyone again. I really thought that we had taken care of it, but you say that you have evidence that it continued after you emailed me.

Angelo Ballasiotes: Right. And I guess I would...I was expecting an email back, you know, saying that this was kind of corrected. Because this was very, very effective for us in not only bringing out what these patient's profiles were, but we were able to address truthfulness with them.

Siri Childs: And we would expect that you would continue to do that.

Jeff Thompson: I think we're preaching a little bit to the choir here. If you actually go out into the community use of drug screens, use of the 120, you know, narcotic is very controversial. There's a lot of physicians, you know, that's not the type of business that they want to be in is ensuring that there is not abuse and we got to do a lot better job of working with the emergency room because that's an area where the prescriptions are ramped and yet there is very little coordination. It's more of an in and out and I'm speaking from actually talking with the providers and going out and using the data.

Angelo Ballasiotes: Well, you know, with the emergency rooms, you know, I was out of two hospitals locally, you know, these physicians are really inundated, you know, and these people work them and they'll give them enough medication just to get them out of their hair and possibly, you know, rightly so.

Vyn Reese: This is Dr. Reese. Who is in charge of developing interagency guidelines on opioid dosing? Who did that work?

Siri Childs: The first name that comes to my mind is Gary Franklin in coordination with a stakeholder group of neurologists and pain specialists across the state, but Jeff if I'm slighting you I don't intend to slight you if you were instrumental in bringing all of that together also.

Jeff Thompson: Well, it was Nancy Fisher and myself and Gary as well as Malcolm Dejnozka and all of the agency medical directors played a hand, but Gary lead the charge and there were 20 pain specialists and neurologists—Rick Reese, Peter Dunbar, many of the people that actually even trained you, Taylor, etc., etc. were at the table to develop this, but still quite controversial and we did get...we were successful in getting letters of support from family practice, ER and anesthesia and then we just passed a resolution at Washington Medical Association where they will actually help us disseminate the guidelines. But within that resolution a lot of controversy about whether, you know, we should be putting "limits" on narcotic use.

Vyn Reese: I think it's an excellent protocol and I think another way to go at it would be to get doctors through their group practices. I mean to go directly to the big practices in the state and to their quality assurance committees and that sort of thing. That's another way to do it is to have that [inaudible] of organizations...it's available on a web site that's sort of hidden away. I didn't even know this until a few weeks ago because we were looking at something for our practice exactly on this issue and it was just very by accident that I happened to find this and now we're implementing it in our big group practice because we actually have this tool available, but we wouldn't have found it except by sort of surfing the web. And I think that, you know, that's another way to go after this problem. If you go to, you know, The Washington State Medical Association, but not just them, but just to the big group practices in the state where you start getting in their quality assurance and then looking at their providers and assuming this type of material...I think it's going to be very effective. I think you just need to try a different way of marketing it. The other thing about it is the pain specialists. That's the weak link I think in this whole thing is that there aren't that many pain specialists and pain clinics out there that...some of them you send them to them and they come back with more opioids then you started with and they give them rotten counsel. The quality of the pain consults is really iffy in my view in the state and, you

know, I hate to say it but a lot of the pain clinics have doctors who are opioid dependent already. So it's like...I mean I've seen that happen, too.

Siri Childs: I think we may be [inaudible].

Vyn Reese: Yeah. I think that we have to have good consultants. If we're going to do a 120 mg rule for morphine then we better have somebody to send them to that is going to say, "Okay, this person has got a severe addiction problem and he should see multiple doctors and he's got all these other issues and he needs to get into a detoxification program." But right now you're not assured that's going to happen when they go to a pain clinic and that's a real weak link in this whole thing. You have a great guideline, you identified the patients, the doctors are all on board, you send them to a pain clinic and they double their opioid [end of Side A]

[Side B]

Siri Childs: Jeff, is that something that you can take back to the Medical Director's Group?

Jeff Thompson: I guess I want to challenge you. We have been a little bit gentle on this just so you know. This was written up in the New York Times magazine. There's...I mean this has actually gotten national press and pushed back nationally. So Gary and I and the rest of the medical directors have spent a lot of time actually talking at the association level, but we've also previewed this with major...at family practice, pain specialists...I just did this out in Yakima to 700 substance abuse professionals who were out there. If you want to invite us to your clinic we'll be there, you know, I guess what I'd like to...if you find value in this talk it up. It can't just be the agencies going out...

Vyn Reese: We're actually going to implement this in our group practice.

Siri Childs: That's excellent.

Vyn Reese: That and because I saw it by accident and said, "Gee, this is great. We should really do this. I mean this is an important thing for our practice for quality assurance."

Jeff Thompson: So you need to turn to Alan and say, "[inaudible] at Harborview."

Vyn Reese: The problem is now we're really worried about where do we send these folks? That's the worry.

Carol Cordy: Is this on the web site?

Siri Childs: Uh huh.

Carol Cordy: And the other thing I was...this is a little aside from that, but...and I don't [inaudible] on the web site, but it seems like that's a big resource for educating providers and this may be on there too, but what I'd like to see on there is some sort of education link to the preferred drug list and the preferred drugs on the preferred drug list.

Jeff Thompson: There is, absolutely.

Carol Cordy: So you go there and there is rationale for why they are on there.

Jeff Thompson: As a matter of fact there is actually a CME on the web site too, on the agency where you can actually go on Mark Sullivan's program about how to do an intervention is on there where you can get a CME and then we're working on another CME that will get accredited maybe through ACOM or somebody like that on how to do pain management. The reality of pain management I just have to tell you you don't need a pain specialist. I mean that's the fallacy that you've got to send it off to a specialist. The reality is you have to take on a very complex client, spend a lot of time with them and dig and dig and dig and there are tools in here that can actually assist you—case management restrictions, prescription monitoring, pain contract, all of those are there. But I'll be honest with you the fact that you have to send it off to a pain specialist, you know, I don't buy it. I just don't buy it.

Vyn Reese: I think the problem is some doctors are easily manipulated and these patients are the master manipulators and they have a...a doctor with a soft touch who is easily manipulated gets tons of these patients and then they can't get away from them, they are kind of like stuck to them and it's a...but then you've got somebody in your practice that's got this problem. How do you get them out of it? So then you...

Jeff Thompson: [inaudible] or out of their problem?

Vyn Reese: No, get them out of their problem and get the patient out of your clinic. That's the problem, too. The patients need to be treated for addiction. That's what needs to happen and I think that, you know, you're saying in your review that you should send them to the pain specialist if they are over a certain level and that is like, you know, you are absolutely right doctors need to be able to say no and be able to set limits and you should have strict contracts and abide by them and the patient's need to understand that.

Jeff Thompson: Actually, let me correct a statement you made. The guidelines say that if you are not improving in pain and function by the tools that we give you, the SF36, the pain questionnaires, the disability questionnaires then take a big, deep breath and send them out. But if you want to prescribe over 120 and they are improving in pain and function, fine. Just keep them breathing and that's all we really want. Where we are asking the second opinion is where you get into a diagnostic dilemma, the pain is going up,

but disability is staying the same, or none of them are improving and that's when there is probably a better signal of noise for sending somebody to a second opinion and so that's what we're trying to do. It's going to be a long process and we'll just have to keep working it. I want to challenge you guys as the DUR to help us play out because there's not enough government resources to go out and educate every provider and it really has to be the providers to tell their buddies, "Hey, this is the best thing since sliced bread because, Hi, we're here from the government and we're going to help you." That doesn't really sell well.

Angelo Ballasiotes: I think there's an implication there that there are clinicians that treat pain. I think they possibly see it as a black/white issue. And it's not a black and white issue. It's not like controlling blood pressure or diabetes. It's more of a personality issue and psychiatric implications.

Jeff Thompson: I guess I would think of it different, you know, 60% of people on antidepressants don't take their antidepressants after 12 weeks. Well, 40% of diabetics are uncontrolled even when, you know...so I think there are...what we want to do is identify who are the highest risk and get you the resources.

Angelo Ballasiotes: Yeah, that's true.

Jeff Thompson: And then how do we work together on the toolkit? I mean it just...I guess what I'm pushing back is if there is something else we can develop let us know. If there is a better...and I'll take your advice. We're out at the Clinic Poly, and I'll call Poly, Virginia Mason, you know, Northwest physicians and we'll be there next quarter and that's a good idea.

Angelo Ballasiotes: You know, I kind of think sometimes a clinician has good intention and then he or she gets caught in a trap and the dose gets away from them and they don't know what to do with it.

Jeff Thompson: Well, here's the question I got. When I gave this presentation to family practice they said, "Yeah, but what do you do at 5:00 on a Friday afternoon, you know, I'm seeing this client and I've never seen them before and they tell me they lost their prescription for OxyContin?" And I had it very simple...I had that happen to me in my practice all the time and two things: (1) I would go to the pharmacy and I would pull their claims history. When I was in the Navy I could get a hold...99 times out of 100 they were trying to find a soft touch and (2) I wouldn't give it to them. I would say, "I can give you Motrin and I'll be more than happy to see you on Monday and we'll sort it out," but I was not a soft touch. And I think physician's need and ARNPs need to stop and take a big deep breath and say, "If you don't know a client and you don't have history and it's for..." The ACP Journal just came out did an evidenced-based review on low back pain and opioids. I don't know if you saw that. No evidence that opioids are effective in treating low back pain. So I think we need to

set a new community standard and challenge us to change it. I want to challenge you to promote it and figure out where we go.

Man: [inaudible]

Jeff Thompson: But I'll give you another example where the community is. When I was at a meeting with the orthopedists at UW and the family practice were just absolute abhorrent that the orthopod would demand that the narcotic dose would be down by the time they went into surgery. That was hand-to-mouth to bribery. You don't get the surgery unless you get your narcotic dose down and they were arguing with each other. That was the first time I ever had to argue it, but that was a difference in philosophy. How could you dare, you know, ask them to get their narcotic dose down before you do surgery? And he said it's a post-operative nightmare to control their pain post operative, but the family practice person said, "You can't do that. It's blackmail."

Carol Cordy: And then they send them back to us to take care of the pain after the surgery.

Jeff Thompson: So that tells you the length and breadth that we are [inaudible] and so anything we can do to promote this or change it, you know, but you're actually...you are the leadership in this...in the Medicaid population for doing this. So talk it up amongst yourselves and then let us know—Siri and Steve and I and Gary what we can do to sell it.

Carol Cordy: Can I...I don't want to insult anybody, but the web site is really not user friendly. It's very busy. There are way too many little things on that first sheet. It's very hard to find even where to sign up to be an endorsing prescriber. So I would suggest doing something...get somebody so I can just go straight to the educational stuff, I can go straight to the opioid stuff.

Vyn Reese: There should be an educational resource section where you can find opioids and whatever else you need to find and doctors can go easily to that section and scroll down and find the things they are interested in whether it's, you know, diabetic drugs or whether it is opioids or any other drug class. There should be a very simple way to get to it.

Woman: [inaudible]

Man: So Alan, what do you think?

Alan: Just one observation is that I would advocate also for an increased service as far as counseling, behavioral counseling because we've done a survey and over 70% of our...80% of our patients with chronic pain have mental health...and we have a difficult time addressing that section. So I would advocate for an improvement in mental health services made available. The other, you know, going back to your...as far as Harborview goes and family medicine we've been doing this for about seven years. So we've

always limited our method. I can't control the rest of Harborview, but at least in family medicine at Harborview we've pretty much followed what they've stated here and so we are trying to keep...and I think overall we've done a pretty good job of keeping our methadone doses low. So I do support this document. I think it's well written. One question I have is as far as the relationship between dose of methadone or equivalent of morphine and deaths. I haven't seen the data, but what I glimpsed at I don't know if I can state for sure that there is a correlation, but as far as the increase in death as related to dose dispensed or I know that the increase in deaths have increased because we're prescribing more, but I just need to confirm that is there a dose relationship that I can for sure factually state?

Jeff Thompson: So when we looked at our death certificate data in one quarter of last year there were no deaths at under 60, there were no deaths at under 90, but there were 19 deaths at 180. So now what we're doing is we're pulling 1,200 death certificates, deaths related to narcotic use in two years, at least deaths that have a narcotic in their system and then we are going to repeat Gary Franklin's study where he did show that dose responds relationship in Medicaid. So this is for non-cancer, chronic opioid use. We'll try and draw a relationship with the morphine equivalent and keep in mind the difficulty is nobody has really done this before where we all agreed to a morphine calculator. So now we have actually a benchmark that we can actually calculate and look for that dose response. At first glance it looks like it is, but everybody will argue, you know, this, that or the other thing, but we'll give it the best shot.

Alan: Right. I support the 120, but I just would like some more solid data to say, "This is true."

Jeff Thompson: So there were no deaths at 60, no deaths at 90 and when you hit 180 we had 19 deaths in a quarter. True, true and related or true, true and not related that's why we have to pull the death certificates.

Carol Cordy: That's morphine equivalent?

Jeff Thompson: Morphine equivalent.

Vyn Reese: Is that why you set the dose at that?

Jeff Thompson: At 120 to be...to be no better than 180. Some people wanted to set it at 200 and again there's no really good literature, but then again nobody has actually even looked at it as a morphine equivalent and so this is where we're actually probably too far ahead of the curve.

Carol Cordy: You talked about a calculator. Is there like a PDA downloadable calculator on there?

Siri Childs: I meant to tell you that the piece I have in your packet tells the web site.

Man: On line?

Siri Childs: Yeah. And so it's just so easy to use.

Jeff Thompson: As far as the PDA you have to actually...did we put the vendor that has the PDA on the web site? We developed a calculator...it's a download spreadsheet on Excel, but as far the PDA you have to go to a vendor to get that.

Siri Childs: Yeah, that's correct. But you can go to the web site...just the general...you could Google it and find it if you wanted to.

Jeff Thompson: Yeah. It's \$25.00 and you can download it to your PDA.

Siri Childs: Or you could use the Excel one that is available at this site. L&I developed that Excel spreadsheet.

Bob Bray: I just had a couple comments. One was this low response rate that you were talking about. You were talking about maybe that's, you know, everybody is just too busy. I guess the knee jerk response I had response was that probably was a reflection of how many patients you talked to about their substance abuse and who were actually willing to do something about it or listen to you talk about. So I don't know how much of that is people being too busy. I think most of it is patient's not being willing to address the issue that you've already identified and then just to sort of tout something that we were able to do on the east side...and east side in my book means the east side of the mountains rather than the east side of the Sound. We have the benefit of most of the hospitals on the east side of the state being on a single hospital information system and so the ER physicians they aren't sharing information necessarily with other ERs, but they can find out who is a frequent flyer and who is a frequent flyer not only at their ER, but somebody else's and there is a system that was put in place by the ERs where when you access that person's hospital information there's a red inked note that comes up that says, "This patient is in this program," and I can't remember exactly the name of it, but it's a connection between the ER and the primary care physician where the primary care physician sets the treatment parameters for what should happen with that patient when they seek care in the ER specifically for chronic or acute on chronic pain and the ER physician then can say, "Dr. Bray says, here's what we should do." Now they have the ability to use their own judgment any time they want, but at least everybody is connected and talking and that has been remarkable in controlling those few people at the top of the system that are really abusing especially the emergency departments. And it's also helped the emergency physicians to feel like when they say no they aren't just being hardnosed, but they are saying no because there's a plan and I don't know what, you know, what similarly could be done if you have hospitals on different systems and that

kind of thing isn't as much a pop up, but that's been very helpful to us on the east side.

Jeff Thompson: So you're talking about the program that Darren Evans started at Sacred Heart?

Bob Bray: Yeah.

Jeff Thompson: We've had numerous conversations with him. The problem is it's very hard to fund that through the hospital association. So, you know, I think people need to support that and tell the CEOs because he's had a real uphill climb with that. Anecdotally, it's working, but when you pull the data it's a little tough to figure out if it really is. There's some migration that's happening as people go outside the Spokane area. So you squeeze one end of the balloon and then they end up at the other end.

Bob Bray: They have to go 100 miles.

Jeff Thompson: We have clients that go to the emergency room 150 times a year across the state. So that's a job. So the other answer is that...there was a legislative...there is a statute where they can actually...where DOH can do an electronic server for all narcotic prescriptions, public and private, but it was not funded and so again if the DUR wants to take a leadership role you all ought to put your signature on a letter to Mary Selecki and tell her that if you don't do this you're going to have more deaths. But DOH has basically been asked to fund it with grants or other resources. They are putting a price tag of about \$3.2 million on it. When Utah and Kentucky did it it was more like \$500,000 and I'll be honest with you, I don't think the state wants to do it because of a little bit of, you know, "Don't tread on me. Keep the government out of my business." So, again, as the leadership and the DUR I would encourage you to write a letter to Mary Selecki saying, "You need to make this work," because without it we're going to have, you know, you've got a public health issue.

Vyn Reese: Jeff, you know, we can draft that letter as a committee and just sign it. I think that is really an urgent need.

Jeff Thompson: Yeah. She needs to hear from the leadership that you guys would be willing to promote it because to be quite honest it's a political football to do that program in this state.

Angelo Ballasiotes: Can we draft a rough?

Carol Cordy: If one of you guys would...

Jeff Thompson: I'll do it. That's fine.

Vyn Reese: We could probably hash it out. Let's bring it up at our next meeting.

Siri Childs: Is that too late to bring it up at the next meeting because that's not until February.

Jeff Thompson: Why don't I just send it around and, you know, if you guys agree on it on email then just email it, you know, back and forth and get all your signatures on it and then as fast as you can work we can send it out.

Carol Cordy: It would probably be quicker if we each just...once it's agreed on signed one and just send them all in separately if that works.

Jeff Thompson: But I mean that's where I think you could exert some pressure because these are things that we don't have any influence on.

Patti Varley: [inaudible] about the presentations did. Is there data regarding financial savings directly related to any of those?

Siri Childs: You know, that's one of the things that we're going to lose with the ACS contract terminating in June because they will not be available to do the data that came from all of this. So that's a problem that I'm going to face without them when it comes time to submit this report because I don't know if you specifically remember, but attachment 6 is the cost savings associated with a GUR activity.

Patti Varley: That's right. I didn't see it here and I was going to...

Siri Childs: Right. It really does bother me. It worries me that I have lost that calculation ability because I don't have a link to it anymore.

Carol Cordy: So even for these in 2007?

Siri Childs: Right. What ACS has done in the past is that these are...they have done a three-month pre-test and a three-month post-test and it's ongoing continuously, but it all stopped when we terminated the contract. So I lost that. And I will have to come up with some mechanism using our own point-of-sale data to calculate what the...if there was any return on our investment for those initiatives. That's a very, very good question and one that I really worry about.

Man: So you also then don't have data about the percent that was actually changed? So, you know, there is 17%...we're thinking about re-evaluating, but what...so we won't have an idea as to how much would change, what percent was actually changed.

Siri Childs: The only way that we would have that is if, you know, I go in and try to jimmy some type of a before and after comparison and see if it actually goes down. What happens often is when you try to do that you find out that it actually goes up. And so...the way ACS was doing it I could actually have a dollar amount because they had a control group that they used and everything else that I've lost.

Man: Do we have a concept as to what percent in each group the prescribers are within, are prescribing PDL drugs versus non-PDL within classes?

Siri Childs: ACS gave me a lot of really good information on our preferred drug classes and our percent compliance to the PDL varied from class to class as you would think and I also got the percent dispense as written which varied from class to class, but overall we had very high compliance and through the years I would say that we have 90% compliance overall to our preferred drug classes. Like the ACE inhibitors we had 99%. The long acting opioids we got as high as 80% and, you know, that was really phenomenal because we started out with 30% use of the preferred drug and the end phase we had a high utilization of Celebrex when we started out and that dropped from 39% utilization of Celebrex, market share, to less than 4%, but we had a lot of things helping us all over the national news and all of that. And the degree of dispense as written, opt out through the years has been very, very good and again it depends on the drug class and I think I've mentioned this to you before, but would anybody like to guess what drug class has the worst dispense as written, opt out? Had the highest dispense as written?

Man: [inaudible]

Siri Childs: Nope. The over-active bladder class. We had about a 30% DAW in that class and it was when we had only the immediate release drugs as a preferred drug and then once we added I think it was Vesicare to the class then it too became like a 90% compliant drug class.

Man: When you go through these, if you have the opportunity to go through that data again look at the outliers. Is there any educational tool left that could be utilized by those folks where the state can utilize the intervene with folks that are high prescribers?

Siri Childs: Well, right now I'm not aware of anything we have since we terminated the contract. Jeff, do you have an idea?

Jeff Thompson: Well, I mean under your per view we could have a closed session and we can show you the actual names if you want and then you can instruct us what to do. I've talked to Siri and the...we've gotta be very careful about doing any kind of profiling or report card. We don't want to pull a Regence and so if you guys would like, you know, we can actually show you the generic utilization, the DAW utilization by provider and then broke it out by drug class. And just so you know the variation in practice for generic utilization is 13 to 99%. And there is about 30 points difference in each type of provider—family practice, it doesn't matter what specialty.

Carol Cordy: Can you...but those aren't...those reports can't be sent to the individual provider. I know at CHPW they are.

Jeff Thompson: I think we would want a lot of people behind us to send report cards to providers.

Carol Cordy: We got report cards for CHPW and they covered, I think, statins and depressants. You can't do that?

Jeff Thompson: [inaudible]

Carol Cordy: That helps an individual to say, "Oh, look I'm way out of..."

Jeff Thompson: If you would like to post a closed session and we could actually show you the names and then you could, you know, start helping us think about what the next steps are that would be phenomenal. But before we would do any kind of report cards, which would be non punitive they would just be informational we would need you to help us sell it through the Washington State Pharmacy Association, Medical Association and key associations so that we wouldn't be accused of profiling physicians. The nefarious DSHS up to it again.

Siri Childs: I would like to put in my two cents here and say that through the years I have been absolutely pleased. I don't know if that's a strong enough word by the compliance to our preferred drug list. I mean to me it's phenomenal that we got the compliance and I think it's a reflection on the work that you guys do too because we have a credible process to evaluate and select the preferred drug and I think the physicians who told us in 2003 when they supported this initiative they said, "You give us a credible process and we will support the preferred drug list." And I think that they are doing a really great job.

Jeff Thompson: And let me echo that just so I don't sound so cynical all the time. It has generated between a \$30 and \$40 million savings of your tax dollars on an annual basis.

Siri Childs: The PDL.

Jeff Thompson: The PDL. We also have one of the highest generic utilization rates in the country for a Medicaid fee-for-service plan at around 63% and so it has actually done I think a phenomenal job of bringing us to a...under a 3% trend for overall pharmacy program non dual. That said, you know, there are also benchmarks which I think, you know, like on narcotics and other things that I think we could go beyond just sort of cost savings and get to actual clinical outcomes with cost savings.

Carol Cordy: I was going to say to me that what we are talking about is public stake along...

Siri Childs: Absolutely.

Carol Cordy: To me that has been some of the exciting moments is when we're not just saving money, but we're eliminating the use of a medication that doesn't necessarily...hasn't proven to be helpful for a condition or could be harmful because side effects. So to me that's the other...

Man: I guess my question...I was, you know, was concerned about people that would outliers in terms of statins or diabetes treatments, but I think I would probably refer you more to narcotics because it really is a frustrating...I worked in a community hospital setting where there are eight providers in maybe 50 square miles or something or 40 square miles and, you know, there's one of them that they have people driving from Vancouver, Washington or wherever to get their OxyContin from them and so no matter what the rest of us do people just say, "Well, heck with you. I'm going to go over there." So it's just frustrating because you really wish there was more tools besides from enforcement. You wish there were more tools for educating people.

Siri Childs: You know, I don't know if we mentioned this, but if you ever have someone that you would like us to look into, a provider, you can email me and I will send it to our medical/dental quality program and depending on the priority of it, if it's a safety issue they get right on it. But any of you can report those to me and I will send them on for us to look into. So please, if there is somebody out there that you think we should know about and look at, please let me know.

Angelo Ballasiotes: We've been talking about narcotics and I was kind of wondering what's going on with benzodiazepine?

Siri Childs: Like what benzodiazepine? Can you give me some more information?

Angelo Ballasiotes: Well, people getting multiple benzodiazepine type drugs from different providers. Basically kind of the same thing as the opioids. It might not be an issue now, but it sure was an issue then and I still see it as a problem.

Siri Childs: So if we were going to do a drug utilization review would it be just looking at combination therapy of the benzodiazepines? Is that what you're suggesting?

Angelo Ballasiotes: That and also multiple prescribers.

Siri Childs: Well, you know, we sure have done multiple prescribers, but it's been of any narcotic or, you know, mental health [inaudible].

Angelo Ballasiotes: That's a class-scheduled drug.

Jeff Thompson: So the issue is, what is the threshold that defines misuse and abuse and there really is none. Where we started out with 10 or more narcotic prescriptions...

Jeff Thompson: ...like us to look at...or something like that we certainly can, you know, profile our clients in a safety risk issue and then work with you on what the intervention would be.

Angelo Ballasiotes: Well, I think that's probably just as much of a problem as the narcotics, but it's not as lethal, you know, unless they mix it with alcohol or...

Carol Cordy: Or narcotics.

Angelo Ballasiotes: But it's still an issue and I wonder how many accidents...car accidents or things of this nature. You mentioned a comment with regards to Soma. Well, that metabolizes...

Siri Childs: When did I mention that? I mean I know that...a couple of years ago we talked about it.

Angelo Ballasiotes: We took it off the formulary, but that metabolizes to a [inaudible], which is a tranquilizer. It's an old one.

Siri Childs: Did I tell you the good news about Soma?

Angelo Ballasiotes: Well, you did but then you said...

Siri Childs: We have about four patients on it.

Angelo Ballasiotes: But you have the doctors arguing with you about keeping them on it.

Siri Childs: No we were...we were really successful. The sad story about Soma in Washington State is that our...all of our fee-for-service patients we started with 4,000 and we got down to four patients. And then along came Medicare part D. And we lost our dual eligibles. And because we pay the co pay, I see the drug orders that they get, and we're up to about 1,000 clients that are getting Soma again on the dual eligible side.

Carol Cordy: You know, I think maybe we should move on. You wanted us to...this is just partly informational. Did you want to give us assignments or do you do that privately?

Siri Childs: I'll do that in February. I don't think any of you are going to work until February on any of this. I'll just give you your regular assignments; you'll all have the same ones that you had before. With Dr. Lessler leaving we'll have to divvy that one up. I guess or give it to someone new. Do you want to just acknowledge that you have approved that report that I just gave you? Please.

Carol Cordy: Do we need to do motion?

Siri Childs: Please.

Carol Cordy: Do we have a motion to approve Siri's report?

Man: So moved.

Man: Second.

Carol Cordy: All in favor?

Group: I.

Carol Cordy: Thank you. So Siri would you like to talk about tamper resistant prescription pads?

Siri Childs: Yes, this is so appropriate to the discussion that we just had, because the government has a solution for tamper resistant prescription pads. And Jim Stephenson has prepared this PowerPoint for my presentation and he appropriately entitles it the zigzagging requirements for Medicaid prescribers and pharmacists, because we're told something one day and then we're told something else the next day. So this requirement was included in an Iraq/Katrina spending bill in early 2007. Medicaid fraud and abuse was going to be the answer to funding the Iraq war. All written Medicaid prescriptions for all drugs, including OTCs would have to be written on tamper resistant paper. The sponsors of the bill introduced it as a cost saving measure to help balance war spending. It was originally set to go into effect on October 1, 2007 and I put it on the agenda when we sent the agenda out early in September, because I thought that this might be something that you would all be eager to know about since it was an October 1st requirement.

At the last minute there was a delay. After many providers protested, congress introduced a six-month delay in the law, but the legislation did not pass both chambers until the last week in September, so we didn't know if we were going ahead or if we were not. So HR 3668, the TMA, abstinence education, and QI Programs Extension Act of 2007 was signed into law on Saturday, September 29th by President Bush. This is the law that extended the new requirement for implementing the tamper resistant prescription pads for six months. The new effective date is April 1, 2008. April fools day, okay. Sorry about that.

Going back in time, the way this all got started is that section 7002B of the U.S. Troop Readiness, Veterans Care, Katrina recovery, and Iraq Accountability Appropriations Act of 2007 had the requirement that we have tamper resistant prescription pads, and that was signed into law on May 25, 2007. And I've got to tell you that we may have heard that through the normal news channels, but there was no information coming out of CMS. And here we are depending on CMS for guidelines and we waited, and we waited, and we waited. And on August 17th, we got the guidelines on implementing and what to implement October 1st. So this new rule requires that all written Medicaid prescriptions for drugs and

over-the-counter medications, not just narcotics, not just schedule 2 drugs, but all Medicaid prescriptions will have to be on special tamper resistant paper by April 1, 2008.

And instructions from CMS...so far, CMS tells us that this does not apply to telephoned, faxed, or electronic prescriptions. It does not apply to Medicaid prescriptions covered by healthy options or the State Children's Health Insurance Program, or CHIP. Administered by private health plans under contract with the state. And just to give you perspective, the healthy option and CHIP programs cover a little more than half of the states 870,000 Medicaid assistant clients statewide. So there is a huge chunk of clients out there that will have to have client...tamper resistant prescriptions on written prescriptions as of April 1, 2008.

The key features of tamper resistant prescription pads—the must not be copied. Pads must present an unauthorized copying of completed or blank prescription pads for example, pantographs reveal the word void when copying. They cannot be altered. Pads must resist erasures or editing on the paper. For example, chemical stains or altered backgrounds that mark any attempt to alter or remove ink or toner. They must not be counterfeited. Pads must be distinctive and include watermarks or other devices that can't be reproduced. CMS gave us a phased in approach to this rule in that they said that as of April 1st, at least one of these key features must be applicable. And then on October 1, 2008, all three features must be available on tamper resistant prescriptions. And that's it in a nutshell.

Vyn Reese: So how expensive are these going to be? That's going to be another unfunded mandate, essentially.

Siri Childs: Exactly.

Vyn Reese: So it's going to be...they're probably going to be quite expensive.

Siri Childs: I heard that they were about ten times more than a regular prescription pad.

Carol Cordy: So the companies or the agencies or the clinicians are funding the war because we have to now either have two sets of prescriptions or you get...right, because I was going to say because otherwise you might write it on the wrong one. We just shredded...I don't know in our institution how many, triplicate prescriptions, which just makes me sick when I think of the financial...

The other thing and I don't know if you said this, but we have electronic ones. Ours don't automatically get faxed yet. But if I print it off my computer and I sign it but I notice that I wanted to say something, I can no longer cross it out and initial it. Is that...that's what I was told was part of this as well.

Siri Childs: That's my understanding.

Carol Cordy: So that I would need to regenerate a whole new prescription on a whole new 8x11 sheet of paper. So it just...

Siri Childs: Anything that you give the patient.

Jeff Thompson: That's not what that says.

Carol Cordy: No, but it is implied.

Jeff Thompson: Well when you...but when you correct something and initial it, that's stating that I want to put something else on there, that's not erasing it and covering it up. And that's not what that...

Carol Cordy: We were told they cannot have any adjustments.

Jeff Thompson: I think that's going a little...yeah, I think that's an interpretation issue.

Carol Cordy: Well, that's why I'm asking for clarification, because that's what our agency has been told.

Siri Childs: Well I will have to say that it requires...

Jeff Thompson: Well I think a couple things from Doug is that when this comes about we'll be publishing where you can get those scripts, trying to find a vendor that will have the least amount of financial impact for you. It's a federal rule; we can't do much about that. We'll be working with the pharmacies to ensure that there's continuity of care, because obviously there will be oopses with things that will come without or with or these things with cross outs. At least what Doug has said is that you have to abide by the federal rules, but as far as our audit and other activities we're going to go slow and easy and we'll work with you on this, because it's a big fee change.

That said there is some rationale to the madness. It's not just about narcotics, there has been several news articles about other medications being sold on the market and God only knows why anybody would want to sell an atypical antipsychotic, but that's one that there's actually been a fair amount of fraud that's been in the newspapers.

Carol Cordy: So now how does this save money to pay for the war?

Jeff Thompson: Well I don't know if it's saving money for the war, but according to...CMS has a fairly significant mindset that there is a fair amount of fraud and abuse going on out there. And they have hired up a huge amount of auditors in the thousand range to be spread out through the United States. And they will be looking at both us and you and the clients.

More us and you than the clients to determine are the federal dollars being spent or the medically necessary services that are appropriate under the law? And that will be for the next few years and I'll be honest with you my take is that I don't think that congress is going to actually contain that with legislation. I think they feel that things need to get under control and they are going to let CMS do it administratively. That's my personal view.

Vyn Reese: This is Dr. Reese. I actually think it's not a bad idea to do this, just the implementation time is too short and I think over time will be the costs of the prescriptions will drop as more manufacturers come into the market, but short term it's going to be sort of a mess. But at least we have a longer timeframe to implement it.

Jeff Thompson: I think Siri's done a very good job in starting to communicate with the pharmacies, we're starting to develop policies, we've got a little bit of breathing room. And then I think from Doug is we're going to ask you to follow the law, but as far as audits and things like that we're going to go slow because this is a huge impact just on the fee for service side.

Jason Iltz: This is Jason. So Jeff, can you explain that auditing piece? And maybe you don't have all the pieces together, but when I'm from the outside looking in and I know there's burden...initial burden in terms of the expense of the prescription pads, but what comes to me in terms of who's going to bear the brunt of this is it's going to be the entity that dispenses the prescription in the long run. And so if there's a mistake that's made or there's an interpretation that's made to say, "Okay I accept this prescription," and then it's audited later, that's a look back period where you're going to take money away from that person who dispensed the prescription or from that entity that dispensed the prescription.

Jeff Thompson: All I can say is that from Doug is that we expect people to follow the law. But as far as audits and sort of look backs and things like that we're going to go slow. The other area we're going to ignore the people breaking the law.

Jason Iltz: Well, absolutely. But then the other piece of it is...this is one thing, but so now is there going to be specific requirements in terms of...how many years do these things need to be kept? Is it going to align with current law in terms of how long you have to save a prescription at this point in time? Is it going to be longer than that? Does the state mandate? Does CMS mandate that? I mean how many more buildings do we have to build to house these prescriptions for our look back period?

Jeff Thompson: For the purposes of audit I believe it goes back three years.

Siri Childs: Six. Our pharmacies have to hold prescriptions for six years, and CMS has been silent on any retention requirement. I do want you to know that I expect that CMS is going to be watching us very carefully, because they

announced their rules on August 17th, and one week later I got a call from CMS asking me to report to them what we have done already to notify the prescribers. So I expect that we are going to be watched very carefully.

Carol Cordy: On that can we have on our new and improved website a link that gives this information or is it already there? I think it would be good to really get prescribers using that website.

Siri Childs: I wanted to also mention that there's an emergency provision in the rules that the pharmacies are allowed to dispense a 72-hour supply so that people don't go without medications. And then they have 72 hours to get the compliant prescription to cover that medication.

Carol Cordy: Any more discussion on this?

Siri Childs: Jeff is going to have to lift our spirits.

Carol Cordy: Okay Jeff. Sounds good.

Jeff Thompson: This'll be real fast, so come back and we'll get you out of here.

Carol Cordy: I've got just about 2:30, how about 2:40.

Jeff is going to talk about the children's mental health bill. You're up. You have the floor.

Jeff Thompson: Okay, so I can be really brief. What I want to do is just sort of update you where we are with mental health drugs and where we're going to go, and sort of get your general buy off and obviously when we get to more particulars I'll come back. So using evidence to drive our integration. And this is actually I think our opportunity to be more integrated not just with the drugs, but you'll hear about how we want to integrate with sort of the family and social side as well as the psychologic and screening side. So keep that in mind.

Next slide. So just to remember where we've been. We talked about narcotics, a very successful program where we stopped narcotic prescriptions and send you a 12-month prescription. 25% reduction right off the bat, and actually we've actually found out that when we stopped these prescriptions, we actually almost doubled or tripled the amount of referrals for substance abuse screening and treatment. So my take is that the passive systems aren't necessarily the best thing. Active systems where we work together actually produce incredible outcomes. Which the same is true for Neurontin use...I mean that's down about \$10 million. My only fear is Neurontin for sleep is now Seroquel for sleep. So we've got to look at that.

Second-generation antidepressants, we started the dialogue what's wrong with somebody being on two or three low dose SSRIs? And we got smart.

Siri did a nice job of publishing a nice little diagram of when you combine an SNRI and an SSRI in a reasonable evidence-based approach and that was a...both savings and safety. The last time we met we talked about sedatives in children and we continue that process. And then I'm going to just talk a little bit about where we are with ADHD and where we're going to go with the anti-psychotics.

Next slide. This one is just...we've got the websites we talked to you about, but these are...we're going to talk about how we change the actual law so that we can now share mental health drug information as well as mental health diagnoses and the medical claims with you. That was one reason why we had to slow down, because we actually had to change statutes because a mental health drug or a mental health diagnosis in the medical claims file constituted a mental health treatment record and therefore it could not be shared with you without patient consent. So we changed that law and I'll show you what that means. And then we talked about the toolkit. And then on the anti-psychotic side we're going to...we'll be reconvening a children's advisory and an adult advisory and I'm trying to work on seeing if I can't pay for that actual activity. So that'll be coming on next year. And then Nate's not here so too bad. But he's always talked about linking not only the drug outcomes with the outcomes and so what I want to do is talk to you a little bit about that.

Next slide. A little hiccup in our giddy up and some changes. Those that don't remember we have a fee-for-service site and a managed care site of which it's 60/40. The problem has been is that when a child enters into the RSN system and is found to have the access to care standards that should be in the RSN mental health then fee-for-service picks up that drug cost. The problem is that there's a whole bunch of confusion in the pharmacy community, in the RSN community, etc., etc. and so that has actually been fairly problematic. So come July, the managed care plans will actually pay for the mental health drugs. There'll be a total carve out. The rules will be the same everywhere.

Woman: [inaudible]

Jeff Thompson: You won't have...but even better than that, we're working with CHPW and Molina to actually have consistency between our preferred drug list and their formularies for mental health drugs. So we're going to work on that. And then with that, we'll have consistency in our prior authorization criteria. And they like what we've been doing, you and I have been doing with the ADHD program. So there may be some momentum to have consistency across managed care, fee for service, and consistency between preferred drug list and formulary. Not on everything, but maybe on a narrow subset. But this has been problematic along with some auditing that's been happening in the pharmacies. So that's why you've seen some...perhaps some disruptions in service.

Jason Iltz: This is Jason. Will that change affect in any way where patients will be able to receive these medications from? What I'm getting at here...the managed care side sometimes will push things off to mail order and with some of these particular medications they may fall under a specialty pharmaceutical because they're injectables, at least a small part of them are. Will that change where they can get their prescriptions or where they'll be forced to...?

Jeff Thompson: Well Molina or CHPW have a mail...do they?

Siri Childs: I'm not aware of any.

Jason Iltz: Molina does.

Jeff Thompson: For their Medicaid population? Well we'll work on that...

Jason Iltz: They use McKesson Specialty Pharmaceuticals a lot for injectables. And I know that's a small piece of it, but I just want to make sure that's not an unintended consequence that they go to their pharmacy to get their depot mental health medication and they go, "Oh, that's an injectable now, you have to get it from A, B, or C."

Jeff Thompson: That's good information, we'll talk about that when we meet with them. The next slide. So this is just the 5773 argument that the, you know, patients that were seen in the...oh actually this is, I'm sorry this is another slide. This is basically this interaction between the healthy options and the fee-for-service client and who pays for the Rx. We're going to move this Venn diagram so they're totally separate. And that will come July 1. So in the interim what we'll be working on is how do we inform the pharmacies about what the appropriate payment systems are, how do we work with the healthy options plans to have consistency? And I can't guarantee it, we're working on it, but Ms. Lindeblad is...and the health plans are actually interested in doing that because they recognize that it's problematic for them and you. And so...and the patients. We're going to be working on that.

Next slide. So just so you know we continue to work with the community on refining the ADHD prescribing, and the reason why I bring this up is that this is sort of our pattern that we'll be moving out for the anti-psychotics. On the combination use the Strattera and combination was somewhat problematic, so we met with Children's, Sacred Heart, and Mary Bridge and came up with what is a compromise and it's sort of in the vein of the Texas algorithm that we would ask that prescribers use monotherapy in the three subclasses either with the dextra-amphetamines, the methylphenidate or Strattera before they put on a combination and we have a window of eight weeks where you can cross over and make this work, but once you want to start in combinations you're going to be required to show a tried and failed with a second opinion or a good rationale why you want to begin with combinations. And that's sort of

consistent with the Texas algorithm. And so we're working on a communication for that. And so that solves I think a major issue that we've had with the second opinions in ADHD.

The next slide. The...I think it's been actually a successful program with some disruption and so before we venture into another class we'll figure out how to do this a little bit better. Sort of in everybody's defense this has never really been tried before, unfortunately we had a death of one of our second opinion docs, which threw us back. I mean anything that could go wrong sort of did go wrong, up to and including a death of one of our second opinion docs, which was a tragedy for the state. But in essence, what we've done here is with the second opinions, 57% of treatment is altered. And in that treatment alteration, it's either adjusted by the second opinion in consultation with the primary care provider, or the mental health professional, or it's denied and treatment is changed, or there's no response. And we went back and actually identified all the no responses, they maintained their same therapy. So that's the Hawthorne effect. Some of the providers said, "Well maybe I don't want to go through this hassle," but nobody had disrupted service, and in this process we only found one ER visit. There were no additional hospitalizations in these children in the 57% and there was one ER visit for a conduct disorder that we saw in all of this. So other than what Patti will say it's been a little bit problematic in implementation. The outcomes I think have been reduced dose, reduced combinations, and improved actually access to pediatric and adolescent psychiatry for both primary care and other mental health professionals.

And so we've looked at this data upside and down with the 800 reviews that we've done and so we can say that actually we do feel that care has been improved. And along with this anecdotally, many of the kids are either being hospitalized to sort of sort out what's going on, we've had three or four of those. We've had referrals over to a psychologist and more diagnostics that have gone on. And that's where we want to go next is how do we integrate this whole thing when we're looking at it? So this is the model that we want to build on with the anti-psychotics and polypharmacy. So this I think has been a pretty successful program working with you and the leadership in the mental health community. What has also been interesting is that we've reduced variation. There was a significant variation between east and west side of the state. And when I say east side of the state I mean over the mountains, not the east side of...there you go. And quite frankly, I mean there was a very big difference of opinion when it came to combination use and the use of Strattera. And by showing, without giving any names, but showing the variation across the three hospitals and by provider, there was an agreement about how we would have...we would reduce the variation and act like a state and not two separate states. So it was kind of an interesting discussion. So what we're going to do is just keep that dialogue and use data and discussion to actually reduce variation. There was really very little variation in the use of these medications under the age of five. The

documentation was actually very well done for the second opinions. Combination use was problematic as I talked about and the dosages, which is the other part of this, have actually been reduced. So very few children now are on a dose in excess of 60 mg of dextra-amphetamine or 120 mg of methylphenidate or Strattera without good indication of why they need to be on this medication. Any questions, comments?

Bob Bray: Just to satisfy my curiosity, when the variances seem to change between east and west side, did the cougar look more like a husky when it was done, or did the husky look more like a cougar when it was done, or did they just become a hybrid?

Jeff Thompson: The cougar looked more like a husky.

Bob Bray: No kidding. I'll talk to you more about that.

Jeff Thompson: Next slide. So you can see where most of the services have been looked at in a second opinion with polypharmacy, under the age of five, most of those we've actually approved and there's been good documentation with the dose limits. A couple that I was involved in, and this was really to get a child hospitalized and so we could figure out what we're actually treating here. And then the no response rate we were concerned about that was the Hawthorne effect. The children were actually continued on therapy. The provider decided not the best thing to up the dose or put a combination. So we actually went back and looked at every single one of those and all we found was one additional ER that could be a result of this program where the child had some conduct disorder. But even finding that I think has been a success.

Next slide. So the next area is to look at the anti-psychotic use. We have roughly 21,000 individuals on anti-psychotics. A third of those are children. And it runs the gambit not only with all of the anti-psychotics of which two have only been studied, but as well as all different dosages. And when we started this operation we actually had a dose that was in excess of somewhere between half and three times the FDA dosing. And you've seen those, but that's where the numbers...we're going to revisit that again because it's probably not the best evidence-based criteria, but we've got some work to do. The numbers are not small. And if we were to look at polypharmacy, we have in the under age 18, we have approximately 1,100 children that are on five or more mental health drugs. We have roughly 2,000 that are on three or more. And so what we're going to do is engage the community on what is a good safety threshold by age, dose, or combinations, and then under 1088 do another second opinion process where we're going to look at not only what's going on with the drugs, but how do we integrate our activities.

Angelo Ballasiotes: Who's prescribing those...what clinicians are prescribing these? Is it specialists or...?

Jeff Thompson: It's mostly mental health professionals with anti-psychotics. So it's nurse
[end side A]

[Side B]

Jeff Thompson: ...medical claims file as well as the prescription histories before again...before this changed I couldn't tell you if you all were prescribing an anti-psychotic to me I couldn't share that information to each one of you. So this change in the statute actually allows us to do that now, without a patient consent. But we're going to try and drive those patient consents and make sure that the clients know what we're doing.

Next slide. Under house bills 1088 which has four pilot projects for wraparound services which basically says that the RSNs more than likely will work with the families to individualize their treatment plans mostly around psychosocial family. But my challenge is going to be how do I engage the community so that not only do the second opinions know what's going on with the drugs, but they also know what the individualized family programs were going to be. There will also be a PCP education-training program that we'll pilot probably with foster care at first, but then we'll move on. And then Dr. Eric Trupin will have an evidence-based practice center where we'll start looking at evidence both from the family and social side, from the psychologic side which is at CBT or whatever treatment's most appropriate, and from the drug side and start coordinating. And then we'll start ruling out new access to care standards from the RSN services and then for children we're going to, as you asked, about increased access to mental health services, the psychiatry visits only 12 a year will go up to 20 a year and will be brought up not just to psychiatrists, but to other mental health professionals come July 1st. Those type of professionals are yet to be determined.

Carol Cordy: Jeff, the numbers increased, is the reimbursement changed?

Jeff Thompson: The reimbursement will not change. Well actually that's not true, actually the reimbursement will change. With the increase of 48% and 12% in the ENN visits so they are going...so there is a 48% increase in evaluation and maintenance for the pediatric population for those 9921s. So that increased. And then also increased on the adult side. So there have been increases.

Patti Varley: My hope would be if both providers can provide adequate care, but also get adequately reimbursed then we would have better access because what you'll find now, is even if you cover it...I have a family right now in Snohomish County that can't find anybody to see them.

Jeff Thompson: So reimbursement has changed and that...Wisdom actually published that, you'll see it. We published it too and those pay increases will start January 1, 2007. And the increased benefit will start hopefully in July of 2008. Sorry, January 2008 and July of 2008.

So that's what 1088 is. Last slide. We're going to...what my hope is is that I can work with the people running the pilot projects so that they'll share their treatment plan with the psychologists that will be doing the CBTs or whatever sort of cognitive therapy. They'll share their plan with then the treating...the prescribing provider and we can really get to integrated service. Because that's not happening that I know about. Tell me if it is, but I don't think it's happening. And that everybody has sort of got their sort of part of the elephant or their smoke stack and we're not sharing about who's doing what. And so that will hopefully be part of the integration and parody and disclosure and transparency. We'll start out at least on the drug side identifying high-risk polypharmacy age dose combinations and you'll get to approve that as we go forward. And then trying to inform the clients and providers with the outreach programs and education and then hopefully in 1088 we're supposed to actually have a report back to the legislature by January, 2009 on early outcomes. And really the only early outcomes you can really expect to have in between now and then are really on the drug side. High school graduation ain't going to happen real quick [inaudible]. So what I'm encouraging them to do is we'll be looking at early indications will be in with the pharmacy services. Intermediate will be with satisfaction, coordination, foster care placement, stabilization, those types of things. And then long term will be actually improved outcomes like graduation, reduced JRA visits, those type of things. And so you'll see actually fairly sophisticated outcome where we're marrying, you know, the triad. Any questions? Comments? So great. We're going to be doing anti-psychotics, so we'll need a lot of help from you, because that will be rather painful for some. So I'll really ask you to help me do some sales and marketing on this.

Jason Iltz: Just to anticipate on the anti-psychotic side of things. There's the information about its use in dementia and there's an issue of efficacy, there's also the issue of safety, but the thing that I think is important in that group of patients is that there isn't anything that's been shown, there is no evidence that would say something's better. Our alternatives also have kind of similar track records in that the difference between placebo and the other treatments is also very small. So I think education is good, but I think proscription of anti-psychotics in demented patients would be medically inappropriate. So I hope we don't go down that road.

Jeff Thompson: Well 1088 is primarily for children. This is all...we're talking all children here. But I think we'll be talking probably more about the adult side too as we go along and just as an aside I'm working with Sharon Farmer and Rick Reese. We've actually now done the runs on...you saw a little bit about adherence, which is horrible. And its association with re-hospitalization and sniff(?) care in the ER use. So King County has stepped up and they'll actually be doing a record review in trying to determine what are the underlying issues that give rise to lack of adherence. Not that adherence drives everything, but obviously there may be homelessness, they enter into the criminal justice system, they have

alcohol and substance abuse, they have side effects, they have lack of positive effects. We don't really know. What we do know is that from the Katie Study as many as 75% of those people that start on one don't end up with the other and a large proportion of those are sporadic adherence. And these are the people that just cycle through our institutions. And until we understand why that happens, we're never going to get a handle on our most at risk population. What I call the trifecta—chronic illness, chronic mental health, chronic substance abuse. That's what my bet is is what's happening.

So the adult side we'll be working with a group of adult consultants to figure out where to go with the adults, and I think the first thing is why are they not adherent to their anti-psychotics? Monotherapy, they take it January through December. But when you get on any more than one it's...in my mind it's a random event whether they take it. And I don't know why. And I don't think the literature even knows why. Everybody's got their ideas, but nobody's actually done a record review like Sharon and Rick and Mark are going to do. So I'll be excited to see what those outcomes are.

Angelo Ballasiotes: There's a lot of different reasons, you know, that I run across.

Jeff Thompson: Right. But it's opinion-based versus...anybody done a systematic analysis of people that have been proven to be non-adherent by claims data and try and list the top three?

Angelo Ballasiotes: Well, one of the top ones is that they stabilize and they think that they're cured.

Jeff Thompson: But again, that's peoples' opinions based on anecdote versus actually...

Angelo Ballasiotes: Right. They tell me that.

Jeff Thompson: But the other thing is I think we would also find that some of those people are probably homeless and some of them have substance abuse issues in combination with...

Angelo Ballasiotes: Well that's a different issue altogether. If they're stable and their case manager and things of this nature, but if they are homeless then you don't have any funding to, you know, help them.

Jeff Thompson: So that's where we're going to go so the next time hopefully you'll see a report out we'll have started to talk through the thresholds about how we implement 1088. Get your blessings and ask you to help do the sales and marketing. And this will be a pretty quick turnaround, so we'll actually have data for you by the end of 2008. That'll be groundbreaking.

Carol Cordy: Any other comments? Questions? Do we need to do a motion to...somebody want to make a motion to...?

Patti Varley: Probably.

Carol Cordy: Anybody want to make a motion to a...

Jeff Thompson: Whatever you want to motion.

Carol Cordy: Whatever you want to motion.

Siri Childs: Just accept the reports.

Carol Cordy: Accept the reports.

Siri Childs: Into the record.

Carol Cordy: Okay.

Man: [inaudible]

Carol Cordy: Is there a second?

Man: I move we accept the report into the record.

Carol Cordy: All in favor?

Group: I.

Carol Cordy: I have three, that was one...three matters of business here. The second one is just to confirm that you will draft a letter for us about the availability of prescribers practices to the prescribers.

Jeff Thompson: What I'll do is I'll send it out to all of you and you guys work in yourself and come to an agreement and draft and then we'll get a final copy, you know, Siri and I will work that out and we'll send you the final draft out for all your signatures.

Carol Cordy: Okay. So what I would be happy to do is if you would send me your comments and edits, I'll try and pull that all together, send a letter back out and then we'll get...

Jeff Thompson: And we'll send you the information on what the legislature...where that was with the electronic and narcotic reporting so you have some background.

Carol Cordy: Okay. And then in January you will give us our assignments?

Siri Childs: February.

Carol Cordy: Oh in February, okay. And then we...so no meeting in December. We meet again here on the 20th of February?

Regina Chacon: There will be no meeting in December. And then next one will be February.

Vyn Reese: Do you have the schedule out for next year?

Regina Chacon: It's not posted yet.

Vyn Reese: So we...

Regina Chacon: I'm waiting for Jeff Graham to get back next week and we'll finalize it then.

Vyn Reese: So all we know is it's the third Wednesday in February, that's the only meeting we know about currently?

Man: Yeah, Jeff's been suffering in Paris, so you need to give him a hard time.

Siri Childs: Regina do you know where it will be at?

Regina Chacon: Not yet. They won't allow me to make reservations that far out.

Carol Cordy: Okay. So unless there's anything else we will adjourn until February. We'll see you on the 20th.