

**Meeting of the
Pharmacy and Therapeutics Committee
December 8, 2004
Minutes
Draft**

Members Present:

Randy Axelrod, M.D., Chair
Mark Szalwinski, Pharm.D
Avtar Dhillon, M.D.
Mariann Johnson, M.D.
Mark Oley, R.Ph.
Gill Abernathy, M.S., R.Ph.
Christine Tully, M.D.
Renita Warren, Pharm.D.

Via phone:

James Reinhard, M.D

Absent:

Roy Beveridge, M.D
Tim Garson, M.D.
Sue Cantrell, M.D.
A quorum was present

Guests:

31 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Manikoth Kurup, MD, Member, Board of Medical Assistance Services

DMAS Staff:

Patrick Finnerty, Agency Director

Cynthia Jones, Chief Deputy Director

Cheryl Roberts, Deputy Director of Programs and Operations

Reatha Kay, Counsel to the Board, Office of the Attorney General

Katina Goodwyn, Pharmacy Contract Manager

Javier Menendez, Pharmacy Manager

Bryan Tomlinson, Director Division of Health Care Services

Jane Woods, Secretary of Health and Human Resources (Via phone)

First Health Staff:

David Adams, Pharm.D, Rebate Support

Debbie Moody, R.Ph, Clinical Manager

Donna Johnson, R.Ph, Clinical Manager

Doug Brown, R.Ph, Rebate Support

Justin D. Lester, Pharm.D, M.B.A Rebate Support

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

At this meeting the P&T Committee will be receiving clinical information on the antidepressant and antianxiety classes that was submitted by manufacturers for consideration, and will be discussing financial information. Mr. Finnerty emphasized again that atypical antipsychotics are excluded from the PDL and are not under discussion. The focus of P&T Committee discussions is only on the antidepressant (including SSRIs) and antianxiety classes.

On October 6th, a P&T Committee meeting was held in which interested stakeholders presented clinical and non-clinical information. As a result of its clinical review, the Committee unanimously voted that these classes become PDL eligible.

Mr. Finnerty noted that the General Assembly has required DMAS to report the status of decisions related to the inclusion of these classes on the PDL. Several steps are being taken to inform the General Assembly of developments with these classes:

- o Following the October 6th meeting, a report was sent to the General Assembly regarding public comments received at the meeting, the Committee's clinical review, and its decision to include antidepressant and antianxiety classes on the PDL. A copy of that report was enclosed in the Committee's notebooks and copies were distributed to all meeting attendees.
- o On November 8th, the Department also provided a detailed status report to the General Assembly on the PDL program and other 2004 pharmacy program initiatives. The report

included a summary of the P&T Committee's activities since its inception. A copy of this report was also included in the Committee's notebooks.

- o Following this meeting, on December 14th, Dr. Axelrod along with Cindi Jones will be presenting to the General Assembly's House Appropriations Committee on the status of the PDL, in general, as well as the antidepressant and antianxiety classes, specifically.
- o Finally, the Department is completing a report, due to the General Assembly on January 1, 2005, which will include the decisions of this meeting and all information regarding these classes to date.

During the meeting on October 6th, the Committee requested that DMAS research other states' policies related to antidepressants and antianxiety medications. Following the clinical discussion of these classes, the Committee wanted to learn if other states included these classes on their preferred drug list or offered a grandfathering provision, as well as determine any specific utilization guidelines.

DMAS and First Health attempted to survey every state and received information from thirty-nine states. Of these thirty-nine states, twenty-six have a preferred drug list in place. A summary and the detail of the survey results were included in the Committee's notebooks. Debra Moody, Clinical Manager with First Health, shared more about the results of this survey.

Debra Moody, RPh. Clinical Manager, First Health Services Corporation

DMAS and First Health conducted a survey of all states for policies affecting antidepressant and antianxiety classes with respect to PDLs.

Each state received a questionnaire. A follow-up phone call was made to states that did not respond or if clarification was needed. At the conclusion, information was obtained from thirty nine (39) states.

- Twenty six (26) states have a PDL in place and thirteen (13) do not have a PDL in place.
- Of the twenty six (26) states with a PDL in place, nine (9) have some sort of legislation that prohibits inclusion of either antidepressants or antianxiety agents in the PDL.
- Fourteen (14) states have selective serotonin reuptake inhibitor (SSRI) antidepressants on the PDL.
- Fifteen (15) states have at least one class (antidepressants or antianxiety agents) on the PDL.
- Five (5) have neither of these classes on the PDL.

Dr Axelrod noted from the detailed information in the packet that there is a wide variation of how these classes are being handled in each state, from not being included in the PDL to being very aggressive, with many staying on middle ground.

Mark Oley asked if any clinical issues have arisen in states that have included these classes on the PDL.

Debra Moody responded that no clinical issues have been identified in any state that has included these classes on their PDL. Michigan successfully had both classes on their PDL for over two years without incident. Antidepressants have recently been removed because of political pressure.

COMMENTS FROM RANDY AXELROD, COMMITTEE CHAIR

Dr. Axelrod thanked everyone for their attendance and called the meeting to order. He relayed that the Committee has been in place for eighteen months and that he has committed to remain with this Committee for the duration of the current Administration.

ACCEPTANCE OF MINUTES FROM October 6, 2004 MEETING

Dr. Axelrod asked if there were any corrections, additions, or deletions to the minutes from the October 6th meeting. None were noted and upon request of the Chairman, the Committee voted on a motion and a second to approve the minutes of the October 6th meeting as written. The Committee voted unanimously to approve the minutes as drafted.

DRUG CLASS REVIEW AND DISCUSSION

Dr. Axelrod noted that each speaker was limited by a time clock to three minutes. Dr. Axelrod asked that each speaker make a declaration of conflict in regards to the pharmaceutical industry at the beginning of their comments. Dr. Axelrod recognizes the importance of this clinical information to the decision making of the Committee and appreciates the time of the presenters.

Michael West representing GlaxoSmithKline, reviewed antidepressants Paxil CR[®] and Wellbutrin XL[®].

Patients have difficulty staying on medications. The biggest reason is due to the side effects. Paxil CR[®] was developed to address the gastrointestinal (GI) side effects seen with the immediate-release formulation. Since Paxil CR[®] is enteric coated and has a slow-release formulation, it is easier on the stomach. Mr. West noted that Paxil CR[®] has the most FDA indications of all the SSRIs and has the lowest incidence of drop out rate. He referred to page 4 of his handout that showed a better adherence rate with Paxil CR[®] compared to other immediate-release SSRIs. He claimed that Paxil CR[®] is more cost effective because of its once a day dosing. Dr. West cited a cost savings of \$1,300 per year per patient when they are on Paxil CR[®] instead of Paxil[®] immediate-release.

Mr. West then similarly reviewed Wellbutrin XL[®]. The compliance rate of Wellbutrin XL[®] (a once daily dosing formulation) is better tolerated, compared to Wellbutrin SR[®] (a twice daily dosing formulation). He claimed better outcomes and more cost savings with once daily dosing.

Dr. Axelrod referred to the thirty percent (30%) drop out rate for all SSRIs (as seen on page 4 of Mr. West's handout). He noted that there is not a significant difference when you take Paxil[®] immediate-release out of the scenario and compare Paxil CR[®] to fluoxetine for the first thirty (30) days.

Dr. Tully questioned the drop out rate chart. She commented that people are on the medications for different reasons and that if the product were stopped because the regimen is completed or changed then it would show as possible non-compliance when it is not. Dr West agreed that this was a study limitation.

Dr. Dhillon noted that people are on these medications for the long term but that changes do occur frequently at the direction of the physician.

Shonda Foster, PharmD, MS representing Eli Lilly and Company reviewed the antidepressant Cymbalta[®] (duloxetine).

Dr. Foster discussed that Cymbalta[®] is a reuptake inhibitor that also has an indication for Major Depressive Disorder (MDD) and for diabetic neuropathic pain. She claims that Cymbalta[®] provides a broad, rapid relief to symptoms of

depression. A 60 mg once a day dosage significantly reduced HAMD scores as early as the first to second week of treatment. Improvement was also seen in back and overall pain associated with depression. Dr. Foster listed Cymbalta[®]'s attributes as safe, well tolerated with few side effects, less nausea; weight tolerable and low sexual side effects. She noted that it does not require titration to therapeutic dose and demonstrated a rapid and high rate of remission rate of up to a 44%.

Dr. Szalwinski asked if there are comparative studies. Dr. Foster noted none to date.

Dr. Tully and Dr. Dhillon asked if it does not require titration why does it come in different strengths. Dr. Foster stated for different age groups and/or if nausea is a concern, then it can be given in divided doses.

Mark Oley asked if Cymbalta[®] is the only product in its class that has the diabetic neuropathic pain indication. Dr. Foster stated yes.

Dr. Dale Grothe representing The Vectre Corporation reviewed the antidepressant Effexor XR[®]. Dr. Dale referred the Committee to the handout summary and safety data. He claimed that this is the first dual action serotonin-norepinephrine reuptake inhibitor (SNRI) on the market in 10 years. It has an indication for depression and anxiety disorders. Indications are MDD, Generalized Anxiety Disorder (GAD), Social Anxiety Disorder (SAD) and for the prevention of relapse of MDD. He noted that trials are beginning to show that there may be a difference in efficacy between dual and single action antidepressants. He summarized that this is a tried and proven antidepressant that is safe with easy dosing.

Dr. Dhillon asked if there was a concern for arrhythmias in overdose in this product. Dr. Grothe replied that no data existed for arrhythmias in normal doses but seizures have occurred at high doses.

COMMENTS FROM THE SECRETARY OF HEALTH AND HUMAN RESOURCES

Secretary Woods thanked the Committee for their expertise and their willingness to be part of the process. She indicated that the process by which Virginia has implemented this program has been a testament to the strength and dedication of everyone on the P&T Committee. Secretary Woods said that she really appreciated that everyone on the Committee has shown extraordinary dedication of his or her time and effort to the process. The goal is to ensure the best possible medical provisions for people whose health care is paid for by Medicaid.

Elbert F. Sholar, MD representing VCU, Department of Psychiatry, and the Richmond Behavioral Health Authority to review the SSRI antidepressant Zoloft[®]. Dr. Sholar does have an affiliation with Pfizer. Dr. Sholar states that he believes in an open formulary but understands the need for cost control. He advocates the use of Zoloft[®] and cited the following reasons: Zoloft[®] has the most indications of all SSRI's; has a lower risk of serotonin withdrawal syndrome; has a partially active metabolite; the parent compound has a reasonable half- life; it can be discontinued without risk of serotonin withdrawal syndrome; and it is cost effective. He is concerned that if Zoloft[®] is not a preferred product, people will be made to switch medications and may suffer a relapse. Dr. Sholar also pointed out that Zoloft[®] is soon to be generic in 2006 and cost will be less of an issue.

Dr. Szalwinski asked if there is a "son of Zoloft[®]" in the pipeline that would compete with the generic.

Dr. Axelrod asked why are there so many different formulations out their like CR, XR and SR.

Dr. Sholar stated that he was not aware of a “son of Zoloft[®]” in the pipeline. He reflected that different formulations are trying to reduce side effects such as nausea.

Dr Axelrod asked if Dr. Sholar believed that Zoloft[®] should be prescribed to children. Dr. Sholar answered that he does not treat children but that he believes that they should be treated and during this treatment be closely monitored for suicidality.

Dr. Tully asked about a recent study that cited Zoloft[®] in low doses was no better than placebo. Dr. Sholar stated that since he is a psychiatrist, in order for patients to see him they must have moderate to severe depression. He knows that mild depression can often be treated by a primary care physician. Often, primary care physicians use these drugs as a panacea for many ailments.

Mark Oley asked Dr. Sholar if he believed that all SSRIs are equivalent? Dr. Sholar answered that he picks medications that fit the bill for what he is looking for, including a lower risk of DI, side effect tolerability, FDA indications, etc.

Dr. Axelrod asked if or when Zoloft[®] becomes generic will that change the likelihood of it being prescribed. Dr. Sholar answered that doctors will continue to use Zoloft[®] for the reasons stated earlier as well as cost. However, he agreed that people do prefer brands. Dr. Axelrod pointed out that when Prozac[®] went generic, its prescribing patterns (brand or generic) dropped off by 50%.

Carl Tullio, PharmD representing Pfizer to review Zoloft

Dr. Tullio wanted to stress to the Committee that caution must be used when switching from one SSRI to another because in his understanding all SSRI's are not alike. One difference he cited is that the SAD and PTSD study times differ; another difference is that Zoloft[®] is the only SSRI indicated in pediatrics for Obsessive Compulsive Disorder (OCD). Zoloft[®] is also the only SSRI that has documented studies for depression in patients with recent Myocardial Infarction (MI) or unstable angina. Dr. Tullio stressed the low drug interaction profile between Zoloft[®] and other drugs. He closed with the idea that Zoloft[®] has 33% of the Medicaid market and that it goes off patent in June of 2006. He stressed that to make Zoloft non-preferred may create a short-term savings but with Medicare Part D on the way, the cost savings will be eliminated.

Dr. Axelrod asked the group if anyone knew what percent of the SSRI market was in dual eligible population. No one was able to answer this question. Dr. Axelrod then commented that most prescribers do not follow published guidelines.

Dr. Szalwinski asked if a “son of Zoloft[®]” is in the pipeline that would compete with the generic. Dr. Tullio said he did not know of any product coming.

COMMENTS FROM OFFICE OF THE ATTORNEY GENERAL

Ms. Reatha Kay from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 33 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 33 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42 U.S.C. 1396r-8(b)(3)(D) requires such pricing information to be kept confidential. On this point federal law supersedes the Virginia FOIA. Since the P&T Committee must discuss this pricing information as part of its duties, pursuant to federal law a confidential meeting must occur for the consideration of this pricing information. She cautioned only this confidential information should be discussed.

Dr. Szalwinski, made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the antidepressant and anti-anxiety classes discussed at the October 6th 2004 P&T Committee meeting and today's meeting. This confidential meeting is authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

This motion was seconded and unanimously approved by the Committee.

The Committee adjourned to a confidential meeting.

The Committee returned to the room and a motion was made to resume the meeting. The motion was seconded and unanimously approved by the Committee.

Dr. Axelrod asked for a motion for the preferred Antidepressants – SSRIs.

Dr. Szalwinski motioned that Paxil Cr[®], Zoloft[®], Lexapro[®], fluoxetine HCL, paroxetine HCL, Pexeva,[®] and citalopram be preferred SSRIs.

The motion was seconded and voted on. One vote was opposed (Dr. Tully), all others approved (Drs. Axelrod, Szalwinski, Dhillon, and Johnson and Mr. Oley, Ms. Abernathy, and Ms. Warren). The motion was accepted.

Given the market dynamics of this class of drugs, it was motioned that this class would be reviewed within the next year. This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod asked for a motion for the preferred New Generation Antidepressants. Dr. Axelrod commented that because of needed clarification the Committee would review SNRIs at the March meeting. During the March meeting, there will be a confidential meeting to discuss the SNRIs and additional public comments will be allowed at that time.

Dr. Szalwinski motioned for the following to be the preferred New Generation Antidepressants: trazodone HCL, mirtazapine, Wellbutrin XL[®], bupropion HCL tablet SA, mirtazapine tab Rapdis, Budeprion SR[®], bupropion HCL, nefazodone HCL, and maprotiline HCL.

This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod asked for a motion for the preferred Anti-anxiety Drugs.

Dr. Szalwinski motioned that the preferred Anti-anxiety Drugs be alprazolam, lorazepam, lorazepam intensol, diazepam, buspirone HCL, chlordiazepoxide HCL, oxazepam, clorazepate dipotassium, Xanax XR[®], meprobamate, hydroxyzine pamoate, hydroxyzine HCL and clonazepam.

This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod asked for a motion for the preferred Tricyclic Antidepressants.

Dr. Szalwinski motioned that the preferred Tricyclic Antidepressants be amitriptyline HCL, nortriptyline HCL, doxepin HCL, imipramine HCL, clomipramine HCL, desipramine HCL, amoxapine, and maprotiline HCL.

This motion was seconded and unanimously approved by the Committee.

The next meeting will be in March 2005.

Chairman Axelrod adjourned the meeting at 11:00 a.m.