Pharmacy and Therapeutics Committee Meeting Record

Date: 04/20/07 **Time:** 9:00 a.m. – 3:00 p.m. **Location:** 3232 Elder Street, Conference Room D

Moderator: Don Norris, M.D.

Committee Members Present: Phil Petersen, M.D.; Thomas Rau, M.D.; William Woodhouse, M.D.; Donald Norris, M.D.; Tami Eide, Pharm.D.; Michelle Miles, PA-C; Catherine Gundlach, PharmD; Bob Comstock, RPh.; Stan Eisele, M.D.; and Richard Markuson, RPh.

Others Present: Jeanne Siroky, Cindi McGuire, Selma Gearhardt, PharmD; Steve Liles, PharmD

Committee Members Absent: Rick Sutton, RPh.

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Don Norris, M.D.	Dr. Norris called the meeting to order.
Committee Business		
➢ *Roll Call*	Don Norris, M.D.	Rick Sutton, RPh. was noted absent.
➢ *Reading of Confidentiality Statement*	Don Norris, M.D.	Dr. Norris read the Confidentiality Statement
➢ *Approval of Minutes from February 16, 2007 Meeting*	Don Norris, M.D.	There were no corrections. Minutes were approved.
➢ *Key Questions*	Tami Eide, PharmD	Key questions from the Drug Effectiveness Review Project: • Pharmacologic treatments in ADHD. There have been several changes from the last review. Evidence on effectiveness as well as efficacy has been added. Daytrana has been added to this review. There was discussion about Modafanil because it was not approved for use in ADHD. The governance group agreed to keep it in for future use. The population inclusion criteria were changed to split out by age. • Beta blockers have not been recently reviewed. There was not a big change in the review other than updates on new literature. A Coreg long acting preparation is now available and will be included in the review. • Hormone Replacement Therapy. This review will no longer be limited to estrogens and will update hormone replacement therapy in total.

DUR Review – Migraine Prophylaxis	Chris Owens, PharmD	Dr. Chris Owens presented via conference call the results of the DUR study on the treatment and prophylaxis of migraine headaches. Dr. Owens reviewed migraine prophylaxis guidelines, benefits, and agents. Mr. Owens also went over DUR activities, educational materials, methods and trends. Dr. Owens also provided results of prophylaxis utilization, intervention questions for Physicians and Pharmacists, comments, review limitations, and conclusions of the study.
Public Comment Period	Don Norris, M.D. Jeanne Siroky, RN, Medical Program Specialist	Thirteen people signed up to speak during the public comment period. Public comment was received from the following speakers:

Speaker	**Representing**	**Agent**	**Class**
Tracey Meeks	Amylin Pharmaceuticals	Byetta Symlin	Incretin Enhancers
Kenneth Carrell, MD	self	Exubera	Insulin and Related Agents
Dr. Jennifer Brzana	GSK	ropinerole	Anti-parkinson Agents
Brad Hedstrom	Solvay	Androgel	Androgenic Agents
Dr. Robert Calder	Merck	Januvia	Incretin Mimetics
Dr. Robert Calder	Merck	Fosamax	Bone Resorption
Jennifer Tinerd	Sun Health	Aricept	Alzheimer's Agents
Dr. Elson Kim	Forest Labs	Namenda	Alzheimer's Agents
John Beaty	Boehringer	Aggrenox	Anti-platelet
John Beaty	Boehringer	Mirapex	Anti -Parkinson's
Mark Balk	Pfizer	Celebrex	NSAIDs
Dave Harper	Sanofi-Aventis	Plavix	Anti-platelets
Janine Fournier	Sanofi-Aventis	Lantus Apidra	Insulins
Sue Heineman	Pfizer	Exubera	Insulins
Scott Silver	Pfizer	Xalatan	Ophthalmic Glaucoma

Drug Class Review		<u>All drug classes reviewed at this meeting were previously reviewed. Presentations focused on updated information since the last review.</u>
➢ ACE Inhibitors	Steve Liles, PharmD	<u>ACE Inhibitors</u> Dr. Liles stated that this drug class was last reviewed August 2006. Trandolapril and moexapril are now available generically. Dr. Liles reviewed one new clinical trial and meta-analysis.
➢ Alzheimer's Agents	Steve Liles, PharmD	<u>Alzheimer's Agents</u> Dr. Liles stated that this drug class was last reviewed in July 2006. Dr. Liles reviewed doneprazil's new indication for severe dementia associated with Alzheimer Disease.
➢ Androgenic Agents	Steve Liles, PharmD	<u>Androgenic Agents</u> Dr. Liles stated that this drug class was last reviewed in July 2006. Dr. Liles reviewed data on

		risks of falls, fractures and on mortality associated with low testosterone levels.
➢ Antiparkinson's Agents	Steve Liles, PharmD	<u>Antiparkinson's Agents</u> Dr. Liles stated that this class was last reviewed in July 2006. Dr. Liles reviewed market withdrawal of pergolide and availability of new drugs (Azilect and Zelapar) and their pharmacokinetics, clinical trial data, adverse effects, and dosages.
➢ Bone Resorption Suppression and Related Agents	Steve Liles, PharmD	<u>Bone Resorption Suppression and Related Agents</u> Dr. Liles stated that this drug class was last reviewed in July 2006. Dr. Liles reviewed new indications, dosages, and clinical trial data.
➢ Hypoglycemics, Incretin Mimetics & Enhancers	Steve Liles, PharmD	<u>Hypoglycemic Incretin Mimetics & Enhancers</u> Dr. Liles stated that this is a revised class. Dr. Liles reviewed new indications, clinical trial data, tolerability, and dosage. New drugs in this class are Januvia and Janumet.
➢ Hypoglycemics, Insulin and Related Agents	Steve Liles, PharmD	<u>Hypoglycemics, Insulin and Related Agents</u> Dr. Liles stated that this class was last reviewed in May 2006. Dr. Liles reviewed the FDA labeling changes for pregnancy category for Novolog. Dr. Liles also reviewed the dosing and clinical trial data of Exubera, a new drug in this class and new clinical trials for insulin detemir and insulin glargine.
➢ Ophthalmic, Glaucoma Agents	Steve Liles, PharmD	<u>Ophthalmic, Glaucoma Agents</u> Dr. Liles stated that this class was last reviewed in August 2006. Dr. Liles reviewed the new dosage form for Travatan and clinical trial data.
➢ Platelet Aggregation Inhibitors	Marian McDonagh, DERP	<u>Platelet Aggregation Inhibitors</u> Dr. McDonagh stated that this is the first update report for this class. Dr. McDonagh reviewed the key questions, inclusion criteria, and literature search. She reviewed new trial data for Acute Coronary Syndrome, Coronary Revascularization, Stent Revascularization , post stroke TIA and Symptomatic Peripheral Vascular Disease. Newer trials did not change conclusions of previous report.
➢ NSAIDS	Roger Chou, DERP	<u>NSAIDS</u> Dr. Chou stated that this class was last reviewed in May 2004. This is the third update. Dr. Chou reviewed the search strategy, data collection and analysis, and key questions. The key questions were updated to exclude rofecoxib (Vioxx) and valdecoxib (Bextra) and to add two Canadian products and salsalate. Dr. Chou reviewed all new evidence. Results were consistent with the last update.

Committee Clinical Discussions and Conclusions	Tami Eide, PharmD	ACE Inhibitors The Committee did not feel that there were any significant changes. They did not feel that the evidence supported differences in efficacy, effectiveness or safety. Alzheimer's Agents The Committee did not feel that there were any significant changes since the last review. Androgenic Agents The Committee did not feel that there were any significant changes since the last review. Antiparkinson's Agents The Committee did not feel that there were any significant changes since the last review. Bone Resorption Suppression and Related Agents The Committee did not feel that there were any significant changes since the last review. Hypoglycemics, Incretin Mimetics & Enhancers The Committee did not feel the need to make any changes to their recommendations for this class. Januvia and Janumet are currently on the non-preferred drug list and are prior authorized. Hypoglycemics, Insulin and Related Agents The Committee felt that Exubera should be available to the low number of patients that need this agent. Ophthalmics, Glaucoma Agents The Committee did not feel the need to make any changes to their recommendations for this class at this time. Platelet Aggregation Inhibitors The Committee did not feel the need to make any changes to their recommendations for this class since the last review. They noted that the Aggrenox used in studies was not the same preparation as the one currently available. NSAIDS The Committee did not feel the need to make any changes to their recommendations for this class. They concluded that the degree of Cox-2 selectivity didn't predict CV or gastrointestinal adverse events consistently and that there was no reason to separate the class into two subclasses.
Public Meeting Adjourned	Don Norris, M.D.	Dr. Norris adjourned the public portion of the meeting.

Closed Executive Session	Paul Leary, Medicaid Senior Bureau Chief	• No executive session was held.

Pharmacy and Therapeutics Committee
Public Comment
April 20, 2007

Tracey Meeks
Hi, I am Tracey Meeks with Amylin Pharmaceuticals and I am here today to request two things; open access for Byetta or exenatide injection and to maintain Byetta as a preferred agent in the incretin enhancer category. Byetta addresses beta cell dysfunction and glucose homostasis, a key physiological abnormality in Type 2 diabetes. It exhibits many of the same effects as the incretin hormone GOP1. Byetta directly binds with the GOP1 receptor and has been shown to elicit five key incretin effects, including acute beta cell responsiveness. Since last year Byetta has received two additional indications, one for the use with TZDs in combination with metforman and also storage at room temperature after Byetta has been placed into use. As far as the value to you and your patients, Byetta continues to be the only Type 2 diabetes therapy to show significant A1C lowering in addition to progressive and sustainable weight loss in most patients. I would also like to request that for Symlin or pamlintide injection open access for your Type 1 and 2 patients and to maintain Symlin as a preferred agent in the incretin enhancers category. Symlin indications have remained the same. It is indicated for Type 2 diabetes as an adjunct treatment for patients using meal time insulin and for Type 1 diabetes as an adjunct treatment for patients using meal time insulin. Thank you.

Kenneth Carrell, M.D.
Hi, I am a physician and I am a diabetic and I am speaking on Exubera, the orally inhaled insulin. I take care of multiple patients who are Medicaid patients. This drug to me seems like a no brainer. I don't know how many of you guys have ever had to give yourself shots, but if you do, you know that everyone in the practice is scared to death of the needle, including me. I don't think that is an exaggeration. This is a drug that you can take and start a patient on and use it without any difficulties. I think anybody can figure it out. I've seen the demonstrations on the inhaler, it is very straightforward and simple. It's a no brainer to me that this would be a very good drug to have on your formulary. This may not be the end all or be all drug but it is a real drug that would help with those patients that have the needle phobia. It is straightforward, three times a day, and for type 2 diabetics this should be all you need for treatment. Thank you.

Jennifer Brzana, Pharm.D.
Good morning, thank you for the opportunity to address the Idaho State Medicaid Drug Committee regarding the addition or maintenance of ropinirole. My name is Jennifer Brzana and I am a PharmD and a Regional Medical Scientist with GlaxoSmithKline. There are three major points that I would like to discuss with you today. Point 1, the 2001 treatment guidelines for Parkinson 's disease recommend dopamine agonists as first line initial monotherapy in newly diagnosed Parkinson's patients. They also recommend dopamine agonists as adjunctive therapy in advanced Parkinson's patients in addition to Levadopa. This is because Levadopa, although the standard of care, is associated with severe adverse events. Newly diagnosed Parkinson's patients treated with ropinirole as initial monotherapy experience significantly fewer dyskinesias at the end of five years. Point 2, ropinirole was the first drug approved for indication in restless leg syndrome. Four double blind placebo controlled 12 week studies showed the ropinirole is effective in treating restless leg syndrome with significant improvement as early as week two. Point 3, Parkinson's is a progressive disorder. Ropinirole can be titrated from 0.75 mg per day to 24 mg per day in a Parkinson's patient to meet the changing needs of patients. The dose ranges from 0.25 mg to 4 mg in the RLS populations. These three points make ropinirole the clear choice for the Idaho State Medicaid formulary. Thank you for your time.

Brad Hedstrom
Hi, I want to thank you for your time today. I am Brad Hedstrom and I am with Solvay Pharmaceuticals. I am an Account Manager with Solvay. The product that I want to talk about has been on your formulary as a Tier 2 product. I would like to request that it stay on Tier 2. I'll just go through some bullet points in concern to Androgel: Androgel has been proven safe and efficacious in a 42 month study; continues delivery of testosterone for 24 hours; the ability to deliver testosterone in low, mid and upper levels when compared to its transdermal patches; convenient once daily dosing; ease of application; skin irritations are very uncommon; also you have no office visits required with administration of this product; no local pain, bleeding, bruising when compared with injections; you have three applications sites. Hopefully you have seen the letters from physicians in the past to the State of Idaho in support of this product. Thank you for you time.

Robert Calder, M.D.
Thank you very much, I am Robert Calder and I am a physician epidemiologist with Merck. I have been with Merck for 17 years and before that I was a preventive medicine officer in the army and a State Epidemiologist in Florida. I am going to talk about Januvia today and make six points. Point 1, Januvia increases the incretin hormones. Incretin hormones were discovered about 100 years ago. If I inject you with glucose you will get an insulin spike. If I give you the same amount of glucose PO you will get a much greater insulin spike. The difference between those insulin spikes is due to the incretin hormones which are given off in the intestines. The incretin hormones cause the beta cells to secrete more insulin and the alpha cells to secrete less glucagon in a glucose dependent matter. So how does Januvia increase the incretins? We increase them by inhibiting the molecular scissors called DPP4 which inactivates and clips these incretins. Point 2, Januvia is indicated for monotherapy or combination therapy. Point 3, Januvia lowers A1C levels in a glucose dependent matter. The higher the baseline A1C the more the A1C goes down. Why is this important? This is important because if you compare two different oral agents and you compare them in populations with different A1C levels you are going to see different reductions because of the different A1C levels. In the report that Provider Synergies gave you, in the conclusion they reference the Medical Letter. The Medical Letter said that Metforman and sulfonylureas have lowered A1C more than Januvia does. When the Medical Letter made that statement they referred to David Nathan's guidelines where in Table 1 he listed the reductions from the various agents. Those reductions were listed right out of the prescribing information for the various agents. Some of which were approved 30 years ago when I was in medical school, like some of the sulfonylureas. The point is they were done in different patient populations with different base line A1C levels, so you can't make those comparisons. Again, the Medical Letter uncharacteristically did that by referring to David Nathan's guidelines. Point 4, Januvia is metabolized to a very small extent (about 21%) and is excreted 79% unchanged in the urine. That means that there are no significant drug interactions but if you have moderate to severe insufficiencies you will need to decrease the dose. Point 5, because of the glucose dependent mechanism of action, hypoglycemia is similar to placebo. Point 6, we don't have an effect on body weight. I would submit to you that most patients with diabetes need to lose significant amounts of weight, much more that you would lose with any oral agent. That is it. Thank you.

I also have Fosamax. Two minutes on Fosamax, again my request on Januvia is that you add it to the PDL. With Fosamax, 5 points really quick. Point 1, efficacy, highly efficacious drug that decreases bone turnover and increases BMD. Point 2, is that it is indicated for the treatment or prevention of osteoporosis in post menopausal women. In the treatment of osteoporosis, unlike the other agents it has been found to reduce hip fractures. I am not saying that the other agents won't do that because they haven't all been studied in exactly the same patient population. Fosamax unlike the others has that in its indication that it reduces hip fractures. Point 3, Tolerability is very good even in patients that have pre-existing GI disorders. Point 4, I am not going to discuss comparative studies because that would take me a couple of hours to do it fairly. Point 5, is that Fosamax is leading the market. It is going off patent in February, so that spells cost savings to you. I certainly recommend and request that you keep it on the PDL. Thank you.

Jennifer Tinerd
Hello, my name is Jennifer Tinerd and I am a board certified Psychiatric Nurse Practioner and I work for SunHealth. The back portion of SunHealth is an inpatient psychiatric facility for patients 62 years old or older. The front portion has four board certified nurse practioners, three of us travel to assisted living and nursing homes and we function on a consultant basis on psychotropic medications. I am here speaking today for Aricept I want to speak to you all from the clinical perspective. The biggest problem that we face is that most of the patients we see haven't been started. By the time we are called in to consult on them it

is pretty far along in dementia, although Aricept does have the indication for severe dementia. The challenge is that we would really have liked to have seen the patients placed on Aracept when they were first diagnosed with memory disorders. It is proven that this medication slows the progression of this severe neurodegenerative disease and can keep patients independent, home longer and function longer. Often can keep patients institutionalized and also prevent practitioners and providers from having to describe expensive medications. Aricept will greatly improve the quality of their life. So, it seems like a no brainer to keep this medication on the preferred list. It does have the indications for mild, moderate, and severe dementia. We are going to treat these patients with congestive heart failure, osteoporosis, diabetes, but we are not going to treat their progressive neurodegenerative disorder? I don't think so. Thank you for your time.

Elson Kim, Pharm.D.
Good morning, my name is Elson Kim and I hail from the great state of California, the city of Sacramento. I came into Idaho and this is my first trip here and I have to say that this city rivals what the great state of California has to offer. I am very impressed and hope that I get a chance to come back. I saw a sign that Cabela's just opened down the road and I am going to try to go there. I am a doctor of pharmacy representing Forest Labs and I am here to address the committee regarding memantine, the first NMDA receptor antagonist approved for the treatment of moderate to severe Alzheimer's disease. The current and future USP model guidelines version 3.0 for 2008 continue to include memantine. Memantine is currently the only available FDA approved drug with this unique mechanism of action. There is proven efficacy in Alzheimer's disease both alone and in combination with acetylcholinesterase inhibitors. I was going to go over the trials, but due to the lack of time I won't. FDA requires two studies to prove efficacy, positive trials. One of the leading causes of institutionalization is for Alzheimer's disease patients due to agitation. Jeffrey Cummings later published last year the reanalysis of the cario data. They found that there is statistical significance where the treatment of memantine "reduced agitation and aggression, irritability, appetite and eating disturbances. Memantine reduced agitation and aggression in patients who were agitated at baseline and delayed emergence and those that are free of agitation at baseline." It has proven efficacious in clinical trials that evaluated mild, moderate, and severe Alzheimer's disease and its indication for the treatment of moderate to severe Alzheimer's disease irregardless of their MMSE. In this trial the MMSE was used to identify 80 patients for the purposes of study inclusion. The MMSE is a non-specific measure of cognitive function in AD. Patients should not be classified by scores that they receive from the MMSE but should be recognized for the hallmarks of treating the disease early with the most effective therapy. The vast majority of patients are presented to their treating physicians with moderate illness and need to be treated early and aggressively to prolong their quality of life. To summarize, memantine is the first and only NMDA receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease both alone and in combination. In combination with the leading inhibitors, memantine statistically improves global measures, cognitive measures, function and behavior when compared to acetylcholine alone. Memantine is also safe and well tolerated with a low potential for drug to drug interaction. Thank you very much.

John Beaty
Good morning, my name is John Beaty and I am a field based Medical Scientist with Boehringer and I am directing my comments for your consideration about Mirapex and Aggrenox this morning. I appreciate the opportunity to speak. First , I will speak about Aggrenox. Aggrenox one capsule BID is indicated for the prevention of current stroke in patients that have had a previous ischemic stroke or a TIA. The Aggrenox prescribing information contains a cautionary statement mandated by the FDA that Aggrenox is not interchangeable with the individual components. Aggrenox has been shown to be twice as effective for stroke prevention as aspirin alone. In the ESPS II trial, Aggrenox showed a statistically significant 22% risk reduction for stroke compared with aspirin. These results were corroborated by the non industry supported ESPIRIT trial which was published weeks ago. There is an increased risk of headache with dipyridamole compared to placebo. Studies with extended release dipyridamole show that headache was generally mild and transient. The addition of dipyridamole to aspirin has not shown to increase the risk of bleeding. Aggrenox is the only combination antiplatelet therapy endorsed as first line therapy for the prevention of non cardioembolic cerebral ischemic event.

My comments regarding Mirapex. Parkinson's disease can be an aggressive nerve degenerative disease with debilitating and devastating motor and non motor symptoms. Annual incidence of PD in North America is 20:100,000. Approximately 1 million people in the US are affected with PD. The precise mechanism of action in Mirapex is unknown. It is a non-ergot dopamine agonist which binds to and activates dopamine receptors in the brain to mimic the action of

dopamine. Mirapex is indicated for the treatment of the signs and symptoms of idiopathic PD in early and advanced stages. It helps delay the onset of dyskinesias and wearing off. It helps to increase the on-time when used as adjunct to Levadopa. Mirapex was approved for the treatment of restless legs syndrome in November 2006. It has a flexible dosing and can be rapidly titrated to an effective dose 1.5 to 4.5 mg per day. In three weeks for patients with normal renal function TID dosing can be given with and without Levadopa. Ninety percent of Mirapex is cleared unmetabolized through the renal system. There are no significant Cytochrome P450 interactions and no dosage adjustment is required in patients with a creatinine clearance of less than 60 ml per minute. Mirapex is well tolerated in all stages in PD. Patients have reported falling asleep without perceived warning signs during activities in daily living including operation of a motor vehicle which sometimes results in accidents. Hallucinations and postural hypertension may occur. The most commonly reported adverse events in early and late disease were dizziness, dyskinesias, hallucinations, headache, insomnia, somnolence, and nausea. Patients and caregivers should be informed that impulse control disorders, compulsive behaviors may occur while taking medications, including prampexole to treat Parkinson's disease. Thanks very much.

Mark Balk

Good morning, my name is Mark Balk and I am a Clinical Education Manager with Pfizer. I am here to speak today on behalf of celecoxib. Really, what I want to do is talk about celecoxib briefly and bring you up to date on some new information and see if you have any questions. The goal today is to maintain access to celecoxib. I understand that it goes through a PA process. A couple of new pieces of information, earlier this year we obtained an indication for celecoxib for juvenile rheumatoid arthritis. With that in mind there are three pieces of information that I want to cover. One is the efficacy of celecoxib, second is the cardiovascular safety and the third is GI tolerability. With efficacy I think the review from Oregon Health Sciences that you all have did a good job stating that the efficacy of all of the NSAIDs is comparable. I really don't think there is anything more to add there. In terms of CV safety, I want to introduce you to new information. In terms of cardiovascular safety with the COX-2 it has been a big issue with flags because the COX-2 is a relatively new agent. A couple of points that I want to make though in terms of cardiovascular safety is one, CV safety has a warning on all NSAIDS. The OHSU review points out the use of 95% confidence intervals and the relative risk. A concern is that people that aren't used to reading the statistics aren't really sure what the confidence intervals are really trying to tell them. That is that anytime the 95% confidence interval crosses one there is no statistical significance in that data. It just reminds you that although the MI data shows up in the OHSU review states that there is a trend toward higher MIs, it is not statistically significant. So, lastly what I wanted to talk about as well is that in terms of GI tolerability just a reminder that COX-2 agents and celecoxib in this instance are very safe and tolerable in the GI. In fact they are comparable to the older NSAIDs with the PPI. The very last point that I want to make is that celecoxib is the only on the market currently, and probably will be the only agent for quite some time. In fact when the FDA did a review they voted in favor of keeping celecoxib on the market at a vote of 31to1. They also voted to have other agents removed from the market. In a recent vote on a newer agent that was up for FDA review has been struck down by the FDA advisory committee at a vote of 20 to 1. The FDA may do something different, but they usually follow those recommendations. Last point is that celecoxib is indicated in both the APS and the Gerontological Association for treatment of rheumatoid and osteoarthritis as a first line agent after failure of acetaminophen. So again, my point is that I would like to maintain access to celecoxib on the market here in Medicaid. I would also like you to consider its use for patients that seem to make additional sense. Lastly, celecoxib is the only NSAID that is indicated for use commonly with aspirin. This is another unique area that needs to be considered for Medicaid patients. Thank you.

Dave Harper

Hi my name is Dave Harper. I am a Senior Medical Liaison with Sanofi-Aventis. I am here today to talk about the anti-platelet agents, specifically Clopidogrel. Obviously aspirin has been the standard for many years in the anti-platelet world; however there are many situations where the newer agents come along and are found to be equal or superior to the use of aspirin, when used in conjunction with or in place of aspirin. I understand that you have a fairly thick review in front of you from the Oregon Health Science Review and I would commend them on providing a reasonable and fairly thorough review. There is a lot of good information in there and they did a good job of whittling it down to salien points. I want to highlight just a few items in there. The first being that in the settings of acute coronary syndrome and coronary interventions, Clopidogrel is the only anti-platelet agent that when used in addition to aspirin has been shown to be beneficial to aspirin alone in those settings. It mentions the issues of stroke, TIA and also peripheral artery disease in which Clopidogrel has been shown to be an effective alternative to aspirin. There are a couple of areas that I wanted to comment on that are not in the report. One is related to the recent issues surrounding

drug eluting stents. I think most of you are probably familiar with the recent emergence of drug eluting stents in the cardiovascular community and some of the problems associated with those. In January of this year the American Heart Association spearheaded a joint task force looking at this issue and came out with a joint advisory to physicians stating that patients who received drug eluting stants, it is a priority to maintain these patients on Clopidogrel for at least a year and they recommend indefinite therapy if possible. The other area that is not addressed in the review is the area of ST elevation MI. This is a recent area of interest in the anti-platelet world obviously aspirin has been used in that setting for a long time as well as Clopidogrel. In the last few years there have been a couple of very large studies evaluating Clopidogrel in ST elevation MI patients that have found that when used in conjunction with aspirin provided additional benefit over aspirin alone. In fact the FDA labeling for Plavix has changed in the last year to include that as a new indication for Clopidogrel use. I really think the data is overwhelming supporting that you maintain Clopidogrel as a preferred agent. Thank you.

Janine Fournier, Pharm.D.

Good morning my name is Janine Fournier and I am the Regional Medical Liaison for Sanofi-Aventis. I am a doctor of pharmacy by training. I am here to discuss briefly with you insulin glulisine and insulin glargene. First, insulin glulisine is a rapid acting human insulin analog that has a unique pharmacokinetic and pharmacodynamic properties that allows it to better mimic physiological meal time insulin. In a PKPD study in non obese subjects and obese non diabetic subjects it demonstrated that insulin glulisine has slightly more rapid PKPD profile that insulin lispro. Insulin glulisine is approved for adult patients with Type 1 and Type 2 diabetes and is also approved for pumps. Injection site does not affect the viability of insulin glulisine. It can be given 15 minutes before a meal or 20 minutes after the start of a meal. This flexible dosing allows for matching of insulin dose to the actual food intake in patients with unpredictable meal consumption patterns. Now I want to talk a little bit about insulin glargene. Glargene is the peakless basal insulin with a once a day dosing, 24-hour duration, and has a five year doctor recommended efficacy and safety. Glargene is to have significantly lower incidence of hypoglycemia compared to NPH. On the other hand insulin detemir has a dose dependant peak and duration of action that eliminates the effectiveness as a basal insulin. Detemir requires twice daily dosing in approximately 100% of people in Type 1 patients. In a head to head study insulin glargene in Type 2 diabetic patients about 50% of the subjects in a detemir arm required twice daily dosing and used the higher insulin dose. Now, a newer study that was presented at the ADA last year by Dr. Bergenstall, this is a study that looked at basal bolus insulin using Lantus and Apidra. It was done in obese Type 2 diabetic patients with approximate mean BMI of 36. They took Type 2 diabetic patients who were failing two or more insulin injections. They were switched to insulin glargene and glulisine as the basal bolus insulin. The baseline A1C was 8.2% and the study compared simple algorithm versus carb counting to just meal time insulin glulisine. The mean end point at the end of the study was 6.7% and more the 70% received an A1C of less that 7. This demonstrates very effective glycemic control when insulin glargene and glulisine are carefully titrated using a simple algorithm or carbohydrate counting. Both glargene and glulisine are available in cartridges and vials. The cartridge is to be used in the opti-click pen. In conclusion, glulisine provides flexible prn or post meal dosing and maintains its rapid glucose lowering action in obese people. Glargene is the only FDA approved once daily dosing insulin in Type 1 and Type 2. A trial demonstrates that glargene and glulisine are very safe and highly efficacious regimens when titrated with extremely simple patient algorithms.

Sue Heineman

Hi, good morning. I am Sue Heineman. I am a pharmacist with Pfizer, living here in Boise. Many of you have seen me here in the last year and a half. Today I am going to talk on behalf of inhaled insulin or Exubera. It is the only inhaled insulin product that is available. Medicaid has not seen any utilization as of yet. When Pfizer launched this product there was a very intentionally slow launch of inhaled insulins just to make sure that the specialists knew how to educate the patients and where this fits in with the pharmacists and the certified diabetic educators. This has been a very slow launch and now it is being fully launched. We are reaching out to other providers. The intent was just to make sure that there was enough education on how to use this new way of providing insulin. Recently the ADA guidelines published their standards of medical care in the January issue of *Diabetes Care*. Insulin is now considered an agent that should be used after lifestyle changes or metformin. Before, it was utilized later on after you have had metformin and two or three oral agents then insulin is considered a last ditch effort. You guys all know that the impact of diabetes on the cost, the medication cost, your whole medical costs to Medicaid is tremendous, so the sooner that you can have that patient controlled and get their A1Cs down. This is the only agent that has no limit on how low it can reduce their A1Cs provided that the patient can tolerate insulin. The inhaled insulin provides that opportunity. It is an agent that is preferred by patients. In an extension study, one of the twelve week studies, versus SQ insulin 85% of those on inhaled insulin wanted to stay on inhaled insulin. Those who were on subcutaneous, 75% of those patients

enrolled in the study chose to switch over to inhaled insulin. Patient preference should be considered because if the patient prefers the agent they are going to be more adherent to the medications. This is an easy medication to use without the needles and it provides better post prandal glucose control than the subcutaneous insulin. When you look at what impacts can come from control of the disease in the macrovascular and the microvascular complications. Having that better control of glucose is important. I would just like to ask that you consider having inhaled insulin as a preferred agent here at Idaho Medicaid. It will be utilized.

If I could real quickly to talk about Aricept or donepezil again requesting that this be an agent that is maintained on the preferred list. It is one of two agents along with memantine that is only agent that has the mild, moderate or severe. When you look at your own data there are not a lot of patients that are on this agent, we lost them all with Part D. Those that are utilizing donepezil, a majority of them are reaching the therapeutic dose of 10mg. When you look at the other agent a majority of them are not reaching that therapeutic level. For those who require these agents it does provide that advantage. Thank you for your time.

Scott Silver

Thank you for your time. My name is Scott Silver and I am a local representative that deals with your glaucoma treaters here in Idaho. The good news is I believe that I am last. I am covering an important subject which is glaucoma. I would like to touch on three quick things. First of all just to request that you keep latanoprost as the first status on your PDL. Those are very supported by the clinical data that you have in your reviews, specifically in two studies. The first is the XLT which was published in 2003 in AGO. It looked at 411 patients looking at efficacy and tolerability. Across the board they were pretty equal as far as efficacy. The true differentiating factor was tolerability. If you look at glaucoma patients, that tolerability translates directly into persistency. There was a study done in 2003 that Dr. Reardon and Dr. Schwartz looked at three large managed care databases. What they did was look at approximately 23,000 patients looking at discontinuation rates of the three prostaglandins specifically. There was no comparison where Latanoprost subsided or was superior to others. What they can directly correlate is if we keep those patients persistent that obviously will keep those visual fields intact and keep their site there and keep them more functioning in the community and less costs for surgery in the future. One new thing that Pfizer as a whole has introduced to those patients is that every time they get a sample of Latanoprost within the office, they get a vision matters card. A vision matters is a program that Pfizer introduced to try to help those patients stay more persistent. Basically it looks like this, they get it in the mail and some of the things it covers within this packet is a point of purchase card for your commercial paid patients, a DVD explaining the disease state in detail, because sometimes it is hard to contemplate all that information. It comes with a Xal-Ease which is a delivery device that actually helps those patients get the drops into their eyes. This device just got an award from the arthritis foundation and comes with patient education. Lastly, it comes with a reminder phone call that can last up to 28 days straight. The patients will get a phone call every night reminding those patients to take their medication for 28 days which should instill that habit into them, keeping them more persistent with the drugs. At this time the data supports keeping Latanoprost or Xalatan preferred on the PDL. Thank you for your time.