Pharmacy and Therapeutics Committee Meeting Record

Date: 6/15/07 **Time:** 9:00 a.m. – 3:15 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; Stan Eisele, M.D. and Rick Sutton, RPh;

Others Present: Rachel Strutton, Bob Faller, Tracy Dana, MLS, OHSU (Call in); Gerald Gartlehner, MD, UNC (Call in) and Selma Gearhardt, PharmD

Committee Members Absent: Richard Markuson, RPh and Bob Comstock, 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.	As noted above – Richard Markuson, RPH and Bob Comstock, RPh were absent
➢ *Reading of Confidentiality Statement*	Don Norris, M.D.	Dr. Norris read the Confidentiality Statement
➢ *Approval of Minutes from April 20, 2007 Meeting*	Don Norris, M.D.	There were no corrections. Minutes were approved.
➢ *DERP Update*	Tami Eide, PharmD	<u>Drug Class Review Updates</u> Annually the OHSU EPC scans each drug class for new evidence, indications and safety concerns. The DERP governance then votes on whether an update will be done. • Recent Updates: 1. Angiotensin 2 Receptor Antagonists will be updated in the format of a journal article. Aliskiren, the new direct Renin inhibitor will be included. 2. Antihistamines and Alzheimer agents will not be updated 3. Opioids will be updated 4. TZDS will not be updated but new information will be included in the Diabetes report. 5. Inhaled corticosteroids will not be updated but new information will be incorporated into the Asthma report. 6. Antiepileptics will be updated and will include diagnosis of mood disorders,

		fibromyalgia and possibly migraine and generalized anxiety disorder. • New Topics 1. Diabetes 2. Atopic Dematitis 3. Asthma

Cost Savings Report	Paul Leary, Deputy Administrator	Legislative session 2006 in HB51 added Personal Health Assistance (PHA) and Disease Management to the Medicaid Program. This gave the direction and opportunity to move our supplemental drug rebate program from a single to multi state program, the TOP$ program. • The rough annual cost per participating account is about $700,000. For each $1 spent it is about $9 return. • There are seven states including Idaho in the TOP$ program. The TOP$ states include: Delaware; West Virginia; Maryland; Wisconsin; Idaho; Louisiana and Pennsylvania. • Quarterly savings increased from $270,802, for 11 drug classes in the first quarter to $2,309,803, in the fourth quarter for 51 drug classes. • Savings are attributed to an increase in the number of drug classes on the PDL, market share shift and increases in individual supplemental rebates. • TOP$ savings is $589,859, more per quarter for the 11 original drug classes. • Classes with the highest overall savings are stimulants; proton pump inhibitors; SSRIs; sedative hypnotics and anticonvulsants.
Public Comment Period	Don Norris, M.D.	Ten people signed up to speak during the public comment period. Public comment was received from the following speakers:

Speaker	Representing	Agent	Class
Dr. Peter Doble	Private Allergy and ENT practice	Veramyst	Intranasal Steroid
Patrick Vojta	Boehringer Ingelheim	Sprivia	Anticholinergic Bronchodialator
Perry Johnson	Graceway Pharm (3M)	Maxair Autohaler	Beta Agonist
Deb Criss	Merck	Singular	Leukotriene Modifier
Bao Hong	Abbott Labs	Humira	TIM
Bao Hong	Abbott Labs	Azmacort	Glucocorticoids, Inhaled
Lori Kamins	Dey LP	Accuneb	Anticholinergic
Lori Kamins	Dey LP	Duoneb	Beta 2/Anticholinergic
Krishna Patel	Schering Pharm	Nasonex	Intranasal Steroid
Krishna Patel	Schering Pharm	Asmanex	Glucocorticoid,

					Inhaled
		Henry Tang	AstraZeneca	Pulmicort Respules Pulmicort flexhaler	Glucocorticoid, Inhaled
		Henry Tang	AstraZeneca	Rhinacort Aqua Nasal Spray	Intranasal Rhinitis Agents
		Meredith Zarling	GlaxoSmithKline	Advair	Glucocorticoid, Inhaled/Long acting Beta Agonist
		Dr Petty (Call in)	self	Advair	Glucocorticoid, Inhaled/Long acting Beta Agonist
Drug Class Review					
➢ Atopic Dermatitis	Matt Hosford, RPh	Atopic Dermatitis Mr. Hosford stated the class was last reviewed August 2006. Only drugs that are reviewed in this class are the Topical Immunomodulators, Elidel and Protopic. Both drugs are second line treatment. The real differentiation between the two products is one, the second line of indication with Elidel being mild to moderate AD and Protopic being moderate to severe AD, which is also available in two strengths for younger patients.			
➢ Bronchodilators, Anticholinergic	Matt Hosford, RPh	Bronchodilators, Anticholinergic Mr. Hosford stated the class was last reviewed August 2006. No new agents or generic products in this class. He reviewed a recent meta-analysis and the current guidelines for treatment of COPD patients. The Committee requested more detailed information on studies showing superiority of tiotropium.			
➢ Glucocorticoids, Inhaled	Matt Hosford, RPh	Glucocorticoids, Inhaled Mr. Hosford stated the class was last reviewed August 2006. Most of these products are available HFA. There is a new agent Symbicort, which is a combination product. It is a long acting bronchidialtor with budesonide and formoterol.			
➢ Intranasal Rhinitis Agents	Matt Hosford, RPh	Intranasal Rhinitis Agents Mr. Hosford stated last reviewed August 2006. New agent Veramyst, it is Fluticasone furoate. Furorate is the only change.			
➢ Leukotriene Modifiers	Matt Hosford, RPh	Leukotriene Modifiers Mr. Hosford stated the class was last reviewed August 2006. Three agents in the class with a fairly new indication for Singular. It now has indication for exercise-induced bonchospasm.			
➢ Ophthalmics for Allergic		Opthalmics for Allerigic Conjunctivitis			

Conjunctivitis	Matt Hosford, RPh	Mr. Hosford stated the class was last reviewed July 2006. There are a number of agents that are grouped into this category. Ketotifin has a new product, an over the counter product Alaway in the 0.025%. Zoditor and Alaway are both now available over the counter. The branded agent Zoditor is currently available either OTC or by prescription. Pataday is a new formulation; it is a once daily formulation of Patanol.
Committee Clinical Discussions and Conclusions	Donald Norris, MD Tami Eide, PharmD	Atopic Dermatitis The Committee concluded that the evidence did not support differences in efficacy, effectiveness or safety. The Committee would like to keep both (need to name the 2 agents) agents on the PDL. Bronchodilators, Anticholinergic The Committee felt that Tiotropium (Spiriva), had some advantages with efficacy, ease of use and compliance. After reviewing the evidence in greater detail at the next meeting, final conclusions will be made. They felt these agents should be the second step in COPD treatment and should be used prior to long-acting beta-agonists. They felt Duoneb should remain non-preferred as it is often overused when albuterol alone is adequate. Glucorticoids, Inhaled The Committee concluded that the evidence did not support differences in efficacy, effectiveness or safety. Although fluticasone and budesonide are the least systemically absorbed, it does not translate to a clinical difference. They concluded the agents were interchangeable therapeutically, but that both powder and pellet formulations were needed since there is patient variation in use. Intranasal Rhinitis Agents The Committee concluded that the evidence did not support differences in efficacy or effectiveness or safety and supported interchangeability. The new drug Veramyst may have some advantages with it's delivery mechanism. Leukotriene Modifiers The Committee concluded that there is not sufficient evidence evaluating the difference between the agents, but that there is more available evidence and usage supports Singulair as a preferred agent. They also recommended that the Department re-evaluate the Leukotriene Modifiers and their place in therapy based on the revised GINA guidelines for asthma treatment. Ophthalmics for Allergic Conjunctivitis Pataday has never been reviewed and should be non-preferred. Pataday is suggested. It was recommended that all Ocular Steroids should be on PA. Committee recommendation is to collect data on utilization of ocular steroids in allergic rhinitis versus other use. Based on utilization results a DUR intervention on stepwise treatment may be warranted.
Drug Class Reviews		

➢ Beta-2 Agonist ➢ Targeted Immune Modulators	Tracy Dana, OHSU EPC (Call in) Gerald Gartlehner, RTI-UNC EPC	Beta-2 Agonist Ms. Dana presented the original evidence report on the Beta-2 Agonists. There is insufficient evidence to support a difference in efficacy or safety for either the long-acting or the short-acting Beta -2 Agonists. Targeted Immune Modulators Dr. Gartlehner reviewed the update report on the Targeted Immune Modulators. This review was completed in January 2007, as an update to the original 2005, review. Insufficient evidence exists to draw firm conclusions about the comparative efficacy; effectiveness or tolerability of the included drugs for the treatment of rheumatoid arthritis; juvenile rheumatoid arthritis; alkylosing spondylitis; psoriatic arthritis; Crohn's disease; ulcerative colitis and placque psoriasis.
Committee Clinical Discussions and Conclusions	Don Norris, MD	Beta-2 Agonists No compelling evidence for change. Targeted Immune Modulators The committee asked who and what were they being prescribed for. The committee requested follow up data.
Closed Executive Session	Paul Leary, Medicaid Senior Bureau Chief	

Pharmacy and Therapeutics Committee
Public Comment
June 15, 2007

Peter Doble, M.D.
Thank you for allowing me to come and speak to you today. I am a private practitioner in an allergy, ENT, rhinology practice in Twin Falls, Idaho. I am one of the few physicians in Twin Falls in the ENT specialty that treats adults and children enrolled in the Medicare program and I have been practicing in Twin Falls since 1990. I represent the American Academy of Otolaryngic Allergy and Head Neck Society and I am a consultant to the American Rhinologic Society. I speak extensively on the use of intranasal steroids as the component part of the treatment of chronic allergic rhinitis and systemic problems associated with allergy as it relates to rhinitis, public work on treatment of sinusitis and mucous related transport. I am speaking here today on behalf of my patients and your patients collectively and would request that you consider, in a positive fashion, the addition of Veramyst to our list of approved drugs. As you have, in your intranasal steroid review by Provider Synergies, you have a fairly extensive outline and a very complete compendium of information dealing with these products and you can see that they are important. I am not speaking against any of the products that you have. I am speaking for the addition of this new device and its intended medication. If, as an ear, nose and throat physician, I was going to select those properties in an intranasal steroid device, that I would like to see combined into one and Veramyst would combine all of them. No fine particulate matter, an effective backbone in its steroid molecule, an effective side chain and a drug that could be used down to the age of two and a drug that has a delivery device that is easy to use and repeatable in its deliverable fashion. Those are

the things that I have been looking for and Veramyst tends to represent all of them positively. It is an interesting side effect that in their recent approval process with the FDA, that they had a finding that said they were useful against ocular symptoms of allergies and then therefore that is in their product insert. I think that is effective, because those of us in practice realize that intranasal steroids as well as intranasal inhaled antihistamine products seem to have some effect in the eye. We have known that clinically, whether we have been able to prove it in placebo controled head-to-head studies has been something that the FDA has not looked at. So Veramyst also has a use maybe for the ocular symptoms. Now would I treat a patient with ocular symptoms with Veramyst, no. But would I get added benefit for someone who has ocular problems, and the answer is yes and I probably would look forward to seeing how that does in clinical trial. I think the reason that Veramyst is an important product for your consideration is, I prescribe an intranasal steroid that is filled with a generic product or is filled with a product that the molecule is less effective or the delivery device is harder for the person to use, either for an older person or specifically in my practice a younger child and the delivery device fails or delivers a product stream that is unacceptable to the recipient, then I've spent your money which is coming out of my pocket, I have prescribed a medication that is ineffective and it just sits on the shelf. So I see Veramyst as a useful product in my hands because I expect people to use it. I know that the backbone of the molecule, in its previous form which was Flonase is a good backbone and I know that the side chain that they have added to it and modified is a good product side chain and is already in use in Nasonex. So we've got a molecule that has been proven, the side chain that has been proven. The sterochemistry of the backbone appears that it is going to be equally effective as the Flonase. The side chain speaks to be more effective and more binding in a sterochemical fashion, so we probably are going to have a better molecule. That remains to be seen clinically, given that it is a new drug. But is should be, if it meets all the sterochemical facility that it should, it should be a better product. However, what is most important thing is the delivery device and the mist and the absence of odor. I think this will mean that I will be able to talk to people who don't like to use nasal steroids into using them and people who are children and are difficult to treat. I think parents will have a better chance at getting their kids to use it. So I think that it would be a welcome addition, especially if the company is competitively priced. Thank you for your time.

Patrick Vojta

Good morning, I am Patrick Vojta, a national medical scientist with Boehringer, Ingelheim Pharmacuticals, out of Boulder Colorado. Here today to speak in support of Spiriva Handihaler or tiotropium bromide in its current formulation. As the committee knows COPD is the leading cause of disability and the fourth leading cause of death in the United States, so it is a major chronic disease. Total cost in the United States in '04 was in excess of $37 billion and more than half of that cost was associated with direct cost of hospitalization related to acute exacerbation. With regard to Spiriva it is indicated for the once daily maintenance treatment of bronchial spasms associated with COPD, including chronic bronchitis and emphysema. The NHLBI and the WHO, as the committee is well aware, put together GOLD guidelines to address treatment and associated co-morbidity and COPD those guidelines were updated for 2006 and really from a treatment strategy perspective the guidelines didn't change substantially. Long acting maintenance dilators are still recommended as the mainstream treatment for COPD and as a maintenance treatment as the disease progresses and to severity stages. With regard to co-morbidities, the guidelines were actually updated quite substantially to address treating individual and addressing comorbid conditions associated with individual treatment as well. So with regard to GOLD, they do recommend a step-wise treatment to the management of COPD. Based on disease severity and that includes patient education, appropriate vaccinations, smoking cessation counseling, etc. for mild disease, short acting bronchodilators are indicated. But as severity of disease increases or progresses, long-acting dilators are indicated. Adding maintenance therapy with one or more bronchodilators along with pulmonary rehab, when stages progress to moderate to severe. In severe and very severe disease and in the presence of repeated exacerbations, the corticosteroids and the oral steroids are also indicated. With regard to Speriva and in close, as you know, as I mentioned the GOLD guidelines recommend long acting dilators, Spiriva is the only once daily anticholinergic on the market as maintenance therapeutic for COPD. Finally with regard to a safety update, Spiriva has an established safety profile now that it has been on the market since 2004, in the United States and an estimated 6.4 million patient lives of world-wide experience to date and with that I will close. Thank you.

Perry Johnson

Good morning, I am Perry Johnson, I am with Graceway Pharmaceuticals and I would bet that most of you have never heard of that company. We were 3M Pharmaceuticals, maybe you would have heard of that. We were purchased by Graceway at the end of last year. I am an account manager, I am not a physician or anything and my comments will not last more than two minutes, I promise you that. I just wanted to make a couple of comments about some of the product that you are reviewing. The short-acting Beta-2 inhalers, we have one called Maxair Autohaler, which probably a lot of you are familiar with and you know most

of the clinical characteristics of it. But there are a few things that you might not know about it that may be significant. It is on your PDL currently, so I would ask that you retain it. The thing that is different about, well there are two or three things that are different about it. It has 400 doses, which doesn't seem to be a big deal, but most of the other inhalers have 200. So there's kind of a built in refill there and I know that you don't talk about cost here, but having 400 doses may impact the cost. The other thing is that it is a CFC containing product, which as you know the CFC's are being taken out of the inhalers, but this still has the essential use. It is pirbuterol, not albuterol, it's a different molecule, so we will keep the essential use for at least through 2009. I don't know for sure what will happen then, but at least the other products are probably going to have to take the CFC's out by 2008, so there is certainly more with it. It is breath actuated, so people who are not able to coordinate using a press and breathe inhaler very well may be able to use the Maxair Autohaler easier because of that. Because of its breath actuation it also has a softer spray which makes it easier for a lot of people to catch the spray, so to speak. To give a comparison, it has 14 grams in the canister and has 400 doses, whereas most of the others have 17 grams and they are 200 doses. So there is a lot more propellant in the other inhalers, thus the softer spray. For some people, it makes it a little easier to catch the spray. You do not need a spacer with it, in fact it would be very difficult to use a spacer with it, it is built to be used without a spacer. It is pretty compact, I am sure you have seen them. It is easier to throw in your pocket or your purse, so it is convenient as a rescue medication. That is pretty much it, unless anyone has a question.

Deb Criss

Well good morning, I am Deb Criss, I am a health science consultant for Merck and I have been employed by Merck for the last 19 years. I am also a registered nurse, licensed in Colorado and a nurse practitioner by education. Thank you very much for allowing me to address the committee members today. I would ask that you would consider removing the prior authorization for Singulair in the treatment of asthma for the following reasons. First Singulair it the only oral medication indicated for the prevention of exercise induced bronchial constriction in patients 15 years of age and older. Three double blind randomized placebo controlled crossover trials in patients with EIB, have demonstrated that Singulair 10 mg provided significant protective benefit against EIB when taken two hours prior to exercise. Some patients were protected from EIM at 8.5 hours post dose and 24 hours post dose, however some were not. Secondly, asthma is a heterogonous disease and response to asthma treatments as you know is variable. So no one drug has 100% response rate. The advantage of the leukotriene receptor antagonist Singular is that it provides another mechanism of action to potentially control asthma. Sigulair has been proven to significantly improve lung function and to control symptoms as monotherapy. Also it has been shown to allow you to taper the dose of inhaled corticosteroids as maintaining control of asthma and you can also combine it with inhaled corticalsteroids to control asthma. For example patients 15 years of age and older, Singulair as monotherapy significantly decreased asthma attacks by 37% verses placebo. Those attacks were defined as ER visit, unscheduled doctor visits, hospital admissions and also the need for Oral or IV Glucocorticoids. Third, the overall effectiveness of any medication is not only the drug's effectiveness, but adherence to the drug. So to facilitate adherence to the drug, Singulair is available in oral granules that can be mixed with certain food, in chewable tablets and tablets. So lastly, as a reminder the indications for Singulair are for the prevention of asthma in patients 12 months and older. For the prevention of exercise induced broncho constriction in patients 15 years of age and older. For the relief of perennial allergic rhinitis symptoms in patients six months and older and finally the relief of seasonal allergic symptoms in patients 24 months and older. I thank you for allowing me to present this morning and if there are any questions I am happy to take those. Thank you,

Committee question:
Has there been any talk about that product going over the counter at all?

Answer (Deb Criss):
At this point I am not aware of that.

Committee question:
Anyone hear about that?

Answer: No reply

Bao Hoang

Good morning my name is Bao Hoang, I am a PharmD., I am a regional clinical liaison with Abbott Laboratories and to begin I want to thank you for the opportunity to highlight several key points of two different drugs in two different classes. One of which is Humira, which is a targeted immune modulator. The other is Azmacort which is an inhaled corticosteroid. Beginning with Humira, Humira is the first fully human monoconal antibody against tumor necrosis factor. Humira has been on the market for over four years, has over six years worth of clinical trial efficacy data and over 180,000 patients have been treated with Humira worldwide. In addition to the indications of Rheumatoid Arthritis, Psoriatic Arthritis and Anklosing Spondolitis, the FDA has recently granted Humira approval for Crohn's disease this year, on February 27th. Humira is the only self injectable biologic agent for Crohn's disease and will offer patients a unique benefit for a convenient, at-home injectable product. In the three pivotal trials for Crohn's disease CLASSIC, SHARM and GAIN. Humira demonstrated efficacy for both induction and maintenance of remission in patients with moderately to severely active Crohn's disease, who have had an inadequate response to conventional therapy. The GAIN study also showed that Humira was efficacious in inducing remission in Crohn's patients who have lost response, or who were intolerant to infiximab therapy. For Crohn's disease, Humira is dosed at 160 mg at week zero, 80 mg at week two and 40 mg every other week there after. For Rheumatoid Arthritis, Humira has been shown to have disease modifying action. Significantly reduces the signs and symptoms of Rheumatoid Arthritis with-in one week. Improves physical function and inhibits radio graphic progression of disease both erosions and joint space narrowing. Humira is also used to reduce signs and symptoms of active Arthritis and Psoriatic Arthritis. The depth study showed that 61% of patients achieve an ACR 20 response in conjunction with 47% of patients achieving a passing score, or a 90 score at one year. In terms of safety, as of February 2006, Humira has over 2000 patients in global clinical trials where serious infections, tuberculosis and lymphoma rates were within the rates of other documented anti-tumor necrosis factor. In conclusion, Humira has abundance to both clinical trail efficacy and safety data. It also has the benefit of ease of administration and every other weekly dosing.

Moving next to Azmacort. Azmacort is indicated as preventative therapy in the long term treatment of asthma. It is also indicated for asthma patients who require systemic orally administered corticosteroid medications, to reduce or eliminate the need for systemic corticosteroids. Azmacort has a dose of 400 micrograms, 1200 micrograms daily. Provides safe and effective relief in adults and children with the added convenience of a built in spacer. In one study of 53 patients receiving Azmacort 300 micrograms twice daily, the need percent enforced the expiratory volume in one second denoted as a FEV1, was 15% as early as one week, compared to 0% for placebo. At six weeks the need percent in FEV1 was sustained over time at 17%, compared to 2% with placebo. In a second study to evaluate the improvements in asthma symptom 60 patients receiving Azmacort 300 micrograms twice a day, achieved a 17.5 % change in FEV1 compared to 2.8% in 61 patients receiving placebo. Of the 60 patients receiving Azmacort there was decrease in Albuterol, a Beta-Agonist use of 3-4 puffs per day compared to 0.6 puffs per day in the placebo group. Adverse events at an incidence of greater than or equal to 3% are summarized from three studies and vary slightly by dose. At a dose of Azmacort 300 micrograms twice a day among 170 patients, sinusitis was recorded in 4%,pharangitis was recorded in 25%, headaches in 21% and flu syndrome was recorded in 5%. Other adverse affects include facial edema, diarrhea, bursitis, dry mouth, rash and chest congestion. In conclusion, Azmacort is considered a preferred agent in controlling asthma in patients. Azmacort inhaled corticosteroid may reduce or eliminate the need for systemic corticosteroid. Patients who need systemic corticosteroid therapy, again Azmacort provides safe effective relief in both adults and children, with the added convenience of a built in spacer. Thank you for your time.

Lori Kamins

Hi, I am Lori Kamins and I am a managed care action account manager, for the West for Dey LP. I have two products to talk to you about today, they are both currently on PA, and they are both Beta-Agonists. The first in Accuneb, it is an Albuterol solution for nebulization and it comes in a sterile dose .63 mg solution. It is designed and FDA approved specifically for children ages two to twelve years old. It is demonstrated efficacy at doses 50 and 75% lower than 2.5 mg adult strength Albuterol. The NIH, NFLBI advisory suggested that patients should use the lowest Beta-2 Agonist dose necessary to control asthma symptoms. The lower dose of Albuterol for children is effective for the management of asthma symptoms. The NAEPP guideline recommends the maintenance dose of nebulized Albuterol for children five years or younger is 0.5 mg per kg, per dose. The case for Accuneb in the treatment of children with asthma is that leave Albuterol is not approved for subjects two to five years of age, because there are increased exacerbations of asthma, than in the racemic Albuterol and the

placebo group. Lower doses of Albuterol help avoid the side effects of tachycardia, tremors and hyperactivity. When these side effects occur, patients frequently just stop giving the medications and do not inform a health care provider. This can lead to increased exacerbations of asthma.

The next product that I wanted to discuss was Duoneb. It is the only FDA approved combination of Albuterol and Ipratropium Bromide solution for nebulized indication. For treatment of bronchospasm associated with COPD for patients who need more than one bronchodilator. Duoneb solution improves bronchodialation more than either agent alone and 24% improvement in peak FEV1 compared to Albuterol alone. Thirty seven percent (37%) improvement over Ipratropium alone. Combination therapy is recommended by GOLD and the New England Journal of Medicine, as part of a specialized therapy for COPD. COPD patients are often prescribed as many as five to eight oral and inhaled medications to be taken at frequent intervals, either regularly or as needed. Whenever possible treatment regiments should be simplified. In a market research study of respiratory patients using nebulization, 82% reported that nebulization controls their symptoms longer that a MDI. Eighty percent (80%) said that nebulizing agents give them a better quality of life than a MDI alone. Douneb patients are significantly more compliant and have had significantly fewer emergency department visits than patients taking generic Albuterol and Ipratropium together. In a third party market research study of respiratory patients 82% reported that nebulizing controls their symptoms longer than a MDI and 80% said nebulizing gives a better quality of life than a MDI alone. Finally Douneb provides maintenance and rescue treatment when patients need more than one bronchodilator. Thank you.

Krishma Patel

Good morning, my name is Krishma Patel, I am a medical science liaison at Schering Plough. Today I would like to discuss two products; I thank you very much for your time. There are two products I will discuss. Nasonex in the nose Mometasure Furoate nasal spray. Then going to the lungs Mometasure Furoate dry compact inhaler and Asthmanex. For the first product, Nasonex is one of the most commonly prescribed nasal steroids. It is indicated for use in the following three patient populations: the treatment of nasal symptoms of both allergic and seasonal Rhinitis in patients two years of age and older, the prevention of nasal symptom of seasonal rhinitis in patients 12 years of age and older, and lastly, for the treatment of nasal polups in patients 18 years of age and older. One of two intranasal steroids in this indication. Clinical studies regarding safety have shown Nasonex has a low total systemic viability of 0.1% or less. No suppression of the HPA Axis and lastly no effects on growth in children three-to-nine years of age in a one-year randomized, placebo-controlled, double blind study.

Moving from Nasonex to Asmanex. Asmanex is the only inhaled corticosteroid FDA approved for once daily administration at both initiation and maintenance treatment of patients with asthma who were previously on bronchodilators alone or inhaled corticosteroids. In clinical studies Asmanex has shown significant improvement in pulmonary function, symptom scores and rescue medication use. Patients with severe asthma have shown significant reduction in oral corticosteroid dose. Asmanex is indicated in patients 12 years of age and older. With regards to safety, it has shown an oral bioavailability of 1% or less with any amount swallowed rapidly degraded via first pass metabolism into an active metabolite. It has shown no significant effects on the HPA Axis at recommended doses. The use of the device itself involves a two-step process: open and inhale. The device has a dose counter which counts down with each dose that is used. I thank you for your kind attention today and for considering Nasonex and Asmanex for inclusion in the Idaho preferred drug list. Any questions?

Committee question:
Is there any plan to seek approval for younger ages?

Answer:
Yes, they are working on that right now. I couldn't give a time frame, but yes. Any other questions? Thank you.

Henry Tang

Good morning my name is Henry Tang. I am the regional scientific manager and also a pharmacist. I am representing AstraZeneca today, which is dedicated to the improvement of asthma care and other respiratory related diseases. AstraZeneca develops our products for the treatment of asthma and rhinitis based on a well known compound adenosine, which I hope you all are familiar with. The clinical experience of badesonide has been well documented and I would like to highlight some the distinguishing characteristics of the different AstraZeneca products. The first one is Pulmicort Respules. In the US, the NHLPI asthma treatment guideline recommends low dose inhaled corticosteroids ICS as preferred treatment for mild persistent asthma. Pulmicort Respules is the only ICS indicated for children as young as 12 months old. It is the only ICS available in a nebulized formulation in the US, the occurring no FDA approved version of this product on the market. The availability of a nebulized formulation is very important for very young patients when the use of midi-dose inhaler is impractical. Respules offers the convenience of once or twice daily dosing. It has been demonstrated in clinical trials that the use of Pulmicort Respules decrease health day utilizations by decreasing the number of days in of break through medication. It is also associated with reduced exacerbation which is defined as emergency room or urgent care visits, hospitalizations or additional systemic or inhaled corticosteroid use in young children with asthma. The safety of Respules has been evaluated extensively in children from age two to ten for up to three years. Other safety measures such as HPA suppression growth velocity, has been evaluated. Also, this is the only ISC that carries the pregnancy category B by the FDA, which is reassuring to parents and caregivers when they give medications to their children.

The second medication I want to comment on is Pulmicort Flexhaler which is a new inhaler device that has just become available in April 2007. Turbohailer will be phased out in a short period of time. Again, according to the US NHLBI guideline, the recommended ISC for treatment of persistent asthma. Flexhaler delivers Budesonide via: a new dry powder inhaler which includes a new mouth design which facilitates the oral correct mouthpiece positioning as well as a more accurate dose counter, which allows for better tracking of drug usage. A small amount of lactose, which is about 1 mg per inhalations, has been added to improve dosing accuracy, which is significantly less than the other dry powder inhaler. Again, the safety has been well established. Pregnancy category B patients can be transitioned from the respules to a Flexhaler so they can have the same molecule without safety concerns.

The third product is Rhinocort Aqua Nasal Spray, which is also part of the budesonide family. It is indicated for seasonal and perennial rhinitis for patients six years and above. There are many differentiating characteristics including one spray per nostril per day. Pregnancy category B, low voluminous spray and also low fragrance, which is preferred by a lot of patients.

The final product is Symbacort, which has been approved by the FDA in 2006 and will be shortly available in 2007. This is also a budesonide compound with a long acting Beta-Agonist fomoterol. The addition of this new product will help to address the unmet need of asthma patients. In summary, AstraZeneca is committed to the improvement of patient care, especially those patients that are insured under the Idaho Medicaid system and also the many young children that are most vulnerable. Restricting the access of these important medication will not only affect the quality of life for patients in Idaho, but also potentially can increase utilization of limited medical resources. Thank you for your attention and if I may answer any questions.

Meredith Zarling

Good morning and thank you for the opportunity to speak to you today about Advair Discus and AdvairHFA. My name is Meredith Zarling and I am a clinical pharmacist as well as a regional medical scientist with GlaxoSmithKline. I would like to present to you information this morning in support of Advair on the Idaho preferred drug list. As my colleagues have mentioned before, the National Heart Lung and Blood Institute panel of experts, after careful review of the literature, issued very clearly defined guidelines on the management of asthma. Patients should be assessed as to severity of disease and then appropriately managed based on that severity. For patients with severity class of mild persistent asthma, the preferred treatment is low dosed inhaled corticosteroids. The panel concluded that strong evidence has shown that the preferred treatment to moderate to severe asthma in adults in children greater than five years of age should be the combination of an inhaled corticosteroid with a long acting Beta-Agonist. Compliance remains a significant problem in patients with asthma. In two recent publications, Stolof and Stempledall found a significant increase with compliance with the Advair Discus compared with inhaled corticosteroids alone or compared with using flauticasome plus salmeterol in separate inhalers. Advair has been available in the United States for seven years, since the year 2000. It

is the only product containing both the inhaled corticosteroid and the long acting Beta-Agonist, which is indicated down to the age of four years for the treatment of asthma. It is also the only combination medication with the indication of COPD associated with chronic bronchitis. We have talked about the GOLD guideline. GOLD recommends adding an inhaled corticosteroid for patients whose FEV1's is less than 50% and has repeated exacerbations. This makes it the only combination product containing steroid approved for this use. It is also the only combination available in both the metered dose inhaler and an easy to use breath actuated discus device, which does not require a spacer contains a dose counter. The reason why a dose counter is important is that it allows patients to see how much drug remains in the device and this improves compliance and prevents the patient from running out of medication. Advair Discus and HFA are also available in three strengths, which allows for maximum flexibility for the clinician to adjust the dose to the individual's response. In conclusion, treatment of both the inflammation and bronchoconstruction associated with both asthma and COPD are important and advocated in national guidelines. Based on the data, the recommendations of the guidelines and the fact that Advair has the most indications, dosage form strengths and a dose counter, Medicaid patients are best served if Advair Discus and HFA are available to patients of the State of Idaho without restriction. Thank you so much for your time. Are there any questions?

Dr. Gene Petty (call-in)

This is Dr. Petty in Idaho Falls. I do Allergy, Asthma and Immunology and I just want to make a plug for Advair and its effectiveness and a plea to consider making it preferred and not require a prior authorization. I have a very busy practice and I would guess 20% or 25% of that practice is Medicaid. When I can get a Medicaid patient on Advair, I get better compliance. I have not had to hospitalize any asthmatic that is on Advair and I heard somebody say that we are not supposed to talk cost, but I am guessing that this is really what this meeting is all about, trying to keep cost effective. The issue of compliance is when you combine a long acting Beta-Agonist with an inhaled corticosteroid, we finally started seeing improvements in the long-term control and even decreasing the mortality rate for asthma. I am so passionate about it that I jump through all the hoops to keep my patients on it and get it preauthorized, but my concern is that the primary care physician, who is maybe even busier than me, doesn't have or take as much time with their patients, certainly isn't going to take the time to jump through the hoops and prior authorize the medication that may be the best for a given patient. So I would ask the committee to seriously consider changing the preauthorization for Advair and to make it more easily accessible for all the physicians, I think it would, in the long run, significantly decrease the cost involved in care for asthmatics. Another little sideline, I had a patient yesterday who is an 11 year old and the mom says that he just refused to take the Patenol eye drops that I had prescribed. I said, well there is a new nose spray that has indications for ocular symptoms, would you consider a nose spray? I was surprise that an 11 year old said that he would rather take a nose spray than an eye drop, so we gave him a handful of Veramyst and it will be interesting to see if that makes a difference. But I have had a couple of patients comment on that already that they are getting relief from not only nasal congestion but from the eye symptoms. The other comment that I have is I can not hear very well, the speakers that are there. I don't know if any thing can be done, but I have been interested in the comments that have been made, but it is hard to hear what the other speakers are saying. That is all I have to say, thank you for your time.