

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES
COLLEGE OF PHARMACY

ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR_x)

QUARTERLY REPORT - SECOND QUARTER 2005



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INTRODUCTION

OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

Providing access to prescription medications is an integral part of ensuring the health and well-being of Arkansas Medicaid enrollees. Medications help Medicaid recipients treat infections, ease pain, and slow or even halt the progression of chronic diseases. While it is clear that medications benefit the health of Medicaid recipients, it is also clear that rising costs and utilization have led to Medicaid prescription spending which will exceed half a billion dollars in the next state fiscal year.

The State of Arkansas can not ensure continued access to medications for the Medicaid population if costs continue to rise at their current annual rate. Consequently, the Department of Human Services (DHS) Division of Medical Services and the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy created the Arkansas Medicaid Evidence-based Prescription Drug Program. The major goals of this program are to create an evidence-based Preferred Drug List, to manage its implementation through a Prior Authorization (P.A.) Call Center operated by the College of Pharmacy, and to track the long term outcomes of these decisions through evaluation of medical and pharmacy claims.

After many months of planning, the program was approved by the state legislature, and authorized by the Governor. A contract between DHS and the College of Pharmacy was executed, and the program began November 1, 2004. This report details the progress of the program from April 1, 2005 through June 30, 2005.

PROGRESS OF COMMITTEES

DRC & DUCC MEETING UPDATES

DRUG REVIEW COMMITTEE (DRC) UPDATE

The DRC held three public meetings in the second quarter of calendar year 2005. During these meetings the committee made recommendations to the DUCC and to DHS. Summary recommendations of those meetings are attached at the end of this report (Appendices A, B, and C). Full meeting minutes are available through EBRx.

DRUG UTILIZATION AND COST COMMITTEE (DUCC) UPDATE

APRIL MEETING

The DUCC met on Tuesday, April 19th at the DHS offices in Little Rock. The committee began by reviewed DRC recommendations on the Calcium Channel Blocker class of medications. The committee opened the sealed supplemental rebate information for the Calcium Channel Blockers. After a thorough review of the net-net costs (i.e. final cost to Medicaid), the committee then deliberated as to which products should be recommended as preferred. Because the DRC requested that at least one product be available in each of the subcategories of the calcium channel blockers, the DUCC issued the following recommendations:

1. Generic Verapamil S.R. tablets in the 120mg, 180mg, and 240mg strengths should be the preferred phenylalkylamine.
2. Generic Diltiazem XR capsules (generic equivalent to Dilacor XR) in the 120mg, 180mg, and 240mg strengths should be the preferred benzothiazepine.
3. Norvasc (amlodipine), Dynacirc CR (isradipine), and generic nifedipine extended-release tablets should be the preferred dihydropyridines.

These recommendations for the Calcium Channel Blockers were then forwarded to DHS.

The Calcium Channel Blockers were fully implemented on July 12, 2005.

MAY MEETING

The DUCC met on Monday, May 23rd to discuss the Inhaled Corticosteroids. The committee reviewed the recommendations from the DRC and opened the sealed supplemental rebate bids. Once the bids were opened it was discovered that two of the three bids received could result in increased expenditure on behalf of the state, if accepted. Phone calls were placed at the time of the meeting to determine if the bids submitted were in error. Neither of the contacts could confirm the validity of the bids. One manufacturers contact stated that while he could not confirm the bid, he admitted that the bid did not reflect the manufacturer's best price. Best Price was not provided for

fear of how it would affect a combination inhaled corticosteroid/beta-agonist product manufactured by the same company.

Clarification on the bids was not received and the meeting adjourned without a decision. EBRx is not aware of any further effort by the Arkansas Medicaid Program to clarify bids in this category.

With no decision being reached, the EBRx program has begun assembling an educational campaign, championed by Dr. Mark Helm, targeting prescribers to highlight the difference in potency and cost among the inhaled corticosteroid products. It is our hope that this outreach will result in more appropriate use of asthma controllers for the state's Medicaid recipients. **It is important to note that while educational campaigns are effective, they can never reach the effectiveness of implementing a product on a preferred drug list.**

JUNE MEETING

The DUCC met on Thursday, June 23rd and again on Tuesday, July 12th to finalize our decisions on the Beta-adrenergic Blocking Agents. The DRC recommendations covered the use of beta blockers in eight different disease states. The DRC made specific mention that for patients with congestive heart failure (CHF) three products, metoprolol succinate, bisoprolol, and carvedilol, have demonstrated efficacy and two of the three should be preferred for the Medicaid population. As a result of these recommendations and in consideration of cost and utilization data, the DUCC issued the following recommendations:

1. The following products should be preferred and will provide an option for all disease states except for congestive heart failure: atenolol tablets, metoprolol tartrate tablets, and propranolol tablets.
2. For patients with a diagnosis of Congestive Heart Failure only (ICD-9 428 through 428.9) the following two products should be preferred: bisoprolol tablets and metoprolol succinate tablets (Toprol XL®).
3. The DRC made a special consideration for African-American patients with Congestive Heart Failure deciding that Coreg (carvedilol) should be available to this patient population. Because SmartPA has a limitation that does not allow race to be read at the Point of Sale, this population will have access to Coreg through the PA Call Center. When a prescriber calls and states that the patient is African-American with a diagnosis of CHF, then a PA will immediately be issued.

These recommendations for the Beta-adrenergic Blocking Agents were then forwarded to DHS.

Full implementation of the Beta-adrenergic Blocking Agents will occur on October 5th.

FINANCIAL IMPACT OF COMMITTEE'S DECISIONS

COST SAVINGS TO THE STATE BECAUSE OF THE PDL

In the last quarterly report, we provided estimates of potential savings generated by the PDL. This report provides actual cost savings to the State. Please note that the cost savings presented in this section attempt to include the CMS rebates that are a part of all state Medicaid prescription drug programs. The CMS rebate data that was used in the calculation of each of these drug classes comes from the information provided the DUCC by DHS.

SECOND GENERATION ANTIHISTAMINES

The second generation antihistamines were fully implemented on March 25, 2005 with loratadine products (tablets, reditabs, and syrups) as the preferred products. In addition, Zyrtec Syrup® and Clarinex Syrup® are available for children ages six to 24 months of age through the SmartPA system. All other second generation antihistamine claims now are denied at the point of sale and must have a prior authorization for Medicaid to cover these medications.

Because the preferred product, loratadine, was a generically available medication that did not offer any supplemental rebates, the cost savings in this category are obtained by moving market share from the more expensive non-sedating antihistamines to the equally effective, less expensive loratadine products. This has resulted in a net-net spend to the State Medicaid Program averaging \$260,000 per month less than the same period last year (Table 1).

TABLE 1

NON SEDATING ANTIHISTAMINE ARKANSAS MEDICAID COSTS

	April	May	June	Total
2004	\$504,000	\$427,000	\$383,000	\$1,314,000
2005	\$187,000	\$180,000	\$148,000	\$515,000
Year-to-Year Savings	\$317,000	\$247,000	\$235,000	\$799,000

While the costs have been reduced by almost \$800,000, the number of prescriptions filled every month has held true to the seasonal trends in this therapeutic category. The chart on the next page (Chart 1) illustrates the trends in prescription volume and net-net cost to the Arkansas Medicaid Program over the last 15 months and the average net-net cost per prescription of a second generation antihistamine to the Arkansas Medicaid Program. *The second generation antihistamines were fully implemented on March 25, 2005, immediately prior to the beginning of the calendar quarter, and at the peak of demand for this class of seasonal products.*

Market Share Shift Second Generation Antihistamines

The table below demonstrates the success that the program has had in moving share from the non-preferred second generation antihistamines to the preferred product, loratadine. Notification of which product was preferred was sent to providers approximately 60 days prior to the March 25, 2005 implementation.

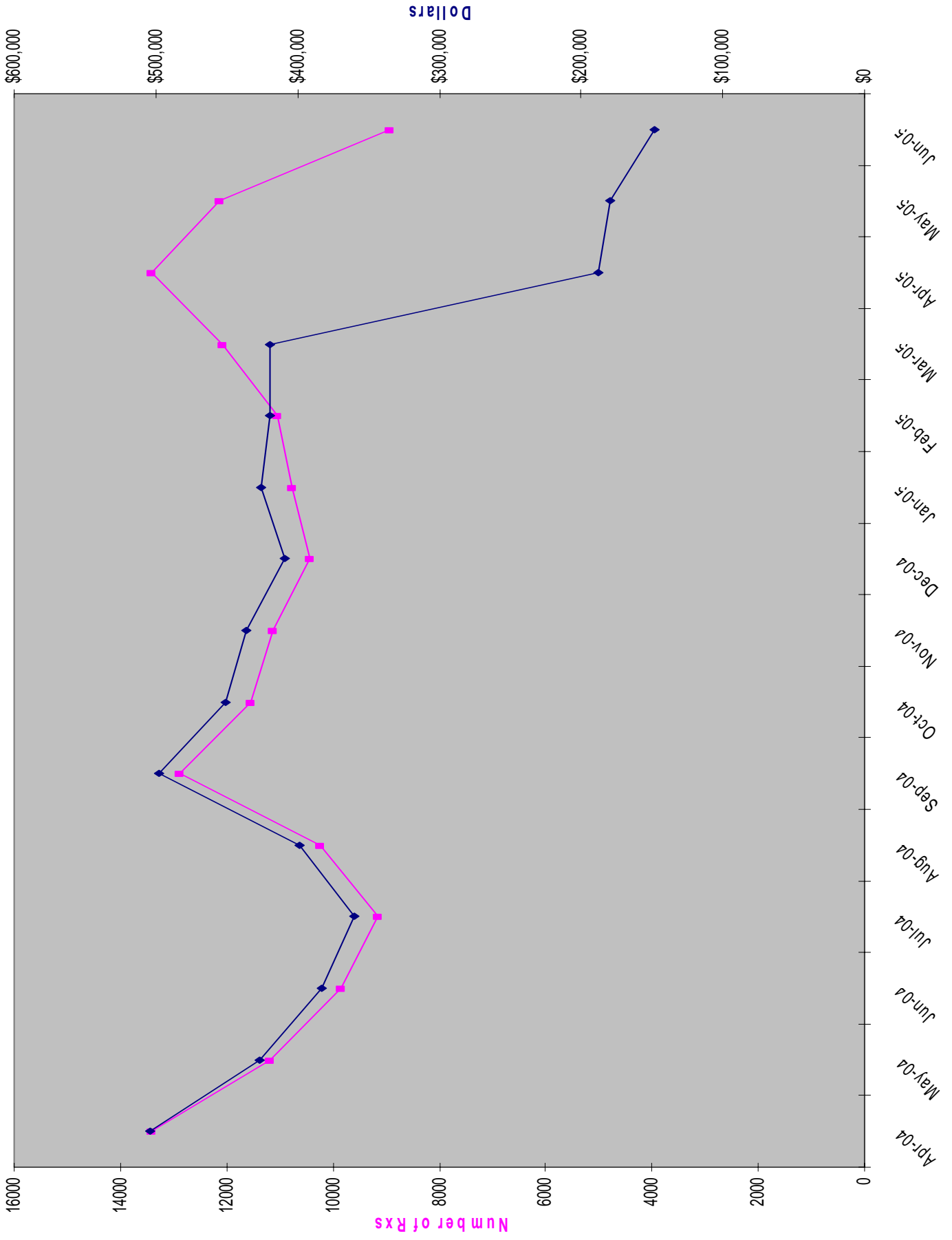
Loratadine % Share of Non-Sedating Antihistamine Market

May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04	Jan-05	Feb-05	Mar-05*	Apr-05**	May-05**	Jun-05**
2.81%	2.39%	2.75%	3.11%	2.71%	2.24%	2.28%	2.64%	2.64%	5.06%	17.59%	93.38%	91.32%	88.03%

** March 25th implementation - **Implemented for entire month*

Chart 1

NSA Trend Data



PROTON PUMP INHIBITORS

The proton pump inhibitor PDL recommendations became effective May 18, 2005 with Prevacid® (lansoprazole) capsules and Nexium® (esomeprazole) capsules as preferred products. In addition, Prevacid SoluTabs® gained preferred status for children under the age of seven and for patients with nasogastric tubes. All other proton pump inhibitor claims now require a prior authorization for Medicaid to purchase these medications.

Both manufacturers of the preferred products submitted supplemental rebate bids. As a result, cost savings will be from supplemental rebates *and* moving market share to the preferred products. The savings estimated below are calculated by taking the difference in the CMS rebated price of the preferred PPIs and the supplemental rebated price that Arkansas Medicaid receives for placing products in preferred position on the PDL. Even though the PPIs were not fully implemented until May 18, 2005, the supplemental rebates began on April 1, 2005. Since April 1st, the average savings per month just on the PPIs was almost \$520,000 (see Table 4 below).

TABLE 4

	Savings as a Result of the PDL
April 2005	\$369,000
May 2005	\$507,000
June 2005	\$681,000
<i>Total PPI Savings to Date</i>	<i>\$1,557,000</i>

The three month estimated net-net savings to the Arkansas Medicaid program on the proton pump inhibitors, is over \$1,500,000. While costs have been reduced by almost \$1,500,000 the number of prescriptions filled for PPIs in May and June 2005 are the largest volumes to date. Simply put, more patients are getting their PPI medications than ever before while cost per prescription has been cut by approximately 75 percent. The chart (Chart 2) on the following page illustrates the trends in prescription volume and net-net cost to the Arkansas Medicaid Program over the last 15 months and the average net-net cost per prescription of a proton pump inhibitor to the Arkansas Medicaid Program. ***Please keep in mind, the proton pump inhibitors were fully implemented on May 18, 2005, although supplemental rebates began on April 1, 2005.***

EBRx staff identified an error in the implementation of the Prevacid SoluTab® criteria. This error permitted processing of all claims for these products regardless of the SmartPA age and condition edits from May 18th through June 8th. This programming error was corrected on June 9th. This error led to approval of over 200 claims that did not meet criteria and increased net-net cost to the state by over \$7,500.

Market Share Shift Proton Pump Inhibitors

The table below demonstrates the programs' success in moving share from the non-preferred proton pump inhibitors to the preferred products, Prevacid® capsules(lansoprazole) and Nexium® capsules(esomeprazole). Notification of which products were preferred was sent to providers approximately 60 days prior to the May 18th, 2005 implementation.

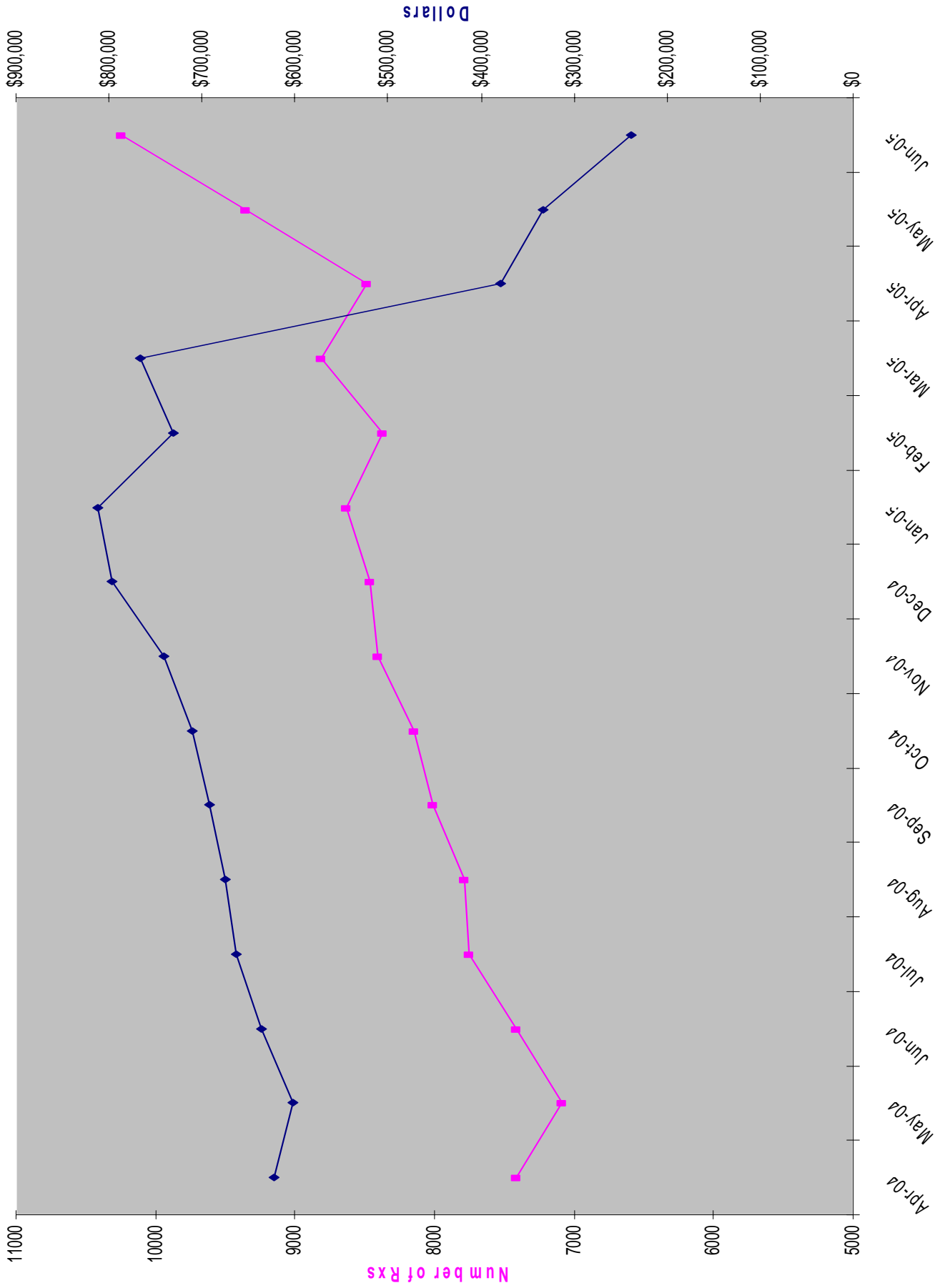
Prevacid & Nexium % Share of Proton Pump Inhibitor Market

May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04	Jan-05	Feb-05	Mar-05	Apr-05	May-05*	Jun-05**
62.98%	63.20%	62.46%	63.25%	63.47%	63.54%	63.45%	63.95%	63.43%	64.02%	64.65%	67.08%	80.89%	99.84%

** May 18th implementation - **Implemented for entire month*

Chart 2

PPI Trend Data



HMG COENZYME-A REDUCTASE INHIBITORS (THE STATINS)

The statins were fully implemented on June 8, 2005 with Zocor® (simvastatin) tablets being selected as the preferred product. In addition, Lipitor® 80mg tabs are available to patients who have been on that specific product for four of the preceding six months through the SmartPA system. All other statins now are denied at the point of sale and require a prior authorization to authorize Medicaid payment for these medications.

The manufacturer of Zocor provided a supplemental rebate bid. As a result, cost savings will be a from supplemental rebates *and* moving market share to the preferred product. The savings estimated below are calculated by taking the difference in the CMS rebated price of the preferred statin and the supplemental rebated price that Arkansas Medicaid receives for placing products in preferred position on the PDL. Even though the statins were not fully implemented until June 8, 2005, the supplemental rebates began on April 1, 2005. Since April 1st, the average savings per month just on the statins was almost \$125,000 (see Table 5 below).

TABLE 5

	Savings as a Result of the PDL
April 2005	\$83,000
May 2005	\$89,000
June 2005	\$204,000
<i>Total Statin Savings to Date</i>	<i>\$376,000</i>

The three month estimated net-net savings to the Arkansas Medicaid program on the statins, is over \$375,000. While the costs have been reduced by almost \$376,000 the number of prescriptions filled in June 2005 was up over six percent from last year this time. There was a drop in prescription volume, however, from the previous month. This drop appears to be cyclical in the early summer and may coincide with vacations. A careful watch will be kept on the volume of this important class of drugs. The chart (Charts 3) on the following page illustrates the trends in prescription volume and net-net cost to the Arkansas Medicaid Program over the last 15 months and the average net-net cost per prescription of a proton pump inhibitor to the Arkansas Medicaid Program. ***Please keep in mind, the statins were fully implemented on June 8, 2005, although supplemental rebates began on April 1, 2005.***

Market Share Shift Statins

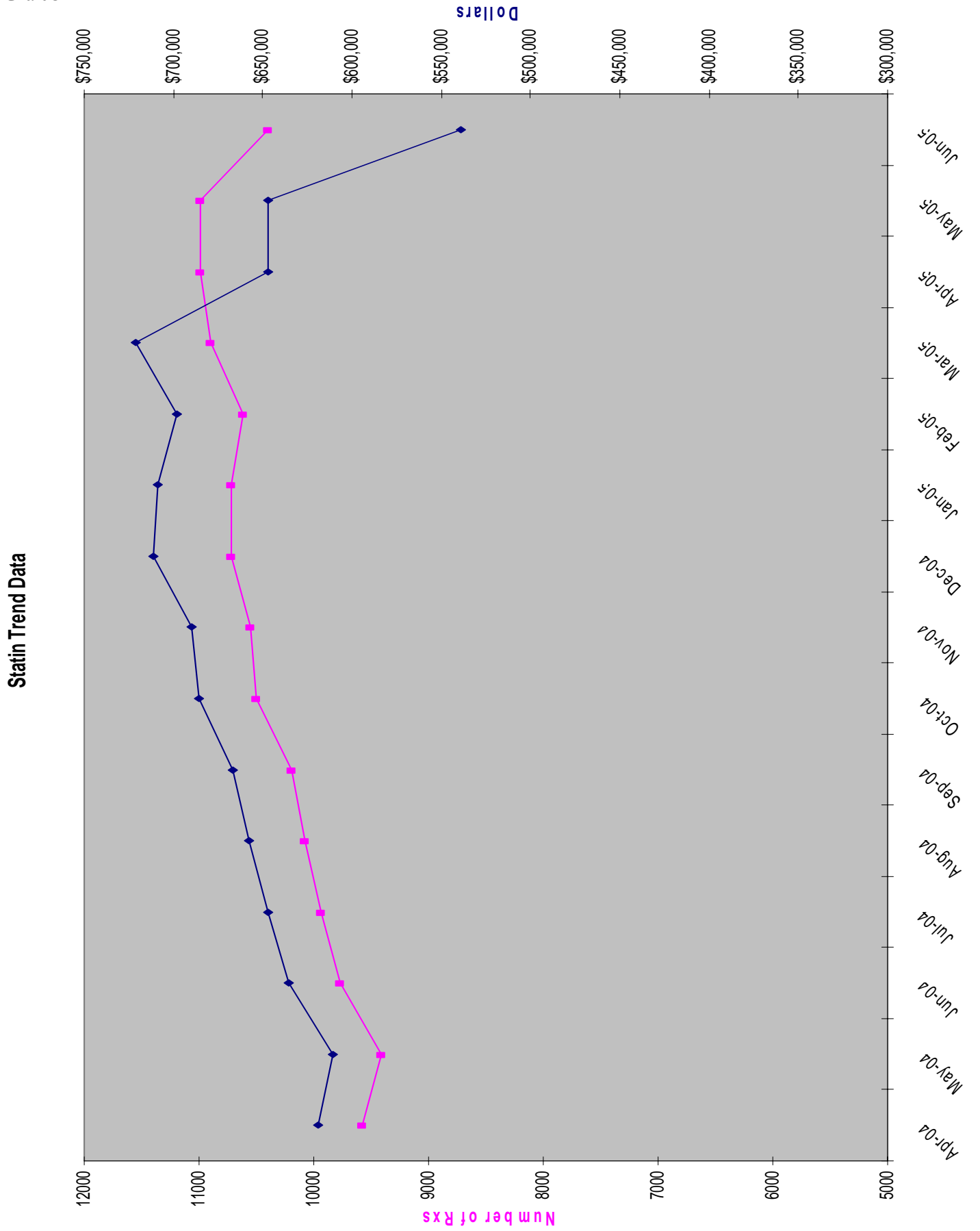
The table below demonstrates the success that the program has had in moving share from the non-preferred statins to the preferred product, Zocor® (simvastatin) tablets. Notification of which products were preferred was sent to providers approximately 60 days prior to the June 8, 2005 implementation.

Zocor % Share of Statin Market

May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04	Jan-05	Feb-05	Mar-05	Apr-05	May-05	Jun-05*
26.54%	26.80%	25.90%	25.84%	25.54%	24.48%	24.35%	24.53%	24.11%	23.99%	23.77%	23.92%	25.57%	62.14%

** June 8th implementation*

Chart 3



CALCIUM CHANNEL BLOCKING AGENTS

The calcium channel blockers were fully implemented on July 12, 2005 with Norvasc® (amlodipine) tablets, Dynacirc CR® (isradipine) tablets, generic nifedipine extended-release tablets, generic verapamil extended-release tablets, and generic diltiazem capsules (AB rated to Dilacor XR only) being selected as the preferred products. All other calcium channel blockers now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

The manufacturer of Norvasc and Dynacirc CR provided supplemental rebate bids. As a result, cost savings will be from supplemental rebates *and* moving market share to the preferred product. The savings estimated below are calculated by taking the difference in the CMS rebated price of the preferred statin and the supplemental rebated price that Arkansas Medicaid receives for placing products in preferred position on the PDL. Even though the calcium channel blockers were not fully implemented until July 12, 2005, the supplemental rebates began on May 2nd and 3rd, respectively. Since the rebates began, the savings on the calcium channel blockers was over \$73,000 (see Table 6 below).

TABLE 6

	Savings as a Result of the PDL
May 2005	\$29,900
June 2005	\$43,300
<i>Total Calcium Channel Blockers Savings to Date</i>	<i>\$73,200</i>

Prior Authorization Call Center Statistics

P.A. CALL CENTER OPERATIONS AS A RESULT OF THE PDL

The PDL Call Center approves or denies prior authorization requests from physicians for products that have been placed in non-preferred status. The approval, denial, and appeal of denials are handled by the clinical pharmacists and medical directors of the EBRx Program. The statistics below represent the Call Center's activity for the second quarter 2005, which includes April 1st through June 30th 2005.

PA Call Center Statistics	April 2005	May 2005	June 2005	Total 2Q 2005
Incoming Calls from Healthcare Professionals	860	756	1001	2617
Number of SmartPA Tickets Created	878	771	1032	2681
Total Number of P.A. Request at the Call Center	660	586	674	1920
Total Number of P.A. Requests Approved at the Call Center	331	375	384	1090
Call Center P.A. Approval Percentage	50.15%	63.99%	56.97%	56.77%
Point of Sale SmartPA Requests	2687	1360	1809	5856
Point of Sale SmartPA Approvals	494	438	708	1640
Point of Sale SmartPA Approval Percentage	18.38%	32.21%	39.14%	28.01%
Average Call Duration	4 min 4 sec	3 min 40 sec	3 min 12 sec	3 min 39 sec

Budget Update

A GENERAL OVERVIEW OF THE PROGRAM BUDGET

The information below is representative of the current budget for the Arkansas Medicaid Evidence-based Prescription Drug Program for the State Fiscal Year 2005 (SFY05). The numbers for SFY05 represent a nine month period, from October 2004 through June 2005. There are a number of personnel positions which remain to be filled; however, as demand arises the program will work within its budget to ensure that it can meet the demand. Additionally, the startup equipment expenses have been scaled back to meet our current employment level. The program will continue to work within the personnel and equipment budget, but request that the budgeted amounts unspent for SFY05 be allowed to be carried over to SFY06. At the end of SFY 05, the program is approximately \$1.7 million under its budget.

	SFY05 Budget	Expenditures To Date <small>(through June 30, 2005)</small>
Personnel – (Salary and Fringes, includes DRC stipends)	\$1,563,656	\$552,699
Miscellaneous – (Supplies, Travel, etc)	\$132,488	\$18,610
Equipment – (computers, phones, furniture, renovation)	\$382,6000	\$334,098
Indirect Costs	\$915,918	\$308,507
TOTAL	\$2,994,662	\$1,213,914

Provider Outreach

EBRX'S EFFORTS TO EDUCATE PROVIDERS ON THE PROGRAM

The most challenging aspect of any new program is educating the parties involved about the process. This has been one of the highest priorities for the EBRx Program. Recognizing that there are many stakeholders, we have actively pursued educating physicians, nurses, physician office staff, and pharmacists.

As part of our efforts, we have done live presentations to the following groups:

- Arkansas Foundation for Medical Care – Medicaid Managed Care Conference – Fort Smith
- Arkansas Foundation for Medical Care – Medicaid Managed Care Conference – Texarkana
- Arkansas Foundation for Medical Care – Medicaid Managed Care Conference – Jonesboro
- Arkansas Pharmacists Association – Annual Convention – Hot Springs
- Arkansas Area Health Education Centers – Directors Meeting – Little Rock

Additional outreach efforts are planned for the upcoming quarter, including meetings with medical staff at hospitals around the state, talks at AFMC Managed Care Conference, and lectures at AHECs around the state.

Data Evaluation

TRACKING OUTCOMES OF THE PDL DECISIONS

One of the most important aspects of the EBRx program is the evaluation of Medicaid data to determine what the long term ramifications of the PDL decisions are. Through the College of Pharmacy's Pharmaceutical Evaluation and Policy (PEP) Division, the Medicaid claims database will be analyzed to determine impact to the Medicaid program, beyond simply the cost of the medications.

Programmers have recently been hired to help facilitate the evaluation of the data. It is our hope to begin providing this outcome data during SFY 06.

Appendix A

Date: April 17, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 04/14/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the calcium channel blockers. Dr. McDonough of the EPC also addressed the Committee telephonically regarding her organization's views on the class. With the understanding that comparable doses of each drug are used the Committee reached the conclusions listed below based upon its perception of the bulk of the best available evidence.

1. Excluding bepredil, none of the available calcium channel blockers is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration.
2. None of the remaining drugs have been proven to cause adverse events of greater severity or frequency among patients of a particular sex, age or race than the others.
3. None of the remaining drugs have been proven more efficacious for patients of a particular sex, age or race than the others.
4. The three classes of calcium channel blockers in use differ pharmacologically to the degree that at least one representative of each should be accessible to prescribers. Accordingly, verapamil, diltiazem and at least one dihydropyridine should be available.
5. When considering the dihydropyridines, the Committee recommends the following:
 - That amlodipine, nicardipine, nifedipine and nisoldipine are considerations for patients with angina
 - That amlodipine, isradipine, nicardipine, nifedipine and nisoldipine are considerations for patients with hypertension
 - That amlodipine be available in the following categories:
 - Patients with both angina and documented left ventricular systolic dysfunction
 - Patients with hypertension and documented left ventricular systolic dysfunction
 - Patients with angina, hypertension, and documented left ventricular systolic dysfunction

Appendix B

Date: May 20, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 05/20/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the inhaled corticosteroids in pediatric outpatients with asthma, adult outpatients with asthma, and adult outpatients with COPD. Specifically considered were beclomethasone, budesonide, flunisolide, fluticasone and triamcinolone. Dr. Richard Hansen of the EPC addressed the Committee telephonically regarding his organization's views on these agents.

With the understanding that equipotent doses of each drug are used, the Committee reached the following conclusions based upon its perception of the bulk of the best available evidence.

1. None of the five available inhaled steroids is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration for patients in the aforementioned three patient populations.
2. None of the five drugs have been proven more efficacious for patients in the aforementioned three patient populations.
3. None of the five drugs have been associated with fewer adverse events among patients on the basis of sex, race, pregnancy, co-morbidities or concomitant use of other medications. However, due to considerations regarding potential growth retardation, fluticasone and budesonide should be available for children based upon the available safety data for these two agents.
4. None of the five drugs has been proven more effective in the three subgroups of patients on the basis of sex, race, pregnancy, co-morbidities, or concomitant use of other medications.
5. When prescribing the inhaled corticosteroids, the Committee submits the following considerations:
 - That budesonide be available by nebulizer
 - That a dry powder inhalation product be available
 - That the PDL not be restricted to either triamcinolone or flunisolide without concomitant availability of a more potent agent
 - That spacers continue to be available.

Appendix C

Date: June 16, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 06/15/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the beta blockers in adults with hypertension, angina, s/p coronary artery bypass graft, heart failure, recent myocardial infarction, atrial arrhythmias, esophageal varices, and migraine.

The Committee reached the following conclusions based upon its perception of the bulk of the best available evidence.

1. There is insufficient data on carteolol and penbutalol for the Committee to comment on their utility for the aforementioned indications.
2. Metoprolol tartrate should be available to Arkansas Medicaid patients for various indications.
3. All of the beta blockers discussed have some efficacy in the treatment of hypertension.
4. Excluding timolol, all of the remaining drugs have some efficacy in the treatment of angina.
5. Acebutalol, propranolol, timolol, carvedilol and metoprolol tartrate have some efficacy in the treatment of patients with recent myocardial infarction. The Committee does not believe that pindolol should be available for this indication.
6. Bisoprolol, Metoprolol succinate and carvedilol have some efficacy in the management of congestive heart failure. At least two of them should be available.
7. Atenolol, nadolol, metoprolol succinate, pindolol, bisoprolol and carvedilol have some efficacy in the management of atrial dysrhythmias. There is insufficient data to recommend labetalol for this indication.
8. Atenolol, metoprolol tartrate, propranolol, bisoprolol, and timolol have some efficacy in the treatment of migraine. There is insufficient data to recommend to recommend pindolol for this indication.
9. Atenolol, nadolol and propranolol all have some efficacy in the management of esophageal varices.
10. There is insufficient data to recommend specific beta blockers to patients simply because they have had coronary bypass grafting.
11. Although none of the beta blockers has been proven more effective on the basis of sex, race, pregnancy or concomitant use of other medications, four of the six voting members felt there was data suggesting that carvedilol was effective in African American patient with congestive heart failure and voted that it should be made available to them. There was discussion that carvedilol might be

beneficial to some patients with decreased renal function but evidence was felt to be insufficient to make a recommendation. Everyone agreed that a beta selective agent should be available to patients with obstructive lung disease.