



Washington State Health Care Authority  
**Prescription Drug Program**

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UNOFFICIAL TRANSCRIPT\*  
WASHINGTON STATE  
PHARMACY AND THERAPEUTICS COMMITTEE MEETING  
June 17, 2009  
Sea Tac Marriott Hotel  
9:00am – 4:00pm

- Vyn Reese: Hi. This is Dr. Reese and welcome to the State Pharmacy and Therapeutics Committee. Let's start with introductions and we'll start over there on the left.
- Chuck Agte: Chuck Agte, Pharmacy Program Manager with Medicaid.
- Siri Childs: Siri Childs, Pharmacy Administrator with Washington Medicaid.
- Jeff Thompson: Jeff Thompson, Washington State Medicaid.
- Jaymie Mai: Jaymie Mai with L&I.
- Doug Tuman: Doug Tuman with L&I.
- Jeff Graham: Jeff Graham, Health Care Authority.
- Janet Kelly: Janet Kelly, P&T Meeting.
- Patti Varley: Patti Varley, P&T Committee.
- Ken Wiscomb: Ken Wiscomb, P&T Committee.
- Vyn Reese: Vyn Reese, Chair, P&T Committee.

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

Carol Cordy: Carol Cordy, P&T Committee.

Bob Bray: Bob Bray, P&T Committee.

Regina Chacon: Regina Chacon, Health Care Authority.

Donna Sullivan: Donna Sullivan with PEBB Plan Management.

Elizabeth James: Elizabeth James, PEBB Plan Management.

Duane Thurman: Duane Thurman, Health Care Authority.

Ray Hanley: Ray Hanley, Health Care Authority.

Vyn Reese: Are there any announcements? Dr. Graham?

Jeff Graham: I don't think so.

Vyn Reese: Let's begin with our first presentation. It's a drug class review on agents for over active bladder and Marian McDonagh I believe is presenting.

Jeff Graham: I think Dana Selover.

Vyn Reese: Is Dana on the line?

Dana Selover: I am.

Vyn Reese: Why don't you go ahead. The first slide is up.

Dana Selover: Okay. I'm trying to get my slides to work here. Okay. Good morning everyone through the telephone on this once sunny and now gray day but we're hoping it will change. Um, quick question. I always check in. You have heard over active bladder presentations before so the consensus is to work on the new information?

Vyn Reese: We've heard them before.

Dana Selover: Okay. So you'd prefer to have it be a focus on the new information and just what's changed?

Vyn Reese: Exactly.

Dana Selover: Okay. Good. And where there is context to be...add I'll go ahead and do that. In any case...so we can skip to slide 3 with the inclusion criteria if that's possible. Here is the list of the medications that were looked at. The only new drug that we have this time is trospium chloride extended release. Other than that we've had everything before. Darifenacin had a couple of new studies published that were in abstract form before, but for the most part we have the same drugs that we had before and I want to just say, um, previously you'll hear...or you'll see long-term and short-term, immediate release short-acting and extended release long-acting. Um, those are synonyms. So immediate release means short-acting. Hopefully we tried to get that right, but just in case anybody was wondering and extended release or long-acting formulation. So we talk a lot about the drug this time in those terms. So we'll move on to the next slide.

Um, the included outcomes are pretty much the same as previous reports. Efficacy measures are the same, incontinence episodes, micturitions and mean number of pads in 24 hours, subjective patient assessment, not a lot of new quality of life information but a little bit. Safety outcomes the same as usual. Overall and specific adverse events and withdrawals due to adverse events and serious adverse events. When we talk about key question 1 we focus on the head-to-head studies and we fill in the gaps with placebo evidence. So we'll move on to the next slide.

We have 44 new studies in update 4 and I forgot to mention on the onset that this is up until December 2008. So just to put it in a date perspective because I'm sure you're listening to reports from all different kinds of dates. So this is the end of last year when the final search was done and when the report was finished. There is one head-to-head study that I had mentioned before that was previously an abstract with darifenacin versus oxybutynin immediate release. Two post-hoc analysis with the OPERA trial and one sub analysis of the STAR trial and that comprises our head-to-head. So two were for comparative efficacy, one for comparative safety, and one was a subgroup comparison. In addition we included 27 active and placebo controlled trials, an observational study for safety, 1 systematic review and 11 others, which are mostly comprised of pooled analysis and they were sub populations and new looks of things. So we'll move on to the next slide.

Um, nothing new here. We're in key question 1 and we're looking at the evidence of comparative efficacy of short-term versus...or short-acting with short-acting. So this is oxybutynin in immediate release compared with tolterodine immediate release and this is no particularly new information so we'll move to the next slide.

Again, short-acting versus short-acting key question 1. We still have the immediate release versus the immediate release and there's new information. The...let's see, sorry about this, I haven't looked at this for a while. All right, I think we'll move on to the next slide and just remind you about the transdermal forms, so slide 8.

Oxybutynin transdermal versus oxybutynin immediate release. This is one trial and again no new information here. Um, the next slide, slide 9 also has a transdermal versus tolterodine extended release. We'll talk about all the details...or the general details in the summary, but we can probably skip this one for the time being.

Slide 10. This is comparative efficacy of long-acting versus other long-acting drugs or extended release. I do want to go through this one real quick because there are some new head-to-head trials...sub analysis and um...so the OPERA trial just as a reminder is oxybutynin extended release compared with tolterodine extended release. It was almost 800 patients and the original study didn't find much difference in the mean change in the weekly urgent incontinence episode so...which was a primary outcome measure and the mean change in weekly incontinence episodes or mean change in micturitions. So there was no difference there. There was a difference in a different outcome, which was percent continent per week and there oxybutynin was somewhat better than tolterodine, but that was the only difference and that was in week 12. So that's the OPERA trial. We'll move on to the next slide.

Again, long-acting versus long-acting and this is the STAR trial. So these are the two big head-to-head trials that we looked at. Solifenacin extended release versus tolterodine extended release and you'll see at the bottom there is some new information, it's a post-hoc analysis done in 2007 and...oh, oh...solifenacin 5 mg was compared with tolterodine 4 mg daily. Originally they had two different doses of solifenacin 5 in 10 mg and it was a noninferiority trial. So now they wanted to compare only those patients who got and were on solifenacin 5 mg to the group that had

tolterodine, which did not change dose. Here they found a greater mean reduction in incontinence episodes for solifenacin 5 mg compared with tolterodine and pad use and you see the numbers there, the significant results were given. But there was no significant difference for the other efficacy outcomes that were measured as the ones that were shown before. So this is a small post-hoc analysis head-to-head. We'll move on to the next slide. Here we have long-acting with short-acting. So immediate versus extended release and the new information is at the bottom. Darifenacin was compared with oxybutynin immediate release in one trial and there were no important differences in efficacy. We'll move on to the next slide.

Also long- versus short-acting and here this is an older trial. This is not new information and in the summary we'll tie that all together. Here is the study that I mentioned at the onset. It was...in the previous version we had only the abstract and now we have the complete paper that was published in late 2005. This is darifenacin compared with oxybutynin immediate release. It was a short cross-over trial, two-week study and it compared 30 and 15 mg doses of [inaudible] with oxybutynin at 5 mg 3 times daily. They found that...well, as you can see here the reductions in mean micturitions darifenacin was somewhat different but...I'm trying to see this...there were...okay...so you can see by the numbers this is the mean micturitions per 24 hours, 30 N 15 and then oxybutynin immediate release versus placebo and you can see that placebo is the lowest one at .91. So the best were oxybutynin immediate release and 30 mg. About the same goes for the urgency and incontinence episodes. Darifenacin 30 mg were effective and the 15 mg and then oxybutynin worked better than the 15 mg. I will tie this all together in the summary. It will be easier to understand. We'll move on to the next slide.

We found no evidence comparing scopolamine [inaudible] extended release, which is a new drug hyoscyamine to another OAB drug. There was one trial and this is old information of flavoxate versus oxybutynin immediate release, a poor quality trial. And there were no trials at all for [inaudible]. So we'll move on to the next slide.

Here's the placebo evidence for the newest drug, trospium extended release and you can see that it was better than placebo in both of the trials for the main outcome measures, incontinence episodes and micturitions were both 12-week studies. We'll move on to the next.

We're moving on to key question 2. Longer term evidence is in general limited and the overall grade of the evidence is poor. Dry mouth is the most commonly reported adverse event for oxybutynin and tolterodine and for that matter for most of the other drugs and the rates of this and other adverse events are similar with both drugs. Move on to the next slide.

This is a longer term study comparison of adverse events and this is no new information. We'll move on to the next one.

This is old evidence, longer term studies in comparison of adverse events, trospium immediate release versus oxybutynin immediate release. We'll move to the next slide.

Here is some short-term evidence also no new information is concluded in the previous report. A little bit about the transdermal drug. Next slide, slide 21.

Also old information. We'll skip to slide 22.

This is the new head-to-head evidence; one of the head-to-head trials did look at safety. It was a post-hoc analysis of the OPERA trial, which was a comparison of the two long-acting or extended release drugs. The post-hoc analysis showed that...they were looking at the severity of some of the adverse events, specifically dry mouth and for overall severity 28% had dry mouth with oxybutynin compared to 21.6% of tolterodine extended release and that was a significant difference. So that's the only new information there. The STAR trial is also old information with comparing adverse events so we'll move on to the next slide.

Here is some short-term evidence. This is again that trial darifenacin extended release compared with oxybutynin immediate release and the newer trials. It was a very short trial, it was only two weeks. It was a cross over trial so you kind of have to remember that when you're looking at some of these adverse events. Darifenacin 15 mg compared with oxybutynin was...so it was better in the dry mouth 13% to 36% and that was significant. If you remember the 30 mg, which was the one that tended to have the higher efficacy rates for the outcomes...or for the efficacy outcomes was not significantly different in dry mouth. So 34

versus 36%. So that's kind of important to remember. We'll move on to the next slide.

This is adverse event information from the STAR trial, which is not new. So we'll move next.

A quick reminder that the short-term evidence from the OPERA trial this was actually a post-hoc from...or the last update and it's from the OPERA trial. It's specifically for CNS evidence. So it's older evidence and we'll bring it back up in the summary. Next slide, slide 26.

A little bit of new information here. Withdrawals due to adverse events and that is another...in addition to adverse events in general be they less serious and serious. Withdrawals due to adverse events is another indicator and there was that...there is this two-week cross over trial again, darifenacin versus oxybutynin immediate release and found that darifenacin 30 mg had fewer withdrawals versus oxybutynin immediate release. So that's 15, 30 mg and then oxybutynin immediate release 0., 1.6 and 6.6 and the rest of the information here is from previous reports. So we'll move on to the next slide.

This is discussing key question 3, subpopulations, which is very interesting in this drug specifically. For gender this is older information. There is no new information there. There were quite a few...there was a post-hoc subgroup analysis and some pooled analysis in older patients, but it just found that they were...that older patients did respond to tolterodine extended release, darifenacin and solifenacin. So [inaudible] head-to-head trials and we'll move on to the next slide.

For differences in race and ethnicity solifenacin was found to have a response and adverse event rates in Hispanic subgroups that were similar to the overall trial population and that was one study. The other information here is older. So we will move on to the next slide. Looking at patients with comorbidity there was one [inaudible]. Of men taking alpha adrenergic antagonists for symptoms of benign prostatic hypertrophy with residual symptoms of overactive bladder and they added...with some of the patients they added tolterodine extended release to that drug and found significantly improved symptoms related to both the active...overactive bladders of both diseases and the benign prosthetic

hypertrophy compared with either of the drugs alone or placebo. So that information came from two studies. We'll move on to the next slide.

And here, um, hopefully I can tie it all together. Um, comparative efficacy, also known as key question 1, extended release compared with immediate release formulations of the same drug no difference in efficacy. Extended release compared with immediate release formulations of different drugs mostly showed superior efficacy for the extended release or the long-acting drugs, but not in all cases. So it's not an across-the-board difference. There was no difference in comparative efficacy of immediate release drugs. That's different drugs compared to one another and in the comparisons of oxybutynin extended release versus tolterodine extended release the better of the two trials found them to be equal. Next slide.

Looking at comparative safety in the longer term observational trials dry mouth was the most common adverse event just as a reminder. The short-term trials made direct comparisons...making direct comparisons so head-to-head comparisons showed a higher rate of adverse events overall and specifically dry mouth was more frequent when oxybutynin than with the other drugs. Differences in adverse event profiles [inaudible] between long-acting and short-acting drugs is unclear and the comparisons of extended release and immediate release drugs found mostly higher rates of adverse events for the immediate release formulations, but the differences in the withdrawal rates due to adverse events and discontinuation were not necessarily found. So we don't have an across-the-board safety difference for long- versus short-acting. The next slide.

This is a summary of the evidence for key question 3. There really was no consistent differences in efficacy or safety found in the two genders, men and women and there was efficacy of oxybutynin and tolterodine, darifenacin and solifenacin found in older patients in some of the post-hoc analyses. Adverse event profiles for older patients were similar to the overall population so they didn't suffer from any of the safety issues more than the younger patients. And older patients are generally defined as, for these studies, as 75, 80, 85, 90. So it's definitely not the 50-year-old population. Comparative efficacy and safety in racial and ethnic subpopulations showed no differences. There's a little bit more on the key question 3 and this will just talk about the men with the comorbidities and that adding tolterodine to the alpha adrenergic antagonists resulted in

improved symptoms for both of the diseases compared with the individual drugs or placebo and that was two studies. And we are finished with the new and the old information. Are there any questions?

Carol Cordy: This is Carol Cordy. I have one question. On the adverse events, the last slide or second to last slide, for elderly compared to younger people were things like falls and dizziness included in those or was it just dry mouth?

Dana Selover: I'm not sure that they looked...they did look at CNS events. So central nervous system events were included in that. But they obviously looked at mainly the...I don't know that they could say that...with definitive evidence that the dizziness and that kind of thing was a specific drug. I can look that up, that question specifically, but as I remember correctly I don't think that was the focus. I think they were looking more at dry mouth and that kind of thing.

Carol Cordy: Thank you.

Vyn Reese: Hi. This is Dr. Reese. I'm still perplexed about CNS toxicity. It talks about older patients having no more adverse events. It doesn't talk about older patients who may have some mild cognitive difficulties to begin with being given these drugs. Those types of patients are excluded from these studies. Is that right?

Dana Selover: Um, sometimes they are and sometimes they aren't. So I can't say in this specific...in these three...there were three new drugs—oxybutynin, tolterodine extended release, the post-hoc analyses so I can't say for sure but I can take a look at that and get back to you.

Vyn Reese: And the other thing is that it was already mentioned in one of the larger reviews is the BEHRS report cautions against using oxybutynin in the elderly because of anti cholinergic CNS events and do we have any evidence that any of these drugs are any different than oxybutynin or is there just no evidence at all as far as CNS toxicity?

Dana Selover: Well, we only had one of the...CNS toxicity you have to look at it mostly in placebo trials because there is not a lot of...we focus on head-to-head evidence and the only CNS toxicity that...or head-to-head trial that we had was that on slide 33, which is the summary slide, the spinal cord patients, so they haven't...there haven't been studies that specifically do

head-to-head trials and focus on CNS toxicity. But I would have to take a look, again, at those pooled analyses that they did and I can't say for sure right now.

Vyn Reese: Any other questions from the committee? Dana, could you remain on the line while the stakeholders comment?

Dana Selover: Sure.

Vyn Reese: The first stakeholder is Dr. Gary Comstalk from Pfizer.

Jeff Graham: Dr. Reese, this is Jeff Graham. I'll be timing each of you. You have three minutes to present and please identify if you're sponsored by anybody.

Man: Dr. Gary [inaudible] has done two published studies on the comparative analysis of cognitive function using the name face recall. He's used oxybutynin as a positive comparator in both studies. One study was sponsored by Novartis using darifenacin or Enablex. It was a three-week cross over study and in that study darifenacin Enablex compared to placebo showed no decline in cognitive function. Oxybutynin in the three-week study showed the patients aging as if they had aged 10 years in cognitive decline. He did a similar study with Detrol LA using oxybutynin as the active comparator and in that three-week cross over study oxybutynin behaved as if the patient's aged 20 years in cognitive decline. His secondary in point in that study was looking at the patient's awareness of their decline in cognitive function and they were not even aware that they had declined at the end of three weeks.

Vyn Reese: Thank you.

Gary Comstalk: So again I'm Gary Comstalk. I'm with Pfizer. I'm a Senior Director in the Regional Medical Research Group. I'm a licensed physician in the State of California and a board certified OB/GYN. Fesoterodine fumarate, brand name Toviaz is a new anti-muscarinic agent. It was approved for the treatment of OAB in late October 2008. There were two registration studies so I'm not exactly sure why it wasn't included in the review. Those registration studies were published in 2007 and again it was approved in October 2008. If you may I'd like to present some of the clinical highlights of that data.

Toviaz has been approved for the treatment of over active bladder and the associated symptoms of urge urinary continence, frequency and urgency. It's a competitive anti-muscarinic receptor antagonist available in two doses 4 and 8 mg for dose titration to achieve optimum symptom control. After oral administration Toviaz is rapidly and extensively hydrolyzed by non specific esterases to its active metabolite 5 hydroxymethyl tolterodine or 5 HMT. The formation of the active moiety 5 HMT does not occur via oxidation of the liver and hence does not require the cytochrome P450 system in its formation. This metabolic pathway is the active moiety...avoids the genetic and metabolic variability of the cytochrome P450 system can exhibit leading to a much more consistent and predictable level of active drug among a variety of patients. Two phase 3 registration trials established the efficacy and safety of both doses in Toviaz, and again these are both published, 2007. Multiple primary and secondary endpoints measured in both trials revealed statistically and clinically significant improvements with Toviaz 4 and 8 mg. For the sake of brevity I'll concentrate on one of the co primary endpoints with perhaps the greatest clinical impact for patients—urge urinary continence episodes per 24 hours were reduced by a median of 80% at 4 mg and 87% at 8 mg versus 50% for placebo and the international study with the reduction 67.4% at 4 mg and 81.8% at 8 mg versus 40% for placebo at 12 weeks in the U.S. study published by Vic Neddy(?), Lead Author. All values are statistically significant versus placebo. The two most common adverse events seen in the study were dry mouth and constipation as is typical for this class of drugs. However, discontinuation due to the most common adverse event, dry mouth, was less than 1% for the highest dose of Toviaz and this reflects the predominantly mild to moderate nature of this AE. Also constipation rates were low, 2% for placebo, 4% for Toviaz 4 mg and 6% for Toviaz 8 mg. CNS side effects were also low and comparable to placebo.

Importantly, Toviaz is the first anti-muscarinic drug to launch with safety data from a three-year, open label extension study that is also included in the label. Over three years 12.6% of subjects discontinued due to AEs, 1.7% dry mouth, 1.1% constipation. There were no unexpected adverse events and no clinically relevant changes in vital signs or...

Jeff Graham:

Gary, would you conclude your remarks, please. Your three minutes is up.

Gary Comstalk: Toviaz is also being launched with a comprehensive patient support plan called Your Way. It's an engaging program that...it's a dual approach using pharmacotherapy and behavioral intervention and focuses on four guiding principles including diet, bladder training, tracking your progress and daily treatment. Thank you very much for your thoughtful consideration. I'm open to any questions.

Vyn Reese: I have a question for Dana. Is there a reason this drug wasn't included in our review? Did it come on board too late?

Dana Selover: Yes, actually that was the case with this drug and we looked...we got comments from the industry probably in November and by then it was too late to include the drug because we started...we start back in June and then we finish our things in August and we did the review last fall and it was completed in December. I think they just missed the cutoff.

Vyn Reese: Can you comment on these cognitive studies that the speaker eluded to? Were there problems with the study design or why weren't they included in our review?

Dana Selover: The cognitive studies that were re...the new drug studies or the original? Oh, the first commentors? Yeah, I was just taking a look again and it does look like most of the older adults in the placebo controlled evidence was done not on...on patients with comorbidities but they were well functioning ambulatory adults. So they were not done on patients who previously had cognitive decline or had some dementia. Probably the nature of the studies...um, why those studies were not necessarily included...did you...for the commentor did you comment on the review of the...in December? And were these added? There's hundreds and hundreds upon thousands of studies so I don't know why these weren't necessarily included.

Man: I'm not sure of...

Jeff Graham: She's asking you if your company commented on the draft reports on this draft report.

Man: No.

Jeff Graham: Okay.

Dana Selover: Okay. Because sometimes...I mean many times some of that information comes in at the last minute. Often times that information...those are not fully published studies. Sometimes they are abstract, sometimes they are different kinds of information that don't necessarily meet the relatively strict conclusion...or inclusion criteria for the DERP reviews.

Vyn Reese: So in some...this new drug was a little bit too late in making this review and, you know, we have a special interest in CNS toxicity so I'm really...would like you to look at that again if we have new studies in that area for our next...the next time we look at this drug class. It's pretty important in making our decision as to differences in the drugs in CNS toxicity.

Dana Selover: Right. I will make a note.

Vyn Reese: Great. Thank you. Thank you Dr. Comstalk. The next speaker is Fred Amburger of Novartis and I want to remind you again you have three minutes to talk.

Fred Amburger: Good morning. I'm Dr. Fred Amburger. I'm a scientific director with Novartis Pharmaceuticals and I thank you for the opportunity to speak to you this morning regarding Enablex. Enablex is a potent selective muscarinic M3 receptor antagonist that's been shown to be safe and effective in the treatment of OAB with symptoms of urge urinary incontinence or UUI, urgency and frequency. In vitro studies using human recombinant muscarinic receptor subtypes show that darifenacin has greater affinity for the M3 receptor than for other known muscarinic receptors. Specifically a 9 and 12 fold greater affinity for the M3 compared to M1 and M5 respectively and 59 fold greater affinity for M3 compared to both M2 and M4.

The safety and efficacy of Enablex was evaluated in three randomized fixed dose placebo-controlled, double-blind, 12-week studies and one similar dose titration study. Reductions in weekly UUI episodes were significantly greater than with placebo in all four studies. In the fixed dose studies reductions in weekly urge urinary incontinence episodes decreased on average by 68 and 77% for the 7.5 and 15 mg doses respectively compared to reductions of 54 to 58% for placebo.

An electrophysiology study at doses up to 75 mg, which is five times the usual...five times the maximum dosage Enablex did not result in QT or QTC interval prolongation at any time during the study state and Phase 2 and Phase 3 clinical studies the change in median heart rate following treatment was Enablex was no different from placebo.

A Phase 4 clinical study compared changes in heart rate between tolterodine extended release at 4 mg and darifenacin 15 mg in healthy participants. Tolterodine is considered a non-selective, anticholinergic with affinity for both M3 and M2 receptors while darifenacin is a selective anticholinergic with greater affinity for M3. Since M3 receptors are located in the heart, anticholinergic medications may have an effect on heart rate. Darifenacin treated subjects at HR levels comparable to placebo over the 24-hour period. Tolterodine treated subjects demonstrated a statistically significant increase when compared to placebo by 1.4 beats per minute. The change in mean 24-hour heart rate from baseline after treatment with darifenacin compared to tolterodine was -1.84 beats per minute and was considered significant. The proportion of patient...of participants with an increase in 24-hour heart rate greater than 5 beats per minute was significantly greater for tolterodine compared to both placebo and darifenacin specifically 1 in 4 versus 1 in 10 for both groups. There were no serious adverse events with the most common event being dry mouth.

Jeff Graham: Would you conclude your remarks, please?

Fred Amburger: I have concluded...one comment is that our dosage recommendation is to begin with 7.5 mg and increased to 15 mg. The DERP report includes studies of 30 mg, which is more than we recommend in the U.S. Thank you for your opportunity.

Vyn Reese: Thank you. Any questions from the committee? Let's move on to our last stakeholder, Ms. Lee Platy(?) from Astellas.

Lee Platy: Good morning. I'm Lee Platy from Astellas Pharmaceuticals and I'm here to talk about Vesicare solifenacin. Vesicare 5 and 10 mg tablets are indicated for the treatment of over active bladder with symptoms of urge, urinary incontinence, urgency and urinary frequency. In our four 12-week, double blind, placebo-controlled pivotal trials with over 1,800 patients the rate of dry mouth for 5 mg was 10.9%. 51% of the patients

that were incontinent coming into the trial were continent on a three-day diary at the end of the trial. And of the patients that decided to continue into an additional 40 weeks for a 52-week trial 81% were still on drug at the end of the trial.

We did a study on urinary frequency...urgency as a primary endpoint because patients told us that urgency was their most bothersome symptom. In a 12-week randomized double blind, placebo-controlled trial of Vesicare 5 and 10 versus placebo it was a statistically significant reduction in mean numbers of urgency and urge incontinence episodes and a decrease in warning time of 31 seconds. That may give the patient a chance to avoid an incontinent episode and warning time was defined as that sense from the first urgency to actually voiding. There was two interesting presentations at AUA last month. One was the Vectra(?) trial; Dr. Sandra Hershorn(?) of Toronto presented it. It was on oxybutynin immediate release 5 mg versus Vesicare 5 mg in OAB patients. It was a randomized, multi center prospective, double blind, double dummy in 132 patients. Dry mouth was statistically significant lower in Vesicare with 75% recorded as mild versus 30% mild in the oxybutynin group. Vesicare was associated with fewer overall AEs, lower severity of AEs and fewer drop outs due to AEs. Two of 68 versus 12 of 64.

Dr. Steven Kaplan of New York also presented a very interesting trial where patients were switched from brand name drugs to generic oxybutynin because their primary care physician either switched them over or their insurance company mandated it. They were switched from Detrol LA, Vesicare, Enablex or Sanctura extended release. There were slight gender differences, but overall patients experienced more frequency, 2.1 to 2.4 episodes, more nocturia 1.2 to 1.4 episodes and more urinary incontinence, 40 to 46% increases when they were switched to the immediate release oxybutynin. In addition, there were increase in side effects in both genders.

Jeff Graham: Would you conclude your remarks, please?

Lee Platy: Thank you. Dry mouth was increased by 14 to 23%, constipation by 32 to 34%. So patients benefited from spending on a name brand drug. Safety, we've gone over the safety [inaudible] trial. CNS related effects were similar to placebo and the other side effects are consistent with the classic [inaudible]. Thank you very much. Questions?

Vyn Reese: Thank you.

Lee Platy: Thank you.

Vyn Reese: I'll now turn over the subject to the committee for discussion and motions.

Jeff Graham: Dr. Reese, could we let Dr. Selover go?

Vyn Reese: Yes. Thank you very much for your presentation.

Jeff Graham: Maybe she already hung up.

Vyn Reese: I think she already left.

Dana Selover: Thank you. I think that was directed to me.

Vyn Reese: Yes. Thank you. You can leave us now. Thanks very much.

Dana Selover: All right. I will do so. Thank you. Bye.

Jeff Graham: That might be Marian.

Vyn Reese: She's on mute. Is there any additional discussion on these drugs or are we ready to make a motion?

Carol Cordy: This is a scan, right?

Vyn Reese: No. This is a full review.

Bob Bray: This is Bob Bray. The only discussion I would mention is that it looks to me like the new evidence would not, in my opinion, change the prior motions that we've made. I suggest that we continue with the same motion.

Vyn Reese: Would you like to make that motion? You made it the time before last, I guess, and Dr. Gaster who isn't with us today made it the last time. Um, would you like to craft that motion, please?

Bob Bray: So after considering the evidence of safety, efficacy and special populations for the treatment of over active bladder, I move that darifenacin, flavoxate hydrochloride, hyoscyamine sulfate, oxybutynin, scopolamine, solifenacin, tolterodine and trospium chloride are safe and efficacious. NO single incontinence medication is associated with fewer adverse effects in special populations. These drugs can be subject to therapeutic interchange in the Washington Preferred Drug List, immediate release formulations cannot be interchanged for long active formulations and vice versa. One long acting formulation must be included as a preferred drug on the Washington Preferred Drug List.

Vyn Reese: The only corrections I would make are a couple of those drugs are only in Canada. So we have to delete them. I think it's scopolamine and hyoscyamine are only in Canada.

Bob Bray: I would agree with that as a friendly amendment.

Vyn Reese: Is there any discussion on Dr. Bray's motion or any other amendments?

Carol Cordy: Just a comment. They should not be capitalized. These are not brands and I don't know if we need to say anything about the short- and long-acting since that's addressed in the next section. We're assuming these are the short and long acting formulations.

Patti Varley: This is Patti Varley. I know at one point the scopolamine Transderm was pulled and I see that there was one form of the scopolamine only available in Canada, but does anybody know is the Transderm back available?

Bob Bray: Yes, it is. This is Bob Bray.

Patti Varley: So that should be included?

Vyn Reese: I don't think it's approved in the U.S. for over active bladder. It's only for motion sickness I believe.

Patti Varley: That's what I...that's why I was confused. Okay.

Vyn Reese: If there's no further discussion can we get a second to Dr. Bray's motion?

Jason Iltz: This is Jason. I'll second.

Vyn Reese: Motion has been made and seconded. All those in favor say, aye.

Group: Aye.

Vyn Reese: Those opposed, same sign. Dr. Bray's motion is passed. Let's move on to our next update on the proton pump inhibitors and Marian McDonagh is the presenter here I believe.

Marian McDonagh: Yes.

Vyn Reese: Are you on the phone?

Marian McDonagh: I am.

Vyn Reese: Great. Just a second. We're trying to get the slides up.

Marian McDonagh: Okay. Just let me know when you're ready.

Vyn Reese: Okay. Now we're ready.

Marian McDonagh: All right. So this is the fifth update of this drug class review and so if we go to the second slide, slide 2, the searches are up through March of 2009 and then we're going to slip to slide 4. So the inclusion criteria are all the same as they have been for all six versions of this report. There is however a new key question that was added this time. This is looking at the evidence; different treatment strategies for treating after eight weeks in patients with gastro esophageal reflux disease and specifically we were asked to look at standard dose versus lower dose proton pump inhibitor, PPI versus an H2 antagonist. So some different strategies there for what to do after eight weeks. Then if we go to the next slide.

Just a quick summary of what was included. We had 55 new studies in this update. So we'll get right into it.

On slide 6 we have...looking at symptom relief in patients for erosive esophagitis. The new evidence doesn't change our main finding that at comparable doses we do not find differences between the PPIs. We did find...add one new study; however, to the esomeprazole 40 mg versus omeprazole 20 mg comparison that made a small change to the pooled risk

difference. Previously it was a risk difference of 5% and now it's 8%. So if you want to look at Figure 2 in the report, page 19, it shows all of the studies and adding this one. On the next slide, slide 7.

For endoscopically proven healing, healing rates in patients with erosive esophagitis again we added a new study that changed the pooled risk differences slightly for esomeprazole 40 versus omeprazole 20. So at 4 weeks previously the pooled risk difference was 8% and with the new study it is 7% and at 8 weeks the pooled risk difference is now 5% and it was 6%.

Vyn Reese: Marian, can I ask you a question real quickly. Isn't there really a difference in potency between the esomeprazole 40 versus the omeprazole 20? Isn't that the 40 mg dose two or three times more potent than the 20 mg dose?

Marian McDonagh: Yes, that is correct. That is why on the first slide there we say that at comparable doses there's really no difference. But when you start looking at the esomeprazole 40 versus relative lower doses of the other PPIs that is the only time that you find differences out of...there are over 30 head-to-head trials so this is the only place where you see any difference at all.

Vyn Reese: Okay.

Marian McDonagh: On slide 8 there is no new evidence.

On slide 9 healing in patients with moderate to severe erosive esophagitis. So looking at the severity we added some new evidence on esomeprazole 40 versus pantoprazole 40 and here at 4 weeks esomeprazole is still superior. That evidence was in a previous report. But at 8 weeks now we find no difference although it was a small study.

On slide 10 prevention of relapse for a maintenance of healed esophagitis we find that there is still good evidence that there's no difference between omeprazole, lansoprazole and rabeprazole over periods of six months to five years. We did add some new evidence however that shows that esomeprazole 20 mg is superior to lansoprazole 15 mg. But we find mixed evidence on the comparison of esomeprazole 20 versus pantoprazole 20 with one study each finding no difference and one finding esomeprazole superior for maintaining healing.

Now on the next slide, slide 11, non-erosive or presumptively treated GERD we don't have any new evidence there.

Slide 12, looking at esophagitis in children we find no new evidence.

On slide 13 for peptic ulcer we did find some new studies here but the bottom line still is that with...we added three new studies overall and there was still no difference now between the proton pump inhibitors for treating gastric or duodenal ulcer.

Now on slide 14 we do have new evidence on the prevention of NSAID induced ulcer. The bottom line finding is that there's no difference between the PPIs in preventing ulcer with non-selective NSAIDs and that was from one study where they were looking at pantoprazole 20 mg, 40 mg and omeprazole 20 mg. The only evidence we have on the COX-2 inhibitors is from placebo-controlled trial evidence where esomeprazole was found to be superior to placebo in a subgroup analysis from a larger study.

On the next slide, slide 15 looking at helicobacter pylori. So this is looking at the eradication rates. It doesn't make a difference which proton pump inhibitor you use. So we know have 29 head-to-head trials in the report and 5 systematic reviews. We went back and did a pooled analysis of eradication rates, stratifying by numbers of days of treatment and the dose comparisons and didn't find a statistically significant difference between any of the drugs. But it is difficult to make good comparisons because the difference is in the other parts of the regimen. So we tried to make everything as similar as we could within each analysis. But I do note that certainly antibiotic choice and the regimens do vary.

Slide 16 simply introducing again that we have this new key question looking at different treatment strategies following resolution of symptoms with gastro esophageal reflux disease.

So on slide 17 we have the first group, which is standard dose proton pump inhibitor versus low dose and in general here with evidence on time to remission, rates of endoscopically verified remission and relapse of symptoms we find that the higher dose is superior to the lower dose with the exception of lansoprazole where the higher dose and lower dose were

not different to each other in the time to remission. And no difference between dose strategies for esomeprazole and lansoprazole in the rates of endoscopically verified remission at six months.

On slide 18 this is looking at standard dose proton pump inhibitor compared to either intermittent dose or on-demand proton pump inhibitor and here we find that in patients who had endoscopically verified esophagitis that the daily dosing is superior. Patients who had endoscopically verified non erosive esophagitis that the regimens are equivalent. But if it's unknown, the patient never had an endoscopy then the evidence is mixed. There's no clear winner there.

On the next slide, slide 19, looking at proton pump inhibitors versus changing over to an H<sub>2</sub> antagonist the proton pump inhibitors are superior in maintaining healed erosive esophagitis in adults and then we have limited evidence, one study in children that also found the PPI to be superior.

On slide 20 is no new evidence here on comparative harms.

But on slide 21 we did find one additional study that does compare the PPIs to one another for harms. So this is the results of a study out of a Pharmacovigilance database in Spain. The database is a collection of spontaneous reports of adverse events and I hear they are looking at PPIs alone or do a drug interaction. So there was a determination made that the report was caused by the PPI. So they had a total of 680 reports for PPIs, but the total number of adverse event reports during this time period is not reported, which is a problem because the odds ratios they present are in comparison to the overall...all the other drugs in the database during that time period.

So if we go to the next slide, slide 22, you'll see they grouped the adverse events by organ system and then they have the PPIs that had an increased odds ratio compared to the other drugs in the database for each of these listed. The other caution that I would say about this study is that they did not control for the volume of prescriptions for each of the drug that were in...given during that time period in Spain. So that is a problem. We have a more numerator data than...it's not controlled for that denominator.

On the next slide we have non-comparative evidence for harms in children and it's very limited. We do find that there were no serious adverse events reported in the observational studies we found although there were elevations in serum gastrin levels and the liver function test elevations are mixed in terms of whether they find increases and which specific enzyme is elevated. It varies across the study so nothing consistent.

Now on slide 24 looking again at non-comparative evidence, so not looking at the PPIs of the class we previously had reported that there was some hint of an increase in risk of community acquired pneumonia with the proton pump inhibitors and based on this new evidence, two new studies, we find that the risk maybe highest immediately after starting the proton pump inhibitor. So the first study a large, good quality nested case controlled study was fairly large and no increased risk within 30 days. But they did find increases in risk looking at shorter time periods. So within 2 days, 7 days and 14 days the odds ratios are statistically, significantly elevated. In a much smaller study, again, a nested case control study they found an increased risk among all current users of our proton pump inhibitor. So again these studies probably indicate that there may be an increase in risk and further research is warranted.

On the following slide, slide 25, again last...we had previously reported on a non-specific diarrhea and also some hints that there might be an increase in clostridium difficile infection, but here we find two new studies that look at the increase in risk for C. difficile diarrhea and the...the first study shows an increase in risk with a relative risk of 2.9 among current PPI users compared to controls. But the second study looked at hospitalization C. difficile diarrhea and did not find an increase in risk for hospitalizations.

On the next slide, slide 26, looking at the risk of bone fractures two studies found an increase in risk with a recent or current use of PPIs, but the third study found no increase in risk among patients who had a high risk for hip fractures in particular. That study was a much smaller study than the other two, but it does have some interesting findings.

So on the next slide looking at colorectal cancer there is a single study that indicates that there is a possible association with colorectal cancer if they had been exposed to a proton pump inhibitor within a year of their diagnosis and here the odds ratio is 2.6. Again, this is not a large study, a

little over 4,000 cases and 44,000 controls. No increased risk was associated with the duration of use greater than a year. So recent uses associated, but duration was not.

On slide 28, moving on to the evidence in subgroups, subpopulations, here looking at age we found a new study, 320 patients with a mean age of 77. This study finds that pantoprazole and rabeprazole are superior to omeprazole in older patients in healing rate at eight weeks and also symptom relief at eight weeks.

Slide 29, some additional new evidence. This is looking at potential for drug interaction for [inaudible] medications. There is an increased risk of cardiac events found in patients concurrently taking a proton pump inhibitor and clopidogrel. The first study is a relatively large cohort study, over 8,000 patients who had recent acute coronary syndrome and have been prescribed clopidogrel and a PPI. They had an increased risk of death or re-hospitalization for ACS with an adjusted odds ratio of 1.25. And in a smaller case control study patients who had a recent MI and were also prescribed both clopidogrel and a PPI after that event had an increased risk of readmission for recurrent MI within 90 days with an odds ratio of 1.27. And you may hear that one of these studies did a post-hoc subgroup analysis trying to look at the risk with a different PPI and found that pantoprazole was not associated with the risk of acute coronary syndrome. But I would caution that it is...that was based on a very small group of patients and it was a post-hoc analysis. So future studies should be done to verify that finding.

If we go to the last slide then that's the end of the summation of our update.

Vyn Reese: Thank you. Now I'll open the meeting to questions from the committee.

This is Dr. Reese. I do have one question. Is there...there's a proposed mechanism, I believe, as to how PPIs effect the metabolism of clopidogrel. Is that correct?

Marian McDonagh: Right. Yes. I believe it's based on the P450 enzyme system inhibition because clopidogrel is a pro drug so it has to be activated.

Vyn Reese: So therefore clopidogrel never becomes activated and therefore is ineffective?

Marian McDonagh: That's correct, yes. That is the theory.

Vyn Reese: And H2 blockers, at least some of them, don't share this drug interaction. Is that right? At least [inaudible] is a safe drug to use in this setting. Is that correct?

Marian McDonagh: That is the assumption, yes.

Vyn Reese: Other questions? Okay. Thank you. There are no stakeholders that want to speak today on this drug class. So I'll open the meeting up to discussion and motions.

Marian, I believe you're excused at this point.

Marian McDonagh: All right. Thanks very much.

Vyn Reese: Ken, I believe you made the last motion here so you're probably up for this one.

Ken Wiscomb: This is Ken Wiscomb. It doesn't look like much has changed. I move to just reiterate the previous motion from August 15, 2007, unless you'd like me to read the whole thing.

Carol Cordy: It's new. It's new, right? Go ahead and read that.

Vyn Reese: You can just go ahead and read it.

Ken Wiscomb: Okay. After considering the evidence of safety, efficacy and special populations, I move that rabeprazole, omeprazole, omeprazole plus sodium bicarbonate, lansoprazole, pantoprazole and esomeprazole are safe, efficacious and have no differences in adverse events in special populations. They can be subject to therapeutic interchange in the Washington Preferred Drug List. A pediatric formulation needs to be included as a preferred drug on the Washington Preferred Drug List.

Vyn Reese: Any discussion? We'll need a second.

Carol Cordy: This is Carol Cordy. I second.

Vyn Reese: All those in favor say, aye.

Group: Aye.

Vyn Reese: Those opposed same sign. Motion has passed.

Jeff Graham: Vyn, I have Kim Peterson come on at 10:20. So we can take a 15-minute break now.

Vyn Reese: Okay. So we'll reconvene at about 10:20.

Jeff Graham: That's good.

Vyn Reese: We're adjourned. There you go. You got it now. Okay. Let's call the meeting to order again. Do we have the next...the next presentation is Kim Peterson who is going to be delivering a scanned report on the calcium channel blockers. Is she on the line yet, Jeff?

Jeff Graham: I didn't hear her beeping. It should be any minute.

Vyn Reese: Are you on the line?

Kim Peterson: Hello. This is Kim Peterson.

Vyn Reese: Welcome. You're going to be doing a...this is Dr. Reese and I guess you're doing the drug class review on calcium channel blockers, a scan report.

Kim Peterson: Yes, that's correct.

Vyn Reese: And the first slide is up so go ahead.

Kim Peterson: Okay. So you're ready for me. All right. So like you said this is a presentation on results from DERPs third preliminary update scan conducted in April of 2009 for consideration of the third update of our drug class review on calcium channel blockers. Next slide.

So last time this review was fully updated was back in March of 2005 and since then we conducted preliminary update scans in December 2006 and December 2007. Next slide.

The next few slides outline the scope of this review starting with the inclusion criteria for populations. So we included adults with hypertension, angina, supraventricular arrhythmia or supraventricular tachycardia and systolic dysfunction. Next slide.

And here we list the nine calcium channel blockers included in the review. Next slide.

For effectiveness for all populations we focused on long-term health outcomes including all cause mortality, cardiovascular disease mortality, morbidity and events and quality of life. And additionally in adults with hypertension we included development of renal failure and also we included symptom control outcomes for adults with angina, supraventricular arrhythmia and left-ventricular functions. Next slide.

For harms we focused on overall adverse events, withdrawals due to adverse events, serious and specific other adverse events. Next slide.

So this is the details of our MEDLINE search. We went back to December 2007, which was the cutoff date for the previous preliminary update scan through April 2009 and the total new citations that we found in this scan was 139.

So let's go on to the next slide where we have the results of the MEDLINE searches and the study selection process. Among the 139 new citations we found, we found a total of 13 new publications that would be potentially relevant if we were to fully update this review and we've stratified those by new trials, new publications of results from previously known ongoing studies and new subgroup analyses from previous included trials. So on the first slide here we just have the new trials. There were four of those and all of them were comparing amlodipine to other antihypertensive treatments or placebo in adults with hypertension; some of them with other risk factors and one in adults in Japan. So let's go on to the next slide.

Also from this scan we found three new publications of final results for the CASE-J and ASCO studies that we have previously known about and cited in the 2005 report as ongoing, but now there's final results. Both of those studies, again, were looking at...comparing amlodipine versus other antihypertensive drugs in adults with hypertension. And then additionally we found six new publications of subgroup analyses from the previously included ALLHAT, VALUE, JMIC-B trials. So together with 27 publications that were identified in the previous preliminary update scans, now there is a cumulative total of 40 new publications that would be potentially added in the full update of this drug class. Next slide.

So here's the results of our searches of the FDA and Health Canada websites for information on new drugs, new indications and new safety alerts. The only thing we found this time was that in January of 2008 the FDA approved a change in dosage strengths for extended release nisoldipine. So the original tablet strengths were 10 mg, 20, 30 and 40 and these were replaced with slightly lower strengths of 8.5 mg, 17 mg, 25.5 mg and 34 mg. Next slide.

So this is the last slide and it's reflecting the updating decision of the DERP participating organizations and...so after considering the new potentially relevant studies and the changes in the dosing strength for extended release nisoldipine that I just went over that we found in this preliminary update scan the participating organizations of DERP, again, voted against a full update of this review this time around. So the next action on this review is anticipated for April 2010 when we will conduct another preliminary update scan of the literature. So I'll turn it back to you for questions.

Vyn Reese: Thank you. Any questions from the committee? I'll take a motion to accept the scan.

Bob Bray: This is Bob Bray. I move to accept the scan as an adequate scan.

Vyn Reese: And a second?

Ken Wiscomb: Second.

Vyn Reese: All those in favor say, aye.

Group: Aye.

Vyn Reese: Opposed, same sign. The scan is accepted. I think, Kim, you can be excused now.

Kim Peterson: Okay. Great. I will let the next presenter know. Should she call in right away?

Vyn Reese: I think this is going to be a very brief discussion. So I think she should be getting in touch with us pretty quickly.

Kim Peterson: Okay. Thank you. Have a good day. Bye, bye.

Vyn Reese: Bye. It looks like there's not much new except for one new dosage formulation. Since the...Alvin Goo isn't here Jason seconded his motion from the last visit...for the last meeting and Carol Cordy seconded the scan acceptance motion. So I'll look to you to give us some...a new motion.

Carol Cordy: This is just a scan?

Vyn Reese: This is just a scan.

Jeff Graham: Vyn, I think that somebody did make a motion to accept it.

Vyn Reese: Basically that is just saying that we're accepting the scan.

Jeff Graham: That's correct. You only have to do a motion now.

Vyn Reese: You don't have to do that. Okay. So we're set. So the next item on the agenda would be the scan...

Jeff Graham: No. Actually you now have to make a motion of what...just continue, yeah.

Vyn Reese: That's what I thought. I thought that you had to make a motion that that was the...to take that. That the previous motion is what we're going to continue [inaudible].

Jeff Graham: Yes. That's right. We still need to do that. Right, right. I'm sorry.

Vyn Reese: Okay. So we do need a motion to basically say what we said previously in the 2007 meeting.

Ken Wiscomb: This is Ken Wiscomb. I move that we support the motion from the previous scan of June 20, 2007.

Man: And I'll second that.

Vyn Reese: Any discussion? All those in favor say, aye.

Group: Aye.

Vyn Reese: Opposed, same sign? The scan is accepted and the motion is passed. Let's move on to the scan on estrogen hormone therapy drugs. The presenter is Nancy Lee. Is she on the line?

Jeff Graham: She should be any minute.

Nancy Lee: Hello?

Vyn Reese: Nancy Lee, are you on the line now?

Nancy Lee: Yes. I'm on the line. Sorry.

Vyn Reese: Great. We have the first slide up for the drug class review on estrogens. You can go ahead and begin.

Nancy Lee: Okay. Hi. My name is Nancy Lee and I'm at the Oregon Evidenced Based Practice Center and I'm going to be presenting the scan on drugs for hormone replacement therapy. Since Kim likely reviewed the general purpose and objectives for this scan I'm going to go ahead and skip to slide number 3.

Slide number 3. The last full update for the hormone replacement therapy report was completed in October 2007 with searches conducted through March 2007. Next slide.

I just want to briefly remind you of the inclusion criteria for this report. This report included pari or postmenopausal women who were recruited

from any healthcare setting or population based sample experiencing menopause. One possible data were considered separately for those with natural versus surgical menopause. Next slide.

Oral transdermal and topical estrogens listed below as a bullet points were the interventions of interest included in this report. Next slide.

Slide number 6. For effectiveness outcomes menopausal symptom relief with a mean outcome of interest in addition to the assessment of quality of life and prevention of osteoporosis or fractures. [incomplete sentence] Next slide.

General harm such as overall withdrawals and withdrawals due to adverse events were evaluated as well as short-term harm such as atypical bleeding, endometrial hypertrophy thrombosis were evaluated and longer term harms such as cardiovascular events, cancers were also assessed. Next slide.

For this scan we searched MEDLINE and MEDLINE In-Process from March 2007 through April 20th of this year. These terms for included drugs and indications in our search strategy and also set limits for evidence in humans that were English language. [incomplete sentence] This scan focused looking at the number of randomized and controlled clinical trials and we also searched the FDA and Health Canada websites for any new drugs, indications and safety alerts. And there was one reviewer that assessed all the citations. Next slide.

Slide number 9. Overall we found 164 citations. Of these we identified 33 new potentially relevant studies. Four of the 33 were head-to-head or had included an active control arm. Study durations for these four ranged from 4 weeks to 1 year and there another four studies that compared different dose forms or dosing regimens of the same drug leaving the remaining 25 or so studies to be placebo controlled in design. All of these...the 33 new potentially relevant trials are summarized in Table 1 in your scan document. From the FDA and Health Canada websites we identified 3 new estrogen products and a new indication for an existing product. Next slide.

For this slide lists new drugs under indications and as you can see estradiol transdermal spray EvaMist, estradiol 0.1% gel or Divigel and the

last box, synthetic conjugated estrogen A vaginal cream were approved by the FDA in 2007 and 2008. Conjugated estrogen or Premarin creams indication was broadened to include treatment of moderate to severe symptoms and there's a new dosing regimen for this indication for administration of twice weekly. Next slide.

Slide 11. We found two safety alerts. One is for Climara, the transdermal system. There were a few case reports of hives and rash with swelling of the throat or eyelid edema and the incidents of this reaction is unclear. The other safety alert was with Estring or estradiol vaginal ring and there were several case reports reported to the FDA. There were reports of toxic shock syndrome, a few cases where the ring had adhered to the vaginal wall making removal difficult, and a few cases of bowel obstruction. There's also mention that this drug should...there's a precaution against this product for patients who have or had liver problem. Next slide.

So having reviewed the information in this scan the participating organizations for DERP have decided not to update this review among other reasons. Instead, the topic was submitted to the Effective Health Care program of AHRQ for consideration and the scope would be broadened for the AHRQ report. Next slide.

This concludes the presentation and I'd be happy to take any questions.

Vyn Reese: Any questions from the committee?

Bob Bray: This is Bob Bray. Do you have an incident rate of the toxic shock syndrome associated with the Estring?

Nancy Lee: No, I do not. I wasn't able to find that information. The information that I was able to find was from the FDA website and they didn't specify the number of cases.

Bob Bray: Thank you.

Vyn Reese: Any other questions?

Carol Cordy: This is Carol Cordy. I have a question. I can't remember which year it was that we stopped recommending estrogen for postmenopausal

symptoms but it...do you have any kind of numbers on how that's dropped? How the use has dropped?

Nancy Lee: I'm sorry. I was not able to get the entire question. I'm having difficulty hearing.

Carol Cordy: I was just wondering how...because estrogen is not necessarily prescribed as much do you have numbers on how that...the utilization has dropped?

Nancy Lee: No. I don't have the number of utilization in terms of...I guess I'm not...

Carol Cordy: Well, I mean percentage of women who are postmenopausal that are using any of these.

Nancy Lee: Yeah. Like the prevalence of how many...I don't have that information. I'm sorry.

Vyn Reese: Any other questions? I'll take a motion to accept the scan.

Ken Wiscomb: This is Ken Wiscomb. I move that we accept the scan as an adequate review.

Carol Cordy: This is Carol Cordy. I second.

Vyn Reese: All those in favor say, aye.

Group: Aye.

Vyn Reese: Those oppose same sign. We're going to have to...Nancy, you're now excused.

Nancy Lee: Thank you.

Vyn Reese: Thank you very much. We're going to have to add the...when you craft this next motion we're going to have to add these new drugs...or old drugs also with new indications into the motion. So I'd like someone to take a stab at that unless there is further discussion.

Janet Kelly: This is Janet Kelly. I wonder if we really should be doing that since we didn't review any data. This is just a scan. I'm not really very

comfortable adding new things on there without having looked at the data. All we did was say that...so...

Vyn Reese: These are new FDA approved indications and drugs. So it seems that these drugs were approved for these indications. In the past we've just added those onto the list and some of these drugs are actually old drugs that are approved for new indications.

Duane Thurman: This is Duane Thurman. I think that you have the option to, on the basis of the scan and your discretion, either consider the new indications or request us to do a full update. But the only thing I don't think you can do is consider new drugs that were not considered in the original update. But I do believe you have discretion on addressing additional FDA indications for existing drugs.

Vyn Reese: These drugs, too are old drugs with new ways of administering them. There's really no new drugs here. It's estradiol, estradiol conjugated estrogen and estrogen cream, but now they are in sprays and gels and a variety of other ways to administer them. So it's not that they are new drugs; they're old drugs with new forms of administration. It seems like in a scan we wouldn't need a formal review to approve those drugs and they've all been already FDA approved. So there's good data on all of them.

Duane Thurman: Right. I would say if you want to consider additional drugs you would have to request a full update. But not additional indications of existing drugs.

Vyn Reese: Right. And that's basically what it was. So...

Man: I'm not so sure the old motion excludes what you're getting at. I think the old motion looks almost like it's adequate.

Vyn Reese: Yeah.

Carol Cordy: Vyn, this is Carol Cordy. I agree with Janet that I think...an old drug in a new form might not be the same as the old drug in the old form just because of absorption and all sorts of variables.

Vyn Reese: Yeah, but they've been FDA approved so we know that they've got good levels and that they are efficacious and they are the same drug as we looked at before just in a new administration system giving the same hormone levels systemically. I don't think it's worth asking DERP to do a whole review of this class just because a few drugs have new indications or new ways of administering them, but I'm open to suggestions.

Patti Varley: This is Patti Varley. I guess as I look this over I'm less concerned about the newer availability in different forms and I'm more concerned about the data for instance with toxic shock with the ring, personally, as far as negative data and that's already on the list.

Bob Bray: This is Bob Bray and I support that concern.

Vyn Reese: It must be fairly rare. It's a rare...it's a new side effect and a serious one, but it looks like it's pretty rare. She doesn't have much in the way of data on that. And the FDA hasn't taken the ring off the...hasn't taken the ring off the market. So I...

Patti Varley: This is Patti Varley. I'm gonna say they never took tampons off the market either. So...and that is not necessarily the outcome, but for me it's more public safety in regard to that...is that a higher risk for people than other options?

Vyn Reese: I don't believe the ring is on the Preferred Drug List in any case. It's a pretty high cost option.

Jason Iltz: But it would be subject to...this is Jason, DAW. Correct? So if we did add some safety issues we would need to make a statement to say that we didn't feel it should be part of the Preferred Drug List based on the safety warning.

Vyn Reese: Right.

Siri Childs: This is Siri. The way we usually handle new products is that we put them...we list them as available but because they haven't been studied by the OHSU or reviewed by the P&T Committee TIP and DAUW(?) doesn't apply, but if a prescriber does want that they must have tried and failed a preferred drug before they go to the newer and in most cases more expensive drug.

Vyn Reese: Right.

Duane Thurman: This is Duane Thurman again. Jeff Graham, do you know if we have a full update scheduled for this drug class?

Jeff Graham: No. There is none scheduled. We have asked this to be...the whole class reviewed by AHRQ in their new program. So there's no plan for DERP to do that. The question about Estring it's already been reviewed and so if that is a problem we should address it here. These other drugs are...they are correct. They are not new drugs, they are just a new delivery system. And I think that they agencies have ways of handling that without us including them in this motion. I mean they're a new form. If they've not been totally reviewed they can be prescribed with PA.

Duane Thurman: So I guess procedurally your options are to not accept the scan as an adequate update for a decision and request that we do an independent update aside from DERP and you can take a vote on that and then if you decide not to then we step away and we'd have to see if we have funding for a full update. If you accept the scan then I think you do have the authority to look at existing drugs with new indications.

Vyn Reese: I think we already accepted the scan.

Duane Thurman: I'm just saying whatever you want to...however you want to handle that as a committee.

Vyn Reese: I don't see what...what...there's any problem with the motion that was made in February either. And we can add these drugs to the list, the ones that were just presented to us with the old drugs with new indications and new delivery systems. And that may not be drugs that we're going to prescribe very much.

Patti Varley: This is Patti Varley and if it...as it reads there, there is insufficient evidence available to compare the relative safety, I'd be okay with that.

Jason Iltz: This is Jason. I made the previous motion and as I read through that that was my only question, Patti, as well, is does that cover some of the recent safety warnings the FDA has put out and if the committee feels it does then I'm okay with making a motion that we re-instate the February 20,

2008 motion and I can read that if you'd prefer me to do that. But I do want to comment on...I don't think this is a medication class that really we should request a full review on. I think the use of this class has substantially declined and I think we'd be better suited spending the money somewhere else on another class, but that's just my opinion as we work through this.

Vyn Reese: I agree with Jason.

Duane Thurman: Yeah, I do too. I would agree.

Jason Iltz: So unless there's other comments I'll go ahead and just re-read this motion from February 20, 2008. So after considering the evidence of safety, efficacy and special populations, I move that the drugs included in the following tables, and I'm making the assumption that we've added these new formulations that are at least part of this scan into that, are efficacious and have no differences in efficacy identified in special populations for the indication of menopausal symptoms and can be subject to therapeutic interchange within route of administration and subclass (oral estrogens, oral estrogen-progestin combinations, transdermal estrogens, transdermal estrogen-progestin combinations, topical estrogen products) in the Washington Preferred Drug List. There is insufficient evidence available to compare the relative safety of the estrogen products at this time. The Committee recommends that practitioners prescribe the lowest effective dose for shortest duration of treatment for the particular estrogen product prescribed.

Vyn Reese: Any further discussion?

Patti Varley: Yeah, this is Patti Varley. I just want to be clear that the rationale behind not having this reviewed, again, is because people aren't using it? Is that what people are saying? And is that true from the data the State has?

Siri Childs: This is Siri. Speaking for HRSA and we will be doing a cost analysis that is based on our utilization. I can't recall off the top of my head whether the utilization now has changed at all since we've reviewed this class last. So unless we pull utilization for you specifically for that purpose I don't have it off the top of my head.

Duane Thurman: This is Duane Thurman. I don't want to complicate this. The point is you have the discretion and I don't think you should look at it in terms of whether we have funds to do this. The question is whether you believe that you have enough evidence in front of you to support the decision? You may have descending votes, you may have a majority one way or another, that's your decision. I think the issue is to whether we have to go and do a full update is internal to us. It shouldn't have anything to do with your decision. But I can say that I don't know...we have not had this situation before. Obviously if we have to do this outside of the DERP project we will have to get funding to do that and we may or may not be successful in doing that. One result could be that this class would not be on the Preferred Drug List, but I guess the main thing is for you to make a decision among yourselves as to what a majority thinks in terms of, "Is this enough evidence in the scan to support the motion that Jason just made?"

Carol Cordy: This is Carol Cordy. Can you just, what would the ramifications be if it were taken off the Preferred Drug List? Patients could still...

Duane Thurman: Then it would revert back to however each agency treats its...this class under its benefits structure. We have not had that occur before.

Carol Cordy: It's still available, it's just not...

Duane Thurman: If you believe the evidence says that it shouldn't be on the PDL that's one thing. If it's because we can't afford it that's not something you need to consider, that's a problem for the agencies. You know, we would have to come back and say, "We do not have the funding to do a full update at this time," and so we would not be able to update this class and we would recommend that we take it off at that point, but you don't need to consider our administrative problems.

Vyn Reese: This is Dr. Reese. I don't see any reason to take this drug class off and I think...I read studies; not our studies but that there is a huge drop in prescribing frequency for this class of drugs, but for patients who have severe vasomotor symptoms it's...this is the most efficacious drug group for those patients who can take for a short period of time and to be tapered off. So I think it's not a class...it's a class that should be used infrequently, but should be made available to patients who are very symptomatic and so...I mean...I don't see...and we don't have any

evidence to dispute that. I think that Jason's motion is very reasonable and I don't think that we need to look at these drugs...they're drugs that are just not being used as much as they used to be. I think it's a waste of time and energy to look at them more than we already have. We've seen a lot of data on this drug class.

Ken Wiscomb: This is Ken Wiscomb. I agree and I'll second Jason's motion.

Vyn Reese: Okay. All those in favor say, aye.

Group: Aye.

Vyn Reese: All those opposed, same sign.

Patti Varley: Aye.

Carol Cordy: Aye.

Vyn Reese: So two opposed, is that right? Okay. Motion's passed. Now the next item on the agenda is clarification of leukotrienes and there's new data that's been presented to the committee and I think we're going to be looking at that right now. Is that right?

Elizabeth James: This is Elizabeth. Can I clarify what we just did? First of all I apologize I missed the first motion and then I wanted to make sure I captured the motion to carry forward the February 20, 2008 motion appropriately as intended.

Jason Iltz: Thank you. You have it correctly. This is Jason. And I think it was Ken who moved to accept the scan.

Elizabeth James: Thank you.

Jeff Graham: Vyn, on leukotriene modifiers I might explain. We sent out a memo to the committee on I believe yester...no, Monday, and it explains why we're bringing this back to the committee. It's not for a new open review, but that the staff after reading...or after considering your recommendation there were some issues around FDA labeling that we wanted to bring back to the committee. And I think we spelled it out here in this memo.

Vyn Reese: Do you have slides to show us?

Man: No.

Vyn Reese: So basically what you're saying is, is that since the last motion was made in February that labeling...there's been labeling changes or was the labeling the same then as it...

Jeff Graham: The labeling is the same as it was at that time.

Vyn Reese: And that Accolate and Zyflo have very strong warnings about hepatotoxicity, including fatalities whereas montelukast or Singulair does not have those warnings...

Jeff Graham: That's correct.

Vyn Reese: ...and therefore we might want to change the motion to read that montelukast may be associated with lower incidents of hepatotoxicity than zafirlukast and zileuton. And so montelukast shall be the preferred drug on the Washington State Preferred Drug List. Is that basically what you're recommending?

Jeff Graham: Correct.

Woman: Yes.

Vyn Reese: Okay.

Ken Wiscomb: I'll second.

Vyn Reese: Okay. I can make that motion. Let's have discussion, though. Is there anybody who doesn't understand or...

Man: I just wanted to also make sure that our comment was that you're able to interpret our comment when we say "shall be preferred"... "montelukast shall be preferred for pediatric patients less than five". I don't think we were saying that we would go down to, you know, one month of age there. I think we were saying that for pediatric patients essentially two years or older. Do we need to clarify that? Would that help as well? Okay. So for pediatric patients two years and older something like that.

Vyn Reese: Okay. Maybe I can just try re-reading it after the new information. This is going to be in the form of a motion. After considering the evidence of safety, efficacy and special populations for the treatment of asthma, I move that montelukast, zafirlukast and zileuton are safe and efficacious. Montelukast may be associated with a lower incidence of hepatotoxicity than zafirlukast or zileuton. Montelukast shall be the preferred drug on the Washington Preferred Drug List for pediatric patients greater than two years of age. Leukotrienes modifiers can be subject to therapeutic interchange in the Washington Preferred Drug List for the treatment of asthma.

Woman: You said the leukotriene?

Vyn Reese: Leukotriene modifiers can be subject to therapeutic interchange in the Washington Preferred Drug List for the treatment of asthma. I might just say montelukast should be the preferred drug on the Washington PDL for adults and for pediatric patients greater than two years of age. It should say adults too because the other two are more risky. It should be for adults and...

Man: There you go.

Carol Cordy: This is Carol Cordy. I'm not entirely clear what we want this to do. In the previous one it said zileuton should not be preferred on the Washington Preferred Drug List. You took that out. Correct?

Vyn Reese: So we may want to say both zileuton and zafirlukast should not be preferred on the Washington Preferred Drug List.

Carol Cordy: They're still on the Preferred Drug List.

Vyn Reese: Yeah. You may want to add that sentence including both drugs.

Patti Varley: This is Patti Varley and maybe it's how I'm seeing it today but when you say in the first they're all safe and efficacious...

Vyn Reese: It's not true.

Patti Varley: That doesn't flow with the rest of that statement and it may just be me.

Vyn Reese: I don't know how that was arrived at last time and I wasn't here for the discussion and I got roped into making this...

Man: We tried to call you.

Vyn Reese: Yeah, right. Well, I think I was still in the ICU at that point.

Man: I would remove safe from the first sentence.

Vyn Reese: Why don't we remove safe at the top. After considering the evidence of...I move that montelukasts are efficacious.

Patti Varley: What?

Vyn Reese: I move that montelukasts, zafirlukast, and zileuton are efficacious. Montelukasts may be associated with a lower incidence of hepatotoxicity than zileuton or zafirlukast. Zileuton and zafirlukast should not be preferred on the Washington Preferred Drug List. Montelukasts shall be preferred for adults and for pediatric patients greater than two years of age.

Siri Childs: Dr. Reese, this is Siri. Jason, do you know the exact wording of the FDA labeling? Does it include two years of age?

Jason Iltz: I thought it's two years and older.

Siri Childs: Yeah.

Jason Iltz: Or specifically for asthma.

Jeff Graham: This is Jeff Graham and Nicole did this research for me that it was two years of age.

Siri Childs: Okay. So we have to make sure that we don't say older than...greater than two. It would be two years and older.

Carol Cordy: Does this just apply to the treatment of asthma?

Man: Asthma and see that there is a perennial and seasonal allergies for two and older as well.

Carol Cordy: For Singulair?

Man: Yeah.

Carol Cordy: Because up here it doesn't say that. It says only...then it's 15 and older.

Jeff Graham: Well, Carol, this is Jeff Graham again. I think the reason we said asthma in this...this is what this report is about is the treatment of asthma.

Vyn Reese: And montelukast has other indications, but we don't need to say that here since we were just talking about asthma.

Carol Cordy: But there's nothing here that says we're talking just about asthma. Does that matter?

Patti Varley: It does at the end.

Vyn Reese: Um...it says in the end. Leukotriene modifiers can be subject to therapeutic interchange in the Washington Preferred Drug List for the treatment of asthma.

Patti Varley: Maybe you could say, at the beginning, if that's clearer, "After considering the evidence of safety, efficacy and special populations for the treatment of asthma."

Carol Cordy: I think I'd do that.

Bob Bray: This is Bob Bray. It looks like between 12 and 24 months the granules are indicated.

Man: Right.

Bob Bray: Greater than two years of age two tabs or granules.

Vyn Reese: So we do need to change the age...

Man: At least 12 months.

Vyn Reese: Right. It's the dosage for pediatric patients 6 to 23 months of age is one packet of 4 mg oral granules.

Patti Varley: So it's 6 months?

Carol Cordy: It goes down to 6 months?

Bob Bray: Six months has an indication for allergic rhinitis down to 6 months.

Patti Varley: This one is for asthma.

Bob Bray: But asthma is 12 months.

Vyn Reese: Twelve months. Right, right, you're right. Right. So asthma is 12 months. It's pretty complicated.

Bob Bray: Was that Patti or was that...

Patti Varley: Which one?

Bob Bray: Janet, I'd agree with that. Why don't you say that a little louder.

Patti Varley: Janet said...this is Patti Varley saying that Janet said, "Shouldn't we just say FDA approved," because they could change it. That way we would get what we're really after, which is that it's used appropriately as FDA approved.

Vyn Reese: For adults and pediatric patients as FDA approved. Let's just leave at least the 12 months off because it may change again. For adults and pediatric patients as FDA approved. So we'll just strike the "at least 12 month".

Carol Cordy: So it's confusing to me that they can be subject to therapeutic interchange if there's only one.

Man: Yeah, you want them to change...

Janet Kelly: Janet Kelly. If they write for one of those others that's not preferred then we can switch them.

Vyn Reese: Exactly. That's why.

Carol Cordy: So say that again.

Jeff Graham: If they write for one of the other ones we can fill it with Singulair.

Vyn Reese: So let's try re-reading. I'll re-read it this one more time since there have been so many changes and amendments. After considering the evidence of safety, efficacy and special populations for the treatment of asthma, I move that montelukast, zafirlukast and zileuton are efficacious. Montelukast may be associated with a lower incidence of hepatotoxicity than zafirlukast or zileuton. Zileuton and zafirlukast shall not be preferred on the Washington Preferred Drug List. Montelukast should be the preferred drug on the Washington PDL for adults and pediatric patients as FDA approved. Leukotriene modifiers can be subject to therapeutic interchange on the Washington Preferred Drug List for the indication of asthma. That's my motion.

Carol Cordy: Carol Cordy. I just want to stick in one word. It should not be preferred drugs, the zileuton and zafirlukast.

Vyn Reese: Okay. I'll accept that from the amendment. I don't want to read it again. Ken's going to second it again?

Ken Wiscomb: Yeah, my second will stand.

Vyn Reese: All those in favor say, aye.

Group: Aye.

Vyn Reese: Opposed, same sign. Okay. Motion's passed. We're adjourned an hour early.

Siri Childs: This is Siri Childs and I just want to thank you for taking that up and looking at that again.

Vyn Reese: You're welcome.

Jeff Graham: Yes, because we have guests and people want to be here at 1:00. So I'm going to have to wait until 1:00.

Carol Cordy: We can't just start the afternoon...

Jeff Graham: We've advertised the DUR at 1:00 and it appears that several people want to come and speak. So we have to delay until 1:00.

Vyn Reese: And our luncheon will probably not be ready for another hour.

Woman: It will be ready within the next few minutes. Just wander on down there and it will be ready. I already asked about getting ready early.

Duane Thurman: Who are we...

Man: I don't think Marian would object if we...

Duane Thurman: No. I think we should go ahead with the...if we want to accelerate the schedule.

Jeff Graham: Oh, we can? Okay.

Duane Thurman: Our agenda is subject to change. So...

Jeff Graham: So we could do maybe 12:30 and we'd be in good shape.

Duane Thurman: Whatever the committee would prefer.

Vyn Reese: So you want to meet back here, again, at 12:30? Is that what you're saying?

Duane Thurman: I'm saying you can decide whatever you want.

Vyn Reese: But we'll be ready to go at 12:30 with the speakers and with...

Duane Thurman: Jeff, will we be ready?

Jeff Graham: I can do whatever you want.

Vyn Reese: There are people who want to give input, they're stakeholders who do want to give input on this I believe. Is that right?

Man: I don't know of any.

Vyn Reese: I have heard that there were...I don't know...

Duane Thurman: No. I'm sure there will be, but what I'm saying is it's their responsibility to react to the...the agenda says it is subject to change. We need to use our time wisely so it's the committee's discretion as to how much time you want to break and we do have our presenters present.

Siri Childs: Could I please add one statement from HRSA? And that is on behalf of Drug Utilization Review and their requirements to have an open public meeting. I really would advise us to stick to the schedule because I know that there is a lot of interest in this. And, you know, I wouldn't want it to be misconstrued as anything other than an open, public meeting.

Vyn Reese: I agree. I think that if you leave the stakeholders out it's going to create a lot of animosity and ill will and so I think we should wait until the stakeholders have time to appear and present their views. So I think it would be wise to wait until 1:00 to reconvene. You may have a longer break to do other things. So that would be my view. I don't know if there are others that have problems with that.

Patti Varley: This is Patti Varley. This particular subject has been, I would say, one of the hotter topics among my colleagues and again would prefer to make sure that it's handled in a way where input and exposure is accurate and thorough.

Vyn Reese: Any other thoughts on that issue? So I'll take a motion for an adjournment now. We'll reconvene here at 1:00 and hear the presentation and have the stakeholder input at that time. So motion to adjourn?

Man: So moved.

Vyn Reese: And a second.

Woman: Second.

Vyn Reese: We're adjourned.

Everyone to the Drug Utilization Review Committee. First, let's start with introductions and again I'll start on my left and I would like people to introduce themselves.

Charles Agte: Charles Agte with HRSA.

Siri Childs: Charles is the Pharmacy Program Manager for Washington Medicaid, and I'm Siri Childs, and I'm the Pharmacy Administrator for Washington Medicaid.

Jeff Thompson: Jeff Thompson, Washington State Medicaid.

Mary Ann: Mary Ann [inaudible], Washington State Medicaid.

Jaymie Mai: Jaymie Mai, Labor and Industry.

Doug Thurman: Doug Thurman, Labor and Industry.

Jeff Graham: Jeff Graham, Health Care Authority.

Janet Kelly: Janet Kelly.

Patti Varley: Patti Varley.

Ken Wiscomb: Ken Wiscomb.

Vyn Reese: Vyn Reese.

Carol Cordy: Carol Cordy.

Jason Iltz: Jason Iltz.

Bob Bray: Bob Bray.

Regina Chacon: Regina Chacon.

Elizabeth James: Elizabeth James.

Duane Thurman: Duane Thurman, Health Care Authority.

Ray Hanley: Ray Hanley, Health Care Authority.

Vyn Reese: Thank you. The first item on the agenda is looking at the minutes from the prior meeting of April 15th. Are there any additions or correction to the minutes?

Siri Childs: This is Siri, and Carol Cordy has already sent me some corrections in writing. Carol, do you want me to read those, or do you have those?

Carol Cordy: Could you?

Siri Childs: Sure.

Carol Cordy: I forgot the pages.

Siri Childs: Carol is directing us to the bottom of page 19, and she's saying that the speaker should be Siri, not Patti. And on page 33, she's asking the question, "What is WASIBRT?" and you'll have to help me determine what that is also.

Jeff Thompson: This is Jeff Thompson. WASIBRT is...there's a national program substance abuse intervention and research team. Basically, it's a SAMSA project to look at screening and brief interventions for people with substance abuse in clinics and ERs.

Siri Childs: These, of course, are...this is a transcription so this is all spelled phonetically. Jeff, do you know what the actual abbreviation is supposed to be?

Jeff Thompson: It's W-A-S-I-B-R-T. Okay. And then the last one that Carol had is on page 42. Carol Cordy's statement should read, "120 morphine equivalents, not 120 methadone equivalents." And that's the end of her corrections.

Vyn Reese: Any other changes to the minutes? I take a motion to approve the minutes as amended?

Bob Bray: Second.

Vyn Reese: All is in favor say, aye.

Group: Aye.

Vyn Reese: Opposed, same sign. Minutes are approved. And now I'd like to turn the meeting over to Jeff Thompson who will be presenting the DUR material.

Jeff Thompson: Okay. So this basically will be a presentation of some ideas that we're considering for implementation of House Bill 5892, and it has a number of moving components, but what's probably most important for the DUR Committee is that you actually are named in the statute and have some interplay with us in how we move things forward, especially as it relates to generic drugs, and so your...not only in federal statute and in our WACs but now in a state statute where you will assist us, and I'll go through each component. But essentially, it's to try and improve our generic performance, and again, I'll go through each moving part as we go forward.

Just a couple caveats. This will be mostly about HRSA or Medicaid. The state employee benefit as well as Labor and Industry, you know, we'll either adopt or take some pieces or parts of what we're going to talk about, but primarily the statute revolves around the PDL and what Medicaid is doing. And we'll be very clear about what's Medicaid, what's Labor and Industry, and what's the state employee benefit as we move forward. So next slide.

So I mean, just as some background, and I've always wanted to bring to you cost and utilization so you can actually get an idea of where we are with the program. I think the first caveat is that the Prescription Drug Program is actually been, I think, a pretty remarkable program and resource to the State of Washington. I mean, it's worked very well for us over the past five years. It's saved a lot of money. It's been very transparent. You've done a very good job in helping us steer through the preferred and non-preferred selections. But the market has changed a little bit and requires us to make a little bit of adjustment with our \$413 million spend; because if you look at the spend, it's 80% brand, 20% generic. Now, that's just on spend. But when you look at generic refill rates, which is an industry marker of how well we are utilizing our generic options, not our generic substitution but our generic options within the

preferred drug list, our 63% generic fill rate is behind an industry standard which is approaching or exceeding 80% in some local, actually, clinics—Group Health, Molina, Everett Clinic are all at or exceeding 80% generic fill rate. And why is this important? Well, for every percentage point that you move generics up, you save the State between 1 and 2% over our overall spend, so that 1% translates to \$4 to \$8 million in savings. And now again, it depends on the drug class. It depends on where you are on the curve, but it is significant savings, and we need to have the opportunity to bring Medicaid up to where the commercial sector is now. And you can also see where Labor and Industry at 83%, and then UMP at 79% says that we've got some movement here. Now, yes, we do have a different patient population. We have a much heavier use in mental health drugs; 40% of that overall \$400 million is in mental health drugs; 25% of that overall is in antipsychotics. That is very differently, obviously, than Uniform Medical and UMP, but the governor, in her budget, has actually given us a goal of moving 63% up to 83%, and that is where the savings we'll talk about and how we can do that, I think, will involve you and some choices and options. Next slide.

Next slide. So what's changed is the 21 drug classes. Now, there's a lot of generic options. I think you remember five or six years ago we were talking about brand-only drug classes, but now, you know, there's only three of those classes right now have brand-only options. There are multi source and generics, and that's why we need to start looking at our generic refill rate. Now, I'm not saying that this is where we're going. I'm not saying this is possible or probable, but this gives you a scale of what is at issue. If everyone on those 28 drug classes were to move to a generic today, that would save an annual cost to the state of \$100 million annually. I'm only just mentioning this because that just gives you the scale of what's possible, not probable, so you can kind of sort of do the math of where we are for every 1% generic refill rate.

The other issue is most of our practitioners are utilizing the DAW very sparingly. They are using the brands and the generics, I think, at an appropriate ratio, but there are a number of providers that are using DAW to get a non-preferred brand, somewhere between 80 to 100% of the time. And it depends on where you cut it. If you cut it by a particular drug class, like say in the statins, there might be about 300 doctors in just the statins alone. If you do it by the overall preferred drug list, you know, we're talking in the neighborhood of 120 to maybe 200 doctors. So we

will be working on a WAC moving forward that will define all the elements, and I'll go through there, of Section 2A about how to communicate and how to interact with these doctors as it relates to their use of DAW, and we'll talk about the first one, which is the Generic News which will be going out in the next week here.

The other issue is, is that as you look forward, in some of our drug classes, off label is becoming an increasingly amount of utilization within some drug classes and of the JAM article, 40 to 60% of some of our drug classes in the Preferred Drug List are off label. Now, we're not saying that that's a bad thing, but I think it is a thing that we need to understand and make sure that we are actually doing the best job and getting the best value for our clients within the prescription drug monitoring...or prescription drug program. And the article that will come out next month with the second opinion will show that when we came to an agreement on too young, too many, too much with the ADHD drugs, and we're now doing with the antipsychotics, there was a 50% change rate regardless of provider type, largely in the off-label use of ADHD drugs, which says that we've got a problem. 50% is really too high. Not only is it an inefficient use of taxpayer dollars, it also presents safety issues to our children and I think to our adults. And I've come and talked to you about narcotics and I've talked to you about antipsychotics and polypharmacy and even a bigger issue with the adherence that as many as 40 to 60% of our clients aren't taking their mental health drugs. That's a huge issue when we talked about re-hospitalization. So what you're constantly going to hear me talk about is, you know, we need to be data driven. We need to see what's going on with our program and need to work with you and the community to try and improve the efficiency.

And that last thing's that changed is there's a lot of me-too drugs, and you've done an excellent job with evaluating the science on what is preferred, what's non-preferred, what allows us to make some cost decisions. But because we have a DAW and you can get a non-preferred, these me-too drugs are driving our generic fill rate down, and so we need to have a discussion about whether these me-too drugs are equally effective in brand, generic sort of options. Next slide.

So the goal by the governor and the budget is to move from a 63% to an 83% generic fill rate, and there are issues that we want to work with you on transparency. We want to make sure that everybody knows what we're

doing so that there's no surprises, and it's an appropriate use of DAW. We want to maintain flexibility of DAW. We're not taking away the DAW or endorsing provider privileges, but we want to look at where it might be used inappropriately. And you see that in everything. You see it in automobile, banking; it doesn't matter. And if you aren't measuring it, you can't manage it. We want to talk to you about generic first options where we're new starts. We're not taking people off their meds, but we're talking about where you have a naïve client in several drug classes. Can we have an option to discuss with the provider that a generics-first option is the best option for the value but where a brand could be medically necessary, more appropriate, why would we say no to that? So that's part of it? We want to maximize our over-the-counter use when appropriate, and we want to control off-label use where inappropriate, and I've talked to you a little bit about the ADHD. And we're now doing second opinions for the antipsychotic use with children.

And then later on, we're going to be talking about putting in a waiver and using the Deficit Reduction Act to introduce co-pays. Small co-pays in the Medicaid population for the selection of preferred, non-preferred, and Mary Ann and I have talked about it, along with Roger Gantz. This is actually, I think, the best use of co-pays. Nobody walks away without a drug. But if you want the more expensive, equally effective, but more expensive, then there is going to be a co-pay, probably in the neighborhood of \$1.00 to \$5.00, but probably not exceeding that. And there's some federal restrictions that we have to work out.

The purchasing initiative's \$109 million, that's actually near...that's an old number. I can correct it, because there was the AWP and other things have corrected our budget. It's somewhere, I believe, in the \$80 million right now. Next slide.

So I think there's some important safeguards in the discussions with Mary Ann and I and Duane have had with the legislature as 5892 goes forward. The existing refill protection still apply, so the mental health drugs, the chemotherapy drugs, the HIV drugs, the Hepatitis C drugs; we're not talking about getting rid of refill protections. That's just part and parcel so we're not going back to the old ways.

Providers can still use their choice of DAW and the endorsing provider privileges. But we do need to inform you about maybe a minority or

maybe a larger group of providers, where if we gave them the data, they would see that, “Oh, maybe I’m not as good as my peer or best practice,” and we’ll talk about what that looks like.

We’re going to talk about dispense as written. Again, you know, we want to maintain, I think, the preferred drug list and the options for people to use that endorsing status, but again, there’s going to be a handful we’re going to have conversations with, and we want to share information and that’s what the generic is and get your input about what do we need to communicate to providers to really talk about what’s going on.

And then the last one that’s not in gear, I think, we also need to talk about samples. When we first start out, we want to be very careful about...especially with mental health drugs and the use of samples, but I think because we have a lot of selection here within the preferred drug list, a lot of options that I think what Medicaid is not going to do is not going to say samples constitute refill protections any longer. And I think I can get a safety aspect of this, because obviously, that if we’re giving out refills, those are not in our prefer...those are not in our POS or pharmacy system. So the only person that really knows about that is somebody that handed out the samples, and they’re only built into the record. So because we paid for drugs, we don’t have co-pays, you know, what we really want to do is we want the record to show what drugs a client is taking and not to basically say samples is honored with the refill protection. So those are basically the safeguards. We can talk about all of them. Stop me at any time, you know, during this presentation if you have questions. Next slide.

So this issue about the minority of providers and DAW, again, it’s a definitional issue. DAW constitutes almost \$20 million out of that \$400 million in non-preferred. Depending upon how you ask the question of DAW, which is, is it the overall drug program, the PDL, or just the drug class? But if you look at overall and the PDL, somewhere between 150 and 300 providers use DAW 80 to 100% of the time. And so what we need to ask them is maybe they are a specialty that requires them to use the non-preferred. But again, you know, as human beings are not very good at statistics when it’s done in their head; and so if you don’t get feedback reports and you don’t compare yourself to a peer, you can’t manage what you can’t measure. And there’s about 600 providers actually, depending upon where you cut off the number of prescriptions,

so there's 600 providers that write DAW 25% or more, and that's when we cut it off at 250 scripts in a year. I just ran the numbers the other day. If you use all prescriptions, you know, onesies and twosies, it's actually about 1,600 docs that write DAW anywhere between 25% and 100% of the time. And so the question will be where do we put the cutoff? And we'll be writing administrative codes about how we action the elements of 5892, but I think internally we're going to have some discussions about what is the appropriate use of resources in sending material out to providers to let them know what their DAW and their brand utilization is. And so that's where the numbers are. I think that the take-home message is of the 16,000 providers that we have in this state, the vast majority of them are using 6088. They're endorsing status DAW appropriately. But now we've got to be a little bit more efficient in actually pointing out where there's some opportunity. Next slide.

So here is your preferred drug list in the DAW, and you can see that this is where, you know, classes have distinction about their DAW percentages. At the high, you have the TZD drugs for diabetes somewhere approaching 40% all the way down to almost nothing but the macrolides. And the question is why is there this differential? You know, given the fact that you've looked at the evidence and you've said that the evidence really isn't that much different between preferred and non-preferred, or you've said that you need to have, because the evidence of this drug on the preferred list as preferred, why is there this much variation? There shouldn't really be this much variation, given your decisions. And quite frankly, I would state that probably in most of these drug classes, you can approach even the 90% generic utilization. But there is a difference, and we need to actually look at each drug. We need to look at each drug and see what the differential is between brand and generic and the cost, what you're prescribing patterns are and the utilization, and make a determination of which drug classes have an opportunity for us to move that 63% generic utilization to 83%.

Yes, ma'am?

Carol Cordy: Can you just clarify...are these all drugs where there is a generic, or is this all the...?

Jeff Thompson: These are all the drug classes.

Carol Cordy: They're all the classes? So...

Jeff Thompson: All the classes.

Carol Cordy: ...in some of those, there is no generic?

Jeff Thompson: Yeah. TZDs, the immune modulators, those that are brand only, and triptans also. But, I mean, it is a wide variation, and so we need to look at this and say where we have opportunity. So next slide.

So what we are asking is there are 12 drug classes which we want to work with you, both in a communication and under the elements of 5892, and these are the drug classes that we think there is opportunity to actually achieve the savings that the governor has to reach the target of 83, because these are the drug classes that have high utilization and have high brand generic differential. Because obviously if you're looking at savings, even if there's \$1,000.00, if there's only 2 prescriptions out there, it doesn't make sense. So these...if you go all the way from the statins at 22% DAW, you can see there's a \$97.00 differential. And then, you know, then the one that causes a lot of people consternation, the atypical antipsychotics, because there is now a generic, there's almost a \$200.00 difference...\$186.00 differential, and we have 20,000 clients on antipsychotics. And that's one of the reasons why it's on there.

Now, I just want to be very clear. We're going to go at this very carefully with a lot of diligence, a lot of communication. We're not asking people to stop the medications that they currently are on, but is there opportunity to interact with the prescriber and ask, "Given these differentials, is there the opportunity for a generic first start for a naïve client?" And so, again, these are the 12 classes, and I'll finish up that we want to work with you on, but we're not talking about taking people that are on existing drugs, that are stable, off those medications. Do these numbers surprise you at all? So next slide.

So this is the process. And it's a little bit dizzy, but it...I think it...Dan Dollar did a very nice job of sort of putting the flow out for all the components of 5892. So section 2A talks about basically educating and communicating with that small set of providers where they have high DAW utilization. You know, the opportunity that can we get them back towards either more in line with their peer or best practices. And then if

they do not, then there is the option to actually ignore their use of DAW. Not to take their privileges away, but to ignore their DAW. I am hopeful that that will be a very rare, if nonexistent, option for us. I am hopeful that in education and good communication and working with them that this just isn't going to happen, because I think this will be the first time they've ever seen this data. And to look at that, I think that there will be quite a bit of change. But that is section 2A is to inform those client...or those providers with high DAW and to work with them on a modification with data that's data driven, and maybe in the future to even talk about a pay for performance, where if you're an excellent provider, an excellent generic, and low DAW utilization, maybe there's a way we can do some administrative simplification. Forgive you a PA or something like that.

On section 2B and 2C, just talks about that we can add the generic or possibly and over-the-counter, what makes business sense, to the preferred drug list where they are AB rated, FDA AB rated, for the same chemical in the case of over-the-counter to the preferred drug list without having to go through another cycle OSHU in your review. And so that's basically something that we've been doing, but now it's stated in the law that we can do that and so it's very clear and transparent. In section 2C, which we'll spend some time on, this is again, are there drug classes that we feel because there's a lot of brand utilization, that we can edit an interaction with the prescriber and say, is there opportunity for a new start with generics and not brand? If they can come up with a medical necessary reason why, good sound evidence, why wouldn't you pay for it? But if 90 or 80% of the utilization is always brand over generic, we need to have that discussion. And so the classes we're looking at that are antidepressants, perhaps the antipsychotics. I'll go a little bit more into that, the long-acting opiates, the NSAIDs, the statins, the PPIs, and the ADHD drugs. And I think, you know, Siri and I have sort of really talked about how can we do this in a very safe, very effective, and transparent manner. I think we have some options here.

And then finally in section 2E is looking at off-label use, because 40 to 60% of some of these drug classes are off-label use. And like in the case of too many, too young, too much when it came to kids, let's talk about some opportunities to educate people about appropriate...what may be more appropriate on label use. And starting July 1, we're going to be looking at low-dosage Seroquel, because we know that is a preferred sleeper out there. Antipsychotic for a sleeping agent is not an appropriate

off-label use. There are FDA indications that we've paid for, that you've looked at, and we should steer people towards those FDA indications. So low-dose Seroquel will be one of those but other opportunities to look at, now, this is not on the preferred drug list, but mood stabilizers, long-acting opiate, and PPIs as well as the appropriate use of antipsychotics for that huge list of off-label use. And again, we'll do this in a very transparent, lots of communication, in a safe and effective way.

Any questions about?

Patti Varley: Oh, this is Patti Varley. I don't know how specific at this point you can defer of any of these, but when I look section 2A, one of the questions probably that I will get has to do with the fact that as I look down that it looks like the taking away of somebody's privilege to write DAW is way down the bottom, and that there are many steps that would occur prior to that happening to any individual where they would have direct feedback, opportunities, etc. Correct?

Jeff Thompson: That is correct. And we will be writing administrative code that will outline all those elements, because there's some language in there that needs to be cleaned up, and I don't think that I would ever...actually it has the medical director's doing this. And that wasn't my suggestion. The only time that we would do something like that is probably after two, three, if not four quarters of data that shows that there is no change and there is no clear explanation of why.

Patti Varley: Okay. My other question has to do with your indication of rewarding for prescribing in some certain framework, and I guess my issue with that is when you look at the difference in practice sites and patient loads across clinicians, there may be some very appropriate prescribing clinicians who are doing the right thing but can't make that quota, because their population is very different. So I'll just express my concern in that realm.

The other question is that there has been in the past, confusion about the existing refill protection. That we have had problems, just so people know where kids have transferred to Medicaid and been on a med and been told they can't have it, and I just want to make sure that as this gets incorporated, that that be reiterated to the powers that be. And then the last thing is, when you write, "may substitute" and they can't buy the generic, they have to call us back and ask us to redo it as DAW. That

logic escapes me, and that has been a constant problem recently. I've been...yes...and it's time consuming. It's illogical to me. If I say, may substitute, you can substitute with the brand name. I don't care. But the holdup of patient's access to prescriptions, the need to duplicate...some will take a verbal okay for a DAW, other's want a signed one. You can't fax these; it's just...so again, when we're willing to be the DAWs and then that's causing us more work, that's going to make this less popular. So those are my comments.

Jeff Thompson: So on the P for P, this is probably at least a year or more away, because we have to wait for our new system, but we'll work with you on that. On the safety elements, you know, Siri, I think, has done a very, very good job of looking at opportunities to inform the pharmacies when there is a safety need, we're going to give emergencies supplies. We're going to give the brand. We're going to give the non-preferred in lieu of any prior authorization. I can't guarantee you that there won't be hiccup now and then, but we're going to try and work with the pharmacies to reduce any of those hiccups when it comes to DAW. And the DAW you're talking about specifically with Foakland(?), has to do with, number one, the shortage of the generic; and number two, we continue to have pharmacies that do not understand therapeutic interchange.

Patti Varley: Interchange.

Jeff Thompson: And we'll have to double our efforts with understanding that it is the law, it is safe, and there is minimal risk when you do that. But you know, as anything, it's...

Patti Varley: This is Patti Varley again. The argument they give me is that from your end, they will not get reimbursed if it's not DAW because of it being, may substitute. So to me, it's a financial glitch that, as a clinician, I'm being involved with that I think makes this a less attractive system to those of my colleagues who are not so knowledgeable or involved.

Jeff Thompson: And so we'll double our communications. The only caveat I have is that we can't drive our pharmacy program to the exception. We can't open up all the gates, because one thing happened. So we'll look to you again, you know, it's always very difficult to communicate to busy practitioners, be the pharmacists or prescribers, and so we'll redouble our efforts on that.

Patti Varley: And again, for me, the inconvenience to me is irritating but livable. The problem is they are not filling the prescriptions until they hear from me; and if I'm here today and I don't get back to them tomorrow and my patient's waiting for their prescription today, I'm the one who gets in trouble, because then I'm...they are told that they called me and I didn't call them back.

Jeff Thompson: So we'll work on that.

Patti Varley: So, yeah.

Jeff Thompson: So the next slide. So assumptions with...now we're going to talk about the communication. And you have a copy of what's called Generic News. I know it's a double entendre. I know it's kind of a smiley. But I thought it was fun and I had to have a little fun writing it, so you have to put up with it.

So average daily cost. This is a new way of looking at cost. One of the difficulties that we've always had is communicating to you cost, because cost can be differential by each drug, each milligram, whether it's an injectable, whether it's a solution, whether it's a pill, or whatever. So one of the things that we've been doing over the past five years is we've been using the average daily cost as a mechanism that when you said, all of these drugs in a class are equally effective and you can make a decision on cost, this is the mechanism that we actually level the playing field for both Medicaid, Labor and Industry, and the Uniform Medical Plan. So what we do is we take what is our average cost in this drug class, in this drug, we multiply it times your utilization, you being the State of Washington, and we come out with an average daily cost. And so then what we do is we add that up across the three organizations, and then we do a ratio of the lowest to the highest. In other words, we should take the lowest, make that the denominator, and then divide that by all of the average daily costs, and you come up with basically a relative average daily cost for each drug. It's a bit new. It takes a little getting used to. It's like the generic refill rate. It's not the glomerular filtration rate. So we've got to work with it a little bit. But if we're not going to use this, then you've got, you know, what I think on [inaudible] you're going to see is this Y differential of cost, the cost all these milligrams. What if I pill split? Well, what if I get a solution? So this, at least to me, seems to be a good compromise looking at our cost and your prescriptions, and so we'll go over that.

In generic news, everything that I write for the most part is going to be...when it comes to a drug class, is a cut and paste out of OSHU. And so it's really your evidence that I'm going to push out there, and obviously, it will be abstracted. It'll be taking 900 pages down to a couple paragraphs is not easy, but at least it's transparent, and I can point back to where the evidence is that you made your decisions.

The savings. Okay. We talked about this is going to be limited to about 12 drug classes, because that's where the brand differential is. That's where the utilization is. And so what we want to do is connect the generic news, to connect the feedback reports, to connect all this to a base of drug classes that we need to work with for a year or two so we can move to our generic fill rate of 83%.

And then finally, just so everybody knows, I've included what if, that what-if statement, what if we moved everything to generics? Not probable; not possible, but it gives a scale of what's going on here. And so next slide.

So what I've done is I've put it into a little table format. I've actually worked with some marketing people that are outside the organization and came up with that you'll see each drug class by total spend, the possible savings if 100% generic, the brand utilization by cost. You'll look at each drug, comparing low to high, on the days per year, and the average daily cost. And again, the DAW will be presented as its selection of preferred and non-preferred, and the average daily cost will be used with each drug within that class. And so this...we're trying to be consistent. If you've got some other ways, let me know; because if we agree to this, the actual letter's going to go out this week. So next slide.

So let me give the example. This is the PPI class. So you said that there...and we just reviewed it, that there really are no significant differences in efficacy across these drug classes. \$16 million in overall spend in PPI. There's \$9 million potential. Again, \$10 million almost potential if you were to move everybody over to over-the-counter or generic omeprazole. The DAW percentages to...are preferred is the Prevacid is to move...is 15%, and then you can see where the utilization on the total day supply and the comparisons in a relative fashion from over-the-counter to the top in class Prilosec . So the question is, if the

evidence shows no difference, do you get nine fold clinical value if you exchange the lowest with the highest? So at least, I think this is a fair way, because it also indicates not only what our costs are across the three agencies but also what you're prescribing is. And so I've characterized in Generic News, the six drugs classes. The next edition will come out in September...August with the other six drug classes, and then we'll probably have a discussion of off-label use within that. And if you want to be a contributor, I'd love it, because these are not easy to write. But at least, I think this is a very transparent way of them finally looking at what is the monthly cost with generic to brand.

Vyn Reese: Jeff, this is Dr. Reese. I had a question. Omeprazole and Prilosec OTC, they're the same drug, okay? If you write generic, may substitute for omeprazole, why can't they substitute Prilosec OTC? They don't do that now. And so...

Jeff Thompson: Generic substitution law only applies to AB rated FDA drugs, so they are not allowed to actually do a substitution of generic for OTC under generic substitution law.

Vyn Reese: So you would have to...if you want to be most cost-effective, you'd have to write a brand name down for that particular drug and not prescribe the generic?

Jeff Thompson: In this particular case...and this is one of the funkiest classes that we'd had. That's a technical term, funky. Because there was a lawsuit that was risen...that went out against the generic company, and so this drug class...where typically a generic with very few exceptions, is typically less expensive than the brand. This is the exception. And now we have, in addition to brand legend drugs, we have brand over-the-counter drugs, and we have generic OTCs. And so we've created this sort of animal of terms which is starting to get confusing, but here it is. Transparent as it possibly could be without opening up what the rebates or the discounts are, because that's the other part of this. I cannot show everybody what the rebates are. That's against the law. So this way you can't back up the rebates, but you can get an idea and ask yourself, do you get three times the clinical value when you prescribe over-the-counter...when you prescribe Nexium versus over-the-counter Prilosec?

Vyn Reese: My concern is just the top two. I mean, that's the problem that I have the most common with, and that's going to be more and more common as more drugs go OTC and they have a brand name OTC. And some big pharmacy groups for insurance companies you have to write the generic, and others you have to write the brand name OTC. And for the provider when you're writing for a whole bunch of different companies, it gets very confusing as to which one is preferred.

Jeff Thompson: I can tell you, though, that likely this scenario of average daily cost looks the same across all payers. I can't speak for it, but I'm almost positive that the over-the-counter is probably cheaper than the generic at this point in time. So you now have the option. You know, and you can look at this.

Vyn Reese: But it's not, though. Like if you go down to Wal-Mart and buy, even a \$4.00 prescription for 30 days of a generic, and that's going to be a lot cheaper than an OTC brand name.

Jeff Thompson: Right. And I don't want to get into the \$4.00 generics, because that's another issue that is rather interesting. You know, all we can do is be transparent. All we can do...Mary Ann, I will make the commitment to work with the health plans, and we've already done that with trying to standardize some of the formularies between Healthy Options and fee for service, and we've done, I think, some good work there. And we'll continue to do that. We...Mary Ann and I have actually talked to the Puget Sound Health Alliance. Could this be the mechanism to be transparent in the State of Washington so that Premera and Regence and Medicaid aren't giving a different sort of definitions and different standards? And we're...Mary Ann and I are working to try and say, could this possibly be the standard? If this isn't, tell us what could be. All we can do is be more and more transparent, because that's what's not happened when it comes to dealing with the preferred, non-preferred, blah, blah, blah. This has not been a transparent system, so we're going to open the books up as much as we can. Next slide.

Siri Childs: This is Siri, and I'd like to mention that in this budget mandate for us, there is a tension that's built in. There's a tension between the targeted cost savings and the tension between moving the generic utilization rate, so the example that we just saw, if you selected Prilosec OTC, which is a lower cost, it would help us with cost. But if you selected the generic omeprazole, it would help us with the movement to the 20 points.

Vyn Reese: Right. And we would be graded on that. That's my concern. This is Dr. Reese. We're going to be graded. Because we do right thing for the patient or Prilosec OTC and for the state, it's cheaper. We would be downgraded if we looked at person to person generic.

Jeff Thompson: So here's a definitional issue. We can have a discussion about whether we called a branded OTC a generic.

Vyn Reese: Right.

Jeff Thompson: And I think we could talk about purposes...

Vyn Reese: We should have...we should...

Jeff Thompson: ...for the purposes, and that's what will be going into the hard work that we'll do with the WAC, with the administrator code, because now we have to be very clear and concise about how we do a feedback report so that we don't get ourselves confused. So I think, you know, finally I think before I start on this slide, the first thing is just want to be very clear. Your hats as a P&T Committee do not change. You evaluate the evidence. You use the OSHU report. You make the preferred/non-preferred selections based on the evidence, the clinical, the scientific evidence. Then what we'll do is we'll close the meeting and you put on your DUR hat, and then I'll start showing you the cost and utilization, talk about safety concerns, maybe bring you the adherence histories, show you that they aren't taking their diabetic drugs, their asthma drugs. What'd we going to do about that? Because to my mind, you've got to take it all together. You've got to look at the whole milieu; otherwise, we start going down rabbit holes again.

So we're looking at generic first options and new starts for 12 classes of drugs. So that is one thing that I'd you to vote on. And the way what we do is we would step this out as you go through your preferred drug list selections. We will actually then introduce a generic first option here for these 12 drug classes. We will talk about if we're going to do this, Mary Ann and I will have a very heated discussion with other people. Can we do this with our resources, because PA costs a lot? Personnel costs a lot. Can we make sure that we get a good, accurate early communication, and what is the impact on each class? Because in the selection of these

classes, we have to look at what the utilization is as it changes, what the brand generic utilize...or differential is. But we'd like to do is, I think, and I think Siri has a very good idea, let's step this out with the selection of preferred/non-preferred.

Now, mental health drugs and antipsychotics. We've now instituted second opinions for too many, too much, too young in antipsychotics using children's. We've had some discussions with them about a generic first opportunity with Risperdal, you know, with using the second opinions. And so we'll have some discussions there. We've had some early discussions about second opinions for adults where we could ask for mental health drugs, including antipsychotics. Is it an option for a peer-to-peer discussion about whether a generic and a naïve client would be the best, most efficacious option in a peer-to-peer discussion. Before we go down that path, before we take on those issues, we'll do it transparently. We'll work with the community. And so we're going to do this, because it is very difficult sometimes to do generics first in some of the mental health drugs, but other states have done it. They are doing it in Ohio. So...and that is truthfully where some of our biggest opportunity is, because it is our heavily utilized classes. Remember 40% generic...or 40% utilization in mental health. So if we do it and everybody else but not mental health, it's going to be very difficult to achieve savings. So we'll work with you on that.

We also want to keep producing the Generic News and communicating the progress and the issues as we move forward. And then also we want to give provider feedback tools with DAW that are consistent and well-communicated; and so that if we ever get down that decision where we have to ignore the DAW, it's done very, very carefully with a lot of communication and a lot of transparency. And I use that word, transparency a lot because that's how we're going to do it.

I think when I talk about the community, you know, interaction, yeah, we'll be talking with you if we have to go to some outside experts, but we have to move on this. We have to achieve these savings in the biennium. We can't have a lot of meetings to go over two years of discussions, what do we mean by generic first? So what I'm asking you is on these 12 classes, for naïve, first-time starts within a discussion with Mary Ann and I where we look at resources, all these things I've talked about, would you allow us, under the law, which says, the DUR gets to help us out with

these decisions to go after this to achieve our goal of the 83% generic bill rate?

Patti Varley: This is Patti Varley again. I have a comment and a question. My comment is that, yes, you do use that word, transparency, a lot, and I would say that what I see lacking is people being educated and informed. Transparency is not what I'm hearing about as much as I'm hearing about what are the rules and why are the rules and how, you know, and you can interpret that as that we're a transparency, but it's more...they just want to know what to do and how to do it and want the facts behind it. So to me, it's more information and education than it is transparency. That's lacking. The other point of clarification, Siri, that goes to the comment you made, because I think I understood, but I want to make sure. And that is that the mandate is for generic. So if I sign, may substitute, but they're not going to get the Prilosec OTC which is really a brand name, and then I would be costing more money but fitting the generic. Was that the example you were describing?

Siri Childs: You know, we're really fortunate, because we have our technical expert with us, our pharmacy program manager, and I'd like to have him take just about two minutes and explain how we hope to set this up in the computer so that when you write substitution permitted, this will be done automatically for the new starts. Can we just take minute and hear that explanation?

Woman: Sure.

Vyn Reese: Great.

Jeff Thompson: Sure. Yeah. Yeah.

Man: So the intent as far as the program design and programming within the system on implementing generics first, would...basically how it would look is when a prescription came in from an endorsing physician, for example, that did say...actually, it doesn't imply that much to when you do sign, substitution permitted, because the pharmacy should just be taking care of that and substituting something. When it does say, dispense as written, and it is for a brand, the system will be set to look back and see if the client has been on drugs in this class before. If the client has been on drugs in the class before, they would not be considered a new start, and

the DAW would work just like normal. If the system could not see a history of drugs in this class, then that DAW would not automatically go through the system as it does now if it was for a brand name drug. If you wrote DAW on a generic, that's still a generic, and it would get through as far as your DAW. But if it was for a brand and it was a naïve client in the class, then what would happen at that point and what is outlined in 5892 is that then you would get a contact about justification of the medical necessity for a brand on a new start, and that is still an extension of privilege to endorsers because non-endorsing physicians in the same situation just get told no when they write...DAW doesn't do anything for them. And if they're trying to prescribe a non-preferred drug without a trial of a preferred, then the answer is just no. Whereas an endorser in this situation, the stop in the system would be a little bit different which would clue our staff to request justification of medical necessity for that brand which would then be reviewed through our normal drug review process.

Ken Wiscomb: This is Ken Wiscomb. I wanted to go back. You talked a little bit...utilization rates about comparing outcomes with commercial third-party payers and efficient clinics, and I don't know which of you is the best to ask this question, but have you thought about a mail-order pharmacy option as things go along as of...for the different point of sales?

Woman: I can talk a little bit about that. You know, we tried that a few years ago, and it was not successful. Again, that does not mean that we couldn't look at it again, and we may certainly consider that. But when we...I'm not sure we ever even had a 100 clients that took advantage of it. So I think operationally we would want to do it differently, certainly, than we had done it, and it may be something that we could associate with our co-pays. So as we move into that, that may be a good way of tying that to it and as an educational piece, too. Because I think it goes along with the comments you were making with Patti about education, and that applies on the client side, too, in just getting them used to doing something quite different. But I think it is a valid question. Patti, I want to make sure you've got your question answered on the Prilosec OTC and omeprazole, because I think from a counting perspective or how we would look at that as it related to a provider, we would certainly, I think, take in consideration that the cost of the Prilosec OTC is going to be less costly, so we don't want to count that against so we would look at that. And you know, from a reporting perspective, look at it like we would a generic. If that makes sense to you?

Patti Varley: This is Patti again. My understanding, and I don't know the details and don't want to, about the rebate thing too is there are times when a brand name might actually be cheaper than the generic. And my understanding is if I write, may substitute, you have the liberty of giving the brand name if it's cheaper. Correct?

Jeff Thompson: So let me be just real...

Siri Childs: That is correct, Patti.

Jeff Thompson: Right. So let me...there are rare circumstances, and we've actually written a report if you want to look at it, where the generic is more expensive than certain brands. Typically, that happens during the six months of exclusivity. Federal government said, if you're brave enough to put a brand...or put a generic out there that competes with a brand, you get six months of exclusivity. Why wouldn't they price it? I can tell you, though, that within two months of there being more generics on the market, we make up all that difference. So with rare, rare, rare exception, generics are always cheaper than brands.

Patti Varley: Right. And this is Patti again. But again, it's when you were talking about this sort of head counting of, you know, how many generics are we using. I think, again, it's education to clinicians that, you know, there's nothing to lose usually with the DAW unless you have evidence, clinically, that that patient needs something else. But that all of these things, I think, at times get confusing to clinicians who aren't part of these wonderful discussions about all that cost rebate benefit stuff.

Jeff Thompson: Average daily cost here is net. Average daily cost takes into account rebates and discounts, so this is all net. So if we use average daily cost, we don't have to talk about rebates. We don't talk about discounts. We don't have to talk about exclusivity, all this other stuff. Average daily cost is the picture of what the ratios are, a differential between the lowest and the highest, when you've made the decision with preferred/non-preferred, and we made the decision on cost. And that's how I would foresee us moving in the future for explaining this, because quite frankly when you get into the discussions about rebates and discounts, it's like trying to understand whether you got the best deal on your used and new car, and you'll never know.

Woman: And I think one of the things we're trying to do is make it simple for the providers to think generics first. So not to have to think about, well, gee, is this one less, more? Whatever. But really getting into the mindset of thinking generics first.

Duane Thurman: So that Generic News would go to every prescriber in the state?

Jeff Thompson: So the way this is going to go for the first go around is we're going to send this out to the 1,600 providers that have DAW between 25% and 100% of the time. We'll then work with WSMA and a whole number of organizations to cut and paste, possibly post this on rx.wa.gov. We'll do a communication, and we'll work with you to get it out to the clinics and others. We've had a lot of help with this. Siri's done a very good job of editing. Sometimes I need help on that, too, because I'm running way too fast, but I think this is how we want to get the message out. And Patti's absolutely right. Even after six years...I have presentations all over the state, how many of you are endorsing providers and know what that means? And not a single hand goes up. So we can continue to try and...it's like when I was at the Marines. To educate somebody, you have to tell seven times. Sometimes you have to hit them over the head. We'll do less of that. Hit them over the head.

Vyn Reese: This is Dr. Reese. First of all, I think we can get lost in the trees for the forest. Okay? I think that actually this is an excellent program. It's long overdue. I mean, the big insurance companies are already giving us grades and percent generics now. It's, at least in the big group practices, we see our grades all the time, and we're constantly getting asked to prescribe more generically just because they may take their business elsewhere if we don't prescribe more generics. In classes where the generics are the rule, which is a lot of classes as you said. So I think that this is an excellent idea. It's long overdue. Implementation may be problematic as we're working the bugs out, but I think it's something that definitely needs to be done, and I think it's a good start. But the devil is in the details, and the things that make it more...less user friendly for providers are going to cause resistance. And the more confusing areas there are where there's a couple of drugs and you write dispense or you can just...

Patti Varley: May substitute.

Vyn Reese: You know, you may substitute instead of dispense as written, and then they still don't substitute, and that happens a bunch of times. And that's happened to me several times. That drives the providers nuts.

Jeff Thompson: You're absolute right.

Vyn Reese: And then the patient doesn't get the meds. They call your office. They scream at the nurse. So we've got to work on that particular interface to make it smooth for the patients and the doctors. And so when we...and just because Prilosec OTC and omeprazole can't be interchanged. I mean, basically, they're the same drug.

Jeff Thompson: If you were to go back to that, I mean, one of the things that we're doing is we're doing PPIs right now, because quite frankly, everybody...not everybody has Barrett's esophagus or erosive gastritis or blah, blah, blah. PPIs are being used for too much pizza the night before, and so...but if you were to look at it, if we were just to move everybody to OTC and generic, it's \$10 million savings right of the bat. But we believe that the brand is more effective than the generic regardless of the science. So we'll start working this. I absolutely agree. Nobody will lose the ability to...

Vyn Reese: That is the myth. You don't have to convince us. We've seen all this data. We believe. We are believers here. We're all on the same page.

Patti Varley: I don't agree with that statement.

Jeff Thompson: All right. I've got 45 minutes. If I have one screw-up here...so in any case, we'll work, and I think you're right. There will be times when supply of generic...you know, we had this emergency. Nobody could get OTC, or nobody could get...PPI in the past. We'll work through that. Nobody will lose their ability to use endorsing, because there's a supply issue. They'll be many, many opportunities to have a discussion about what the data is saying before we ever would actuate section 2A and somebody would lose the ability for us to recognize a DAW. Because we're very clear. We're not taking away their privileges. It would be just our look at whether you're DAW has recognition or not.

Vyn Reese: And Jeff, one other suggestion, we're being graded by all the insurance companies on percentage generics, instead of dispensed as written percentage. It might be easier to refer to it as percentage generics, because otherwise you'd sort of have to flip it around in your mind, and it's actually the reverse. Doctors like to get higher grades instead of lower grades. And so if they see their higher grades going up. They're very, you know, motivated towards that.

Jeff Thompson: So the next time we meet, I will give you a sample of the feedback reports, and you're absolutely right. We are going to actually give feedback on each individual drug class by generic utilization. So it's a positive thing. They will get their DAW. They will get the brand, generic. They will get the number of clients, and they'll actually get some cost savings or expenditures as they move over trend. So we'll give them all that information. This is actually modeled, I think, after some of the excellent work that Donna Sullivan and the Uniform Medical did. They've been doing the feedback reports now for a number of years to clinics, and all we're going to do is take that very good model and we're going to then apply it to the provider specific and we're going to provide them the opportunity to compare themselves against a peer, a peer to be decided. We're working on that and best practice. And if you don't like which peer you want, tell us which one you want. I'm not sure I'll change an M.D. over to an ARNP or vice versa, but we'll figure that out.

Siri Childs: Jeff, let me say one other thing. I just want to assure the prescribers and all of you on the board that we will design the computer edits so that your substitution right will be preserved. You will not have to worry. Our computer edits will be designed to give you the results that you intend when you write, substitution permitted.

Patti Varley: So in other words, even though they're DAWing all the Focalin right now, in our record keeping about us, it will look as if we have put, may substitute. Correct, Siri?

Siri Childs: Absolutely. We will make sure that you get credit when you write, substitution permitted.

Patti Varley: And can you make them be able to substitute?

Man: You know, in regard to the Focalin, that's something that we can take away from here and look at our procedure in house, because there's a couple of ways that we could and should be dealing with that, but it doesn't sound like is happening completely correctly. So I will take that back when we go back...

Patti Varley: And again...

Man: ...and find out what's going wrong, because the pharmacy shouldn't be doing that.

Patti Varley: It should substitute with what they have.

Man: The pharmacy should be able to call us and indicate the...

Patti Varley: Reason why it's...

Man: Yes. And indicate the shortage issue and not have to interact with you on that and not have to run it as a DAW, so we need to do a double check on our in-house process and find out what's happening there.

Patti Varley: Yeah. And I'm going to use another term again about what I think we need to do, and it has to do with what you alluded to, and that's marketing. I mean, we're really selling something here to the providers *and* to our clients. Because if they're...if we're holding them up from getting scripts and then the clinicians are being treated hostilely by clients and pharmacies, because we're not getting back to them on time, when we're doing the rules, that doesn't sell your program really well. And again, it's like life. One negative outweighs twenty positives.

Jeff Thompson: Right.

Patti Varley: And I think sometimes we're just trying to point out that we embrace this. We love this. We're all behind this. We understand it, but it's very hard to sell or market to our colleagues who say, but...it's not working, but how come it's Molina and it does this? And I can't keep track of who does what, even though they're all on medical coup...you know, those are the things that make this unappealing to our colleagues who we're trying to encourage to use it. So life isn't perfect. I don't expect it to be perfect, but I think if you're really pushing this, you have to acknowledge that the

more we can fix these glitches, the more inviting and encouraging and embracing everyone will be.

Ken Wiscomb: Well, and It's much more palatable to be practicing cost-effective evidence-based medicine than it is to maybe making up for a budget shortfall.

Jeff Thompson: But, you know, one of the things...and this is a pushback and it probably...but I can tell you, though, if we had in each class 90% generic, 95, whatever, there's some high number in there, PA goes away. All these things go away. The reason why there is such complexity is because of all the things that we all do together that all go against each other, and it's the variation, the prescribing population. It's basically our rules and regulations that we have, both federally and state. It's the activities of the commercial market and our capitalized sort of market system, and quite frankly, all these have come together to create the problems that you're talking about. So I think the simple communication is if we can get the brand generic up to a level, a lot of all this goes away, but that requires us all working together, and that is the most difficult thing to do.

Patti Varley: Although I have shared this with some of you today already, and...on a marketing, personable, educative comment on a life changing moment, was 20 years ago when a nice pharmacist called me and politely and respectfully had a discussion with me about the cost of my signing that Ritalin script as may substitute versus dispense as written, and the amount of money difference that was and the equal stability of my patient. That five-minute phone call changed my signing of my prescriptions every day since then. So the power of that, let's just talk about this niceness, no pressure, not a have to, but did you know, I don't think I'm alone in that that has such a different appeal. It wasn't yelling at me that I had written it wrong. It was all about, you know, I see this, and I'm just asking would it be okay, and this is why I'm asking, and this is the situation. And I swear, ever since that day even before all this, I have always put may substitute when I can. So that is what I'm hoping we can do with the system is most people want to do what's right and best on all those levels, and I just think there's a need to look at that marketing end.

Jeff Thompson: Go ahead.

Duane Thurman: Just one comment on, in terms of the overall program, I just want to make very clear that there's nothing in this bill that was meant to change the way that the P&T Committee does its job, and that was something that the people were very, very pleased with as we went through the legislative session. It's not meant to introduce any kind of cost analysis into your process, anything like that, and I guess the easiest way...the way I've been explaining it to people is in your roles as a P&T Committee member, you are looking at the evidence and you're making recommendations to us as to what we should include in our preferred drug list. We'll continue to do the cost analysis that results in the ultimate preferred drug list. And then in your role as the DUR Committee, the idea is what's an appropriate way to implement that drug list, particularly for HRSA, so I just wanted to make that clear.

Vyn Reese: So as I understand...this is Dr. Reese, we're asked to make a motion on this and pass it with the committee, and we'll need stakeholder input today, too, is that right? Are there stakeholders here that want to speak? I don't have a list of stakeholders, I don't believe in this.

Regina Chacon: No one signed up.

Vyn Reese: Okay.

Regina Chacon: There was a sign-up sheet in the foyer.

Ken Wiscomb: What are these sorts of...?

Vyn Reese: Come on down. Oh, sure. You can go ahead and go to the podium there and introduce yourself; and if you're affiliated with someone, with the pharmaceutical comp...yeah, go ahead.

Bill Struyk: Bill Struyk, Johnson & Johnson. I just had some questions about the process. As I understood the information about the motion that you're entertaining or about to entertain, it isn't...the 12 classes or however so many classes there are, are not being targeted for action today, but those...your recommendations will be brought back to the DUR in a future date?

Siri Childs: No.

Jeff Thompson: Basically, what we will do is take these 12 classes, and within our resources, communication, and impact we will action on those to achieve the budget savings and the generic fill rate that the governor has outlined. So this only impacts new starts, not existing clients, not refill protections.

Siri Childs: We...this is Siri, and we are asking for approval for us to go ahead with these 12 drug classes now, and we may come back to the board at some time in the near future with additional drug classes but we want approval today to get started on these 12 drug classes.

Chuck Agte: Okay...and this is Chuck Agte, and I wanted from a procedural perspective the way we've been looking at doing this is, again, within our resources, depending on how much utilization in the class. What the plan would be is to keep it as unconfusing as possible. We would, on a quarterly basis, figure out what of these classes were within our ability to implement with that quarter, along with whatever PDL changes might be happening at that time. And not necessarily a class that was being implemented at that time but just to keep that rollout quarterly so that we're not changing things at odd times when people aren't necessarily expecting a change to the PDL process.

Vyn Reese: This is Dr. Reese. If we added drug classes, it's going to come back to the committee. But we're going to start with this group; and then as this proceeds, we may add other classes.

Siri Childs: That's right.

Jeff Thompson: So just so we're very clear, Bill, 12 classes don't start July 1st, but we will portion these out, based on our resources over the course of the year.

Bill Strike: Yeah, and I appreciate that. I guess there's one nuance, and let me identify my foible up front. We have a drug, Johnson & Johnson, in the ADHD class, and currently, as I understand the preferred drug list, there's stimulants, there's separate...different drug classes categorized out. And then whether they're short acting or long acting, and their distinction's made in the PDL. Will your recommendations recognize the previous work of the P&T Committee with respect to those differentiations?

Siri Childs: Bill, this is Siri, and I want to assure you that we will preserve the clinical intent of the P&T Committee in our generics first on new starts initiative.

Bill Strike: Okay. I just want to clarify it for the record. Thank you. And then one of the things that I think would be beneficial in the process is...Mary Ann, I see the question before the proceeding began, but it would be helpful for us to know as an industry who speaks for HRSA and who we should be...should we contact you?

Mary Ann: Should contact Jeff.

Bill Strike: Jeff? And then copy Duane?

Mary Ann: And Duane.

Bill Strike: Okay. Thank you.

Vyn Reese: Thank you. Any other stakeholders that would like to comment?

Ann Simons: Thank you. Quick question. Ann Simons with Wyeth. Is are you then proposing the use of samples will no longer have refill protection? When are you contemplating implementing that?

Jeff Thompson: July 1st.

Ann Simons: And as you may...you're well aware there's the concern of unfortunately and for whatever reason SNRIs have not been reviewed for two years, and we missed the deadline to have PRISTIQ reviewed by approximately six weeks. So that does bring a little bit of concern in that perhaps there're going to be a bit of foot dragging reviewing drug classes, because then you know you can completely lock out certain drugs. So I would just encourage that as you look at your reviews, that they are prompt and that I think two years is too long. Six months, perhaps a year would be more appropriate.

Duane Thurman: This is Duane. I just want to respond Ann that there's absolutely no attempt at manipulating the timing of this, and I apologize that these things have dragged out. I think we've done a pretty good job of getting on a yearly update schedule with everything, and I hope to return to that, you know, with the antidepressant drug class. In terms of the issue of samples, I mean, the questions is, it goes back to our current definition of continuation of therapy. We're not looking at whether it's a sample or

not. We're looking at whether you've taken the drug before and whether you're compliant with that drug.

Vyn Reese: But the problem is, is that...this is Dr. Reese. That you can't tell if somebody's been compliant if they've been getting samples under the radar, and nobody knows that that was prescribed before and nobody knows that they've gotten that drug before, and it suddenly shows up as a prescription. And therefore, it's not...samples aren't protected as previous prescriptions are.

Duane Thurman: Right. I guess my question is what happens when somebody writes dispense as written for a non-preferred drug that they had given somebody samples to? That's something I'm unclear on.

Carol Cordy: Well, it looks like a new start.

Vyn Reese: It looks like a new start. This is Dr. Reese. The problem I have, too, is that we are getting a lot of patients transferring over from private insurance to Medicaid, and they're on brand-name drugs. So and they're all in the...a lot of those of antidepressants, so we're in that...and you're afraid to stop them. And that's a real problem. I mean, it doesn't...it won't show up on the Medicaid formu...that's been prescribed before. It's going to be showing up under previous insurance that that was prescribed before, so I don't know how you rectify that.

Chuck Agte: This is Chuck Agte, and from a procedural perspective, it's not any different with the generics first than it is now, and right now, our staff have direction that when they receive a call...so maybe the system can't recognize it; but when they receive that phone call from the pharmacy, if the pharmacy indicates the client has been on this product on another insurance, we just take the pharmacy at their word, and we then treat it as a...not a new start. We treat it as a continuation.

Vyn Reese: So you don't call us back, right and hassle us about that?

Chuck Agte: No.

Jeff Thompson: So and I just want to be very clear that that is very liberal compared to the insurance market. Typically, when you change insurance and you walk over between a brand that's non-formulary, you have 90 days to go on

formulary or you go into a PA process. So we are being very liberal in Medicaid to make sure that we have continuity of care, that we don't disrupt somebody, especially with mental health, and I think that's very important for our clients. So that we are going against industry standard with that.

Patti Varley: Although some of us know how to get around the industry standard, which is, what hospital would you like to pay for to admit this patient to while we make that change? Usually, they're allowed to stay on their meds. But with that the question was you won't bug us, but the question I really want to know is there are times where a pharmacy might call us. And one of the things that I've started doing is I've started, and this is just a suggestion in the comment section of my online prescriptions, is writing paragraphs about this person just lost their insurance. They've been on this med for four years, da, da, da, da, da. So it saves me a phone call.

Jeff Thompson: And I think what we can do is we can start to better communicate with the pharmacies about how to work through this.

Vyn Reese: Go ahead.

Bill Bronkhorst: Thank you, sir. Bill Bronkhorst with Pfizer Pharmaceuticals. I was wondering if you could please provide the citation where the 80% generic utilization rates for local health plans was derived from?

Jeff Thompson: I will provide that to you. Some of it is anecdotal; some of it is actually published. I know the Everett Clinic is at or near 80%. Molina is at or near...so we can provide that.

Bill Bronkhorst: Thank you.

Vyn Reese: This is Dr. Reese. I've seen some of the data. I know it's at high 70s for sure for several big groups. It's very close to 80. Anyone else? Any other stakeholders who would like to talk? Thank you. So we'll call...I'll call for a motion to accept this recommendation.

Ken Wiscomb: This is Ken Wiscomb. I'd so move...I move as a committee we authorize...begin just supporting the generic first process for new starts. This class is reviewed in the P&T Committee that we encourage the use of Generic News to communicate process...or progress and issues and to use

the provider feedback tools for issues with dispense as written and brand utilization.

Vyn Reese: Is there any further discussion?

Siri Childs: Could you actually read those drug classes into the motion, please?

Ken Wiscomb: Okay. Drug classes include statins, long-acting opiates...well, one problem is my glasses. It looked like a Q from here. NSAIDS, PPIs, antidepressants, ADHD products, beta blockers, nasal corticosteroids, antihistamines, ace inhibitors, muscle relaxants, and hypnotics.

Vyn Reese: Any further discussion? I'll take a second.

Patti Varley: Patti Varley, I'll second.

Vyn Reese: Motion's been made and seconded to accept this recommendation. All those in favor say, aye.

Group: Aye.

Vyn Reese: Opposed, same sign? This motion is passed. Thank you. And that's...concludes our business today, I believe.

Siri Childs: I would like to say...this is Siri...and I would like to tell you that we plan on bringing you back an update of our progress at the DUR board meetings in the future so that you can keep track of where we are with this process.

Vyn Reese: Thank you and the committee is adjourned.