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STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Meeting Minutes

November 8, 2012 P&T Committee

Spring Hill Suites
Las Vegas Convention Center
2989 Paradise Rd.
Las Vegas, NV 89109-1220

Committee Members Present

Adam Zold, Pharm.D.; Eveyln Chu, Pharm.D.; Shamim Nagy, MD; Weldon Havins, MD; Joseph Adashek, MD; Constance Kalinowski, MD; Ronald Shockley, MD**;** Kevin Desmond, RPh; Michael Hautekeet, RPh

Absent: David Fluit, RPh;

Others Present

DHCFP: Gabriel Lither, Deputy Attorney General; Coleen Lawrence, Chief Program Services; Mary Griffith, RN, Social Services Program Specialist

Catamaran: Carl Jeffery, Pharm.D., Kevin Whittington, RPh; Rob Earnest, Pharm.D., JD; Mariellen Rich, RPh, Irene Tobarak, Susan McCreight

HPES: Ed Arnold, PBM Liaison

Others: Peter Berggren, J&J; Stephanie Roberts, Acorda; Steve Fox, GSK; Anh La, AZ; Brian Brown, AZ; Sandy Sierawsh, Pfizer; Jenny Blackham, Lilly; Soheyla Azizi, Eisai; Anthony Duca, Eisai; Eileen Gottstein, Eisai; Mike S., Pfizer; Mary Kay Queener, Johnson & Johnson; Jennifer Davidson; Zack Bellus, Alcon; Phillip Kenner, Accorda; Camille Kerr, Allergan; Brian Streng, GSK; Chito Rondttel, Novartis; Melissa Walsh, Novartis; Robert Mull; Eunmee Lee, Pfizer; Janet Fox, Pfizer; Bret Ferguson, Pfizer; Vinson Lee, Amgen; Helen Liao, Lilly; Tom O'Connol, Novartis; Laura Ptaszek, Novartis; Michael Sullivan, Blocen; Efrain Alton, Merck; Brooks Hubbard, BIPI; Bill O'Neill, BIPI; Phil Walsh; Carol Ricciotti, Sunovion; Dr. Suba; Brad Peacock, Kadmar; Tania Simon, Astellas; Deron Grothe, Teva; Deb Profant, Teva; Carbin Smith; Luvell Robinson, Abbott; D. Prucel, Forrest; Lisa Borland, Vertex; Charissa Anne, J&J; Scott Larson, BMS; Gustavas Avande, BMS; Y. Yamamee, Merck; Curt Scherer, Merck; Scott S., Novo Nord; Gil Astur, Takeda; Mike Pinocei, Pfizer; Laura Litzenberger, Janssen Pharm; Sammy Garcia, Sunovion; Micahel Casey, MD; Greg Rasmussen, Vertex; Andi Stratton, Vertex; Marc Jensen, VCB; Fred Meister, Merck; Ben Skoog, Abbott; C. Stiles, BMS; Toya Bowles, Otsuka; Chad MacGregor, BMS; Jessica McKeon, Novo; Scott Sepien, Novo; Kevin D. Vertex; Steve Farmer, Amgen; Julie Bertulat, GSK; Bill Wausen, Affymax; VM Mur, MD; Shanda Verabial, Pfizer; John Stockton, Astellas.

AGENDA

I. Call to Order and Roll Call

Dr. Nagy called the meeting to order at 1:04 PM
Roll call is taken.

Members present:
Mike Hautekeet, Kevin Desmond, Joseph Adashek, Shamin Nagy, Weldon Havins, Constance Kalinowski, Adam Zold, Evelyn Chu

II. Status Update by DHCFP

A. Public Comment

B. Program Updates

Introduction by DHCFP:
Coleen Lawrence: The chairman or committee has asked us since last year to re-review something in this class. Whatever the reason may be that they've asked us, we're going to review it during this meeting. The second one is that there may be a new drug in that class, there may be a new indication and may be new clinical trials; there is some type of new information that is coming out within a specific, for a specific drug within this class. That is why you, friends and manufacturers that are here are very important. This is one of the ground rules; you're here to tell us what is new or a new indication about this drug. We ask, and we've asked this since 2003 so please do not rehash the information that we already know. Your expertise is to tell us what's new, what the new information is here. If the committee members have already heard it, they're going to ask you to please stop the testimony. So it's very important that you're only presenting new information to the committee. Okay? The third reason is more, that is in the best interest of the state. The NRS does prohibit committee members to review cost when they're looking at the PDL, however it's not prohibited obviously for the state to do it, we were partnered with the manufacturers and ourselves, to look at what is in the best interest of the state. So things have changed obviously the last year between our partnerships, between us the state our self and you and so there are reasons that we may re-look look at our partnership and what we're doing with the preferred drug list.

So you will hear us make the comment; we're doing this backup because it's the best interest of the state. We will not get into a dialogue. If my committee members try to slide down that slope I will stop them, then I will say we're done with that discussion we're just bringing this back up please review the drug class. I'll ask you please to turn off all your cell phones, don't put them on vibrate because a lot of us in the room right now. We go through a lot of them in a very short amount of time so we try to move this meeting very quickly. If we get sucked into something too much, we may just say we're going to table this and move it to another discussion, another meeting because we can't get too far down in the

weeds sometimes in some of these classes. We're going to try to do something a little bit different this time, we're very transparent; if you've been with Nevada long enough, Tom you've been here with us since 2003. Oh, I'm lucky you guys only send reports.

If you've been with us since 2003 we do have a great transparency here in Nevada. We have nothing to hide, so a lot of the things that we're going to do as committee members know what's preferred and what's not going to be preferred. We want to share that with you too with the committee members so we don't have anything to hide, so we're trying something new, we're going to put it up on the projector for you where we're doing the presentation so you can follow right along because well honestly some of your classes are very big and it gets kind of hard to follow verbally. So we're going to put it right in here for you guys to follow also. Okay, if you're one of those manufacturers that you have to testify, you're more than welcomed to please continue to testify. Okay? That is pretty much all the ground rules, we don't have microphones so try to talk very loud you guys and Doc maybe, I think we're still in the public comment so you probably want to ask if there is any further public comments.

III. Public Comment

Dr. Nagy: Any public comment? Please come. Take a seat.

Victor Muro: Good afternoon. My name is Victor Muro I'm a practicing Internist here in town, I'm the Medical Director for Jacobs and Modaber it's a seven physician, two locations at primary care practice. I'd like to first of all thank you folks for allowing me to address the committee I know you're extremely busy. I just like to share a little bit of my thoughts regarding fesoterodine and how it impacts the way we help treat our patients.

In today's ever changing medical environment we as physicians are supposed to be the stewards of scarce resources, knowledgeable of the latest research and best treatment modalities. In addition to being caring, empathetic providers with a keen clinical acumen. With all of all these diverse functions supervised medical care cannot only effectively helps us treat the patient's disease states but also improves the quality of their lives.

As clinicians we rely on a variety of resources to help achieve this ever elusive goal. I'm here to ask specifically that fesoterodine to be added to the current list of therapeutic options available on the current Medicaid formulary given its effectiveness where other agents have failed. My clinical experience, the ability to effectively titrate the dose of fesoterodine provides as, as clinicians with an invaluable therapeutic option. I have no doubt that my clinical experience will be mirrored by the clinical research and data which I'm sure will be presented later on. As a practicing internist with a very busy practice that includes a large number of patients with the overactive bladder disease it is imperative that effective medication be readily available. The ability to treat in a timely manner at the level of a primary provider not only improves patient care it also reduces a need for referral and at times unwarranted further diagnostic studies.

I make this request not with the disregard for the therapeutic options that are currently available but rather as the result of an overwhelmingly good response to fesoterodine that I've seen in my day to day practice. It is impossible to overstate what successful control of overactive bladder can mean to a person's quality of life. And so I'm specifically requesting that fesoterodine be added to the Medicaid formulary for the following reasons.

- It's proven effectiveness where other agents have failed,
- The ability to titrate the dose with a proof, proven improvement response.
- And most importantly the immeasurable impact that adequately controlling over active bladder can have on a person's quality of life.

Once again I thank you for your time; I know you're extremely busy, thank you.

Dr. Nagy: Thank you. We'll visit this issue towards the end when we're discussing this issue. Like to… any comments?

Indiscernible: Yeah I'm not sure are we talking about any particular pharmaceutical now or… I'm not sure…

Gabe Lither: The doctor actually had an additional appointment so he needed to leave soon but there'll be additional time for each, you know each class to make your comments then. But if there is additional general public comment about any general matter this would be a good time to make that comment at this time.

Coleen Lawrence: One thing I will remind everybody there is five minutes on the agenda for individual organization for agency, for public comment as at all of our meetings. I just want to put that out there for everybody as a reminder. So we'll kind of give you guys a signal for time, we'll keep informing you guys.

Dr. Nagy: So we're taking public comments for antipsychotics, atypical.

Displayed on screen in meeting room:

- *clozapine*
- *olanzapine*
- *quetiapine*
- *ziprasidone*
- *Risperidone*
- *Abilify ®*
- *Fanapt ®*
- *Saphris ®*
- *Seroquel XR ®*

Robert Mauley: You're doing, I've only been like in one or two of these meetings in the last 20 years I'm I, I'm going to be speaking on two specific medications, one is not an atypical anti-psychotic but one is…

Dr. Nagy: Could you please come forth.

Robert Mauley: Thanks, hi my name is Robert Mauley I work at University Medical Center I'm being cut in between patients also and low income clinic and I'm here today speaking about Latuda. Will it be appropriate to speak up now?

Dr. Nagy: Yes.

Robert Mauley: Well you know I have patients who were in the hospital for long, long periods of time. I've had patients at University Medical center up to two and a half years, I have patients who are suicidal, homicidal who have damaged themselves irreversibly. A large majority of them I take onto my services from the other services who are schizophrenics. These schizophrenic have attempted suicide and they are under my care at University Medical Center. Some of them are there for five and six weeks, some are there for five and six months. And on the use of Latuda where other medications have really failed they either had a *NEUROLEPTIC* malignant syndrome. They don't like the side effects of other medications, they can't afford them, they're not available, they're just not compliant. In my brief experience with Latuda over the last several months you have a person who has going to be in that hospital for a long period of time, they've been on several medications and Latuda seems to really work well with my patients. I'm impressed with it; I don't have anything new to say about it. The point it seems to work where other things have not worked.

Weldon Havins: Doctor, so Latuda is on a non-preferred list.

Robert Mauley: Yes.

Indiscerniable: So that when you have a failure, a preferred agent you can ask for Latuda. Were you aware of that and we could obtain it for the patient.

Robert Mauley: Yes we can but when the person gets out of the hospital that seems to be a problem in getting the medication if it's not by for…special circumstances, my patients have no insurance. Unlike many hospitals that are, they have paid insurance, my people are there, we don't have insurance and more certainly if the other insurances would prefer UMC, they are likely to go there because my patients and UMC is great. But if they don't have a pay source it's really a problem to get these patients back on medication

Weldon Havins: We are talking Medicaid here.

Robert Mauley: Yes Medicaid yes. And I believe it should be placed on availability under certain circumstances for patients especially the patients who have failed who are chronically ill and don't need acute psychiatric intervention; the medication seems to work really well on the maybe of only 15 or 20 I've had in the last year or so.

Male Speaker: So it's my understanding, if you had the Medicaid agent they failed the preferred agents, and you requested Latuda for your Medicaid patient who had problem receiving approval for that?

Robert Mauley: I have… I don't have any problems while they are in hospital but while they are out of the hospital perhaps they are on, now they are not on Medicaid because all my patients may not qualify but Clark county they're not, it's very difficult for them to get their medications without a lot of prior authorizations, primary care physicians, a lot of my patients cannot, don't have the ability perhaps to follow up even at the local psychiatric facilities. It takes a lot to get them in there.

Weldon Havins: But we're only Medicaid?

Robert Mauley: Yes. Yes I know a lot of Medicaid my patients are pending Medicaid.

Coleen Lawrence: Right so Doctor let me see if I can assist you on this one. So this preferred drug list that we are talking about here today is only for those who are already on Medicaid.

Robert Mauley: Yes and a lot of my patients who do get out will get Medicaid.

Coleen Lawrence: Right. So but they are pending Medicaid that is not, they are not subject to this list.

Robert Mauley: Okay.

Coleen Lawrence: Okay. So when they are in the hospital though and they are discharged we do have continuity of care clauses already and so the call center when you call in let's just say that there are on Medicaid okay not pending Medicaid.

Robert Mauley: Right.

Coleen Lawrence: I know it's a little confusing. When they are pending Medicaid and they are on the Clark County indigent program which we do work close with, if they are on the Clark county indigent program which UMC uses a lot, I used to work with the pharmacy department all the time. This is not a population we are talking about today.

Robert Mauley: Yes I know it's the Medicaid the people who have Medicaid.

Coleen Lawrence: Right and if you discharge them from the hospital and they are on a stable program already and you call into the call center and you say that they are have been on the medication already we have continuity of care clauses already built into this program and you can say that you are… they are on a medication the call center will continue that therapy…

Robert Mauley: They don't seem to be available 24 hours a day or on the holidays or Saturday or a Sunday at times that's a different that's a problem.

Dr. Nagy: You mean the call centers?

Robert Mauley: Yes the call center. You can't get through…

Coleen Lawrence: For the Medicaid eligible recipients?

Robert Mauley: Yes the Medicaid, Medicaid eligible recipients.

Coleen Lawrence: Okay so I will take that concern and Carl and I will work with you directly on that concern okay, to make sure that you are getting your prior authorization taken care for Medicaid eligible recipients…

Robert Mauley: Yes.

Coleen Lawrence: But not Medicaid pending….

Robert Mauley: No not Medicaid pending.

Coleen Lawrence: But to those that are definitely Medicaid eligible I can assist you on that part of it.

Robert Mauley: Great. Thank you so much.

Joseph Adashek: Is it fair to say that these patients that are on Medicaid and you wanted to prescribe this medication, to make these types of patients jump through extra hoops,it's so difficult?

Robert Mauley: I think that it's very difficult and I mean you can have so many problems I mean but not only you can have Medicaid but you can get so isolated in the community not to know what to do and for them to jump through one or two extra hoops, if they are homeless, you know down and out or their care providers can't take them here and there that's a real problem. And I really believe these patients deserve to be able to get their medications without jumping through one or two extra hoops that was my main concern. I'm sorry to have wasted your time.

Indiscernible: It's alright.

Coleen Lawrence: No, no.

Robert Mauley: I'm here because I feel very strongly about this and I wouldn't be here just to talk about Latuda or another medication I'm going to talk about later.

Dr. Nagy: Thank you for your time.

Robert Mauley: Thanks.

Joseph Adashek: Thank you.

Dr. Nagy: Going back to the…

Indiscernible: I just want to talk about it.

Dr. Nagy: On that? Yeah we are still on it. Any additional comments?

Laura Litzenberger: My name is Laura Litzenberger and I'm with the Health Economics and Outcomes Research group at Jansen Pharmaceutical and I'm here to provide information regarding INVEGA. I don't see it on the list are those just the currently preferred agents or?

Carl Jeffery: It's our proposed list.

Laura Litzenberger: Proposed list?

Carl Jeffery: That we're proposing to the P&T board.

Laura Litzenberger: Okay. Thank you. INVEGA it's a different agent than some of these other agents.

- Number one because of the dosage form it actually can be given at the recommended dose the very first day so there is no titration, this is different than other anti-psychotics, so you get an effect right away. The demonstrated effect in the pivotal trials was seen as early as day four which was the first day that it was looked for. So that makes it a little bit different than some of these other products.
- It also is the only orally atypical agent that's indicated for schizo-affective disorders and that was trials that were done specifically on that disorder as opposed to mixing them in with the regulars or with the other schizophrenics.
- INVEGA SUSTENNA or INVEGA oral also is one of the only agents that is excreted almost entirely renally, so you don't need to worry about drug interactions or there is less drug interactions with this agent.
- And then the last thing that I want to say is that not included in your packet or in the information was one particular study in it was a comparison of INVEGA oral with *QUETIAPINE* in patients that were recently hospitalized; and the results that trial suggested that INVEGA had a faster on set of action and was statistically different in its effect on the PAN score the positive and negative symptoms scale score as early as day five. It separated from *QUETIAPIN*E. Also in that particular clinical trial six percent of the people discharged or six percent of the people were… stopped taking the medication in the paliperidone group versus 10% of the people in on *QUETIAPINE* group so there was a difference in the tolerability of the two agents.

Are there any questions? Okay.

Manny Garcia: Hi, my name is Manny Garcia. I'm a Psychiatrist and Medical Director for Sunovion Pharmaceuticals. I'm here to talk about LATUDA LURASIDONE. The package insert was updated last April-May to expand the dose range from 20 milligrams now up to 160 milligrams once a day. Tablet strengths are now available from 20, 40, 60, 80 and 120. This increase in our labeling was primarily due to the clinical trial we did with lurasidone 80 and 160. During a six week study where we used Quetiapine XR as sensitivity arm, both doses separated out from placebo significantly. And that study had continued blind year data which showed continued improvement throughout the course of the year and actually ended up separating out from the XR over the course of the year with improved weight, cholesterol and metabolic data. The other changes in our labels include our updates in the numbers of trials and safety data base. We now have over 29 clinical trials in the safety data base that range from three weeks to just under two years in length. And our longer term studies when you pull all the data together we have drops in cholesterol, triglycerides, prolactin, and in weight. And to summarize you know schizophrenia is an illness that does lead to shorten life span by 10 to 15 years primarily due to

cardio vascular disease I would ask you to reconsider putting Latuda on the formulary based on what I'm seeing as a drugs that you currently have on. Thank you. Any questions?

Dr. Nagy: Any other public comment?

Fred Meister: First of all thank you for allowing me to present to you today, my name is Fred Meister. I am a Pharm D with a strange back ground but that's really not all that important. I am currently a Regional Medical Director for Merck and I would like to present some aspects of the drug Safaris for your consideration. Unlike some of the newer drugs that have come out in this class, Safaris which is one of the atypical,second generation anti-psychotic agents. It has avariety of indications. Those indications include schizophrenia both the acute treatment of schizophrenia as well as maintenance treatment of schizophrenia. It has activity in bipolar disease, individuals can receive it and as it is indicated for mono therapy and acute treatment mainly on mixed episodes associated with bi-polar I disorder. It is approved also for adjunctive therapy with lithium and valproate as therapy in the treatment of acute manic and mixed episodes associated with bi-polar disorder and it is also indicated as maintenance therapy either as mono or as adjunctive therapy with lithium and valproate, so it has a variety of different indications both acute and long term.

As with any other drug, this drug has side effects and toxicities, sometimes the side effects and toxicities are as bad or may be worse in some cases than the actual disease that you're trying to treat. But that's where the clinician gets to use his or her judgment in the benefits verses risk. And some of the more outstanding complications in this group of drugs are the metabolic aspects based on data on Safaris from a 52 week clinical trial. These are some of the data that they've come up with. The average weight gain in a patient over this 52 week period of time compared to base line is 0.9 kilograms, total cholesterol actually decreased 6 milligram percent, triglycerides decreased 9.8 milligram percent, prolactin decreased almost 27 percent and glucose, which is fairly well known with this category of drugs to fluctuate all over in this case, the main change from base line was 2.4 milligrams which I think we pretty well put those on the clinically insignificant. And I probably wouldn't recommend them to treat hypercholesterolemia.

If you look at the dosage formulation it's somewhat different from other drugs in the category, it comes only as a tablet which is sublingual. It actually comes in two forms one is black cherry flavored, and the other is not flavored. It is placed under the tongue for a matter of just few seconds and it dissolves. Patients are not to have any food or water ten minutes before ten minutes after you have taken the medication, but other than that there is no contraindication in taking it around meals or before or after.

Because it's sublingually administered, it doesn't undergo that first pass effect so it doesn't hit the liver, the first shot to the body before it ever gets to the sight of activity. Some people say that is all theory you learn in school. You pass the test and you forget about it, but it does have some practical applications here. One is that with sublingual administration, you can actually get peak levels in 30 minutes which is pretty fast, probably faster than intermuscular type of injections. If you give the drug orallywhat you find is that, instead of having a 35% bio-availability, we have less than two percent which means if someone wants to ingest a large number of these tablets to perhaps to try suicide it's going to be ineffective because it will be essentially zilch in the way of systemic activity.

The drug is given twice a day even though it does have a half-life of about 24hours, so once you reach a steady state in three days you can fluctuate the time of dose which really isn't recommended but it is

not really going to have an impact. Okay, if you look at all the data that's come out on safaris within the different indications for the drug, what you find is that it has multiple side effects, a black box warning which does not fall within the indications for the drug and the same series of adverse effects which are found with most of these drugs are found to be relatively minimal by comparison to other drugs in this category. If you have any questions I would be glad to try to answer them.

Dr. Nagy: Thank you

Toya Bowles: Hello my name is Doctor Toya Bowles I am a Senior Medical Science Liason for Otsuka Pharmaceuticals and thank you for this opportunity to provide testimony on Abilify or aripiprazole, Aripiprazole is approved for a wide range…

Weldon Havins: Doctor? Are you a physician or are you a therapist or are you a psychologist?

Toya Bowles: I'm a Pharm D. board certified in psychiatric pharmacy. Aripiprazole is approved for a broad range of indications ranging from adult to pediatric adolescent populations. The safety and efficacy of aripiprazole has been studied in multiple indications resulting in 14 approved FDA indications. One thing that I want to point out is that 2012 there was a publication regarding Finling, a maintenance treatment of Bipolar I disorder in pediatric patients ranging from 10 to 17. This is a 52 week study showing significance in terms of its efficacy in the maintenance of bipolar I. The mechanism of action of Abilify, I do want to remind you that it is proposed to be mediated through partial agonism at $5HT^{1A}$ and anti-partial agonist at the D2 and the D3 receptors as well as antagonist activity at the 5HT2A receptors. I do want to bring you back to the important safety information in terms of being fairly balanced. We do have two box warnings for aripiprazole, increased morbidity and mortality in elderly as well as suicidal and anti-depressant drugs with children, adolescents, and young adults.

In closing aripiprazole has one of the broadest indications among the atypical antipsychotics across adults and pediatric populations. Given this breadth of indications and information provided today Bristol Myers Squibb and Otsuka pharmaceuticals respectfully ask that aripiprazole status on the Nevada state preferred drug list be expanded from treatment of irritability associated with autistic disorder in pediatrics ages six to 17 to instead include all 14 FDA indications for Ability. Thank you and I will take any questions you may have.

Dr. Nagy: Is there any head to head studies with GEODON?

Toya Bowles: We don't have head to head with Geodon.

Melissa Walsh: Sorry it takes a while to get from back there, good afternoon my name is Melissa Walsh I am Scientific Director of Novartis Pharmaceuticals we are here today on behalf of Fanapt. I respectively request that you leave Fanapt on the PDL for Nevada. Earlier this year the Fanapt package insert was updated to include an analysis of metabolic effects both short term and long term studies were looked at. Nine various studies were looked at. If you look at long term 52 week studies, the mean value of lipids did not increase from base line and mean glucose levels ranged from between the low to slightly above base line levels. If you focus specifically on Fanapt 10-16 milligrams over the 52 week period you see that the main change in glucose from base line was 5.4 milligrams per decimeter and the mean change in cholesterol was a decrease of 7.7, and the mean change of triglycerides was a decrease in 17.7 across all short and long term studies, the overall mean change in weight was 2.1 kilograms. In May of

this year, data from the Fanapt study IFANS was presented. This was a 12 week randomized multi center complete study that evaluated two methods of switching to Fanapt in patients with sub-optimal efficacy and or poor tolerability on an optimal dose of either risperidone, Olanzapine or Aripiprazole. A study found that whether the switch to Fanapt was gradual or immediate, the switch was associated with an improvement of the integraded clinical global impression of change score. The scores improved both in the efficacy domain of the scale as well as the safety tolerability domain improved regardless of which of the three agents the patient was originally on. The types of frequencies of adverse events were similar whether the patient switched gradually or immediate. But more patients in the immediate switch group did discontinue due to adverse events. In summary Novartis requests that Fanapt remain on the Nevada PDL and I'll take any questions.

Dr Nagy: Any other comments?

Anh La: My name is Anh La. I am a Pharm D. by training and I am a medical liaison with Astra Zeneca. The main two points I have today, one of them you will be able to read on that hand out. It's a very short one, and it is really to differentiate the broad range of indications that SEROQUEL XR possesses. We heard some testimony earlier today about head to head studies and I do want to ensure that when we are looking at head to head studies we differentiate head to head versus SEROQUEL or quetiapine compared to SEROQUEL XR which is still a branded agent. I thank you , I still see that that agent on this proposed list.

It's in this class of drugs SEROQUEL XR has indications, and this is not new, but for bi-polar depression as a mono-therapy agent, as well as for an adjunctive agent, for the treatment of MDD. So my first point was really what you will see on the chart when you see that it is the broad range of indications that SEROQUEL XR has among this class of oral atypical anti-psychotics.Then my second point is just the fact that SEROQUEL or quetiapine and SEROQUEL XR do not have an AB rating. Quetiapine, the generic formulation is not an AB rated equivalent to SEROQUEL XR. They have different dosing regiments which you will see on the second page of your hand-out. Thank you.

They have different dosing regimens, different approved indications and SEROQUEL XR is the only true once daily agent. I also wanted to come out here to see if there were any questions that I could address regarding quetiapine or SEROQUEL XR being that they are different products with different pharmaco-kinetic profiles and indications and dosing regimens.

Dr. Nagy: Any questions? No questions, thank you.

Anh La: Thank you for your time.

Dr. Nagy: Any other public comment, none? So I would ask Dr. Jeffery to present.

Carl Jeffery: So first of all we'll take a look at these products to ensure that they're therapeutically equivalent. I think what the class entails, and this is kind of a tougher class because even though they are all within the same class, all of them have kind of their own little special features that treat individual symptoms and from a psychiatrist standpoint, each of them has their own special points in each patient. So we heard a lot of testimony about the...you know the different products.
And I'm not going to go through it line by line, I think that we've heard enough. So the list we have here is Catamaran's list of proposed preferred agents and so we can, I think after we take the first vote make

sure that they are all, you know, therapeutically equivalent within their class as much as they can be. I mean of course these aren't AB rated medications so we can switch back and forth but they all do have their unique usage in therapy.

Weldon Havins: And when you say preferred agent you are talking about what we, we got a list here effective September 24th 2012 all those drugs?

Carl Jeffery: The list you have in your binders and for the public it's the same one as posted at our website list, that's the current list now. So the one we have here is what we propose.

Weldon Havins: It's therapeutically equivalent.

Carl Jeffery: No these are what we propose I think we're jumping ahead, so this is our proposal for what is being, for what we would like; what we think should be on preferred list on the PDL.

Weldon Havins: Okay.

Dr. Nagy: So are you adding something to it?

Carl Jeffery: For this one, the only thing here is we want to, as was suggested to remove the restrictions on Abilify because there are multiple indications for Abilify. We think clinically its a good medication, it should be expanded. It gives another option for treatment for Medicaid clients.

Weldon Havins: For Safaris also?

Carl Jeffery: Yeah, Safaris as well. So a lot of the other established medications there are now generic.Because they have been on the PDL for a long period of time I think that they're well engrained within the standard therapy.

Joseph Adashek: I move that we approve the list but also add Latuda to that list as a preferred agent. Okay I move that they are all therapeutic equivalents.

Dr. Nagy: Second?

Weldon Havins: Second. When you're talking about the list, you're talking about this list or that list?

Carl Jeffery: So the drugs that are listed in the table in the therapeutic class overview of the atypical antipsychotics, the second generation, we feel that these are all therapeutically equivalent.

Joseph Adashek: Okay I move that we approve these all as therapeutic equivalents.

Dr. Nagy: Second?

Weldon Havins: Second

Vote is unanimous Ayes from the board members.

Carl Jeffery: As listed here and I am not going to read all of them but, in addition to the current list is to remove the restrictions for Abilify and add Safaris to our preferred list and I think Dr. Adashek has some other additions as well. As it is listed here it is Catamaran's proposal for how the preferred list should be.

Joseph Adashek: I move that we approve those agents but also add lorazadone add to the list of preferred agents given the physicians testimony.

Weldon Havins: I'll second but the problem, the only hesitation, I guess, I should second so that could move the discussion.

Indiscernible: Yes.

Weldon Havins: The only hesitation I have with that is it is available as a secondary agent if there is a failure of a preferred agent, and he was discussing the patients with failures on the PDL.

Joseph Adashek: I understand that you can't say this with especially anti-psychotic medications. The easier that we make it as a preferred agent the better; I don't think we are talking about some other classes here where it's not as crucial that they get on medication. That's why to me the argument was good for putting it on the preferred drug list. That was my reasoning for adding that.

Weldon Havins: Can we get an opinion on that from Catamaran?

Carl Jeffery: I think it's… I already agree with Dr. Havins that typically Latuda is not necessarily always a first line agent. Sometimes clinically other agents maybe tried before this so if that's the case then they meet the criteria for the non-preferred agents anyway.

Gabe Lither: Any other discussion on this matter?

Constance Kalinowski: Yeah I think some of the concerns that were raised about people getting the medication following discharge from the hospital sounded more to me like issues around coordination of care and discharge.

Dr. Nagy: Okay, getting back to motion that's on the table. Should we go for voting now?

Joseph Adashek: You call for a vote?

Dr. Nagy: Yes, calling for a vote from the right side.

Mike Hautekeet: To add Latuda, I would say, aye.

Kevin Desmond: Desmond aye.

Joseph Adashek: Adashek, aye.

Dr. Nagy: Nagy, Aye

Weldon Havins: Havins, aye.

Constance Kalinowski: Kalinowski, aye.

Adam Zold: Zold, aye.

Evelyn Chu: Chu, no.

Dr. Nagy: Motion carried

Coleen Lawrence: For fairness right now. We are going to ask, do we have any physicians who are practicing down here right now that are going to testify? What classes are you going to be testifying on and you are serving patients right now and we're taking time out of your schedule. This is an extraordinarily long meeting today, so a little bit different than normal. So I think we'll ask for public comment again.

Dr. Nagy: Yeah, public comment again.

Christian Stone: Hi, I'm Christian Stone I'm a Gastroenterologist and director of Inflammatory Bowel Disease at the University of Nevada. Who should I address?

Dr. Nagy: Everybody.

Christian Stone: So I think you're reviewing the injectable anti-tumor necrosis factor agents.

Dr. Nagy: Yeah.

Christian Stone: I believe Humera is on the formulary now.

Dr. Nagy: Yeah.

Male Speaker: And the other is CIMZIA and I'm here to testify that CIMZIA is another viable option as an injectable for patients. The data indicates that the safety profile and efficacy are very similar to Humera. It also has the advantage of not crossing the placental barrier so for women of child bearing agewhich there are many patients with Crohn's disease in that age group. It might be an ideal agent for them if they are concerned about placental transfer of the agent.

Indiscernible: And we are currently using Humera in these patients?

Christian Stone: We currently use all three anti TNF agents. CIMZIA, Humera and Remicade infusion .

Dr. Nagy: Another questions so…

Weldon Havins: What category it this?

Dr. Nagy: Immune.

Robert Mulligan: Robert Mulligan from UMC. Maybe I shouldn't say I mean I hope I'm not going to waste your time because I'm here not to speak about anything new. About XARELTO, I just called the Medicaid prior authorization office and they wouldn't give me information without having a patient's number and so forth. But XARELTO is a… has been a boon to my patients at the University Medical Center and that is the reason I'm mainly here today.

It gets them out of the hospital, they don't have to follow up in Coumadin clinics. It has really changed their ability to function out on the street, in particular my patients. They may have Medicaid but they don't have anything else. They may not qualify for anything else and getting them out of the hospital on a timely basis for people who do have non-valvular A-Fib aand now have deep venous thrombosis or pulmonary embolisms without jumping through a bunch of hoops regarding Coumadin anticoagulation regarding bridging subcutaneous shots until they can get an appointment in a Coumadin clinic. XARELTO is really a boon to these patients and I don't know if it needs prior authorization on Medicaid patients or is it…but I just want to know what hoops can my patients jump through or what can I do for them. They are on the street, they can't do coumadin and I don't want them to be jumping through a bunch of hoops to prove that they failed coumadin or that they failed another anti coagulant.

Joseph Adashek: I think it is already on the preferred drug list

Dr. Nagy: Yes, it is already on the PDL

Carl Jeffery: The DUR Board did approve some clinical criteria for XARELTO, is not in place yet
But it will be probably January, February.

Robert Mulligan: For the pulmonary embolism and DVT ?

Carl Jeffery: Yes, It will have some clinical criteria in and certainly the criteria doesn't imply that they need to fail first. We don't want people to stroke out before they move onto another agent. And so the criteria should be some kind of compelling argument of why they need the Xarelto and certainly lack of monitoring fits that criteria. I think we've discussed this.

Robert Mulligan: And thank you for helping me out on that first one I appreciate that about jumping through hoops. Again I'm here because I really feel that these patients need the consideration. That's why I'm taking a time out. Thank you so much guys.

Dr. Nagy: Thank you.

IV. <u>For Possible Action</u>: Review and Approval of the March 22, 2012 and June 28, 2012 Meeting Minutes

Dr Nagy: So moving back to the approval of minutes of the meeting of March 22nd 2012 and June 20th 2012, any comments, corrections? If none do I have a need a motion for an approval?

Joseph Adashek: I move we approve the minutes.

Weldon Havins: Second.

Dr. Nagy: So voting from the right side.

Board members vote unanimously: Aye.

Dr. Nagy: Motion approved.

So moving on now to established drug classes: Acne Agents. Public comments on acne agents? No public comments?

V. Established Drug Classes

A. Acne Agents: Topical, Benzoyl Peroxide, Antibiotics and Combination Products

Displayed on Screen in meeting room:

- *Azelex® 20% cream*
- *Benzaclin®*
- *benzoyl peroxide (2.5%, 5% and 10% only)*
- *clindamycin*
- *erythromycin*
- *erythromycin/benzoyl peroxide*
- *sodium sulfacetamide*

Carl Jeffery: Okay. So the topical benzoyl-peroxide and combination classes are addressed in the binder here, and really there's a couple of different agents. The difference between all the commercially available agents is theconcentration between the benzoyl peroxide and usually clindamycin. So it really comes down to in what concentration the provider prefers. But we think that they're all kind of therapeutically equivalent. And one takes the place of another if the… you know if that was available.

Dr. Nagy: Any discussion, any comments?

Joseph Adashek: I move they're all therapeutic equivalents.

Adam Zold: I second.

Dr. Nagy: Any discussion on this? Move to voting.

Board members vote unanimous: Aye

Dr. Nagy: The motion carries

Carl Jeffery: So currently the only thing we've got on the preferred list is the Benzaclin . And you know we maintain the Benzaclin but as you can see on the slide up here, Catamaran proposes adding additional agents, in addition to some generic topical antibiotics as well, for this class of treatment for acne, and this is simply to open up access to the treatments.

Joseph Adashek: I'm sorry can you say this specifically? Which would you recommend be preferred?

Coleen Lawrence: This is the recommendation on the screen

Joseph Adashek: Okay, I move we approve the recommendation.

Mike Hautekeet: Second.

Dr. Nagy: Any discussion? So voting from right side.

The board members vote unanimous: aye

Dr. Nagy: Motion approved.

B. Analgesics/Anesthetics: Topical

Displayed on screen in meeting room:

- *lidocaine*
- *lidocaine HC*
- *lidocaine viscous*

Dr. Nagy: We'll move along to the next topic: anesthetics- topical, public comment? No public comments.

Carl Jeffery: Okay so this is also another diverse class. We've got a couple different classes of agents that actually are in here. We've got the topical analgesics which is the lidocaine. And this comes in a couple different forms. The straight viscous lidocaine and it also comes in a patch, the Lidoderm patches. The other class that falls in here is the NSAID the topical NSAIDs. These are approved for treatment of osteo-arthritis in addition to a few others, I think it's one of the biggest ones, whereas the lidocaine is indicated for skin ailments, postherpetic neuralgia is one of the biggest ones. We feel a lot of these products are interchangeable. And you can use one of the products as a starting point. Yeah so the first thing is that you know, we think that they're therapeutically equivalent.

Dr Nagy: A motion for therapeutic equivalency?

Indiscernible: I move to consider all of these products as therapeutically equivalent.

Joseph Adashek: Second.

Dr. Nagy: Any discussion? Voting from the right side.

Mike Hautekeet: Carl, because in the handout it says that currently the Voltarin gel is preferred but the lidocaine is not preferred, can you clarify that?

Carl Jeffery: That's right, that's how it is currently. The Voltarin is preferred.

Mike Hautekeet: Okay so the Voltarin is bioequivalent to Lidocaine? Because you're asking about the equivalency so lidocaine is not quite equivalent to Voltarin?

Carl Jeffery: For a standard treatment you can start with lidocaine.

Mike Hautekeet: But they are not equivalent?

Weldon Havins: Yeah generally, therapeutically equivalent.

Board members vote unanimous: aye

Dr. Nagy: Motion approved.

Carl Jeffery: And so as you can see on our proposed list we wanted to start with the viscous lidocaine as the preferred agents, kind of shifting people to try one of these agents before they move on to something else like that, like an NSAID or something else.

Joseph Adashek: I move that we accept their recommendations but we also add Voltarin gel. I have many patients on Voltarin gel and I don't really believe it's therapeutically equivalent. It acts differently than lidocaine. They get good relief from it, and so I would say to add Voltarin gel to the preferred list.

Mike Hautekeet: I second the motion..

Weldon Havins: I would agree with that because there are some people allergic to lidocaine and if that's a starting point that's not reasonable.

Coleen Lawrence: So can I clarify for a minute? So the board in a previous meeting, had already determined that, that they are not, we're not taking their substitution, related drugs okay. We're just saying that they're in the general world of the drugs okay and so for example if there's an allergy indication. Voltarin may be utilized first okay. So...

Weldon Havins: They would have to give a…

Coleen Lawrence: They would make a call. No I'm not saying that you can't if you want to make it preferred. But I think we need to be careful of what we're saying is therapeutic equivalent..

Joseph Adashek: We would like to add Voltarin gel to that.

Coleen Lawrence: Then absolutely make it a preferred drug.

Joseph Adashek: That's what we want.

Coleen Lawrence: Because we're using the therapeutic alternative definition as the AMA. They may have different chemical structure but which are of the same pharmacological and/or therapeutic class and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses.

Joseph Adashek: Okay that's fine I think we already voted on it so now we want to addit as a preferred drug. Call for vote.

Vote is unanimous. Ayes by board members.

Dr Nagy: The motion is approved.

C. Antibiotics: Cephalosporin 3rd Generation

Displayed on screen in the meeting room:

- *CEFDINIR CAPS and SUSP (generic Omnicef®)*
- *CEFPODOXIME TABS and SUSP (generic Vantin®)*
- *Suprax® 400mg tablet and suspension*

Dr Nagy: Cephalosporins, third generation antibiotic. Public comment? No public comment so Dr. Jeffery.

Carl Jeffery: Okay third generation cephalosporins is as I'm sure you're all aware, is a broad spectrum antibiotic. It's been out for a long time now with a couple of generics and Cefdinir, the generic spectracef, the brand names still out there Cedax and Suprax. I think they're pretty similar in targeting what bugs they hit. But we did notice that the Suprax had better coverage, it hits the gonorrhea and E-coli and the Cedax does not. And overall we did feel that this class is therapeutically equivalent.

Dr. Nagy: Do I have a motion for a clinical and therapeutic equivalency of these drugs and this class?

Joseph Adashek: And that they're all therapeutic equivalent.

Mike Hautekeet: Second.

Dr. Nagy: Any discussion? Voting, starting on the right side…

Board members vote unanimous: Aye.

The motion carries

Carl Jeffery: So as you can see our proposed list here, we've got the two generics that are available as proposed to prefer the Cefdinir and cefpodoxime. What we're proposing is to add Suprax and remove the Cedax and most of it is because we wanted to provide an additional option and also a drug that covers the N. gonnorhea and E-coli better than Cedax.

Mike Hautekeet: I make the motion to include Suprax into the preferred list.

Dr. Nagy: Any second?

Kevin Desmond: Second.

Dr. Nagy: Voting on the right side, starting.

Vote is unanimous. Ayes by board members.

Dr. Nagy: The motion carries

D. Anticoagulants: Oral

Displayed on a screen in the meeting room:

- *Warfarin (Generic Coumadin® and Jantoven®)*
- *Xarelto ®*
- *Pradaxa ®*

Dr. Nagy: Next group up, medications: oral anti-coagulants. Public comments?

Michael Casey: I'm Doctor Michael Casey. I'm a trauma surgeon and critical care specialist at the University Medical Center in Las Vegas, and I probably didn't understand Xarelto the medication we're talking about oral anti-coagulant. Is it a preferred drug now?

Carl Jeffery: Xarelto is currently preferred, yes.

Michael Casey: Because I was here to talk about its indication for me as a trauma critical care doctor, I get called a lot to the ER with people with pulmonary emboli as a critical care doctor. If I was able to treat someone who was not hypoxic, not distressed, give them a little anti-coagulant like Xarelto and treat them, within four hours make them therapeutically anti-coagulated, I could clear some beds in my emergency room. As they come through, I'm not stressed about its effication. Unlike, I know Pradaxa is another drug similar in this class Pradaxa and Xarelto do not have good indications for reversal, and as a trauma surgeon they concern me for reversal however the half-life of Xarelto is very short.

By the time people recognize a traumatic patient that's taken it, classically they have taken medications in the morning, if they're involved in a motor vehicle collision it will be, early in the afternoon within seven hours to nine hours, the half-life is exceeded and by 18 hours it's out of their system essentially, and I can give them things like PCCs if I needed to for a brain bleed, which I could do for Pradaxa as well. But Pradaxa lasts longer than Xarelto, and for me I think it's a great drug for my population of patients and I'm sure a lot of the patients that Dr. Maul has like I often give him my patients because they have no place else to go. Those patients have, when they leave the hospital, if they're on this medication, to be able to continue. The Medicaid patients who leave our hospital because right now, we send them out on Lovenox, on occasion it's about $ 80 a day for therapeutic Lovenox for these people. This would be a much cheaper alternative to Lovenox, there's no bridging to Coumadin and I think for me it's a much more effective drug for the treatment of DVT and PE, not always for the prophylaxis because there are other medications but for the treatment of DVTs, and even the prophylaxis to prevent it, it's an ideal drug for my population of patients.

Gabe Lither: Just one reminder, we don't consider cost in this committee. You mentioned that something was cheaper than something else, that's something…

Michael Casey: But for me and my practice, my concern is my patients are uninsured or they have minimal ability to obtain these things, and I have to actually think about that from the beginning.

Gabe Lither: That's fine, but it's probably not the best type of testimony to present to us, because that may imply that one member of this committee takes some action based on that it's…

Michael Casey: On finance, I apologize, thank you.

Bill O'Neal: Alright good afternoon, it's nice to see you all up close and personal like this. My name is Bill O'Neal and I am a pharmacist but I'm also an Associate Director with Bohringer Ingleheim and their health and economic outcomes research group. I'm here to give a very brief testimony on our anti-coagulant, Pradaxa. I just want to bring just two new pieces of information since the last time this drug was reviewed. The first is a label change, and I'll read it just to make sure I get it right. Then the other is an announcement from the FDA that just happened last Friday, so those are the two pieces of information I'll be sharing with you today.

So in May of 2012, the FDA came out with a label change, and I'm just going to read that for you now. Pradaxa is a direct thrombin inhibitor, indicated to reduce the risk of stroke and systemic embolism in patients from non-valvular atrial fibrillation. Pradaxa 150 milligrams twice daily was superior in reducing ischemic and hemorrhagic strokes, relative to warfarin and this is based on efficacy data from the RELY study that shows, one, it was statistically significant reduction in the risk of stroke or systemic embolism relative to warfarin. And two, a statistically significant reduction in both ischemic and hemorrhagic stroke relative to warfarin. So as we all know, these agents are given to patients with A-fib to prevent the ischemic stroke and so we now have a product that is not just statistically, but label-wise significant than the gold standard of warfarin, and then just Friday, the FDA who has been monitoring Pradaxa since it came out in the market two years ago, announced the results of their mini sentinel assessment. So evaluating new information about the risk of serious bleeding associated with the use of anti-coagulants, Pradaxa and warfarin and so what they stated was that the bleeding rates associated with new use of Pradaxa, do not appear higher versus new use of warfarin, results are consistent with observations from the pivotal RELY trial. So the FDA investigated the actual rates of gastro-intestinal bleeds, inner cranial bleeding and the new users of Pradaxa versus new users of warfarin, and this assessment was done using insurance claims and administrative data from the FDA ongoing mini-sentinel pilot of their sentinel initiative, and so as a result of this information that they gathered, the FDA has not changed its recommendation regarding Pradaxa, and Pradaxa provides an important health benefit when used as directed. Just as a quick reminder, it is still not indicated for patients who have pathological bleeding, who have any kind of hypersensitivity reaction, you do want to be careful in terms of lapses because you can have risk of ischemic stroke and then blood levels are impacted by PDP inducers and inhibitors and as well as renal function. So renal function should be assessed. So in summary, Pradaxa is superior at reducing strokes relative to warfarin, and has similar rates of major bleeding with this new label. Iit is the first and only anticoagulant to show superiority in reducing both ischemic and hemorrhagic strokes relative to Warfarin in patients with non-valvular A-Fib and so based on that, this new information, it is our recommendation to this committee that Pradaxa be added as a preferred agent.

Dr. Nagy: Thank you.

Bill O'Neal: Any other questions I'd be happy to answer them, thank you.

Dr. Nagy: Another public comment?

Mary Kate Queener: Good afternoon, my name is Mary Kate Queener**.** I'm a Pharm D. with the Health Economics and Outcomes Research group at Janssen Pharmaceuticals and I'm here to testify about Xarelto. in addition to the DVT prophylaxis, post-orthopedic surgery indication and non valvular A-Fib indications that we currently have or had already, last Friday on November 2nd, Xarelto received three additional indications for treatment of DVT, PE and also for secondary prevention ofDVT and PE, following resolution of the active clot. These approvals were based on three clinical trials, a trial for DVT and PE were designed similarly, they were open label, non-inferiority trials being compared to standard care which would be an enoxaparin one milligram per kilogram twice a day followed by warfarin bridging over until the patient was therapeutic. The Xarelto dose was 15 milligrams twice a day for three weeks, followed by 20 milligrams for anywhere from three to twelve months hree, six or 12 months based on physician discretion.

The results were that Xarelto was not inferior to the standard of care and from a safety perspective there was no increased incidents of bleeding during the course of therapy compared to the standard of care, nor during the BID dosing during the first three weeks. In addition, the secondary prevention was a separate trial and these patients had already received appropriate therapy for their active clot and were deemed to have a risk of recurrent thrombo-embolism. This trial was a double-blind placebo-controlled trial and was conducted for six to 12 months and as I said compared to placebo, and the dose was 20 milligrams per day, for six to 12 months. In this trial the relative risk reduction of a recurrent clot was 82 percent and an absolute risk reduction of 5.8 percent. There was only a modest increase in clinically major believing compared to the placebo group, and a low incidence of major bleeding. In addition, I just wanted to share briefly the dosing rationale for the 15 milligrams twice a day for the first three weeks was based on the phase two dose ranging studies that were done. The pharmacokinetics show that there was a higher trough which may be beneficial to have that intensified anti-coagulant effect on the initial treatment phase. Can I answer any questions; I wanted to be brief since the meeting is going to be running long.

Dr. Nagy: Thank you. Any other comments? There is none, so I need a motion for therapeutic equivalency in this class of therapy?

Carl Jeffery: Yeah we discussed this pretty in depth a few meetings ago, I remember this past meeting before, so there's been some new information and as they just stated with additional indications added and Pradaxa has new information about thebleeding risk since they originally introduced it. We believe these drugs are therapeutically equivalent in the class.

Adam Zold: Making a motion that all of these drugs that they're therapeuticly equivalent.

Dr. Nagy: Is there a second?

Weldon Havins: Second.

Dr. Nagy: Any discussion? Voting from the right side.

Vote is unanimous. Ayes from the Board.

Carl Jeffery: So our recommendation to make preferred is the addition of Pradaxa onto the preferred side and this is simply just to open up the access to Medicaid recipients.

Weldon Havins: I move that Warfarin, Xarelto, Pradaxa now be placed in the PDL list.

Joseph Adashek: Second.

Votes are unanimous. Ayes from the Board.

Dr. Nagy: The motion carries.

E. Antipsychotics: Atypical

Discussed Above – item taken out of order.

F. Antivirals: Hepatitis C Protease Inhibitors

Displayed on screen in meeting room:

- *INCIVEK®*
- *VICTRELIS®*

Dr. Nagy: Next class of medications antiviral hepatitis C Protease Inhibitors. Public comment?

Kevin Prince: Hi my name is Dr. Kevin Prince. I am a staff physician at UMC; you were kind enough to listen to me a year ago when we first started putting the class on, thank you for allowing me to come back. I'm a primary care physician at UMC but for the past five and a half years have been doing their Hepatitis C clinic, as I understand it, currently Incivek, it's the only one on Medicaid, most of my patients have Clark county social services but we do have some Medicare and Medicaid and possibly a whole lot more in the future, so I see that you had both of them up, I'm not sure what action you're planning but if you could have both of them on the formulary, that would be preferred for me.

Gabe Lither: And just to remind everyone, what's up here is the recommendations to be on the preferred list. So that's the recommendations.

Kevin Prince: I don't have to say anything else. If you have any questions I'd be happy to answer, that'll work.

Dr. Nagy: Any other comments?

Indiscernible: Can I ask a question? Is this limited to the Hep C class, the direct acting anti virals or the other components of therapy as well?

Carl Jeffery: This is only the Protease Inhibitors.

Lisa Warland: My name is Lisa Warland; I'm a medical affairs representative with Vertex Pharmaceuticals, here today to address the committee regarding Incivek which is known generically as

telaprevir. I just want to thank you for the recommendation and I wanted to let you know that I'm here and available, if there are any questions, thank you.

Dr. Nagy: Any other public comment?

Fred Meister: Hi my name is still Fred Meister; I think I'll be very brief on this. I think that you've reviewed these two drugs in the past. The fact that the recommendations have been made to include both of them on the preferred drug list sort of makes it a moot point, I guess. I would ask that you do the same thing. So with that I will just leave you to your voting and your discussion, thank you.

Dr. Nagy: Any other public comment? Can I have a motion for therapeutic equivalency?

Joseph Adashek: I move they are therapeutic equivalents.

Adam Zold: I second.

Dr. Nagy: Any discussion? I'm voting from right side.

Vote is unanimous. Ayes from the board members.

Dr. Nagy: Motion carried. Dr. Jeffery.

Carl Jeffery: Yeah, so as you can see Catamaran recommends both Incivek and Victrelis being preferred. This is to open up access to Medicaid recipients.

Constance Kalinowski: I move we accept the recommendation.

Weldon Havins: I second.

Votes are unanimous. Ayes by board members.

Dr. Nagy: Motion carried.

G. Cardiovascular: Antihyperlipidemics, Statins and Statin Combinations

Displayed on a screen in the meeting room:

- *atorvastatin*
- *lovastatin*
- *pravastatin*
- *simvastatin*
- *fluvastatin*
- *Crestor®*

- *Grandfather Recipients Currently on Advicor ®, Simcor® and Vytorin®*

Dr. Nagy: Now moving to the next class of medication; cardiovascular antihyperlipidemic statins and statin combinations. Public comments? No public comments. Dr. Jeffery.

Carl Jeffery: Alright so we feel like since the statin class has been out for a long time, really nothing new except a lot of generics, so I think since the last time these have been reviewed Lescol has gone generic. Definitely one of the big ones is now available the Lipitor, atorvastatin, but all in all we think that even though some of them have a higher potency than others, I think that they're all therapeutically equivalent.

Weldon Havins: I move we accept the drugs on the list as therapeutically equivalent.

Dr. Nagy: Second. Any discussions, if not we move for voting.

Votes are unanimous. Ayes by the board.

Dr. Nagy: Approved, so.

Carl Jeffery: So a recommendation for the preferred list includes all of the available generics there currently available now in addition to the Crestor, we wanted to make sure that Crestor is on there, so the physicians have another option for a high potency product. Crestor has some additional benefits that the others do not. It does a little better at reducing the LDLs.

Weldon Havins: I move that we accept this list of drugs to the PDL.

Joseph Adashek: Second.

Dr. Nagy: Voting on the right side.

Voting is unanimous. Ayes from board members.

H. Central Nervous System: ADHD/Stimulants

Displayed on a screen in the meeting room:

- *ADDERALL XR®*
- *AMPHETAMINE SALT COMBINATION*
- *DEXMETHYLPHENIDATE*
- *DEXTROAMPHETAMINE*
- *DEXTROSTAT®*
- *FOCALIN XR®*
- *INTUNIV®*

- *METHYLIN®*
- *METHYLIN ER®*
- *METHYLPHENIDATE (generic Ritalin®)*
- *METHYLPHENIDATE ER (generic Ritalin SR®)*
- *METHYLPHENIDATE SOL (generic Methylin Sol®)*
- *RITALIN LA®*
- *VYVANSE®*
- *Grandfather Recipients Currently on STRATTERA®*

Dr. Nagy: Moving on the next…

Indiscernible: I'm sorry you didn't give us much of a chance for the public comment. We… need some clarification on the grandfathering of these agents. Does that mean their currently on and will remain on the PDL?

Carl Jeffery: The way our grandfathering system works is that we have a 90-day look back and so if a recipient is currently receiving that drug within the past 90 days, they will be able to continue receiving that as long as they stay on it for 90-days within that 90 day period. If they stop taking it for whatever reason for 90 days or more, they'll have to get a prioritization to restart on the medication.

Indiscernible: Okay, well I didn't understand, it wasn't clear that those were being removed. So that's what the vote was… that those were being removed?

Carl Jeffery: Yes.

Indiscernible: That wasn't made clear.

Carl Jeffery: Maybe we'll need to clarify that before to make sure it's understood.

Coleen Lawrence: Did the Board understand that grandfathering was occurring?

Carl Jeffery: And that these three agents will be made non-preferred.

Gabe Lither: Yes, anybody on the Board who did not understand what they were voting for? Okay, I think the Board knew. Thank you. Keep going...

Dr. Nagy: Central nervous system stimulants. Public comments? None, so Dr. Jeffery.

Carl Jeffery: Again this is an established class, a couple of new agents have been added, some of the alpha blockers, like Intuniv for the treatment of ADD. These classes have been made available for a long time, all have similar mechanisms of action either amphetamine stimulants or have some kind of an alternative product like guanfacine. So we think that they are all therapeutically equivalent within the class.

Dr. Nagy: Any comments?

Adam Zold: Make a motion that these are therapeutically equivalent.

Mike Hautekeet: I second.

Dr. Nagy: Any discussions, voting on the right side.

Votes are unanimous. Ayes from the board members.

Dr. Nagy: Motion to carry.

Dr. Nagy: Dr. Jeffrey, for the presentation.

Carl Jeffery: Okay, so we've got listed our proposed list of preferred agents and there's three that we are removing from the list, Strattera**,** Concerta**,** and Metadate ER. The Provigil is kind of confusing at this point. It's got some special criteria where a PA is not required for a narcolepsy ICD-9 diagnosis. We wanted to also to move that to the non preferred side but continue the ICD-9 approval for the narcolepsy diagnosis but we don't want to imply that that's a preferred medication for the treatment of ADHD. And then also the grandfathering we proposed only doing the grandfathering on the Strattera since this is an agent that's a little bit different, there is really nothing else like it, exactly like it. Whereas Metadate ER and the Concerta those can easily be switched to another methylphenidate product.

Weldon Havins: Why grandfather it?

Carl Jeffery: Oh why grandfather it? We just think that it's with the year around school for the kids now it's just going to be a disruption during the school year to have them stop one agent and then start on a new agent.

Weldon Havins: One that you are taking it off, so you can't start someone on Strattera, as an initial drug right?

Carl Jeffery: Yeah any new start would have to require prior authorization.

Weldon Havins: And why is that?

Carl Jeffery: To make the Strattera nonpreferred? We think that there are other agents that are just as effective and…

Weldon Havins: Is it because it is in the best interest of the State?

Coleen Lawrence: And we need to clarify that, the ADHD treatment drugs we know already reqiuirea clinical preauthorization also so it's a one stop shop for those new treatment drugs. There is a clinical preauthorization on those drugs right now. So I want to point that out.

Constance Kalinowski: So how would that work with taking the Strattera off?

Coleen Lawrence: The new starts? Not ones that are already existing, but the new starts, when they start a treatment regimen, if they need to be on Strattera then when they call for their clinical prior

authorization, if they can be on Strattera then they will talk with the call center why they need to be on Strattera and they will give clinical rational why they have to be on Strattera also.

Mike Hautekeet: Does it also have to do that Strattera is the only one which is a non-controlled that more physicians can't do with prescribing more or… I wonder if that has something to do with removing Strattera off the books.

Constance Kalinowski: I don't know let me see.

Carl Jeffery: Mostly has to do with because it's in the best interest of the state.

Constance Kalinowksi: I think my only concern would be that we see quite a few adults who also have ADHD and it tends to bring concern and in general we prefer to avoid treating with stimulants because of cardio-vascular risk and I wonder if some of those folks might get caught in…

Coleen Lawrence: You can do age requirement things on the PDL too, if that's appropriate for you, if you would like to.

Carl Jeffery: And Dr. Kalinowski we also have Intuniv preferred so we do have a non-stimulant option.

Dr. Nagy: No discussion.

Indiscernible: I move that.

Jenny Blackham: Thank you, my name is Ms. Jenny Blackham and I am Outcomes Liaison for Lilly Pharmaceuticals and I'm here to talk to you guys about Strattera. After hearing your recent discussion I just to want to point out a few things that we bring to the table. Strattera is a non-stimulant, a non-controlled agent that is used as a mono-therapy for the treatment of children, adolescents, and adults. As you guys heard it's not a scheduled substance it has not shown a pattern of response that suggests stimulant properties. We've seen in our clinical study data of over 2,200 patients, that there were a few isolated incidents of drug diversion or inappropriate self-administration associated with Strattera. Strattera has over 10 years of evidence demonstrating its clinical value in treating ADHD core symptoms in both with patients with and without co-existing anxiety, ticks and potential drug abuse.

That is a really important thing and if you look at the guidelines Strattera is recommended as a first line agent in five guidelines for patients with this co-morbid anxiety, ticks and substance abuse or if it's preferred by the physician or the parents. Strattera is also preferred if the patient experiences severe side effects due to stimulants. When you look at the American Academy of Child and Adolescent Psychiatry treatment guidelines it suggests an initial treatment plan that includes Strattera. Strattera also provides a 24 hour continuous symptom relief in children and adolescents. In closing, the evidence provided today supports for your consideration to put Strattera back on the PDL as unrestricted and available for the Medicaid beneficiaries. Do you have any questions?

Dr. Nagy: Any questions?

Weldon Havins: I move that we accept the PDL list, grandfather Strattera for children but not grandfather it, included as is on the PDL for adults 18 and over.

Joseph Adashek: So you are not grandfathering it for adults?

Weldon Havins: Not grandfathered to be used primarily on adults.

Joseph Adashek: So you want it preferred for adults?

Weldon Havins: Prefer on the PDL for adults.

Joseph Adashek: Okay, I'll second that.

Ayes from the board members. Except Dr. Nagy: Abstain.

Joseph Adashek: So it's back to preferred in adults, right okay?

I. Electrolyte Depleters

Displayed on a screen in the meeting room:

- *CALCIUM ACETATE*
- *Eliphos ®*
- *RENAGEL®*
- *RENVELA®*

Dr. Nagy: Move on the next class of medications. Electrolyte Depleters Public comment. No public comment.

Carl Jeffery: So just real quick this is agent for the phosphate binders most commonly used for dialysis patients. There is a new agent that's calcium acetate called Eliphos. It's newly on the market and that's what brings it here with the Board today but we think that given all these agents that they are therapeutically equivalent or interchangeable.

Dr. Nagy: Discussion.

Joseph Adashek: Motion that they are therapeutic equivalents, second.

Mike Hautekeet: Second

Dr. Nagy: Voting on the right side.

Votes are unanimous. Ayes from the board members.

Carl Jeffery: So Catamaran proposes that we keep the preferred agents currently on the list and add Eliphos.

Joseph Adashek: I move we approve them all as preferred.

Weldon Havins: Second.

Dr. Nagy: Starting voting from the right side.

Vote is unanimous. Ayes by the board members.

Dr. Nagy: The motion carries.

J. Gastrointestinal Agents: Proton Pump Inhibitors

Displayed on a screen in the meeting room:

- *NEXIUM® CAPSULES*
- *NEXIUM® POWDER FOR SUSP (for children ≤ 12 yrs.)*
- *PANTOPRAZOLE*

Dr. Nagy: Moving to the next. Medication: gastrointestinal agents: Proton Pump Inhibitors. Any comments? No public comments.

Carl Jeffery: The Proton Pump Inhibitor class is a staple of therapy it has been there for many years, lot of generic products are available. We feel they are therapeutically equivalent, there is some slight benefit with the esomeprazole, which has been shown to have a higher healing rate of erosive esophagitis and GERD compared to lansoprazole, omeprazole, or pantoprazole. We think in general they're all therapeutically equivalent.

Dr. Nagy: Any discussion? Can I have a motion for therapeutic equivalency?

Joseph Adashek: So moved.

Adam Zold: Second.

Dr. Nagy: Voting from right side.

Voting is unanimous. Ayes by board members.

Dr. Nagy: Motion approved, Dr. Jeffery.

Carl Jeffery: Catamaran's proposal is to remove the omeprazole products from the PDL and keep the Nexium capsule, powder, and then the generic Protonix which is pantoprozole.

Joseph Adashek: I move that we approve them all as preferred. These three.

Dr. Nagy: Also removal for the…Omeprazole?

Mike Hautekeet: I second the motion.

Dr. Nagy: Voting on the right side.

Voting is unanimous. Ayes by the board members.

Dr. Nagy: The motion Carries

K. Growth Hormone Agents

Displayed on a screen in the meeting room:

- *Genotropin®*
- *Norditropin®*
- *Grandfather Recipients Currently on NUTROPIN®*

Dr. Nagy: Moving to the next class; Growth hormone agents. Public comment? No public comment. Doctor, go ahead.

Jessica McKeon: My name is Dr. Jessica McKeon I'm an MD by training and I am a growth hormone disorder medical liaison for Novo Nordisk. And I would like to thank you for the recommendation. I just want to provide you with more information on why, on why Norditropin deserves to be on the preferred drug list, Nevada, PDL. Chemically Norditropin has phenol as its preservative instead of benzyl alcohol. And benzyl alcohol is contraindicated in infants. Also Norditropin has histidine as a buffer and it does not have....which is not associated with stinging or injection site reactions. It has five approved FDA indications, it's indicated for pediatric growth hormone deficiency, adult growth hormone deficiency. For short stature associated with Turner Syndrome. It is the only FDA approved growth hormone therapy for Noonan syndrome. And also it's indicated for small for gestational age with no catch up growth. And it is available in the flex pro and one of the more important features of the flex pro is the storage flexibility, especially in Nevada when it can be very hot, Norditropin can be stored, the flex pro at room temperature after the first use for three weeks. And this is really very convenient for the patients especially for children when they travel if you have to store a medication in the refrigerator, it is one of the main reasons why they skip their doses so it affects compliance. And it also reduced product wastage, if you can preserve the drug. And just lastly I just want to demonstrate Norditropin flex pro, so it is prefilled it's premix no loading of cartridges, no changing of the battery, no mixing all you need is remove the cap, insert the needle, dial the dose and inject the medication. Norditropin also has comprehensive patient services so we have Spanish and English staff. They can assist the patient with reimbursement, they go to the home and provide at home training. So once again I'd like to thank the committee for their recommendation.

Dr. Nagy: Thank you. Any other public comment?

Carl Jeffery: Okay, the growth hormone class has been available for a long time. Really no new changes, this has been reviewed before so…Catamaran believes these are therapeutically equivalent.

Mike Hautekeet: I move the motion that they are therapeutically equivalent.

Dr. Nagy: I need a second. Do I have a second?

Weldon Havins: Second.

Vote is unanimous. Ayes by the board members.

Dr. Nagy: Approved.

Carl Jeffery: Catamaran believes we should remove Nutropin from the PDL and add Norditropin as preferred. And we also recommend adding some grandfathering to the Nutropin, and this is simply because even though we think that a child that started in Nutropin would probably do just as fine on Norditropin. But there is some emotional attachment to this and it would mean another visit to the endocrinologist and additional cost to the state just to see the switch. So we recommended removing Nutropin and adding Norditropin along with keeping the Genotropin.

Dr. Nagy: Need a motion for rule to pass.

Joseph Adashek: Make motion approve the list.

Mike Hautekeet: Second.

Dr. Nagy: Voting on right side.

Vote is unanimous. Ayes from the board members.

Dr. Nagy: Motion Carries

L. Immunomodulators: Injectable

Displayed on a screen in the meeting room:

- *Humira®*
- *Cimzia®*
- *Grandfather Recipients Currently on Enbrel®*

Dr. Nagy: To the next class of medications; immunmodulators injectable. Public comment?

Ben Skoog: I'm Dr. Ben Skoog and I'm a Pharm D. and I'm from the Clinical Evidence and Outcomes at Abbott labs and thank you for the opportunity to address the committee today. Thank you for making one of our agents a preferred agent, I just want to make you aware of some new information as of October this year. So Humira as you all may know before had six indications for Rheumatoid Arthritis, Juvenile Arthritis, Psoriatic Arthritis, Ankylosing Spondilitis, Crohn's Disease, and Psoriasis, then in October of this year Humira got a seventh indication, so it now has the indication of Ulcerative Colitis as well. In Ulcerative Colitis it has the indication to induce and sustain remission in patients that have moderate to severe disease, that have failed conventional therapies such as azothiaprine and corticosteroids. So I just want you to be aware of that new information and thank you for your time.

Dr. Nagy: Thank you.

Chad McGregor: Good afternoon I am Dr. Chad McGregor an MD and an Executive Medical Science Liaison with Bristol-Myers Squibb. I thank you for the opportunity to provide public testimony on Orencia or Abatacept for Rheumatoid Arthritis. Orencia is available as an IV formulation that was

approved for RA in 2004, and as a subcue formulation that was approved in 2011. While the intravenous and subcutaneous Orencia are indicated for the treatment of moderate to severe Rheumatoid Adult Arthritis; in reducing the signs and symptoms inducing a major clinical response inhibiting the progression of structural damage, and improving physical functioning. Orencia is also indicated for the treatment of moderate to severely active poly articular JRA in pediatric patients age six years of age and older.

Use of Orencia does not require an inadequate response to another non-biologic agent or to a non TNF inhibitor. Orencia has a unique mechanism of action that differs from other biological agents. Orencia is a key cell post stimulation modulator that provides for upstream modulation of the Rheumatoid Arthritis inflammatory cascade, and it has been show to decrease inflammatory cytokines such as TNF alpha and interleukin six. Orencia has a weight based dosing for the IV formulation, the sub-q formulation is a flat dose of 125 mg once a week. The efficacy and safety of Orencia was assessed in over six randomized double blind controlled trials in adult patients. The efficacy and safety of Orencia as a sub-q was assessed in five randomized double blind clinical trials including one noninferiority study that compared the Orencia and sub-q formulation. The efficacy of the sub-q formulation of Orencia was proven to not be inferior to the IV formulation in any way. A recent head to head study proved that the sub-q formulation of Orencia was not inferior to Humira at 12 months. The safety experience and immunogenicity of Orencia sub-q was consistent with the IV studies. Orencia is the only biological drug to treatment Rheumatoid Arthritis that has both sub-q and an IV formulation, and of all the sub-q biologics, it is the only one that has a different mechanism of action. Because of the unique mechanism of action, I will respectfully request that you place Orencia on the preferred drug lists of biologic treatment forrheumatoid arthritis allowing it to be used as a first line biologic. This is supported by the newly published guidelines for the treatment of Rheumatoid Arthritis from the American College of Rheumatology, which supports the use of Orencia as a first line biologic for patients who have established RA. Thank you and I'll be happy to answer any questions.

Vincent Lee: Good afternoon my name is Vincent Lee, I am a Senior Regional Medical Liaison with Amgen, pharmacist by training. I respectfully ask the board to retain the current PDL with Enbrel as a preferred agent, it has been a preferred agent in the past on the PDL and not to accept these current updates to grandfather recipients on Enbrel. I would request that, we don't really have any new information for you to provide but with Enbrel, we do have the five indications that we are the only fully human monoclonal TNF receptor with a different mechanism of action that's unique to entanercept.We are a dimeric fusion protein which makes it a little bit different than the TNF inhibitors which also leads to additional safety information in that we are, different than the other monoclonal antibodies. We don't show it within our PI, we don't, we've been shown not to have any induction of neutralizing antibodies as do some of the other TNF inhibitors and we do have over 17 years of collective clinical experience with over two million patient years of exposure being one of the first products on the market. Again over 10 years of post-marketing experience in RA space, JIA and over seven years in Psoriatic Arthritis and Ankylosing Spondylitis and five years of Plaque Psoriasis. So again I respectfully ask that you retain the current PDL with Enbrel as a preferred agent, I'll happily take any questions from the Board.

Dr. Nagy: Thank you.

Mary Kate Queener: Sorry, my name is Mary Kate Queener, this is the second time I am up here for Jansen Pharmaceuticals, I don't have any new information to present but I do represent the three

biologics that we have in this category: Infliximab or Remicade which is an IV product, Simponi or golimumab, which is an injectable product for Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis and also Stelara which is an anti IL12-23 agent for Plaque Psoriasis, so I just wanted to say that I am here if anyone has any questions.

Mark Jensen: Good afteroon my name is Mark Jensen, I'm a Medical science Liaison for UCD Pharma, representing the drug Cimzia, I noticed it's on the preferred drug list, so I wanted to clarify what was stated earlier about Cimzia with regard to the pregnancy data. It is now included in our prescribing information but it's not true that it doesn't cross the placenta, a study of ten women who had Crohn's Disease and were pregnant, levels were taken in maternal blood, cord blood and in newborns and there was some detectable Certolizumab in … or Cimzia, in the newborns.

Dr. Nagy: So it's a class C?

Mark Jensen: It, no its class B.

Dr. Nagy: Class B?

Mark Jensen: Yeah, so do you have any questions around those data specifically? All right, thank you.

Dr. Nagy: Any other public comments? Dr. Jeffery.

Carl Jeffery: So and again this is a very broad class, lots of different mechanisms of action within the different agents, it's difficult to have compared these agents because there is really no head to head studies with these comparing one drug with another for those. They have all been shown to be very effective for their approved indications but Catamaran feels that these agents within this class are pretty therapeutically equivalent.

Joseph Adashek: I move we approve them as therapeutic equivalents.

Weldon Havins: Second,

Dr. Nagy: Voting on the right side, right?

Vote unanimous. Ayes from board members.

Dr. Nagy: Motion approved so moving on.

Carl Jeffery: Our recommendation is to keep Humira as is, add Cimzia and remove Enbrel with the caveat that there is a grandfather clause with this because again these are agents that people are usually stabilized on and go to specialists to see, to get these stabilized and then to remove Enbrel, add Cimzia and keep Humira.

Weldon Havins: Enbrel has been around for a long time, why grandfather it?

Carl Jeffery: Why grandfather it? You mean why remove it?

Joseph Adashek: Yeah, why remove it.

Carl Jeffery: I hate to use the phrase, but it is in the 'best interest of the state'.

Joseph Adashek: I move that we, do not grandfather, Enbrel include that as part of the preferred class and include the other two medications. I'm a high risk pregnancy specialist and use Enbrel all the time and I know it could be not preferred to ask permission but I move that we approve all three as preferred and not grandfather Enbrel.

Dr. Nagy: Any second?

Weldon Havins: I second that.

Dr. Nagy: Any discussion?

Weldon Havins: I just want to ask Dr. Adashek, so you do high risk pregnancy…

Joseph Adashek: It's all I do, yes…

Discernible: Use it all the time, comfortable with it?

Joseph Adashek: Very comfortable, I'm comfortable if we don't use class B, C, D in high risk pregnancies because those are put out by the drug companies and we give class D every day and most anti-seizure drugs are class D, so whatever they come to us on, we leave them on. Of course if their Rheumatoid Arthritis gets much worse during pregnancy whatever the rheumatologist recommends we leave them on it and we should just use one that we are not, you know even no matter how much we use it or not use it, almost there is no teratogenicity with that in this class, so we leave them on it.

Weldon Havins: Have you tried Humira…or Cimzia

Joseph Adashek: Yeah.

Weldon Havins: Or Cimzia? Does it work…?

Joseph Adashek: Enbrel is the one that's used the most and that is from our patients and maybe most rheumatologists would be most comfortable with it but we would, if they come to us on it or if the rheumatologist puts them on it, it's been on for a long time, we leave them on it, more so than the others.

Weldon Havins: Well if they are on it then they would fall under the grandfather.

Joseph Adashek: Right but even if they have it really bad and then their rheumatologist started them on it and they are most comfortable, we would agree with that. So even if they are on it, if a rheumatologist is comfortable as a first line agent, we would agree with that, it's been around a long time if they are most comfortable with that, that's what we would use too.

Carl Jeffery: So will the board consider any if, and I appreciate your feedback Dr. Adashek, so if we keep Enbrel on here, will the board consider keeping it as is with Humira and Enbrel?

Joseph Adashek: So taking off Cimzia?

Carl Jeffery: Right from our list.

Joseph Adashek: Then I have these questions because we did have a physician here who used it and strongly recommended it, which this person carries a lot of weight with me so, and you must put it on it for a reason so I would like to keep Enbrel and keep the other two medications on. That would be my, well that's my motion, it's been seconded so I guess we can vote on it and if its' no, then we could take, do another motion.

Carl Jeffery: You know it's just; if that eases the Board…

Joseph Adashek: All right…

Weldon Havins: Let me just ask if your reason to be in the interest of the state?

Carl Jeffery: In the interest of the state.

Weldon Havins: You find a significant difference of interest of the state between Cimzia and Enbrel?

Carl Jeffery: Yeah, there is.

Weldon Havins: There is more interest of the state to stay with Enbrel than more interest of the state to stay with Cimzia?

Carl Jeffery: Yeah, you know the best case scenario is the Cimzia scenario, second best is Humira and Enbrel.

Joseph Adashek: Well we have a motion, and it's been seconded, so you can call for a vote first?

Dr. Nagy: Yeah discussion is over.

Joseph Adashek: All right.

Dr. Nagy: Okay, well starting voting on the right side.

Voting is all ayes except Kalinowski: Nay

Dr. Nagy: motion carried.

Weldon Havins: Yeah, it's just a general question about, assuming the Board will adhere to its changes and assuming the governor approves the Medicaid increase, will that include payment for the mediations through Medicaid?

Coleen Lawrence: I'll do that question right now; actually we have a question into CMS right now because we don't know if we're going to copy authority under, right now our particular program is under Section in 1927 Social Security Act and we do not know if the pharmacy program will be, will have the authority to run our program, that's what we're getting at with right now is feedback from CMS, so we don't really have the answer.

M. Ophthalmic Quinolones

Displayed on a screen in the meeting room:

- *CIPROFLOXACIN*
- *MOXEZA®*
- *OFLOXACIN®*
- *VIGAMOX®*
- *BESIVANCE®*

Dr. Nagy: And moving on to the next class of medication: Ophthalmic Quinolones. Public comment? No Public comment?

Carl Jeffery: Okay the Ophthalmic Quinolones, again this is a class that's been out for a long time. A relatively new agent is Besivance. That's what's prompted us to review this here. We believe that there're all therapeutically equivalent.

Joseph Adashek: I move that they're all therapeutic equivalents.

Mike Hautekeet: Second.

Dr. Nagy: Any discussion? Voting from the right side.

Unanimous ayes from the board members.

Carl Jeffery: So Catamaran recommends keeping the current list of preferred agents in addition to adding Besivance.

Dr. Nagy: Motion for approval?

Joseph Adashek: I move we approve recommendations.

Joseph Adashek: Second

Dr. Nagy: Voting from the right side.

Voting is unanimous. Ayes from the board members.

Dr. Nagy: The motion carries

N. Respiratory: Short Acting Beta Adrenergics-Inhalers/Nebulizers

Displayed on a screen in the meeting room:

- *ALBUTEROL NEB/SOLN (generic Proventil®, Ventolin®)*
- *ProAir*
- *PROVENTIL® HFA*

Dr. Nagy: Next class of medication: Short acting Beta-Agonists- Nebulizers. Public comment. No Public comment?

Carl Jeffery: This is just a short acting beta II agonist. I think in there, there may be some confusion in which the… the binder includes the long acting agents but we're just discussing the short acting agents today. So these are albuterol products in here. We think these products are all therapeutically equivalent.

Joseph Adashek: Wasn't, Xopenex on the preferred list last time?

Carl Jeffery: Xopenex is on our preferred list now, yes.

Joseph Adashek: Are they taking it off?

Carl Jeffery: We'll get to that.

Joseph Adashek: All right. I move they are all three equivalents.

Adam Zold: Second.

Carl Jeffery: So Catamaran recommends removal of the Ventolin and keeping the Proventil along with the albuterol neb solution and adding Proair, and removing the Xopenex products. And this is mostly because the clinical studies show levalbuterol has not consistently demonstrated improved outcomes of the levalbuterol over albuterol. So we don't think levalbuterol should be a first line agent. Patients should be able to try an albuterol agent before they move to the Xopenex. Catamaran recommends the albuterol nebulizer solution, Proair, and Proventil HFA.

Joseph Adashek: Well I'd like to make a comment and make a motion. There was a reason like two years ago we added, Xopenex, I was here in Nevada and to speak to the side effect of levalbuterol versus albuterol. Regular albuterol has a lot of shakes, tachycardia in pregnancy, that's why we added the Xopenex, levalbuterol, and I'd like to prescibe, at least for all patients I take care of, Xopenex, I haven't seen a lack of efficacy you're talking about but I've certainly seen the side effects. I know albuterol, people don't like it, they might not take it and Xopenex increases compliance and it keeps them out of the hospital, I would make a motion that we re-add Xopenex to that list and put the other ones on our list.

Weldon Havins: Second.

Dr. Nagy: Any Discussion? Is there voting on the right side?

Votes are unanimous. Ayes from the board members.

Dr. Nagy: The motion carries

VI. ANNUAL REVIEW-DRUG CLASSES BEING REVIEWED DUE TO RELEASE OF NEW DRUGS

A. Analgesics: Tramadol and Related Drugs

Displayed on a screen in the meeting room:

- *TRAMADOL (GENERIC ULTRAM®)*
- *TRAMADOL/APAP (generic Ultracet®)*

Dr. Nagy: So this is the end of class reviews, drug review also drugs due to release of new drugs and analgesics: tramadol and related drugs, public comment?

Mary Kay Queener: Me again from with Health Outcomes Research Group with Janssen pharmaceuticals. Today right now, I'm here to speak to you briefly about Tapentadol ER, which is not recommended to be added, or Nucynta as well as Nucynta IR which I believe currently is on the PDL which appears to be recommended for removal. I just wanted to, first of all, clarify that the two products are different; tramadol is indicated for moderate to moderately severe pain, whereas Tapentadol is indicated for moderate to severe, acute and chronic pain with the IR and ER the two products have a different group of patients in their clinical trials and are used in the different setting within chemical practice. Just to sort of, elucidate that, the tramadol was generally compared to placebo or to hydrocodone containing products while as Tapentadol was compared to oxy containing products, so it is a different group.

In addition Tapentadol ER is indicated for neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults. And … you know, we would ask that you consider adding Tapentadol, or maintain Tapentadol IR as well as add Tapentadol ER to the formulary. In addition, primarily because it is effective and also from an adverse event stand point it is well tolerated, has a decreased instance of gastrointestinal side effects in particular constipation. And in the long term safety study, that was one year the Tapentadol patients stayed on therapy for about 268 days compared to 59 days in the Oxycodone arm, primarily due to discontinuation due to GI side effects. In addition for the DPN indication, there was only one clinical trial included in the monograph, but there was a second trial also conducted that was recently presented and was included in the indication and those results were replicated similar to the trial that you do have in your packet. Are there any questions that I can answer? One last thing from an abuse perspective, we do have data on the immediate release product for the first 18 months of use, which showed that it typically had a low abuse potential lower than the Oxycodone and Hydrocodone agents and do not yet have any information on abuse potential with the ER formulation.

Carl Jeffery: So if that's the case, is it being considered for rescheduling since it is now a schedule two?

Mary Kay Queener: Not that I'm aware of at this time. Any other Questions?

Dr. Nagy: Any other public comment? No one?

Carl Jeffery: Okay. So the tramadol and related products are as we've just heard that they include Nucinta and the Nucinta ER, they are the new agents available now. And again these are classified as CII. They are… as she statedare compared against the oxycodone products and have shown to be equally effective to oxycodone, but we think that these are all therapeutically equivalent.

Joseph Adashek: I move that we accept the recommendations for therapeutic equivalents.

Dr. Nagy: Do I have a second?

Adam Zold : Second

Dr. Nagy: Fine, any discussion?

Board members vote unanimously: Aye.

Carl Jeffery: Catamaran recommends that we just have the tramadol and the tramadol/acetaminophen, which is the Ultracet brand on the preferred drug list and this is simply because most patients can start with the tramadol product and move up to the Nucinta if necessary.

Joseph Adashek: I have a question for you and my colleagues experienced using Nucynta I haven't yet, is it the difference between that and oxycodone, it's less abuse potential, or is it that what the state thinks and if people have a history of drug addiction, would that be a good choice? If it is, is it a non preferred drug and how does that? That was like four questions in there. What do you think of Nucynta in terms of alternative for Oxycodone for patients at risk for addiction?

Carl Jeffery: Unfortunately I don't have a real world experience with it, just what I have read only academic information, well I think as far as, you know using in place if drug addicted patients I think they have the same issues with the addiction potential, does that answer your question?

Joseph Adashek: I thought it was way less, I know it's scheduled two but I thought the abuse potential, I have seen people come in the street coming up to me you want some Nucynta, you know I mean. Of course they don't come up to me anyway, all right, and so I move that we approve tramadol.

Mike Hautekeet: Second.

Board Members vote unanimous: Aye.

Dr. Nagy: The motion carries

B. Central Nervous System: Anticonvulsants, Misc

Displayed on a screen in the meeting room:

- *BANZEL®*

- *CARBATROL ER®*
- *CELONTIN®*
- *DEPAKENE® and generic VALPROATE ACID*
- *DEPAKOTE® and generic DIVALPROEX SODIUM*
- *DEPAKOTE ER® and generic DIVALPROEX SODIUM ER*
- *EPITOL® and generic CARBAMAZEPINE*
- *FELBATOL®*
- *GABITRIL®*
- *KEPPRA® and generic LEVETIRACETAM*
- *KEPPRA XR®*
- *LAMACTAL ODT®*
- *LAMACTAL XR®*
- *LAMICTAL® and generic LAMOTRIGINE*
- *LYRICA®*
- *NEURONTIN® and generic GABAPENTIN*
- *SABRIL®*
- *STAVZOR® DR*
- *TEGRETOL® and generic CARBAMAZEPINE*
- *TEGRETOL XR® and generic CARBAMAZEPINE XR*
- *TOPAMAX® and generic TOPIRAMATE*
- *TOPIRAGEN® and generic TOPIRAMATE*
- *TRILEPTAL® and generic OXCARBAZEPINE*
- *VIMPAT®*
- *ZARONTIN® and generic ETHOSUXIMIDE*
- *ZONEGRAN® and generic ZONISAMIDE*

Dr. Nagy: Move on to the next class of medication that was central nervous system anticonvulsants miscellaneous. Public comment?

Brian Strang: My name is Brian Strang, science liaison with Glaxo-SmithKline, and just wanted to point out some highlights for newly approved antiepileptic drug and that is Potiga which is ezogabine, it just became available in May of this year, so it's been out about five to six months so far, and some of the important points here, it's the longest drug class listed out there but why is it important anymore to come out with additional oral agents. First off I just wanted to point out in treating epilepsy about 20 to 30 percent of patients plus the newly diagnosed patients despite all the different therapies that are available will continue to experience seizures over time and so hence you see a lot of the mild therapies and adjunctive therapies. So this product is an oral tablet, it's a schedule five drug and it's indicated as adjunctive therapy specifically in partial seizures in adults.

And just to focus in on the mechanism of action because again there's still lot of different types as you know, mechanism of action, this one is unique and that it's the first that affects the potassium channels, the neuronal potassium channels. So in the adjunctive category when you are using multiple products, this one again is a different mechanism than what's currently available, so on the clinical trials, it's about 1200 patients overall, specifically studied in those patients that were on anywhere from one to three concurrent therapies and this obviously was added to it over the course of treatment. And in that

population we are still experiencing on average eight to twelve partial seizures per month. It reduced the seizure frequency about 20 to 40 percent. So that is what's different with this drug.

From a safety perspective, again with the unique profile especially in the potassium channels, we noticed in the pre-clinical work and monitored all through the clinical trials that because it affects potassium channels, we also saw that it did in some patients inhibit bladder contractions and so as we monitored through that it caused urinary retention in about two percent of patients in the trial.So because of that, talking with the FDA, the FDA required we put a communication REMS program in place not restrictive but communicative. And so specifically, communication is going out to the prescribers of this type of population, so are the epileptologist, the neurologists that are seeing a lot of epilepsy patients and also to the ER physicians, pharmacists and so on in there as well. And so it's important to know it does cause urinary retention and then some of the most common adverse events are typically CNS related as you know within this class especially somnolence and sedation, in here dizziness and then there is a parameter to monitor those patients QT prolongation, if they already have QT prolongation or are on other medications, they can prolong the QT interval. And then the class one for all AEDs as well, so that's really the highlights for this product and new indication and we are asking that this be available on the preferred drug list for those patients. That's…

Dr. Nagy: Thank you. Any other public comments?

Coleen Lawrence: Madam Chair, this is Coleen, just for clarification for the Committee Members and for the public who have not been around us long enough, the reason why this list is so long, we have it in statute that for the anticonvulsant class, if the patient was prescribed the medication prior to June 30th 2010 in this classification of medication, it is to be preferred. So a medication that comes out after June 30th 2010, we may consider it non-preferred but if the medication was on prior to the then, we may not.

Carl Jeffery: Okay and so just real briefly and this class has been around for a long, long time, as Brian just mentioned, the new drug is the Potiga is out there, it has a place in therapy and as he went through it, it's a little bit different mechanism of action but it is again adjunctive therapy so it's not indicated for monotherapy, its always added after the fact. Given the information we have, we believe that all these products are interchangeable and equivalent.

Dr. Nagy: Any discussions? Not, then do I have a motion for clinical and therapeutic equivalents.

Joseph Adashek: I move they are all therapeutic equivalents.

Adam Zold: Second.

Board members vote unanimous: Aye.

Dr. Nagy: Motion carried.

Carl Jeffery: So I… if you can read the list up there, you noticed the one drug that's not in it, we want to make non-preferred is Potiga and this is only because it is not considered first line therapy or monotherapy it's adjunctive therapy so it is an attempt to influence appropriate prescribing we want to consider this non-preferred.

Mike Hautekeet: I make the motion to accept the recommendation.

Adam Zold: I second.

Board members vote unanimous: Aye.

Dr. Nagy: The motion carries

C. Central Nervous System: Sedative Hypnotics

Displayed on a screen in the meeting room:

- *ESTAZOLAM (generic ProSom®)*
- *FLURAZEPAM (generic Dalmane®)*
- *ROZEREM® (PA not required for ICD-9 code 307.42)*
- *TEMAZEPAM (generic Restoril®)*
- *TRIAZOLAM (generic Halcion®)*
- *ZOLPIDEM (generic Ambien®)*

Dr. Nagy: Next class of medication, erythropoiesis stimulating proteins. Public Comments?

Dr. Nagy: Sorry Sedative hypnotics. Any public comment?

None.

Carl Jeffery: So the sedative hypnotic class, again this is an established class, one new product that prompted us to review this is Intermezzo, it is another zolpidem product, it's got a unique indication for sleep onset and maintenance, but we think that overall that the class, and we do have some other products like the Rozerem is one and a slightly different mechanisms of action that we think they are all therapeutically equivalent.

Adam Zold: I make the motion that all the drugs in this class are therapeutically equivalent.

Weldon Havins: Second.

Dr. Nagy: Discussion, voting on the right side.

Board members vote unanimous: Aye.

Dr. Nagy: Motion carried.

Carl Jeffery: So our recommendation for the preferred drug list considers almost all of the generic products plus the Rozerem. Rozerem is not a controlled substance. And it can be used as an alternative to the benzodiazepine or the benzodiazepine-like agents.

Weldon Havins: I move that we accept these drugs to the PDL.

Joseph Adashek: Second.

Board members vote unanimous: Aye.

Dr. Nagy: The motion carries

D. Erythropoiesis Stimulating Proteins

Displayed on a screen in the meeting room:

- *ARANESP®*
- *PROCRIT®*

Dr. Nagy: So moving on to erythropoiesis stimulating proteins. Any comment? No public comment okay?

Carl Jeffery: Alright. So, we have a new product available in this class, Omontys and if you listened in on the DUR meeting a few weeks ago, we learned all about it. It's a new agent that is strictly limited to dialysis centers its under very strict distribution program so it's only administered at dialysis clinics and so to the others who may not know these always come in on a physician administered drug claim or PAD claim. PAD claims are exempt from PDL criteria. So if we, whatever we decide to do that this drug is going to be exempt from the PDL anyway but to go through the first step, we think that they're all therapeutically equivalent.

Mike Hautekeet: I make the motion that they are equivalent?

Kevin Desmond: Second.

Dr. Nagy: Voting, from the right.

Board members vote unanimous: Aye.

Motion carries.

Carl Jeffery: So our recommendation is to make Aranesp and Procrit preferred and to make Epogen and Omontys nonpreferred and this is simply to encourage appropriate prescribing.

Dr. Nagy: Do I have a motion of approval?

Evelyn Chu: I motion to accept the recommendation

Joseph Adashek: I second.

Dr. Nagy: Voting from the right side.

Board members vote unanimous: Aye

Dr. Nagy: Motion accepted.

E. Gastrointestinal Agents: Pancreatic Enzymes

Displayed on a screen in the meeting room:

- *Creon®*
- *Pancrelipase (Generic ZenPep® 5)*

Dr. Nagy: Gastrointestinal agents; pancreatic enzymes. Public comment?

Laura Litzenberger: My name is Laura Litzenberger and I'm with the Health Economics and Outcomes Research Group at Janssen Pharmaceutical and I'm here to speak today on Pancreas. The information that I want to provide you is on page nine of the monograph that you received. There is a clinical study by Vander Vedgurs and that should be attributed as a Pancreas clinical trial that's a second clinical trial for our indication. That's the clinical trial that shows that it's safe and effective in infants and toddlers. There is a second part of that trial which actually looked or asked caregivers about giving the product to infants and toddlers how well they actually accepted it when they opened the capsule and put it on the apple sauce. Did they spit it out or were they able to tolerate it? And on the scale of zero to three the mothers were care givers that were giving a Pancreas rated as a mean score of two point eight. So it was easy to give to these kids. You open the capsule. The size of the micro tablets is two millimeters which is a little bit smaller than the one millimeter of the other products but it's only a millimeter. Are there any questions about Pancreas? This is the product that has been available for ever that was listed as Pancreas MT it's the exact same product during the time that the FDA asked for these drugs to be approved the name was changed to Pancreas but it's the exact same product also during that time there was a label change with regard to the amount of label lipase protease amylase for all these products at the FDA's request but it's the exact same product that has been uses for many, many years as Pancreas MT.

Dr. Nagy: Thank you, any questions?

Ben Scope: I'm Dr. Ben Scope from Abbott Labs, I just want to be respectful of your time and thank you for the recommendation I just want to give you an opportunity to ask me any questions. Do you have any about our product Creon? Okay, thank you.

Dr. Nagy: Any other public comments?

Carl Jeffery: Okay. Just go briefly the pancreatic enzymes again, I don't know if everybody knows the history but these weren't shown to be safe and effective or they were on the market before for 1938 FDA rules so they weren't required to jump through all the necessary hoops to be shown safe and effective so, back in 2004, the FDA told the manufactures they need to show these products are safe and effective. So these have been trickling back to market, we're getting more and moreand the newest one here is the Ultrace and its available now. But the biggest difference between all of these agents is the different levels of the different enzymes that are all included into the single capsule, the one that I will call out as a little different is the Viocase. It's the only one that's not enteric coated and this requires it be administered with a proton pump inhibitor at the same time so it can pass through the

stomach to the duodenum soit can be absorbed inthe system without being destroyed by stomach acid. Catamaran believes these are all therapeutically equivalent.

Weldon Havins: I move that we consider all these therapeutically equivalent.

Joseph Adashek: Second.

Board members vote unanimous: Aye

Motion carries.

Carl Jeffery: Our recommendation for the board is that the Creon and just generic Zenpep and it gets confusing because they are all called pancrealipase, so we are going to make sure we specify it's the generic Zenpep.

Mike Houtekeet: All the strengths.

Carl Jeffery: Just the five.

Dr. Nagy: Did you get your answer?

Joseph Adashek: I don't understand why they're always in generic name or so the differences between them.

Mike Hautekeet: It is just a combination of the individual drug initial, individual components.

Joseph Adashek: Okay.

Mike Hautekeet: So you know you, you get fourth, a thousand, thirty four and its, that's pretty much all the difference.

Joseph Adashek: Okay.

Mike Hautekeet: So on the Zenpep only the 5000 is going to be approved?

Carl Jeffery: It's preferred, that is correct.

Mike Hautekeet: Oh, preferred, okay, what about the the others?

Carl Jeffery: The Creon covers all the other strengths with that?

Indiscernible: Okay the Creon covers all, okay.

Dr. Nagy: So voting on the right side?

Board members vote unanimous: Aye.

Gabe Lither: Who made the motion?

Weldon Havins: Yeah did we have a motion?

Gabe Lither: What's the motion?

Weldon Havins: I move that we accept these two products as preferred.

Gabe Lither: We don't even need motions anymore we're good.

Mike Hautekeet: I'll second that.

Dr. Nagy: Moving along. Okay.

Gabe Lither: Technically, we should vote again. We have a motion and a second.

Board members vote unanimous: Aye.

Dr. Nagy: The motion carries

F. Respiratory: Intranasal Steroids

Displayed on a screen in the meeting room:

- *FLUTICASONE (generic Flonase®)*
- *NASONEX®*

Dr. Nagy: Respiratory, intranasal steroids. Public comment?

Deborah Befont: I'm Deborah Befont and I am a Medical Science Laison here on behalf of Trevor laboratories for QNasal. I'm a PhD molecular biologist by training. Okay so QNasal is Beclamethasone diproprionate, a nasal aerosol indicated for treatment of nasal symptoms in patients with both seasonal and perennial allergic rhinitis in adults and adolescents, 12 years and older so this is non-aqueous nasal spray. It may be an option for patients who are dissatisfied with the aqueous formulations that are available so we recognize that lots of patients are on the aqueous formulations back when the CFC drive products were available, about 30 percent of patients prefer the dry option. The efficacy was proven for seasonal and perennial allergic rhinitis, showing statistically significant improvement in nasal symptoms starting on day two and then finally back when there were CFC propellant dry sprays available, there has been retrospective claims analysis using the Florida Medicaid data and that showed that the patients on the dry products have higher medication possession ratio. Our thinking is that they, for those patients they would also have greater accounts to the product when they prefer the dry versus the aqueous attributes so I'm asking you to consider addition of QNasal to the PDL list. Safety information here and the short-term studies, the safety events, the adverse events are similar to the placebo groups for patients who suffer from allergic rhinitis. The common safety events are nasal ulcers, there is a warning about if you've had recent nasal surgery or nasal trauma to avoid using this product.There is monitoring for, its recommended for glaucoma and cataracts, there have been reports of hypersensitivity and for all the corticosteroid products, there is the worry about immune-suppression, suppression of the immune

system and then as well we don't have a pediatric indication. There is the thought that the corticosteroids cause reduction in growth velocity, and so if it does come to be that we have pediatric studies, you have to visit and monitor growth for those patients. Thank you. Questions?

Dr. Nagy: Any other comments?

Carl Jeffery: Okay, the reason why we're reviewing this again is because if you remember the last meeting we had a presentation about Zetonna, a new agent on the market and we didn't have the information and so we brought this up to review Zetonna again. Aside from this one addition to the class, there is nothing new. We feel these are all therapeutically equivalent.

Joseph Adashek: I move they are all therapeutically equivalent.

Mike Hautekeet: Second

Dr. Nagy: Any discussion?

Board members vote unanimous: Aye

Carl Jeffery: So Catamaran recommends keeping the preferred list the same with the Nasonex and Fluticasone.

Weldon Havins: I move that we keep the two, Fluticasone and Nasonex on the preferred list.

Mike Hautekeet: Second.

Board members vote unanimous: Aye.

Dr. Nagy: The motion carries

G. Urinary Tract Antispasmodics

Displayed on a screen in the meeting room:

- *DETROL LA®*
- *OXYBUTYNIN TABS and SYRUP (generic Ditropan®)*
- *SANCTURA XR®*
- *VESICARE®*
- *TOVIAZ®*

Dr. Nagy: Onto the next class of drugs, urinary tract antispasmodics. Public comment.

Ani Lee: Good afternoon, I'm Ani Lee, Pharm.D. with Pfizer US Medical, thank you for including Toviaz on the list; it hasn't been on the PDL so I want to just highlight a few studies. Your review is very comprehensive and I just want to highlight that there's one study or two studies that looked at efficacy and safety of Toviaz eight milligrams directly versus Detrol LA four milligrams and I just want to point

out that these are only two studies that have been designed to be superiority designs. So over 4000 adults who avoid these symptoms were randomized and eight milligrams of Toviaz was found to be superior to Detrol LA four milligrams in reducing UUI and so is for 24 hours.

The one thing I want to mention is that clinicians have expressed desire for increase in the dose of Detrol from the currently recommended four milligram dose and a higher than four milligram dose of Detrol LA cannot be developed due to assumed concentration variability and the potential of high exposure to parent compound tolterodine. This was substantiated by a cross over study in healthy volunteers which compared pharmacokinetics of both Toviaz and Detrol LA at doses of four and eight milligrams. Analysis of the blood levels show a significantly less variability with 5-HMT compared to tolterodine. As you may recall, the orally administered fesoterodine or Toviaz is extensively hydrolyzed by non specific estimates is to its active metabolised 5-HMT and 5-HMT is the only active moiety of Toviaz with anti-muscarinic effects where as tolterodine and 5-HMT are both equal potent active moieties of Detrol LA and as you were told earlier from a physician who had testified, the availability of two doses of Toviaz provides dose flexibility to achieve optimal symptom control. So in summary Toviaz possesses partial efficacy in reducing UNUI and the superiority of eight milligrams of Toviaz over Detrol four milligram in reducing UUI was demonstrated in two large placebo controlled robust head-to-head studies. Toviaz offers two effective doses allowing individualization of OAB patients and Toviaz is the only agent for the treatment of OAB that is accompanied by the UOA program which is a support program designed to help patients take an active role in their OAB management. Thank you for your consideration and I'll take any questions.

Dr. Nagy: Thank you.

Tammy Simon: Hello, my name is Tammy Simon, I'm a doc in sciences and I'm the Scientific Manager for Managed Markets with Steles pharmaceuticals and Vesicare is our product but I'm actually here today to speak about mirabegron or myrbetric and its not on that list, maybe I can ask Carl if that's being reviewed.

Carl Jeffery: When is it, or when was it available?

Tammy Simon: We had approval on June 28th and it was launched three weeks ago.

Carl Jeffery: Ok, so we typically only review products that are currently available on the market, so we can review this next meeting.

Tammy Simon: Okay so should I then do the trade?

Coleen Lawrence: Yes so what she'll do is we'll just review it in a future meeting for the board; what we'll do is we need a future meeting where we have the information that's going to be available. But if you want to testify with it, you are more than welcome to have your five minutes of fame and testify, since you're here you're in charge of the whole thing.

Tammy Simon: Okay well I'll make it short; it'll be less than five minutes then, okay, great. So mirabegron is a beta3 adrenergic agonist indicated for treatment of OAB with symptoms of urge urinary incontinence, urgency and frequency. It represents a distinct mechanism of action and distinctly different therapeutic class for treatment of OAB. Mirabegron relaxes the detrusor smooth muscle

during the storage phase of the fill void cycle by activation of adrenergic receptor which increases bladder capacity. Additionally Myrbetriq improves storage capacity of bladder without impairing magnitudes of contraction during bladder emptying. First Databank and Medi-Span had both assigned Myrbetriq to a different classification from other agents used to treat OAB, it was placed under a newly created class called adrenergics in First Databank and beta3 adrenergic agonist in Medi-Span. It was evaluated in three 12 week, double blind, parallel group placebo controlled and multinational studies and patients with symptoms OAB. The 25 milligram and 50 milligram doses of Myrbetriq each shows statistically significant improvements versus placebo in both co primary and efficacy endpoints of frequency and incontinence episodes.

The recommended starting dose is 25 milligrams once a day with or without food and is effective within eight weeks based on individual patient efficacy and tolerability, the dose may be increased to 50 milligrams once a day and it should be taken with water, swallowed whole and not be chewed, divided or crushed and in dose adjustments at specific populations, it should not exceed 25 milligrams in patients with severe renal or moderate hepatic impairment. In three pivotal twelve week trials in one of the safety study, Myrbetriq was evaluated for safety in over 4,000 patients most commonly reported treatment of emergent adverse events across all groups where hypertension, nasal pharyngitis, UTI and headache and the most frequent adverse events leading to discontinuation in the three trials were nausea, headache, hypertension, diarrhea, constipation, dizziness, tachycardia and Myrbetriq can increase blood pressure in OAB patients in clinical trials with a mean increase in systolic and diastolic blood pressure at the max a dose of 50 milligrams with approximately half a millimeter to one millimeter mercury greater than placebo worsening a pre-existing hypertension that was reported infrequently in Myrbetriq patients.

Urinary retention in patients with bladder outlet obstruction and the patients taking antimascurinics for treatment of OAB has been reported in post marketing experience and a control clinical safety study of patients with bladder outlet obstruction did not demonstrate increased urinary retention; however it should be administered with caution in these patients. Any questions?

Dr. Nagy: Anyone, any comments?

Carl Jeffery: So the reason why we're talking about urinary antispasmotics is there's a new formulation of oxybutynin called Gelnique, other than that nothing much has else changed with this class except the new product will take to our review in the next meeting but Catamaran feels these products are all therapeutically equivalent.

Dr. Nagy: Do I have a motion for therapeutic equivalence?

Adam Zold: I move that these products are therapeutically equivalent.

Evelyn Chu: Second.

Board members vote unanimously: Aye.

Carl Jeffery: Catamaran recommends to prefer the Detrol LA, oxybutynin tabs and syrup, Sanctura XR, Vesicare and Toviaz, this would remove Enabelex from the preferred list and make it non-preferred.

Weldon Havins: I move that these five products be placed on the PDL.

Adam Zold: I second.

Board members vote unanimously: Aye

VII. ANNUAL REVIEW – Drug Classes Without Proposed Changes

A. Public Comment

B. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by SXC Health Solutions and the Division of Health Care Financing and Policy Without Changes

1. Acne Agents: Topical, Retinoid Agents and Combinations
2. Alzheimer's Agents
3. Analgesics: Long Acting Narcotics
4. Anaphylaxis: Self-Injectable Epinephrine
5. Antibiotics: Cephalosporin 2nd Generation
6. Antibiotics: Macrolides
7. Antibiotics: Quinolones 2nd Generation
8. Antibiotics: Quinolones 3rd Generation
9. Anticoagulants: Injectable
10. Antidepressants: SSRIs
11. Antidepressants: Other
12. Antiemetics: Oral, 5-HT_3
13. Antifungals: Onychomycosis Agents
14. Antihistamines: Second Generation
15. Antihyperuricemics: Xanthine Oxidase Inhibitors for Gout
16. Anti-Migraine Agents: Non-ergot Dopamine Agonists
17. Antiparkinson's Agents: Non-ergot Dopamine Agonists
18. Antivirals: Hepatitis C Non-Pegylated Interferons
19. Antivirals: Hepatitis C Pegylated Interferons
20. Antivirals: Hepatitis C Ribavirins
21. Benign Prostatic Hyperplasia (BPH) Agents: 5-alpha-reductace Inhibitors
22. Benign Prostatic Hyperplasia (BPH) Agents: Alpha-blockers
23. Bone Ossification Agents: Bisphosphonates
24. Cardiovascular: ACE Inhibitors and Diuretic Combinations
25. Cardiovascular: Angiotensin II Receptor Blockers and Diuretic Combinations
26. Cardiovascular: Antihyperlipidemics, Bile Acid Sequestrants
27. Cardiovascular: Antihyperlipidemics, Cholesterol Absorption Inhibitors
28. Cardiovascular: Antihyperlipidemics, Niacin Agents
29. Cardiovascular: Beta Blockers
30. Cardiovascular: Calcium Channel Blockers and Combinations
31. Cardiovascular: Direct Renin Inhibitors and Combinations

32. Central Nervous System: Anticonvulsants, Barbiturates
33. Central Nervous System: Anticonvulsants, Hydantoins
34. Diabetic Agents: alpha-glucosidase inhibitor
35. Diabetic Agents: Amylin Analogs
36. Diabetic Agents: Biguanides
37. Diabetic Agents: Incretin Mimetics
38. Diabetic Agents: Insulin Products
39. Diabetic Agents: Meglitinides and Combinations
40. Diabetic Agents: Sulfonylureas
41. Diabetic Agents: Thiazolidinediones
42. Gastrointestinal Agents: H_2RA's
43. Gastrointestinal Agents: Ulcerative Colitis
44. Herpetic Antiviral Agents
45. Herpetic Antiviral Agents: Topical
46. Immunomodulators: Topical
47. Impetigo Agents: Topical
48. Leukotriene Modifiers
49. Multiple Sclerosis Agents: Disease Modifying
50. Multiple Sclerosis Agents: Specific Symptomatic Treatment
51. Nasal Calcitonins
52. Ophthalmic Antibiotics: Macrolides
53. Ophthalmic Antihistamines
54. Ophthalmic Non-steroidal anti-inflammatory agents
55. Ophthalmic Glaucoma Agents
56. Otic Fluoroquinolones
57. Progestins for Cachexia
58. Psoriasis Agents: Topical
59. Pulmonary Arterial Hypertension agents: Inhaled Agents
60. Pulmonary Arterial Hypertension Agents: Oral Agents
61. Respiratory: Inhaled Anticholinergic Agents
62. Respiratory: Oral COPD Agents
63. Respiratory: Inhaled Corticosteroids/Nebulizers
64. Respiratory: Long-Acting Beta Adrenergics
65. Skeletal Muscle Relaxants
66. Respiratory: Intranasal Antihistamines and Combinations
67. Cardiovascular: Antihyperlipidemics, Triglycerides Lowering Agents

C. **For Possible Action**: Committee Discussion and Approval of Drug Classes Without Changes to the PDL

Dr. Nagy: Next agenda annual review the classes without proposed changes, public comment?

Carl Jeffery: There is nothing in the binders specifically regarding this, the entire list is in the very front. The remaining drug classes, Catamaran does not have any recommended changes.

Dr. Nagy: So motion for approval?

Coleen Lawrence: So on this one the Board just recommends that we accept the recommendation that there are not changes to the classes at this time.

Mike Hautekeet: I make the motion to accept the remaining classes without changes.

Joseph Adashek: I'll second.

Board members vote unanimously: Aye.

VIII. Report by SXC on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Carl Jeffery: Alright so I think the last item on the agenda here is the Rx Outlook, it is a report of new drugs and generics in the very back. I just got a note today that the generic Revatio is available. That will be something discussed at a future meeting. For March, we will be looking at Revatio, but we might have to break the class out because there are some other class products on the PDL for pulmonary hypertension that contains Revatio. There are some pretty big name brand medications that will be going generic soon.

Dr. Nagy: So we don't have to take any action?

Carl Jeffery: No, this is just for your information

IX. Review of Next Meeting Location, Date, and Time

Dr. Nagy: So next meeting?

Carl Jeffery: Next meeting is going to be March.

Coleen Lawrence: December.

Weldon Havins: December or March?

Carl Jeffery: I'm sorry; it's going to be December 20th.

Coleen Lawrence: And that's the meeting we've always kind of move around a little bit.

Gabe Lither: Yeah are you guys going to get a quorum on December 20th?

Carl Jeffery: It is five days before Christmas, so it may be hard to get a quorum. The location scheduled to be back, the Las Vegas meeting's location will be back at the Charleston address, well actually we've never had a meeting there, sorry we've had a couple meetings there with the DUR, I don't have the address with me, it's on Charleston and across Valley View.

Gabe Lither: In the Health Division Building.

Dr. Nagy: Any public comments before we adjourn? Yes please.

Indiscernible: I just have one question, when will the new PDL take effect? The items there were voted on today?

Coleen Lawrence: As soon as it is posted on the website. Definitely this year. .

Dr. Nagy: Any other questions, comments, so the motion for adjournment.

X. Public Comment

None.

Adjournment

Weldon Havins: Move to adjourn.

Dr. Nagy: Any second?

Joseph Adashek: Second

Board members vote unanimously: Aye.

Dr. Nagy: Oh that's the end.

Meeting adjourned at: 2:44 PM