

Pharmacy and Therapeutics Committee Meeting Record

Date: 7/18/08 **Time:** 9:00 a.m. – 3:00 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, M.D.-Chair; Stan Eisele, M.D.; Catherine Hitt, PharmD; Michelle Miles, PA-C; Rick Sutton, RPh; Tim Rambur, PharmD; Mark Johnston, RPh; William Woodhouse, M.D.; Donald Norris, M.D.; Tami Eide, PharmD;

Others Present: Steve Liles, PharmD; Bob Faller; Rachel Strutton

Committee Members Absent: Andrew Olnes, M.D.; Dennis Tofteland, RPh

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Dr. Donald Norris	Dr. Norris called the meeting to order.
Committee Business		
➤ <i>Announcements</i>	Donald Norris, M.D.	Dr. Norris announced his move to Pennsylvania and recognized Dr. Petersen in his new role as Committee Chair. Dr. Eide announced newly updated guidelines for the P&T Committee. Those updates will be posted on the Website http://www.healthandwelfare.idaho.gov/site/3551/default.aspx and will be available for discussion and approval by the Committee at the August 15, 2008 P&T meeting.
➤ <i>Roll Call</i>	Phil Petersen, M.D.	Dr. Petersen read the Roll Call and welcomed Catherine Hitt, PharmD as a new member to the P&T Committee.
➤ <i>Reading of Confidentiality Statement</i>	Phil Petersen, M.D.	Dr. Petersen read the Confidentiality Statement
➤ <i>Approval of Minutes from January 18, 2008 Meeting</i>	Phil Petersen, M.D.	There were no corrections. Minutes were approved as proposed.
➤ <i>Key Questions</i>	Tami Eide, PharmD	Dr. Eide presented the following Key Questions from the Drug Effectiveness Review Project: <u>Agents for overactive bladder</u> <u>Targeted Immune Modulators</u>

<p>➤ <i>Anticonvulsants Update</i></p>	<p>Tami Eide, PharmD</p>	<p><u>Newer Antiemetics</u> <u>Triptans</u> <u>Antiepileptic drugs for non-epilepsy conditions</u></p> <p><i>Anticonvulsants Update</i> Dr. Eide shared a power-point presentation describing the Department's evidence-based process using the implementation of therapeutic guidelines for anticonvulsants as an example. Included were usage and outcome studies and expenditure trends prior to and after implementation of therapeutic guidelines.</p>
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<p>Public Comment Period</p>	<p>Phil Petersen, M.D. Bob Faller, Medical Program Specialist</p>	<p>Twelve (12) people signed up to speak during the public comment period. Public comment was received from the following speakers:</p> <table border="1"> <thead> <tr> <th>Speaker</th> <th>Representing</th> <th>Agent</th> <th>Class</th> </tr> </thead> <tbody> <tr> <td>Chris Johnson</td> <td>Self</td> <td>Levaquin</td> <td>Fluoroquinolones, Oral</td> </tr> <tr> <td>Randy Legg</td> <td>AstraZeneca</td> <td>Rhinocort Aqua</td> <td>Intranasal Rhinitis Agents</td> </tr> <tr> <td>Randy Legg</td> <td>AstraZeneca</td> <td>Pulmicort Respules</td> <td>Glucocorticoids, Inhaled</td> </tr> <tr> <td>Randy Legg</td> <td>AstraZeneca</td> <td>Symbicort</td> <td>Glucocorticoids, Inhaled</td> </tr> <tr> <td>Dan Manning</td> <td>Schering Plough</td> <td>Nasonex</td> <td>Intranasal Rhinitis Agents</td> </tr> <tr> <td>Dan Manning</td> <td>Schering Plough</td> <td>Asmanex</td> <td>Glucocorticoids, Inhaled</td> </tr> <tr> <td>Adam Shprechur</td> <td>Schering Plough</td> <td>moxifloxacin</td> <td>Fluoroquinolones, Oral</td> </tr> <tr> <td>Karen Lewis</td> <td>Novo Nordisk</td> <td>Insulin Analogs</td> <td>Hypoglycemics, insulin and related agents</td> </tr> <tr> <td>Perry Johnson</td> <td>Graceway Pharmaceuticals</td> <td>Maxair auto-haler</td> <td>Bronchodilators, Beta Agonist</td> </tr> <tr> <td>Deb Criss</td> <td>Merck</td> <td>Singulair</td> <td>Leukotriene Modifiers</td> </tr> <tr> <td>Meredith Zarling</td> <td>GlaxoSmithKline</td> <td>Advair</td> <td>Glucocorticoids, Inhaled</td> </tr> <tr> <td>Meredith Zarling</td> <td>GlaxoSmithKline</td> <td>Veramyst</td> <td>Intranasal Rhinitis Agents</td> </tr> <tr> <td>Jesse Hong</td> <td>Amylin</td> <td>Byetta & Symlin</td> <td>Hypoglycemics, Incretin Mimetics & Enhancers</td> </tr> <tr> <td>Laura Litzenberger</td> <td>Ortho McNeil Pharmaceuticals</td> <td>Levaquin</td> <td>Fluoroquinolones, Oral</td> </tr> <tr> <td>Rhaliene Patojo</td> <td>Boehringer Ingelheim</td> <td>Spiriva</td> <td>Bronchodilators, Anticholinergic</td> </tr> <tr> <td>Glen Ingrum</td> <td>Merck</td> <td>Januvia</td> <td>Hypoglycemics, Incretin Mimetics & Enhancers</td> </tr> <tr> <td>Glen Ingrum</td> <td>Merck</td> <td>Janumet</td> <td>Hypoglycemics, Incretin Mimetics & Enhancers</td> </tr> </tbody> </table>	Speaker	Representing	Agent	Class	Chris Johnson	Self	Levaquin	Fluoroquinolones, Oral	Randy Legg	AstraZeneca	Rhinocort Aqua	Intranasal Rhinitis Agents	Randy Legg	AstraZeneca	Pulmicort Respules	Glucocorticoids, Inhaled	Randy Legg	AstraZeneca	Symbicort	Glucocorticoids, Inhaled	Dan Manning	Schering Plough	Nasonex	Intranasal Rhinitis Agents	Dan Manning	Schering Plough	Asmanex	Glucocorticoids, Inhaled	Adam Shprechur	Schering Plough	moxifloxacin	Fluoroquinolones, Oral	Karen Lewis	Novo Nordisk	Insulin Analogs	Hypoglycemics, insulin and related agents	Perry Johnson	Graceway Pharmaceuticals	Maxair auto-haler	Bronchodilators, Beta Agonist	Deb Criss	Merck	Singulair	Leukotriene Modifiers	Meredith Zarling	GlaxoSmithKline	Advair	Glucocorticoids, Inhaled	Meredith Zarling	GlaxoSmithKline	Veramyst	Intranasal Rhinitis Agents	Jesse Hong	Amylin	Byetta & Symlin	Hypoglycemics, Incretin Mimetics & Enhancers	Laura Litzenberger	Ortho McNeil Pharmaceuticals	Levaquin	Fluoroquinolones, Oral	Rhaliene Patojo	Boehringer Ingelheim	Spiriva	Bronchodilators, Anticholinergic	Glen Ingrum	Merck	Januvia	Hypoglycemics, Incretin Mimetics & Enhancers	Glen Ingrum	Merck	Janumet	Hypoglycemics, Incretin Mimetics & Enhancers
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Drug Class Reviews and Committee Recommendations		
<ul style="list-style-type: none"> ➤ Antiparasitics, Topical 	Steve Liles, PharmD	<p><u>Antiparasitics, Topical</u> This is the first review of this class. Dr. Liles provided an overview of the (4) products including their indications, adverse effects, dosage/administration and contraindications/warnings within this drug class. The Committee reviewed five (5) clinical trials, one (1) systematic Cochrane review and guidelines for head lice, crab lice and scabies.</p> <p>Committee Recommendations The Committee felt there was not clinical evidence to support any one product as superior. The Committee recommended lindane be designated as non-preferred because of toxicities. The Committee also recommended that the DUR Program provide education on drug efficacy and potential toxicities as well as Medicaid coverage of over the counters (OTCs).</p>
<ul style="list-style-type: none"> ➤ Antibiotics, Vaginal 	Steve Liles, PharmD	<p><u>Antibiotics, Vaginal</u> This is the first review of this class. Dr. Liles provided an overview of the four (4) products in this class including indications, adverse effects, dosage, administration and pregnancy implications. Two (2) clinical trials were reviewed.</p> <p>Committee Recommendations The Committee felt there was no clinical evidence to support either restrictions or inclusion of any one product. The Committee recommended that there be at least on clinidamycina and one metronidazole product available on the PDL.</p>
<ul style="list-style-type: none"> ➤ Antivirals, Topical 	Steve Liles, PharmD	<p><u>Antivirals, Topical</u> This is the first review of this class. Dr. Liles provided an overview of the three (3) products in this class including indications, adverse effects, dosage and administration. One (1) clinical trial was reviewed.</p> <p>Committee Recommendations The Committee concluded that the evidence does not support restriction or inclusion of any specific product..</p>

<p>Drug Class Reviews and Committee Recommendations continued</p> <p>➤ Antifungals, Topical</p> <p>➤ Antifungals, Oral</p> <p>➤ Antivirals, Oral</p> <p>Infectious Disease Guideline Update</p>	<p>Steve Liles, PharmD</p> <p>Steve Liles, PharmD</p> <p>Steve Liles, PharmD</p> <p>Steve Liles, PharmD</p>	<p><u>Antifungals, Topical</u> This class was last reviewed August 2007. Dr. Liles provided information on three new products for this drug class including a generic form of Penlac and a ketoconazole foam. He also shared the results of a systematic Cochrane review.</p> <p>Committee Recommendations There is no new significant evidence to support any changes to the PDL. The Committee recommendation is to include the addition of OTC topical products to the PDL if there are comparable costs.</p> <p><u>Antifungals, Oral</u> This class was last reviewed August of 2007. Dr. Liles provided clinical information on two (2) new products for this class including generic terbinafine and a terbinafine granule formulation for tinea capitis in children. He also presented an updated study of voriconazole adverse effects.</p> <p>Committee Recommendations The Committee recommendation is to consider the addition of generic terbinafine to the preferred drug list if cost is comparable.</p> <p><u>Antivirals, Oral</u> This class was last reviewed August 2007. It was noted there is sporadic availability of famciclovir. Dr. Liles presented data from three (3) clinical trials, one (1) Meta-Analysis on genital herpes suppression and the May 2008 Advisory Committee on Immunization Practice guidelines on prevention of Herpes Zoster and Zoster vaccine.</p> <p>Committee Recommendations The Committee felt that there was no new significant evidence to support inclusions or restrictions to the current PDL for the anti-herpetic agents. The Committee recommended to make no changes to the antiinfluenza PDL at this time.</p> <p><u>Infectious Disease Guideline Update</u> Prior to discussing the various antibiotic classes, Dr. Liles provided updates of the Community Acquired Pneumonia, Gonorrhea and uncomplicated Urinary Tract Infections (UTI) in non-pregnant women guidelines.</p>
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<p>➤ Cephalosporins & related antibiotics</p>	<p>Steve Liles, PharmD</p>	<p><u>Cephalosporins & related antibiotics</u> This class of drugs was last reviewed August 2007. Dr. Liles stated that generic cefdinir is now available. He presented an update to the FDA safety labeling on the risks of <i>c.difficile</i> associated diarrhea. The Committee reviewed a new clinical trial on acute otitis media a Meta-Analysis on <i>Group A beta-hemolytic streptococcal</i> tonsillopharaginitis. It was also noted Suprax tablets have been reintroduced since cefixime tablets are the only pill formulation recommended by the CDC for uncomplicated gonorrhoea.</p> <p>Committee Recommendations The Committee concluded that there was no clinical reason to change the current PDL. They recommended adding the new generic formulations if cost advantageous. They felt there should be at least one product from each generation and that Suprax tablets should be included.</p>
<p>➤ Fluoroquinolones, Oral</p>	<p>Steve Liles, PharmD</p>	<p><u>Fluoroquinolones, Oral</u> This drug class was last reviewed August 2007. Generic ciprofloxacin extended release is the only new product for this class. There is also a new indication for ciprofloxacin for complicated UTI and pyelonephritis in children one (1) year and older. The Committee reviewed safety updates for this class and one (1) new clinical trial.</p> <p>Committee Recommendations The Committee had no recommendation for removal of any agents from the current PDL and felt the Department should consider generic ciprofloxacin extended release for addition to the preferred drug list. They also felt it was not necessary to continue the same antibiotic at discharge that was administered during an inpatient stay. They did not feel this was a compelling reason to place an agent on the preferred list.</p>
<p>➤ Macrolides and Ketolides</p>	<p>Steve Liles, PharmD</p>	<p><u>Macrolides and Ketolides</u> This drug class was last reviewed August 2007. The only new drug is extended release clarithromycin. Dr. Liles presented a safety update and FDA labeling changes and one (1) new clinical trial on PID treatment.</p> <p>Committee Recommendations The Committee recommendation is to consider the generic form of clarithromycin extended release for inclusion on the PDL. No other changes were recommended at this time.</p>
<p>Diabetes Guideline Update</p>	<p>Steve Liles, PharmD</p>	<p><u>Diabetes Guideline Update</u> Prior to discussion of the drug classes used in Diabetes, Dr. Liles reviewed the AACE 2007 Guidelines for Type 2 Diabetes mellitus.</p>

<p>➤ Hypoglycemics, Insulin and Related Agents</p>	<p>Steve Liles, PharmD</p>	<p><u>Hypoglycemics, Insulin and Related Agents</u> This drug class was last reviewed April 2007. Dr. Liles shared FDA labeling changes for this drug class. The Committee reviewed three (3) clinical trials for type 1 diabetes and eight (8) clinical trials for type 2.</p> <p>Committee Recommendations The Committee felt there was no new significant evidence to support clinical inclusions or exclusions of any products to the PDL. They felt it would be necessary to maintain Lantus and Humalog as preferred because of current utilization patterns.</p>
<p>➤ Hypoglycemics, Incretin Mimetics & Enhancers</p>	<p>Steve Liles, PharmD</p>	<p><u>Hypoglycemics, Incretin Mimetics & Enhancers</u> This drug class was last reviewed April 2007. Dr. Liles shared FDA labeling changes for this drug class as well as one (1) new product (Pramlintide pens) in this class. The Committee reviewed seven (7) new clinical trials.</p> <p>Committee Recommendations The Committee did not feel there was evidence supporting a change for the current PDL or guidelines. They felt clinically Januvia should not be used first line over those agents with demonstrated outcomes.</p>
<p>➤ Ophthalmics for Allergic Conjunctivitis</p>	<p>Steve Liles, PharmD</p>	<p><u>Ophthalmics for Allergic Conjunctivitis</u> This drug class was last reviewed June 2007. Dr. Liles shared one (1) new product in this drug class, ketotifen 0.025% solution which is OTC. The Committee reviewed two (2) new clinical trials.</p> <p>Committee Recommendations The Committee felt there was no new significant evidence to support any changes at this time.</p>
<p>➤ Intranasal Rhinitis Agents</p>	<p>Steve Liles, PharmD</p>	<p><u>Intranasal Rhinitis Agents</u> This drug class was last reviewed June 2007. Dr. Liles shared five (5) new products including Omnaris, Veramyst, generic flunisolide, generic fluticasone and Pantanase. Also reviewed were the adverse effects and dosage for both steroid and antihistamines products. The Committee reviewed six (6) new clinical trials.</p> <p>Committee Recommendations The Committee recommendation is to consider adding the generic formulations of flunisolide and fluticasone to the PDL. The Committee recommended no other changes to the PDL at this time.</p>

<p>Respiratory Disease Guidelines Update</p> <ul style="list-style-type: none"> ➤ Leukotriene Modifiers ➤ Bronchodilators, Beta Agonist ➤ Glucocorticoids, Inhaled ➤ Bronchodilators, Anticholinergic 	<p>Steve Liles, PharmD</p> <p>Steve Liles, PharmD</p>	<p><u>Respiratory Disease Guidelines Update</u> Prior to the review of the respiratory classes, Dr. Liles shared the NAEPP (National Asthma Education and Prevention Program) 2007 guideline, update for asthma and the ACP (American College of Physicians) practice guidelines for COPD.</p> <p><u>Leukotriene Modifiers</u> This drug class was last reviewed in June 2007. Dr. Liles presented information on the new product, Zyflo CR which replaces Zyflo. He also presented a new indication for monteleukast use in exercise induced broncospasm. The Committee reviewed one (1) new clinical trial.</p> <p>Committee Recommendations The Committee felt there was no new significant evidence to support any changes at this time.</p> <p><u>Bronchodilators, Beta Agonists</u> This drug class was last reviewed June 2007. Dr. Liles provided information on two new long acting products, Brovana (arformoterol) and Performist (formoterol). The Committee reviewed one (1) new clinical trial and one (1) systematic review.</p> <p>Committee Recommendations The Committee recommendation is for inclusion of a long-acting inhaler to the PDL, however there is no preference as to which long-acting product. The Committee felt there was no new significant evidence to support any changes to the short-acting products on the PDL. The Committee recommends a long-acting inhalation solution be added to the inhalation solution PDL. No changes to the oral products PDL were recommended.</p> <p><u>Glucocorticoids, Inhaled</u> This drug class was last reviewed June 2007. Dr. Liles shared an updated FDA Labeling for Advair in COPD. The Committee reviewed one (1) clinical trial and (1) Meta-Analysis.</p> <p>Committee Recommendations The Committee felt there was no new significant evidence to support any changes to the PDL. They felt there was no reason clinically to differentiate the combination products and the clinical criteria should be continued for both products.</p> <p><u>Bronchodilators, Anticholinergic</u> This drug class was last reviewed June 2007. Dr. Liles shared the availability of a generic albuterol/ipratropium solution. He presented information on the ongoing safety review of tiotropium and stroke risk.</p>
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		<p>Committee Recommendations The Committee felt that there was no new significant evidence to support any changes to the PDL. They felt there was no need for either the generic or albuterol/ipratropium combination unless there was a cost advantage over using the separate products.</p>
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**Pharmacy and Therapeutics Committee
Public Comment
July 18, 2008**

Chris Johnson

I'm Chris Johnson, I'm a PharmD and infectious disease trained. I moved into retail because I have six kids and need the money. My comment right now is based on fluoroquinolones. I came here last time where the change in the fluoroquinolone status, I believe a floxacin was requested, and the P&T committee did do that and I'd like to thank you very much. It's been a big help in the retail environment as far as continuation of care, especially in our customers in our pharmacy. We've seen quite a few, since we're a 24-hour store, and I speak for all the retail pharmacists out there, is that prior authorizations are a headache. They are very difficult to get through sometimes and Medicaid has made it much easier lately as far as decisions made on the P&T committee and the system that Tami has mentioned where it goes through that little box and bounces out of, and authorization has been very helpful for us, so I'd just like to thank the P&T committee for that and to request that they maintain the current formulary as it is for the fluoroquinolones, and that's my comment. Thank you.

Randy Legg

Good morning. I'm Randy Legg, I'm a PharmD from Spokane and I work for AstraZeneca and actually I have four products and I'll try to do them in about a minute and a half if that's all right. Can you hear me okay? All right. The first one is Rhinocort Aqua and that's our drug for rhinitis. It's a nasal spray. It's a water based product, there's no scent, it has no alcohol, the lowest volume in a spray, and like budesonide, it's the only category-B FDA pregnancy related product that's available.

Number two is Pulmicort respules. It's a nebulizer product, budesonide for the nebulizer. It's the only ICS available currently for a nebulizer. It's for asthma, age one year to eight years of age for children with asthma. It comes in a 0.25 mg, a 0.5 mg, and a 1 mg ampule for nebulizer, and as well is a category-B inhaled corticosteroid.

Our third product is Pulmicort Flexhaler, and that was launched last year. It's a reformulated version of Pulmicort Turbuhaler. The dosage size dropped down to 120 puffs. There are two strengths; there's a 160 µg and an 80 µg. It's b.i.d. dosing for asthma age six and above, and again it's the only category-B inhaled corticosteroid available in the United States.

The last product is Symbicort, that was launched last year as well. That's a combination product of budesonide and formoterol. Formoterol is a long-acting β_2 agonist. It's an HFA product, a metered dose inhaler, age twelve and above for asthma, for those patients who aren't currently controlled on inhaled steroids alone. In June, we filed an SMDA for a COPD indication and in April we just filed for age six and above for asthma, an SMDA. This month, there will be a counter added to that Symbicort canister and that should be in the pharmacies probably in a couple of months, and we just completed a one-year, double dose trial of 160/4.5 μg strength double dose for a year to look for side effects, and we're happy to report that there were no increased side effects of that versus the label dose of Symbicort. It's available in two strengths; there's a 160 μg budesonide and 4.5 μg formoterol and then an 80 μg budesonide and 4.5 μg formoterol, two puffs b.i.d. for asthma.

Any questions for me on the AstraZeneca respiratory line? Thanks.

Dan Manning

Good morning, my name is Dan Manning, I'm a PharmD with Schering Plough's global medical affairs, and I'm here to talk about two products out of our Respiratory Allergy Division. The first product being Nasonex, which is mometasone furoate. It is a nasal spray, it is scent free, alcohol free, and Nasonex has a broad range of indications, including it's indicated down to two years of age, which is one of the lowest in this class. It is the only nasal steroid approved for the prophylaxis of seasonal allergic rhinitis. It is the only nasal steroid approved for nasal polyps. Studies have known no HV axis or gross impression in pediatric and adult patients, and it has a systemic bio-availability of <0.1%.

The second product I'm going to talk about is Asmanex Twisthaler, which is mometasone furoate too. Asmanex, which is a high-potency steroid is the FDA approved inhaled corticosteroid approved for once-daily dosing. Asmanex is now approved down to four years of age, which was as recent as of March of 2008, and it's available in two strengths, which is the 110 μg dose and the 220 μg dose, and both of those are approved for once-daily dosing. Asmanex offers a proven safety profile and Asmanex as a device is a dry powder inhaler, so unlike the MDIs, it does not require hand-eye coordination for the patient. It also has a dose counter on it, which lets the patient know how many doses are left, so each time that you use the inhaler, it counts down by one and when it hits zero, it locks up. So Schering Plough would like to ask the Idaho Medicaid Board to maintain the status of Asmanex and Nasonex on the formulary list. Thank you. Any questions?

Adam Shprechur

Hi, my name's Adam Shprechur and I'm a pharmacist working with Medical Affairs at Schering Plough. Thank you for considering Avelox (moxifloxacin) for continued coverage under the Idaho Medicaid system. Moxifloxacin is a broad-spectrum fluoroquinolone that is especially known for its excellent gram-positive activity, and all indications at a 400 mg dose in the United States for patients greater than eighteen years of age including acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, community-acquired pneumonia (including multi-drug-resistant *Streptococcus pneumoniae*), uncomplicated and complicated skin and skin structure infections, and complicated intra-abdominal infections. Moxifloxacin is the only fluoroquinolone approved as a monotherapy to treat complicated intra-abdominal infections, and in the community-acquired pneumonia in the elderly trial, dubbed CapRI, Avelox therapy was efficacious and safe for hospitalized elderly patients, achieving a >90% cure in all severity in age groups and was associated with a faster clinical recovery than Levaquin therapy with a comparable safety profile, and that was published in CID by Anzueto & Colleagues. In a second publication generated from the CapRI study by Morgenroth & Colleagues demonstrated that Avelox had a comparable cardiac rhythm safety profile to

Levaquin in high-risk elderly patients with community-acquired pneumonia. In 2007, the IDSA and the American Thoracic Society convened a joint committee to develop a unified CAP consensus guideline to update physicians regarding advances in the management of CAP, including decreased mortality, improving patient care, and preserving antibiotic susceptibilities. Respiratory fluoroquinolones such as moxifloxacin is strongly recommended for the treatment of outpatients with comorbidities, in non-ICU patients, and for use in combination with a β -lactam for treatment in ICU patients and when discussing resistance to *Streptococcus pneumoniae*, the guideline states “Data exists suggesting that resistance to macrolides and older fluoroquinolones, such as ciprofloxacin and levofloxacin, results in clinical failure, and to date, no failures have been reported with newer fluoroquinolones, such as moxifloxacin and gemifloxacin”. The second quote I read from the guidelines is “Although increasing the doses of certain agents, such as penicillin, cephalosporins, or levofloxacin, may lead to adequate outcomes in the majority of cases, switching to more potent agents may lead to stabilization or even an overall decrease in resistance rates”. Avelox is not approved for treating urinary tract infections or infectious due to *Pseudomonas*. When a fluoroquinolone is used for these infections, generic ciprofloxacin is available and continues to be the most active agent for *Pseudomonas* and common UTI pathogens, and is associated with a lower potential for producing *Pseudomonas* resistance. In a retrospective case control study in patients in a large teaching hospital by Kaye & Colleagues, a multivariate analysis demonstrated use of levofloxacin was associated with an increased risk of isolation of fluoroquinolone-resistant *Pseudomonas aeruginosa* while in comparison, exposure to the ciprofloxacin was not associated with an increased risk. I thank you for your time and thank you for considering moxifloxacin for its current status on the PDL. Any questions?

Question: Could you comment on the recent data of all the fluoroquinolones? I think some other folks are going to be talking the other fluoroquinolones with regards to the tendon rupture risk.

Answer: There is a recent update from the FDA and there are going to be some changes to the safety profile black box warning, essentially for all of the fluoroquinolones as a class. We have known for a long time that fluoroquinolones carry a risk of tendon rupture and Avelox is similar to other fluoroquinolones in terms of incidence, and it will have that same warning as the other fluoroquinolones when the FDA makes that change to the PI. Thank you.

Karen Lewis

I'm Karen Lewis. I am Medical Scientific Liaison for diabetes for Novo Nordisk, a Nurse Practitioner, and a CDE. I am presenting today, our new modern insulin analogs, of which Novo Nordisk has three. The reason for the change from insulin therapy from human insulins to analog insulins is our goal to try to provide insulin therapy in a more physiological way. The new analogs provide us that opportunity. The three that Novo Nordisk has are Levemir or insulin detemir which is a long-acting basal insulin analog. It is indicated for once or twice a day, which is an advantage in children or young adults who have type-1 diabetes who have variant insulin basal requirements. What we have found in all our registration trials with Levemir is that there is less variability which means that from injection to injection, you can expect similar glycemic response. That means that it's easier to adjust insulin and there's less hypoglycemia, and in all of our registration trials, we have found that there is less weight gain with using Levemir insulin. With the Cline study, the profile is similar to that of insulin glargine when compared to time-action curves. Our rapid-acting insulin analog is insulin NovoLog. It is approved for patients using insulin, requiring insulin in both adult and pediatric patients, it is approved for pump therapy, it is also now with a new category-B for pregnancy, and it is a rapid-acting analog that can be used to support mealtime insulin requirements, and one of the goals of new therapy for diabetes is not only to treat the fasting blood glucoses, but also the mealtime blood glucoses, which are often associated with some inflammation and vascular changes which could be associated with complications of diabetes. Our last, using insulin aspart is NovoLog mix 70/30 insulin. This is a new type of mix insulin that has no NPH in it. It has rapid-acting insulin NovoLog with a protamine added to it which provides both basal and bolus requirements for those patients

who do not require multiple daily dosing in the form of basal and bolus insulin. NovoLog mix 70/30 analog has been shown to have less hypoglycemia than the human mix and has been shown that it is safe to give once, twice, or three times per day to provide both basal and bolus needs for those patients who doing multiple daily doses with two kinds of insulin might be too involved. Thank you very much.

Question: You said in the beginning that with your Kevemir there was less hypoglycemia and less variability is that correct?

Answer: Yes, the HIC study shows less variability. All long-acting basal insulins have shown less hypoglycemia over the standard NPH which has, in the past, been used for basal. In our clinical studies, there's less hypoglycemia, and one of them would be Hermison to refer to.

Question: We weren't comparing to other long-acting insulins?

Answer: Less hypoglycemia in respect to the other long-acting basal insulin which is L-Argine is similar in most of the studies. The difference is definitely weight when you compare the two insulins.

Perry Johnson

Good morning, I'm Perry Johnson, I'm with Graceway Pharmaceuticals. I'm from Olatha, Kansas, where Bob used to live, so he's very familiar with that. I wanted to just give you a really quick update on one of the rescue, short-acting, β_2 s that you're reviewing today. Ours is Maxair Autohaler, the generic is pirbuterol acetate. It is unique in this category. It is reviewed by DERP, so I won't go into any of the clinical information, but I just wanted you to know that it is unique in two ways, actually. It is a unique molecule, so it's an alternative to the albuterol products, plus it has breath actuation, so patients who are not able to use their present breathe inhaler adequately are able to actuate it by just taking a deep breath, and it doesn't require a spacer, which is an advantage to some people as well. It also has 400 doses, which is usually twice the amount that are in most of the other inhalers, and it is approved for twelve and above. It is a CFC-containing, short-acting β_2 inhaler, but it's a different molecule and since it is pirbuterol, we are not under the same mandate as albuterol as far as removing the CFCs by the end of this year. We know that Maxair Autohaler will be on the market in its present form through the end of 2009 and we've applied for additional time to get an alternative propellant as well, and we would ask that you consider retaining Maxair Autohaler on your PDL. Any questions anyone? Thank you.

Deb Criss

Good morning, I'm Deb Criss, and I'm a nurse practitioner. I've been employed by Merck Human Health for the past twenty years and my current position is Health Science Consultant in the Respiratory Division, and I'm here today in support of Singulair, a leukotriene receptor antagonist. So asthma as we know, is a complex and variable disease, and we're fortunate to have many therapeutic choices to manage asthma. However, despite these many choices, we know that many patients are not controlled. Today, we have no "one-size-fits-all" to manage asthma. Now the NAEPP guidelines, the new EPR-3 guidelines, acknowledges this variability to response of therapies and in addition, they recognize that patient preference may affect treatment adherence and, finally, they recognize that certainly there is variability in a patient's ability to tolerate certain medications. So Singulair is listed as an alternative asthma controller medication for the treatment of mild, persistent asthma and moderate asthma, as monotherapy or as add-on therapy to inhaled corticosteroid. Singulair has been prescribed to millions of patients worldwide for the past ten years. Its efficacy in the treatment of asthma in both adults and children has been documented in numerous clinical trials. We know that reduction in symptoms and improvement in lung function occurs on day-1 with the first dose, and that tolerability has not been seen, and also rebound has not occurred when the drug is discontinued. Singulair recently received a new indication, and that is for exercise-induced bronchoconstriction in adults fifteen years of age and older. A single 10 mg tablet given two hours prior to exercise challenge resulted in a reduction, or I should say benefit, in protecting the patient against a reduction in FEV-1, and that was at two hours post dose. Singulair is

indicated for the relief of allergic rhinitis and the symptoms associated with it, and we know that the toll on the quality of life, loss of school attendance, loss at work, due to these symptoms, has been well documented due to allergic rhinitis symptoms and just as in asthma, we know that there's no one medication that's the magic bullet to treat those symptoms. So therefore, if a patient has not had control of their symptoms using over-the-counter medications, Singulair may be an appropriate option. Placebo- and active-controlled clinical trials conducted with Singulair have demonstrated it to be very effective in reducing nasal symptoms, such as runny nose, as I touch my nose, nasal congestion, and sneezing. Singulair is indicated for the reduction of symptoms associated with perennial allergic rhinitis in children six months of age and older, and for seasonal allergic rhinitis in two years of age and older. In placebo-controlled clinical trials, the overall incidents of side effects with Singulair have been similar to placebo. The side effects have varied by age and in general include headache, otitis media, sore throat, and upper respiratory infection. The frequency of somnolence has been similar to placebo. So as a reminder, Singulair is available in a 10 mg tablet for patients fifteen years of age and older, 5 mg chewable tablet for patients that are 6-14 years of age, and a 4 mg chewable tablet or 4 mg granule packet for kids who are 2-5 years of age, and finally a 4 mg granule packet for kids that are 6 months to 23 months of age. So in summary, patients who have asthma and/or allergic rhinitis have heterogeneous responses to treatment and, in addition, because of patient preference, this can affect treatment adherence. Finally, patients differ in their ability to tolerate medications, so that's individualizing management of these diseases, tantamount to disease management excellence. So individualized treatments require multiple drug options. So I ask you to please continue the availability of Singulair for the prevention and treatment of asthma, for the prevention of exercise-induced bronchoconstriction, and for the relief of symptoms associated with allergic rhinitis. I thank you for the opportunity to present today. Questions for me?

Question: We frequently get requests for Singulair 10 mg twice a day- is there an indication or data supporting that?

Answer: There's no indication for Singulair twice daily. It's recommended once daily, and I don't know what they're planning to do with that, what they're planning to treat, but in asthma the trial showed that there was no additional benefit in relieving asthma or improving lung function when you go past 10 mg once daily. Any other questions? Thank you.

Meredith Zarling

Good morning and thank you for the opportunity to speak to you today. I have two drugs I'm going to talk about; Advair diskus and HFA and Veramyst. My name is Meredith Zarling and I'm a pharmacist, as well as a Regional Medical Scientist for GlaxoSmithKline. I'd like to present to you, information in support of having Advair and Veramyst on the Idaho Preferred Drug List without restriction, so first I'm going to talk about Advair. The National Heart, Lung & Blood Institute panel of experts which has been referred to previously, after careful review of the literature, issued very clearly defined guidelines last year on the management of asthma. According to the guidelines, patients not on a controller already, should be assessed as to severity of disease and then managed based on that severity, so for patients greater than twelve years of age with a severity cost of mild, persistent asthma, the preferred treatment is low-dose inhaled corticosteroids. However, patients who meet the criteria for moderate asthma, it is recommended that the patients initiate therapy at step-3, which the preferred therapies are low-dose inhaled corticosteroid plus a long-acting β agonist, or a medium dose of inhaled corticosteroids. Now for patients who have severe asthma, these patients should initiate therapy at step-4 or -5, which the preferred therapy is medium or high-dose inhaled corticosteroid plus a long-acting β agonist combination, and if you look further into the evidence in the text of the NIH guidelines, it clearly shows superiority of combination therapy over monotherapy with an inhaled corticosteroid for patients with moderate to severe asthma. Advair is the only combination product in the US approved for COPD associated with chronic bronchitis and/or emphysema, which is a new indication. Advair also has another new indication for the reduction of exacerbations in patients with COPD who have a history of exacerbations. Unlike other combination products, Advair has been available in the US for seven years, so it has a proven record of safety. It's the only product containing both an inhaled corticosteroid and a

long-acting β agonist that's indicated down to the age of four years for treatment of asthma. It's also the only combination product available in both a metered-dose inhaler and an easy-to-use diskus device which contains a dose counter. In conclusion, treatment of the inflammation and bronchoconstriction associated with both asthma and COPD are important and advocated in national guidelines. Based on the data and the recommendations of the guidelines, Medicaid patients in Idaho are best served if Advair diskus and HFA are placed on the Idaho Medicaid PDL without restriction.

Next, I would like to just quickly review with you, Veramyst. Veramyst is a nasal steroid that's indicated for the treatment of the symptoms of both seasonal and perennial allergic rhinitis for patients two years of age and older, and it's one of only two products on the market that are indicated down to the age of two. It's administered once a day and offers a flexible dosing option based on the patient's symptom control. It is a unique corticosteroid molecule, has a very high binding affinity to the human glucocorticoid receptor, with 1.7 times more binding affinity than fluticasone propionate. Veramyst is the only nasal steroid proven to help relieve not only all four nasal symptoms such as congestion, rhinorrhea, itching and sneezing, but also proven in five prospectively designed and replicated studies to help relieve ocular symptoms of seasonal allergic rhinitis such as itching, burning, tearing, watering and redness in patients twelve years and older with seasonal allergic rhinitis. There's also head-to-head data in two studies with patients twelve years of age and older with seasonal allergic rhinitis with fexofenadine, which showed superior relief of all four nasal symptoms and comparable relief for all three ocular symptoms that I just described. Adverse events of clinical trials were similar to those seen with other nasal steroids and were comparable to placebo. The device with Veramyst is an important attribute of this product. The device is innovative and designed based on feedback from not only patients, but also physicians. It has a side actuator, which releases a consistent dose of low volume mist, half that of Flonase, and this decreases the amount of product that runs down the patient's throat. It also has a shorter nozzle, has no scent, and has no alcohol. In summary, Veramyst is approved down to the age of two years of age for both seasonal and perennial allergic rhinitis. It's the only nasal steroid on the market with proven ocular symptom improvement in five prospectively designed replicated studies and is available in a unique nasal delivery system. Based on these advantages, I'd like to ask the Committee to recommend that Veramyst be available for your patients in the State of Idaho. Thank you. Are there any questions about Advair or Veramyst? Thanks for your time.

Jesse Hong

Good morning. My name's Jesse Hong. I'm a pharmacist with Amylin Pharmaceuticals. We're the makers of Byetta and Symlin. I'm here this morning to ask the Committee to keep Byetta and Symlin on your preferred drug list. Currently, both Byetta and Symlin are on your PDL with a smart PA. Byetta was approved by the FDA as an adjunct to improve glycemic control in patients with type 2 diabetes who are either taking a single or a combination of oral antidiabetic agents. It is currently the only incretin mimetic that has been approved by the FDA in the marketplace with breakthrough technologies. Byetta improves glucose control through the most mechanisms. First, it enhances the glucose-dependent insulin secretions, so for patients who are type 2 diabetes and whose insulin is diminishing, Byetta will restore their base point response and also help control their glycemic control. Additionally, Byetta has also been shown to suppress inappropriately elevated glucagon secretion. It reduces food intake and slows gastric emptying. All these actions combine to cause significant H_{1c} reduction, as well as progressive weight reduction in patients, and these improvements also lead to improvement in cardiovascular risk over long term treatment. Our clinical trials have demonstrated the efficacy and safety of Byetta. Last year, we actually published our three-year clinical trial to show that the H_{1c} reduction is consistent over three years and you see a progressive reduction in weight over these three years as well. Unlike all the other current antidiabetic agents in the marketplace right now, all of those are associated with either weight gain or, at best, most of the time they are weight neutral. The significant progressive reduction of body weight is a distinct human benefit of Byetta therapy, and couple that with a consistent H_{1c} reduction, Byetta makes patients feel better about themselves because they can see the result of the treatment. Two recent studies have shown that Byetta treatment resulted in similar H_{1c} reduction as either insulin glargine or insulin aspar. However, Byetta was distinguished from these other treatments in

that it allows patients to have tighter post prandial glucose control and weight loss, while these other insulin treatments cause significant weight gain, but they do give the patient better reduction in fasting plasma glucose. So what the study suggests is that Byetta is effective in maintaining glycemic control just like insulin, but it does that without some of the negative side effects of insulin. The economic value of Byetta has also been demonstrated in use of cost utility and cost effective models to project out Byetta over thirty years in south benefit as a result of those models.

A quick word about Symlin. Symlin is our other product. Symlin is used for patients that have nonfunctioning beta cells and are on insulin therapy already. Symlin is used to lower post prandial hyperglycemia and is indicated as an adjunct therapy to mealtime insulin. Symlin will give patients better post prandial glucose control, as well as allow the patients to lose weight over therapy. In conclusion, I would just like to again ask the members of this Committee to continue to keep Byetta and Symlin on your PDL and this will allow the patients in this state a chance to have access to these new and breakthrough agents in their struggle against type 2 diabetes. Is there any question? Thank you.

Laura Litzenberger

Good morning, my name is Laura Litzenberger, I'm a pharmacist and Medical Science Liaison with OrthoMcNeilJanssen Scientific Affairs. I'm here today to ask the Committee to retain Levaquin as the preferred fluoroquinolone on your PDL. Levaquin has eleven FDA-approved indications, including respiratory infections, skin and soft tissue infections, and GU infections. It's maintained its excellent activity in both gram-positive and gram-negative bacteria. The TRUST-11 study, which is a study that looks at respiratory pathogens and has been going on for eleven years shows that Levaquin remains >99% effective against Streptococcus pneumoniae. In the State of Idaho, Levaquin also maintains >99% activity against Streptococcus pneumoniae, and in the last two years in the reporting laboratories, there has been no resistant Streptococcus pneumoniae to Levaquin. As Dr. Johnson said at the beginning of public testimony, continuity of care is something that's very valuable within antibiotics and switching people from inpatient to outpatient and maintaining them on the antibiotic that they were on in the hospital is essential. Currently, all of the hospitals in the Treasure Valley have Levaquin as a preferred agent on the formulary and most of the hospitals in Idaho have Levaquin as a preferred fluoroquinolone agent. As we also heard this morning, the IDSA and ATS guidelines for the management of community-acquired pneumonia include Levaquin as one of the fluoroquinolones to treat community-acquired pneumonia in patients with comorbidities or patients who have previously been exposed within the last three months to antibiotics. The guidelines support the use of high-dose, short-course Levaquin, which is the 750 mg for a five-day therapy. Levaquin is the only fluoroquinolone approved for high-dose, short-course therapy for community-acquired pneumonia, sinusitis, common urinary tract infections, and acute pyelonephritis. The benefits of high-dose, short-course therapy include promoting patient adherence with only five days' of therapy, faster resolution of symptoms, increased tissue penetration, and the potential to reduce the emergence of resistance. Short-course therapy is recommended by the World Health Organization as one of the tactics to decrease resistance to antibiotics. We also heard that in the CapRI study comparing Levaquin to moxifloxacin that the drugs were equivalent and there may have been faster resolution of symptoms with moxifloxacin, but I would ask the Committee to consider the fact that the dose that was used of Levaquin in that study was 500 mg for ten days, not the 750 mg for five days. We know when we compare the 750 mg for five days to the 500 mg for ten days that there is a faster resolution of symptoms with the 750 mg compared to the 500 mg. We also know that there are no differences in the adverse events that patients experience in the incidence of the adverse events or the types of adverse events with the 750 mg compared to the 500 mg. Levaquin is an established fluoroquinolone and the clinical value of Levaquin includes its broad spectrum of activity, its low resistance rates, its sustained susceptibility to key pathogens, the availability of the high-dose short-course dosing regimens, and the inclusion of the drug on major treatment guidelines. Thank you very much. Are there any questions?

Rhaliene Patojo

Good morning, my name is Rhaliene Patojo and I'm a pharmacist and a Manager of Regional Medicine for Boehringer Ingelheim and thank you for the opportunity to speak on behalf of Spiriva. Spiriva Handihaler is indicated for long-term, once-daily maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. Long-term bronchodilators such as Spiriva are recommended in expert guidelines, such as the GOLD and ATS/ERS for first-line maintenance therapy. In studies versus ipratropium, Spiriva has demonstrated superior FEV-1 improvement that has been sustained throughout one year. In studies versus salmeterol, Spiriva has also shown improved bronchodilation with improvement in peak FEV-1 versus salmeterol being a difference of 46 ml. This was in a 12-week study, and in a six-month study was 83 ml. Spiriva has also been studied in exercise trials, with one study showing improvement in PFTs (pulmonary function) and decrease in hyperinflation leading to an increase in exercise endurance time of 23%, and this was also confirmed in another study, however the impact of increasing exercise endurance time as it relates to activities of daily living has yet to be established. As far as safety is concerned, the most commonly reported adverse event is dry mouth, which usually resolved over time with continued treatment. Other commonly reported adverse events are anticholinergic related, including increased heart rate, constipation, blurred vision, glaucoma, urinary difficulty and urinary retention. Spiriva is a predominantly renally excreted drug, so its use should be monitored closely in patients with moderate to severe renal impairment or a creatinine clearance of 50 ml/min or less. Overall, Spiriva has an established safety profile with more than six million patients' worldwide experience, and if you'd like any other information, package insert, I'd be happy to provide that or answer any questions you have at this time. Thank you.

Glen Ingrum

Good morning, I'm Glen Ingrum with Merck. I'm in the Cardiovascular Specialty Division and thanks for the time for us all to be able to present this morning. You might have seen recently there was a report published by the American Association of Clinical Endocrinologists, the ACE group, and they confirmed which a lot of us already knew, two out of three people with type 2 diabetes have failed to meet their HA1c goal of $\leq 6.5\%$. That's also been confirmed by the ADA, which is the 7% goal. So as they go on to say, there's significant room for improvement in diabetes management in the United States. So with type 2 diabetes being a progressive disease according to the ADA, the addition of medications is the rule, not the exception if these treatment goals are to be reached. The products I have today are Januvia and Janumet, and some practitioners refer to these as incretin enhancers. I think that's probably the best way to think of them. We're not an insulin secretagogue, we're not a TZD, we're not a mimetic, we're an incretin enhancer, so we're the still the first and only in class of these DPP-4 inhibitors. You might recall how it works, so I'll just give you a quick little bullet on that so we can move on, but it's the GLP-1 and the GIP, those are the incretins that we're enhancing through the pancreatic beta cells and through the alpha cells. So if we can work through GLP-1 and help with the insulin release, as well as oppressing hepatic glucagon production through the alpha cells, that's what we're all working toward, that glucose homeostasis. It is a novel mechanism of action and these two actions alone, the insulin release and the suppression of glucagon production, those address two key defects of type 2 diabetes. When you bring in Janumet, the Januvia/metformin combination, then you're hitting all three core defects because the metformin brings in the insulin sensitizing component with insulin resistance. Your Provider Synergies report that you've received, it mentions this. It mentions Januvia's novel mechanism of action, which is certainly very true, because it works in a glucose dependent manner. It's kind of a smart product if you will; it only kicks in when it's truly needed to enhance those incretins. One thing I wanted to mention that kind of gets back to that Synergies report, the higher the baseline HA1c in any trial, the more the HA1c will go down, and the reason I bring this up is because we've had a couple of mentions in there, even going back to the medical letter. If you compare two different oral agents and you compare them in populations with different HA1c levels, you're going to see different reductions because of the different baseline HA1c levels, so it makes sense, but it makes it really hard to compare one oral agent to the other when you're looking at different studies with different population groups and different HA1cs. Provider Synergies did report, you

might have seen this, on the Non Inferiority Trial comparing sitagliptin (Januvia) 100 mg once a day to glipizide and what they found out in that fifty-two weeks, the bottom line was, there was really similar HA1c reduction, but compared to hypoglycemia, there was a 32% adverse event of hypoglycemia in the glipizide group versus 5% in the Januvia group. Also, there was weight gain in the glipizide group versus some weight loss in the Januvia group. I should mention that we're not indicated for weight loss, we're actually in the weight control category. Then a couple of other points here, they did point out the initial therapy choice of Januvia and metformin, and that was looking at over twenty-four weeks; patients in that trial had 8.8% baseline HA1c and when they looked at the placebos of tracked HA1c, the Janumet 50/1000 mg b.i.d. had a placebo subtracted HA1c reduction of -2.1%, also with large decreases in both fasting plasma glucose and post prandial. Getting back to these goals with ACE and ADA, 66% of the patients on the Januvia/metformin combination, 66% did achieve their ADA goal in that 24-week trial versus 38% of those who were on metformin 1000 mg b.i.d. So wrapping up here, back to these goals, ADA and ACE, it's really a call to action to achieve these goals. It is going to take more than one medication and obviously from different classes as well. Provider Synergies, they do mention in the report, that the 2008 update to the ADA treatment algorithm, that sitagliptin (Januvia) is one of the agents appropriate for individual patients to help them achieve their glycemic goals. They go on to mention that the ACE recommendations for the treatment of type 2 diabetes includes sitagliptin as an additional treatment option, so hopefully you've seen some of the letters that have come in from some of your Idaho physician groups recommending Januvia and Janumet to be added to your formulary without prior authorization, and if there are any comments or questions, I'd be happy to try to answer those.

Question: Those guidelines your proposing or brining forward, how old are those guidelines?.

Answer: Those are current. The ACE guideline of 6.5% and the ADA of 7%. They are looking to update them, they could even be coming down more, but everything that I've seen is the current, 2008 guidelines.

Question: We are just writing on the data for accord setting, which shows that there is a 100 mortality rate with tight control and it's very unlikely that those will stand as is?

Answer: That's possibly true.

Question: So we are trying to achieve lower HA1c may or may not be a good thing?

Answer: And you're right, there's always that, it's like you're hearing from the specialists, the risk of hypoglycemia. There's that borderline. You want to teeter where it's beneficial for the patient without incurring any undue risk, so you are right, I'm sure we'll see some more changes. Thanks.