

**Meeting of the
Pharmacy and Therapeutics Committee
August 31, 2005
Minutes**

Members Present:

Randy Axelrod, M.D., Chair
Mark Oley, R.Ph.
Avtar Dhillon, M.D.
James Reinhard, M.D.
Gill Abernathy, M.S., R.Ph.
Renita Warren, Pharm.D.

Absent:

Sue Cantrell, M.D.
Mariann Johnson, M.D.
Arthur Garson, M.D.
Christine Tully, M.D.
Roy Beveridge, M.D.
Mark Szalwinski, R. Ph.

A quorum was not present

Guests:

Thirty-five (35) representatives from pharmaceutical companies, providers, advocates, associations, etc.

DMAS Staff:

Jane Woods, Secretary of Health and Human Resources
Patrick Finnerty, Agency Director
Cynthia Jones, Chief Deputy Director
Cheryl Roberts, Deputy Director of Programs and Operations
Louis Elie, Director of Program Integrity
Tom Edicola, Director of Program Operations
Moses N. Adiele, M.D., Director of Medical Support Services
Wayne Turnage, Director of Policy and Research
Jack Quigley, Project Manager, Policy and Research Division
Reatha Kay, Counsel to the Board, Office of the Attorney General

Rachel Cain, Pharm.D, Clinical Pharmacist
Katina Goodwyn, Pharmacy Contract Manager

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

WELCOME AND INTRODUCTIONS FROM PATRICK FINNERTY, DMAS DIRECTOR

Mr. Finnerty welcomed everyone in attendance. He reviewed the agenda, noting the various presentations scheduled. Mr. Finnerty commented that the Committee would find the presentation of the methodology, analysis and results from the PDL evaluation very interesting. The PDL program results reflect the quality of the Committee's work. Mr. Finnerty announced that late yesterday the Department learned that one of the Committee members could not attend the meeting. This made it impossible for the Committee to achieve a quorum. He discussed the consequences of not having a quorum present. The presentations could be made and the Committee could receive information from the manufacturers but, unfortunately, the Committee is not able to transact business such as voting on any agenda items including adopting the minutes from the last meeting. Without a quorum, it reduces what the Committee is able to do; however, the Committee could proceed and outstanding votes will be conducted at the next meeting. He noted that this makes the October meeting even more important. The October meeting will now include votes on the phase one annual review of 14 PDL drug classes, all items requiring votes at today's meeting, and other new drug class reviews. Mr. Finnerty stated that this meeting would still be useful because of the presentations being provided. He thanked the Committee again for their participation.

COMMENTS AND WELCOME FROM THE SECRETARY OF HEALTH AND HUMAN RESOURCES

Secretary Woods stated that this would be a different kind of meeting but a very exciting one for the Committee who have given generously of their expertise throughout this process. Secretary Woods referred to the PDL research report being presented at the meeting and stated that it is historic in the country because it evaluates the outcomes of the PDL beyond the budgetary outcomes. This report evaluates all of the work the Committee has done. The driving factor with this program were that the clients and the consumers would

be virtually unaffected by the work of the Committee, with no negative impacts. Secretary Woods also expressed her interest in Dr. Axelrod's presentation sharing information on specialty drug program which is vital to the Medicaid program. The Committee will also review information and receive presentations from two different drug classes (Sildenafil), one used for the treatment erectile dysfunction and the other for the treatment of pulmonary arterial hypertension. Secretary Woods reminded the Committee of comments made at the last meeting concerning the Governor's quick response to the knowledge that erectile dysfunction drugs were being provided to registered sex offenders. These products were provided not by Virginia Medicaid's choice but because the Department was directed to do so by the federal government. The federal government's direction was that no recipients could be omitted from coverage of any drug class. Once the Governor learned of the situation he immediately directed termination of coverage and the Department moved incredibly quickly and accurately to carve out coverage of this lifestyle drug to the registered sex offenders in Virginia. Now we are addressing the market introduction of a new drug, Revatio[®], specifically for the treatment of pulmonary arterial hypertension. The Committee will have to discuss and decide how to handle this similar but different drug that has come into the market. Secretary Woods believes that it is at this meeting that the Committee learns about the work they have done and the related outcomes. The PDL evaluation report again puts Virginia ahead with quality first for consumers and the most efficient and effective system.

Secretary Woods expressed her sadness and confirmed the news that Dr. Tully would not be returning to the Committee due to illness. She wished Dr. Tully a speedy recovery and requested that everyone keep Dr. Tully in their prayers. She expressed gratitude to Dr. Peter Boling at MCV for making a recommendation for an appointment to the Committee. This person will be joining the Committee at the October meeting and representing a geriatric perspective.

MINUTES FROM June 8, 2005 MEETING

The minutes could not be adopted because a quorum was not present. This task is deferred until the October meeting.

MANAGEMENT OF SPECIALTY DRUG CLASSES (See presentation attached)

Dr. Axelrod provided a general overview of the specialty drug market, which he called "Specialty Pharmacy 101". This review was not intended to be in-depth but provided some definitions and patterns within the specialty drug area as well as explored the current environment for distribution, pipeline and future opportunities. The details are shown in the attached presentation which was distributed to both the Committee and all meeting attendees.

Overall, Dr. Axelrod feels that there are some specialty drug categories that can be managed through the PDL. He recommends that the Committee start with specific disease states where there is equivalency of treatment and a relatively large portion of specialty pharmacy expenditures. The Committee will also have to address the distribution, fulfillment and care management approaches or determine if there will only be PDL guidelines. Most all of the classes have a disease management component that will be important to make the entire program work. He stressed the importance of establishing programs to address the appropriateness and compliance for these products.

Dr. Axelrod's recommendation to the Committee was to stay away from specialty drugs for cancer treatment because this area is too complex; developing guidelines and formularies for these drugs can be done but it is a long term process given the new drugs being introduced and the related clinical trials. He also believes that the Committee should wait to address specialty drugs used for Crohn's Disease because of all of the impending changes expected with inflammatory bowel drugs in the future.

Dr. Axelrod recommended that the place for the Committee to begin is with specialty drugs for the treatment of conditions such as Hepatitis C, Immunomodulators for Rheumatoid Arthritis (RA), Psoriasis, Psoriatic Arthritis and Multiple Sclerosis. The next steps will be to have experts address the Committee to discuss step therapy.

Secretary Woods asked if she understood correctly that the national prevalence is not representative of the Medicaid population. She asked Dr. Axelrod if we had the Medicaid prevalence either nationally or in Virginia. Cheryl Roberts stated that DMAS could provide these data. Dr. Axelrod noted that he thought that he could help with data from the managed Medicaid side. He noted that for Hepatitis C, but the number will likely be underreported because it is just that prevalent.

Dr. Axelrod opened the floor to questions from the audience. There were none.

Gill Abernathy asked Dr. Axelrod his thoughts on products for Rheumatoid Arthritis (RA). Dr. Axelrod replied that with RA products it is important to understand that there are two paths, infused products and injected products. When the PDL is compiled, if the Committee chooses to stay with one path then they would be dictating the treatment path, delivery path and the drug. The Committee must be cautious if they decide select only one path for the PDL or select drugs from each path. From a mechanistic stand point, there are at least two different molecular mechanisms for the treatment of RA. There is a new product coming out in the next 6 months. Dr. Axelrod stated that RA is a category that will require review by the Committee more frequently than once a year because of the new products being introduced. Currently, there are 26 products in phase two development or later with other new drugs expected.

EVALUATION OF PDL PROGRAM (See presentation attached)

Wayne Turnage, Director for the Division Policy and Research, provided a presentation on the evaluation of Virginia Medicaid's preferred drug list. The details are shown in the attached presentation which was distributed to both the Committee and all meeting attendees. Mr. Turnage stated that the Department's analysis of the PDL program was completed based on a directive from the DMAS Director and the General Assembly through the most recent Appropriations Act. Budget and forecasting staff, the Pharmacy staff, and First Health Services' contractor staff provided support in the development of the analysis.

The presentation included the components of the evaluation, movement of prescriptions through the PDL operational process, budget savings, review of the study design for the assessment of health impact, PDL health impact study results, and conclusions. The time period reviewed was the first 19 months of the program January of 2004 to July 2005. The study research questions included:

- Has the PDL program been implemented in a way to ensure a high rate of compliance by physicians without adversely affecting patients access?
- Is there evidence that total spending in DMAS' pharmacy program has been reduced since the PDL was established as the linchpin initiative in the agency's pharmacy program?
- Is their evidence to suggest that the PDL program has adversely impacted patient health outcomes for those Medicaid recipients who are switched from non-preferred drugs?

The study conclusions include:

- **Compliance** -- The PDL compliance rate, measured as the percent of patients being prescribed "preferred" drugs, remains high. While the compliance rate varies among the different drug classes, the overall compliance rate across all drug classes is 93%. This rate exceeds the compliance level (85%) needed to achieve the necessary budget savings. There is minimum variation in compliance among various, select therapeutic classes.
- **Prior Authorization** -- There have been no denials of medications as a result of the PDL prior authorization process. Since the beginning of the program, 81% of all requests for prior authorization have been granted and 16%, the prescribing physicians voluntarily switched to the preferred drug. The remaining 3% were technical denials for retrospective prior authorization requests from long-term care facilities that have already dispensed the medication but did not comply with the appropriate PDL processes. Therefore, there is no evidence that any patient has been denied access to their medications as a result of this program. All retrospective prior authorization requests will be denied going forward based on new policy, effective August 1, 2005.

- **Cost Savings** – Market shift analyses show that as of June 2005, preferred drugs account for 91% of the share across PDL eligible drug classes. Evaluation results also show the average cost per prescription has decreased below the projected amount since PDL implementation, approximately \$3 decrease per script. In addition, the actual pharmacy expenditures are significantly below the Department's official forecast. The estimated savings in the pharmacy programs since implementation of the PDL exceed \$35 million. The projections provided were based on the overall pharmacy savings including all new initiatives and cannot be totally attributed to the PDL; however, the PDL accounts for the largest portion of savings. As several pharmacy programs can affect the same claim, it is difficult to specifically tease out the precise savings due to PDL program.
- **Health Impact** -- The health impact study questions included:
 - Net of the influence of other factors, are there meaningful differences in the total amount of Medicaid spending observed for the PDL and non-PDL groups during the follow-up period?
 - Are Medicaid spending levels for hospital care higher for persons on the PDL after accounting for the impact of other factors?
 - What, if any, differences are observed in the utilization of inpatient hospital care?
 - Do PDL recipients utilize emergency departments for care at a higher rate than their counterparts, after controlling for other factors?

The results of the health impact study were as follows:

- There were key differences in the demographics and type of medications used by the PDL study group and comparison group
- The spending of the typical person, based on the median spending level, on preferred drugs is actually less than the amount observed for persons on non-preferred drugs
- The typical person, based on the median spending level, on preferred *and* non-preferred drugs had no hospital expenditures during the first 9 months after submission of a PDL-eligible drug claim.
- A higher proportion of PDL recipients visited the emergency room in the nine month follow up period. This is likely due to the demographics of this group
- There was no difference in the number of emergency room visits; the typical recipient, based on median ER visits, had no emergency room visits in both the PDL and comparison group
- There was no difference in the number of hospital days for the typical recipient, based on median days in hospital; there were none for both the PDL and comparison group.
- The program does not appear to adversely affect the health status of recipients changing to preferred drugs.

Study results of the implementation of PDL in Virginia continue to be very favorable. Mr. Turnage commented that he continues to evaluate the data to look for more evidence, particularly to exclude data for Medicare recipients. The positive results are due to the education provided to the pharmacy provider community and recipients about the program, the great care taken by the P&T Committee under the leadership of Dr. Axelrod in determining the PDL status of drugs, and the competence of the First Health Services staff (rebates, call center and clinical management).

Questions posed to Mr. Turnage:

Mark Oley asked if the comparison group (all non-preferred drugs) were more likely to process pharmacy claims at point of sale in a retail setting or in a long term care/ nursing home setting. Mr. Turnage stated that this was not addressed in his analysis; however, the analysis of the two groups shows that the PDL group includes an older population which is likely to be nursing home residents.

Were the 7% in the comparison group (all non-preferred drugs) on a particular therapeutic class of drugs such as those classified for the central nervous system? Mr. Turnage stated that he would need to review the data but he believes that the majority of comparison group were taking asthma, allergy and cardiac

medications. Central nervous system drugs were only used by a small portion of both the PDL and comparison group.

Do you think that could be a real benefit of concentrating management efforts on the population of patients with the high costs, high numbers of medications, high emergency room visits and high hospital costs as a way to decrease to health care costs? Mr. Turnage's response was yes, he did believe that there could be a benefit to a targeted care management program. In fact, DMAS is in the process of implementing a disease management program. Dr. Axelrod added that there must be a combined approach with both population-based programs and a more laser approach to really make a difference.

IMPACT OF MEDICARE PART D IMPLEMENTATION (See presentations attached)

Jack Quigley, Project Manager with the DMAS Division Policy and Research, provided a presentation on Medicare Part D implementation. The details are shown in the attached presentation, which was distributed to both the Committee and all meeting attendees. Mr. Quigley noted that DMAS has been working closely with the Centers for Medicaid Medicare Services (CMS) and the Social Security Administration (SSA) as well as all of the agencies within the Secretariat, provider associations, and advocacy groups (such as the hospitals, nursing home groups, medical society, Virginia CSBs, non-profit homes for adults, etc.) who have been interested in participating and learning more about this program. There is a large workgroup involved with training and communications in place as well as a DMAS internal workgroup to implement this program. The goal of DMAS internal team is to implement this program as effectively and efficiently as possible. The systems changes have been completed and the required data is being provided monthly to CMS. The Department provided information to the General Assembly members this past spring. The Department has also communicated once with all of the dual eligible recipients and those who are in the Medicare savings plan program. At least two more communications will be provided to the affected recipients prior to the implementation of Medicare Part D. In May 2005, an all day training program featuring CMS and SSA speakers, via videoconference, provided an overview of the Medicare Part D implementation. This training was broadcasted at 31 health partner sites and viewed by over 500 participants.

The phased-down state contribution, "Clawback", was explained by Mr. Quigley. Virginia and most of the states throughout the country take issue with the methodology of the "Clawback" because it is based on 2003 data. In Virginia, several new cost-saving pharmacy programs were implemented in 2004, including the PDL and Maximum Allowable Cost (MAC) programs, which will not be reflected in the "clawback" methodology. Secretary Woods and Mr. Finnerty noted that Virginia has worked to educate Congress on the financial impact of the "clawback" as it is based on 2003 figures. At this time, there is no resolution. The state share is set at 90% of costs for 2006 and decreases to 75% by 2015.

Justin Lester of First Health Services Corporation, DMAS' PDL contractor, provided a presentation on the impact of Medicare Part D implementation on the Virginia PDL program. The details are shown in the attached presentation, which was distributed to both the Committee and all meeting attendees. Mr. Lester reviewed the impact Medicare Part D on recipients and utilization as well as strategies First Health is proposing to prepare for 2006. Dual eligibles, individuals who are entitled to Medicare and some level of Medicaid benefits, comprise 7.5 million (13.6%) of Medicaid's 55 million recipients nationwide (FFY 2003 data). Nationally, this population accounts for approximately 51% of Medicaid prescription drug expenditures and 40% of total Medicaid costs. With Virginia Medicaid-specific information, the dual eligibles are estimated to represent approximately 18% of the state's total Medicaid population and an estimated 57% of all drug expenditures within the fee-for-service (FFS) population.

PDL classes treating disease states dominated by the elderly will see a dramatic decline in drug spend with Medicare Part D implementation such as Cardiovascular Disease, Diabetes, Osteoporosis, Glaucoma, and COPD. Disease states effecting a younger population will assume a larger proportion of Medicaid drug

spend post-Medicare Part D implementation. This will include drug classes such as Antidepressants, Antipsychotics, and CNS stimulants (ADD/ADHD). First Health Services encourages the addition of new PDL classes for comprehensiveness and to continue to add year-over-year program savings. They also recommend the addition of PDL classes that will retain a high proportion of utilization in Medicaid and/or will have significant future cost implications. These classes currently rank lower in spend on the PDL but will require more attention post-Medicare Part D implementation.

Many of the high spend drug classes have been very well controlled by the PDL. It is recommended that the Committee continue to review those areas growing at a faster pace than the rest of the pharmacy program such as specialty pharmacy products. In conclusion, Virginia's fee-for-service Medicaid program will lose a significant portion of its drug spend to Medicare effective January 1, 2006. Classes predominantly used in the elderly and disabled will see the largest reduction in utilization. FHSC will continue to assist the state in maximizing PDL savings through the addition of new drug classes to optimize the current program.

REVIEW OF NEW DRUG CLASSES FOR PDL ELIGIBILITY

Paul Fairman MD, Pulmonary division at MCV/VCU, specialist in Pulmonary Arterial Hypertension (PAH), discussed Sildenafil (Revatio®)

Dr. Fairman noted that he was in attendance to encourage the inclusion of sildenafil to treat PAH on the PDL. There are 5 agents approved to treat this uncommon deadly disease, PAH. He noted that there are no studies that compare these products in relative effectiveness due to lack of large numbers of patients to review over a reasonable time. Even trying to compare these drugs from study to study can be flawed. Because this disease is uncommon it is difficult to get the comparative data needed.

Dr. Fairman reviewed the Sildenafil versus Endothelin Receptor Antagonist for Pulmonary Hypertension (SERAPH) Study that was published in June of 2005 in the American Journal of Respiratory and Critical Care Medicine. He noted that two outcomes were measured. The secondary was the 6-minute walk distance; this endpoint correlates well with the hemodynamic of the disease and is a fairly good predictor of outcome in patients. In this trial they were not able to show any significant difference between bosentan, a drug that now been around for several years and is the standard of care for oral therapy, and sildenafil. His assessment is that sildenafil is at least as good as bosentan. The other endpoint, the mass of the right ventricle, was evaluated and here again there was no significant difference in the two groups. From his point of view as a clinician, the trial supports that these two drugs are equivalent and both would be beneficial for patients.

Dr. Axelrod asked if there are indeed 5 drugs and, in his opinion, if this is an appropriate category to pick only two drugs as preferred. Dr. Fairman noted that, within this class, there are two intravenous drugs that are much greater burdens to patients because of their administration form and monitoring; however, these are also the best drugs at treating the disease with the best outcomes. As far as the oral drugs, he does not know which one is best. He did note that one disadvantage of bosentan is that it requires monthly measurement of liver function, which is an added expense and inconvenience to the patients. There is also an inhaled drug that is also burdensome because it must be administered 6-9 times per day at 5-10 minutes each.

Dr. Axelrod asked if he had any comment on the one sudden death in this study. Dr. Fairman responded that this population is very sick patients and they die. There are deaths in most studies, this was not surprising. In the larger trial, with 280 patients, no difference was noted in the placebo group and the treated group when comparing deaths.

Gill Abernathy asked if he stated that that the two best drugs were epoprostenol and treprostinil. Dr. Fairman replied, yes. Gill Abernathy asked about the conventional treatment referenced in this study was? Dr. Fairman explained that conventional treatment is considered the use of diuretics, digoxin and sometimes warfrin.

Mark Oley asked if Dr. Fairman saw any correlation with the use of sildenafil and an occurrence of non-arteritic anterior ischemic optic neuropathy (NAION). Dr. Fairman said he had not seen it, but it is a very rare problem.

It is difficult to say whether there is an increased incidence. This problem would be more common with those in an advancing age group or with chronic conditions such as hypertension, diabetes, vascular diseases, rather than in this population. Most of the patients Dr. Fairman treats are in the 30-50 year old age group where this is less prevalent.

Geraldine Anastasio, PharmD- Director, Regional Medical Research Specialist for Pfizer, Inc. discussed Sildenafil (Revatio®); Pfizer's P5 for Pulmonary Arterial Hypertension

Dr. Anastasio noted that the average life expectancy of a patient with PAH is only 2.8 years. Only about 10 patients in a year can undergo a transplant to resolve the condition. The treatment is aimed at alleviating systems by improving functional class. The original treatment was with inhaled Nitrous Oxide. The sildenafil that is in Revatio® is identical to the sildenafil that is in Viagra®. Pfizer studied it at much higher dose to get the new indication of functional class 2 to 4 for PAH. Revatio is the only FDA approved oral therapy for functional class 2 and is indicated for classes 2-4. Some physicians used sildenafil for PAH before the FDA indication. The safety data from studies using up to sildenafil 240mg (2x the max dose for ED) found no patients discontinued from treatment-related adverse effects. Revatio® is rated as a pregnancy category B. In this study, Revatio® was found to be safe and effective at a fraction of the cost compared to other previously approved treatments.

Mark Oley reviewed clinical information for Phosphodiesterase 5 Inhibitor's for Pulmonary Arterial Hypertension:

There is currently only one Phosphodiesterase 5 inhibitor available in the United States for the treatment of pulmonary arterial hypertension (PAH). Pfizer released sildenafil under the brand name of Revatio® in July of this year. Revatio® comes in only a 20 mg tablets and is approved to treat pulmonary arterial hypertension (PAH). It is dosed at 20 mg TID.

Pulmonary Arterial Hypertension is a disease that causes the arteries of the lungs to constrict leading to right heart failure. Sildenafil (Revatio®) as discussed earlier increases cGMP within the pulmonary vascular smooth muscle cells resulting in relaxation. In patients with PAH, this can lead to vasodilatation of the pulmonary vascular bed and, to a lesser degree, vasodilatation in the systemic circulation.

PAH is a rare and potentially fatal disease, receiving a diagnosis is lengthy and complex. The average time from symptom onset to diagnosis is 2 years. No available pharmacological cure for PAH is currently known. Treatment is aimed at alleviating symptoms and prolonging survival. Revatio® treatment of PAH is to improve exercise tolerability. The average age for PAH is 20 to 40 years of age and is predominantly seen in women.

While this use of sildenafil marketed as Revatio® in PAH is new, similar drug to drug and side effects are seen as with sildenafil marketed as Viagra®

The following is considered to be class effects, i.e., generally all drugs within this class share these properties:

- The drugs are contraindicated when used with nitrates (e.g., nitroglycerin).
- Caution is suggested with the use of alpha-blockers like doxazosin (Cardura®), prazosin (Minipress®), and terazosin (Hytrin®) when used with Levitra® and Cialis® because of adverse effect of a decrease in blood pressure.
- Most common adverse effects seen with this drug are headache, flushing, dizziness, diarrhea, dyspepsia, abnormal vision, nasal congestion, rash, and decrease in supine blood pressure.
- It has not yet been assessed the relationship with the possible eyesight loss (NAION) has not yet been assessed in this population.

The Committee could not conduct a vote on the PDL eligibility of this class because a quorum was not present. The class information will be reviewed again for the Committee at its next meeting.

Scott Williams, Marketing/Public Affairs Manager for The Men's Health Network

The Men's Health Network is a patient advocacy and information network. Mr. Williams reviewed an article from Am J. Cardiol. 2005 Jul 15; 96(2):313-21: Sexual dysfunction and cardiac risk (the Second Princeton Consensus Conference). For generalist and specialties alike the management of patients with ED and concomitant cardiovascular disease or risk factors presents challenges and opportunities. The current guidelines stress the need for a complete medical history, physical exam, and laboratory testing, as needed. Recent studies have highlighted the relationship between erectile dysfunction (ED) and cardiovascular disease (and its comorbidities). He provided a quote that suggests chronic conditions are often diagnosed when a patient visits physicians with ED symptoms/complaints. They believe that addressing erectile dysfunction allows men to become engaged earlier in the health care system which can serve to detect other conditions. In conclusion, it is the Men's Health Network strongest opinion that ED treatment has significant value in maintaining strong and healthy relationships for men and their family. ED afflicts men of all walks of life and effective treatment and drug access is critical to their health and well being of their loved ones.

Geraldine Anastasio, PharmD- Director, Regional Medical Research Specialist for Pfizer, Inc. discussed sildenafil (Viagra®) Pfizer's P5's for Erectile Dysfunction

Dr. Anastasio reviewed a non-published study done at the University of Maryland School of Medicine. She stated that according to this study 87% of men stopped taking their antihypertensive medications because of a perceived side effect of ED from their antihypertensive medication.

Dr. Axelrod asked for a clarification of these study results. Dr. Anastasio stated that the men were asked two yes or no questions - "Have you ever stopped taking your medications as you felt they were causing your erectile difficulties? If so, did this improve your erectile function? From their opinions they gave their answers and 87% said yes, that they had stopped taking it.

Dr. Axelrod asked for the scientific-based statistics on side effects of ED based on medications/ treatment of chronic conditions. Dr. Anastasio responded that it was around 30%. Dr. Axelrod questioned the 30% rate stating that he has not seen this statistic in all of the placebo controlled trials related to this condition, it has always been less than 5%. Dr. Axelrod noted this represents an opportunity for further patient education.

Dr. Anastasio reviewed the Pomara, et al trial from the Journal of Andrology (Vol. 25, No. 4, July/August 2004) entitled "Cardiovascular Parameter Changes in Patients With Erectile Dysfunction Using Pde-5 Inhibitors: A Study With Sildenafil and Vardenafil". In conclusion, she stated that Viagra is highly effective for the treatment of ED and the best and most extensively studied all of the ED medications.

Mark Oley reviewed the clinical information for Phosphodiesterase 5 Inhibitors for Erectile Dysfunction

There are currently three phosphodiesterase 5 inhibitors available in the United States for treatment of erectile dysfunction.

- **Pfizer** has sildenafil the brand name is Viagra® it comes in tablets of 25, 50 and 100mg. The Onset of action is 30 minutes to 1 hour
- **Bayer** has vardenafil band name is Levitra® it comes in tablet of 2.5, 5, 10 and 20 mg. The Onset of action is 30 minutes to 1 hour
- **Lilly** has tadalafil the brand name is Cialis® it comes in tablets of 5mg, 10 mg, 20 mg. The Onset of action is 30 minutes to 1 hour

The major differences in the products are the duration of action:

- Viagra® is up to 4 hours
- Cialis® is up to 36 hours
- Levitra® is 8 to 12 hours

All of the drugs appear to have the same benefit of improving the quality and duration of erection, and increase the likelihood of successful intercourse in many men with erectile dysfunction, regardless of etiology.

The following is considered to be class effects, i.e., generally all drugs within this class share these properties:

- Adverse effects most commonly seen are headache, flushing, dizziness, diarrhea, dyspepsia, abnormal vision, nasal congestion, and rash.
- The drugs are contraindicated when used with nitrates (e.g., nitroglycerin).
- Caution is suggested with the use of alpha-blockers like doxazosin (Cardura[®]), prazosin (Minipress[®]), and terazosin (Hytrin[®]) when used with Levitra[®] and Cialis[®] because of adverse effect of a decrease in blood pressure supine blood pressure.

We are aware of the general warning from the FDA and information on blindness in respect to the use of this class of drugs. The FDA basically said that it is not known at this time if Cialis[®], Viagra[®] or Levitra[®] causes non-arteritic anterior ischemic optic neuropathy (NAION). NAION also happens in men who do not take these medicines.

Gill Abernathy asked for the Virginia drug spend for ED drugs. The answer from the audience was 0.10%. DMAS and First Health Services will validate this figure.

Dr. Axelrod noted that at the next meeting with the Committee's vote and discussion on this class as well as the review of 2nd generation quinolones and the macrolides, the Committee will need to determine if, particularly with erectile dysfunction drugs, there will be different approaches for urologists compared to primary care physicians. If you have ED should you seek an urologist? or can primary care physicians make that determination? He noted that ED drugs seemed relatively broad in terms of variation of utilization.

Gill Abernathy noted that when reviewing different classes in the past, the Committee has required certain diagnostic information. Should the Committee consider the two indications require some documentation of illness, and especially with PAH, some documentation of diagnostic test.

Dr. Axelrod agreed that certainly in PAH it should be prescribed by a pulmonary doctor and maybe a cardiologist. He stated that he did not know if this approach was practical; however, it seems that in some of the classes being reviewed it should be considered.

Dr. Axelrod asked if there are quantity limits set for ED drugs today. The answer was given, yes, a quantity of 4 per month and registered sex offenders do not have access to the drugs.

Mark Oley asked to see utilization statistics and information on which types of physicians are prescribing these medications. Dr. Axelrod agreed that market information would be useful.

Secretary Woods asked Dr. Axelrod if the Committee could get the total drug spend for ED drugs as well as total drug spend by dual and non-dual, to determine how many will be managed by the Department post-Medicare Part D implementation. She also asked if ED was a covered drug class under Medicare Part D. A conversation occurred of whether this was a Medicare Part D covered drug and the consensus was that, yes, it will be covered by Part D.

Gill Abernathy asked if we had PAH recipients receiving sildenafil now and not limited to the quantity of 4 per month.

The answer is, yes, for both Viagra and Revatio; however, there is a prior authorization process for Viagra used for the treatment of PAH which is required to override the quantity limit. There are currently only three recipients using Revatio since its market introduction in July 2005.

Review of New Drugs in PDL Classes; Drug Class Discussions

Dr. Axelrod asked the Committee if they would like to review the new drugs in existing PDL classes. Dr. Axelrod withdrew the recommendation because two requested presentations were cancelled as there was no quorum to vote on the new drugs. The Committee decided to hold all discussion of new drugs for the next meeting.

Dr. Axelrod adjourned the meeting. The next meeting is scheduled for October 19, 2005.