

UNIVERSITY OF ARKANSAS  
FOR MEDICAL SCIENCES  
COLLEGE OF PHARMACY

# ARKANSAS MEDICAID EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM (EBR<sub>x</sub>)

---

QUARTERLY REPORT – SECOND QUARTER 2006



4301 W. MARKHAM SLOT 522-9  
LITTLE ROCK, ARKANSAS 72205  
501-526-4200

# INTRODUCTION

---

## OVERVIEW OF THE EVIDENCE-BASED PRESCRIPTION DRUG PROGRAM

---

Prescription medications are important tools in treatment and prevention of medical problems. Prescription drug coverage is an optional component of the Medicaid benefit, but Arkansas along with most other state Medicaid programs, extends some coverage to enrollees. Arkansas Medicaid drug expenditures exceeded \$400 million dollars in the last fiscal year. Spending for prescription drugs is budgeted to exceed one-half billion dollars in the current fiscal year. Over the past nine years Medicaid prescription drug spending has grown at a compound annual growth rate exceeding 16 percent. This growth has been due only in part to increases in the number of Medicaid and ARKids enrollees. The largest contributor to the increase in total medication expenditures has been increases in average medication costs. The medication cost growth rate far exceeds state revenue growth, and jeopardizes continuation of the drug benefit, or other Medicaid benefits at current levels.

The prescription benefits available under Arkansas Medicaid currently provide no limits on the number of prescription medicines per month for individuals under age 18, or in nursing homes. For other adults eligible for full Medicaid benefits, three prescription products per month are covered. With an Extension of Benefits, Medicaid covered individuals may receive up to six medications per month paid for through the Medicaid program. With each prescription dispensed, Medicaid recipients are expected to contribute a minimal co-payment, ranging between fifty cents and three dollars.

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 Arkansas Department of Health & Human Services' (DHHS) 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 DHHS and the College of Pharmacy was executed, and the program began November 1, 2004. This report details the progress of the program from January 1, 2006 through June 30, 2006.

# MEDICARE PART D

---

## THE IMPACT ON THE PREFERRED DRUG LIST PROGRAM

---

On January 1, 2006, the new Medicare Part D program began. Medicare Part D is designed to provide prescription benefits to Americans who are eligible for either Medicare Part A or Medicare Part B. As such, any recipient of Arkansas Medicaid who is eligible for Medicare will now, effective January 1, 2006, receive their prescription benefit from a private Medicare Part D prescription drug plan. As a result, the Preferred Drug List program no longer applies to these Medicaid-Medicare Dual Eligibles, instead, they are bound by the formularies of the Medicare Part D prescription drug plans.

Part of the implementation of Medicare Part D involved the Dual Eligibles being automatically enrolled into a Medicare Part D plan. Despite this auto-enrollment, many of the dual eligibles, who formerly received prescription benefits from the Arkansas Medicaid Program, did not have prescription coverage on January 1<sup>st</sup> as was expected. Because of this, Governor Huckabee issued a state of emergency and ordered the State's Medicaid program to continue covering prescription medications for these recipients. The State provided payment for dual eligible patients, whose Medicare Part D coverage was not working properly, through March 17, 2006.

The utilization and cost savings included in this report is inclusive of prescriptions that were filled for dual eligibles and billed to Arkansas Medicaid during the first quarter of 2006.

# FINANCIAL IMPACT OF COMMITTEE'S DECISIONS

---

## COST SAVINGS TO THE STATE RESULTING FROM THE PDL

---

### METHOD OF ESTIMATING COSTS AVOIDED/SAVINGS

Estimates of the cost impact of PDL selections are presented below. Calculation of the potential avoided costs requires certain assumptions.

First, the net cost to Medicaid prior to the PDL selection must be calculated. This cost for each product is less than the amount reimbursed to pharmacies. This is because Medicaid programs receive mandatory rebates per unit purchased. The product specific rebate amounts are calculated by the Centers for Medicare and Medicaid Services (CMS) based on a complex formula. The net costs for each product in a drug category are provided to EBRx in advance of a Drug Utilization and Cost Committee meeting. Updates on CMS net costs are not provided, and expected costs of a category are based on an average net price per prescription. This average net price per prescription is calculated over a three month time period immediately prior to the effective date of a PDL selection. The average net price is not adjusted for subsequent price changes, and CMS discounts are estimated for products which enter the market after the PDL becomes effective. The average net price per prescription reflects the costs of the category market mix prior to market share changes resulting from the PDL selection.

Second, the calculated average net price per prescription in a category is multiplied by the number of prescriptions dispensed after the effective date of the PDL selection. This product is the estimated CMS cost for the category, or the "pre-PDL expected net cost." As the average price per prescription is constant, month-to-month changes in the total cost reflect increases or decreases in prescription dispensing.

Third, the actual net costs for a drug category are calculated using the CMS net costs, or the contracted net costs from the contract bids provided by manufacturers. All of these data are summarized to the total costs for each category. These "post-PDL net costs" reflect units dispensed multiplied by pricing based on CMS rebated prices, maximum allowable costs, and/or the manufacturer net price bids for Arkansas' Medicaid program.

The projected potential savings are simply calculated by subtracting the post-PDL net costs from the pre-PDL expected net cost. While this amount is reported as "savings" it is more accurately described as avoided excess costs. The projected potential savings/excess costs avoided are affected by both prices and prescription dispensing trends, and the methods described almost certainly underestimate the full potential savings/excess costs avoided.

The reported savings or costs avoided do not consider the impact of PDL decisions on total care costs. There may be either increases or decreases in others categories of Medicaid spending as a result of the PDL. The UAMS College of Pharmacy's Pharmaceutical Evaluation and Policy Division will conduct ongoing analysis and review of the impact of the PDL on total Medicaid costs.

## OVERALL RESULTS

The first PDL selection became effective March 25, 2005. By the end of June, 2006 preferred drugs had been selected in fifteen drug classes. The effective dates for two of the fifteen drug classes are scheduled after June 30, 2006. Preferred products represent therapies with proven advantages over other alternatives, or cost-effective selections in categories where no important differences between products could be found.

Since the first PDL selection, EBRx estimates that the PDL process has yielded potential savings/excess costs avoided of at least \$18.8 million. Total pre-PDL projected spending in the categories reviewed was estimated to have been at least \$45.2 million since the first class became effective. Prescriber cooperation with the PDL recommendations resulted in avoidance of almost 45% of expected costs through the use of preferred products.

In the fiscal year ending June 30, 2006, the expected costs for the PDL categories were at least \$34.4 million. Costs avoided, or prescription cost savings resulting from the PDL are estimated to be \$16.1 million, or 46% of the expected amount. Considering only the second quarter of 2006, expected costs in the PDL categories would have been at least \$7 million dollars without the Medicaid Preferred Drug List. Instead, actual costs were estimated to be \$3.7 million. The costs avoided are estimated to be at least 47% of expected costs, or \$3.3 million for the quarter.

Table I shows implementation dates, and costs avoided in fiscal year 05 and 06 for each category reviewed.

TABLE 1 – Summary of Estimated Prescription Costs Avoided to Date by Category

<b>Drug Category</b>	<b>PDL Effective Date</b>	<b>Fiscal Year 05 Costs Avoided/Savings</b>	<b>Fiscal Year 06 Costs Avoided/Savings (or Costs Incurred)</b>
Less Sedating Antihistamines	3/25/05	\$ 810,000	\$ 2,340,000
Proton Pump Inhibitors	5/18/05	\$ 1,680,000	\$ 8,540,000
“Statin” Cholesterol Agents	6/8/05	\$ 240,000	\$ 1,940,000
Calcium Channel Blockers	7/12/05	\$ -	\$ 580,000
Beta Blockers	10/5/05	\$ -	\$ 650,000
Long-Acting Opioids	10/26/05	\$ -	\$ 1,240,000
ACE Inhibitors	11/16/05	\$ -	\$ 320,000
“Triptan” Antimigraine Agents	2/7/06	\$ -	\$ 120,000
Angiotensin Receptor Blockers	2/21/06	\$ -	\$ 140,000
Skeletal Muscle Relaxers	3/20/06	\$ -	\$ 100,000
Estrogens	4/17/06	\$ -	\$ 20,000
Sedative Hypnotics (Sleep Aids)	5/9/06	\$ -	\$ 100,000
Targeted Immune Modulators	6/13/06	\$ -	\$ (20,000)
<b>Grand Total</b>		<b>\$ 2,730,000</b>	<b>\$ 16,070,000</b>

## **LESS SEDATING ANTIHISTAMINES**

Loratadine products were selected as the preferred less sedating antihistamines for the PDL, effective March 25, 2005. Within this category of products, none showed differences in the most important clinical outcome – patient assessment of allergy symptom scores. At the time of the PDL review, loratadine products were widely available over-the-counter at approximately 25% of the cost of other competing prescription only agents. Prior to reclassification as an over-the-counter product and the loss of patent protection, loratadine (marketed as Claritin®) had once been the most widely prescribed less sedating antihistamine, with a dominant market share among prescribed products.

The makers of Claritin® never pursued approval of loratadine in patients under 24 months of age, although they did secure approval of desloratadine, the major component after metabolism by the liver, for patients as young as 6 months. Cetirizine is also approved for very young patients. There is no evidence establishing any advantage of less sedating antihistamines over older, generic antihistamines such as Benedryl®(generically available as diphenhydramine) in children under the age of two. Nevertheless, DHHS permitted coverage of Zyrtec Syrup® and Clarinex Syrup® without a prior authorization call center request for children ages six to 24 months of age. This is accomplished at the time a prescription is dispensed through the SmartPA system. All other less sedating antihistamine claims now are denied at the point of sale and must have a prior authorization for Medicaid to cover these medications.

Because loratadine was a generically available, over-the-counter medication available through many manufacturers, no supplemental rebates were secured. Cost savings in this category resulted from moving market share from more expensive agents to the equally effective, less expensive loratadine products.

In the fiscal year ending in June 2006, the expected costs of less sedating antihistamines would have been at least \$4.6 million without a PDL. As a result of physician acceptance of the PDL recommendation the costs for this category in the fiscal year were instead 50% less at \$2.3 million. Table 2 presents estimated costs avoided/savings for the less sedating antihistamines by quarter, and for the fiscal year.

**TABLE 2 - Less Sedating Antihistamine Medicaid Prescription Costs**

	<b>Q3 05</b>	<b>Q4 05</b>	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$1,090,000	\$1,150,000	\$1,090,000	\$1,290,000	\$4,620,000
<b>Post-PDL Net Cost Estimate</b>	\$540,000	\$570,000	\$540,000	\$630,000	\$2,280,000
<b>Costs Avoided/Savings</b>	\$550,000	\$580,000	\$550,000	\$650,000	\$2,340,000

## **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. As with the less sedating antihistamine category, no differences in clinical outcomes could be found when equivalent doses of the various products were compared.

Prior to Preferred Drug List selection all agents in this category required prior authorization through a telephone response system. Removal of this barrier to use of these products resulted in dramatic increases in the use of proton pump inhibitors among Medicaid recipients. Without lower net costs for the preferred agents, relative to the pre-PDL costs, this increase in use would have dramatically increased total prescription costs.

Both manufacturers of the preferred products submitted net price bids which resulted in supplemental rebates. Cost savings in this category result from supplemental rebates *and* movement of market share to the preferred products. As a result of the PDL implementation, the average cost per proton pump inhibitor prescription has been reduced by 74 percent. Table 3 demonstrates estimated costs avoided through the use of the preferred proton pump inhibitors.

**TABLE 3 – Proton Pump Inhibitor Medicaid Prescription Costs**

	Q3 05	Q4 05	Q1 06	Q2 06	Fiscal Year 2006
<b>Estimated Expected Costs</b>	\$3,430,000	\$3,820,000	\$2,310,000	\$2,060,000	\$11,630,000
<b>Post-PDL Net Cost Estimate</b>	\$880,000	\$990,000	\$630,000	\$580,000	\$3,090,000
<b>Costs Avoided/Savings</b>	\$2,550,000	\$2,830,000	\$1,680,000	\$1,480,000	\$8,540,000

**HMG COENZYME-A REDUCTASE INHIBITORS (THE STATINS)**

Review of this class revealed only three agents with evidence for prevention of both an initial heart attack, and a subsequent heart attack. This proven prevention of a significant event was judged to be the most important clinical effect of this class of medicines. The DRC’s recommendation stated that only those three products should be considered for addition to the Preferred Drug List. One manufacturer submitted a net cost bid which resulted in a significant supplemental rebate.

The PDL recommendation for cholesterol reducing ‘statin’ products was implemented on June 8, 2005 with Zocor® (simvastatin) tablets being selected as the preferred product. Lipitor® 80mg tablets are available without prior authorization to patients regularly using that product, or to patients who previously used the highest dose of the preferred agent. All other statins now are denied at the point of sale and require a prior authorization call before Medicaid payment is authorized.

Cost avoidance/savings in the statin category results from supplemental rebates on the preferred product, and moving market share to the preferred product. As a result of the PDL implementation, the average cost per statin prescription has been reduced by 30 percent. Table 4 summarized estimated costs avoided. Note that in this category, many patients were moved to Medicare part D prescription drug plans in January 2006.

Late in June 2006, a generic version of simvastatin was introduced. Additionally, the contract with the manufacturer of Zocor will expire early in the next fiscal year. Typically when generics enter the market, they have higher net costs for Medicaid than do established brand name products. As time passes, and more generic manufacturers compete, prices and Medicaid costs fall. It is not clear what will be the impact of these market changes on future Medicaid costs for this class of products.

**TABLE 4 – Statin Medicaid Prescription Costs**

	<b>Q3 05</b>	<b>Q4 05</b>	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$2,240,000	\$2,330,000	\$930,000	\$710,000	\$6,210,000
<b>Post-PDL Net Cost Estimate</b>	\$1,540,000	\$1,600,000	\$640,000	\$490,000	\$4,270,000
<b>Costs Avoided/Savings</b>	\$700,000	\$730,000	\$280,000	\$220,000	\$1,940,000

**CALCIUM CHANNEL BLOCKING AGENTS**

The calcium channel blocker recommendations became effective 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 are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

The manufacturers of Norvasc and Dynacirc CR provided net price bids resulting in supplemental rebates. The Norvasc contract was for a one-year term, and expired on June 30, 2006, consequently this was the last date that product was listed as a preferred agent. As a result of the PDL implementation, the average cost per calcium channel blocker prescription has been reduced by 11 percent. Table 5 presents estimates of costs avoided through use of preferred Calcium Channel Blockers. As with the Statin products, a significant number of Medicaid recipients using these products moved to Medicare Part D prescription drug plans in January, 2006

**TABLE 5 – Calcium Channel Blocker Medicaid Prescription Costs**

	<b>Q3 05</b>	<b>Q4 05</b>	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$1,470,000	\$1,470,000	\$570,000	\$420,000	\$3,930,000
<b>Post-PDL Net Cost Estimate</b>	\$1,260,000	\$1,230,000	\$500,000	\$370,000	\$3,360,000
<b>Costs Avoided/Savings</b>	\$210,000	\$240,000	\$70,000	\$50,000	\$580,000

## **BETA BLOCKERS**

Review of Beta Blockers for a wide array of clinical uses was conducted. From this review, the DRC identified some evidence of superiority for three agents in only one clinical application, congestive heart failure. All other uses for beta blockers revealed few advantages for one agent over another. The beta blocker recommendations became effective October 5, 2005 with generic atenolol, metoprolol tartrate, and propranolol immediate-release being selected as preferred products for all conditions except congestive heart failure. Bisoprolol and Toprol XL® (metoprolol succinate) were selected as preferred agents for patients with congestive heart failure. As a consequence of the late implementation date, no costs were avoided prior to the Fourth Quarter of 2006. All other beta blockers now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

The manufacturer of Toprol XL provided a net price bid which resulted in a supplemental rebate. The remaining preferred agents are available generically, and for the most part have an assigned maximum allowed cost. As a result of the PDL implementation, the average cost per beta blocker prescription was reduced by 55 percent. Table 6 shows the estimated costs avoided through the PDL recommendations. As with Statins and Calcium Channel Blockers, a large percentage of patients receiving Beta Blockers shifted to Part D plans in January, 2006

**TABLE 6 – Beta Blocker Medicaid Prescription Costs**

	<b>Q4 05</b>	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$770,000	\$300,000	\$230,000	\$2,170,000
<b>Post-PDL Net Cost Estimate</b>	\$420,000	\$130,000	\$100,000	\$1,530,000
<b>Costs Avoided/Savings</b>	\$350,000	\$170,000	\$130,000	\$650,000

## **LONG-ACTING OPIOIDS**

The DRC review of this class revealed no apparent clinical advantages for one product over any other. The review was limited to studies of patients using these agents for chronic pain. The DRC was specific that their recommendations applied to patients with chronic pain, and DHHS allows any patient with a terminal cancer diagnosis an exemption from the preferred drug list selections. Even so, the preferred agents are appropriate treatment options for terminal patients.

The long-acting opioid recommendations became effective October 26, 2005. Methadone and extended-release morphine sulfate tablets were selected as preferred agents both for their utility in managing chronic pain, and for their relatively low costs. Additionally, while all opioids whether short or long-acting are subject to abuse and diversion, the two preferred agents are not the most requested opioid products by patients who express a preference. In addition to the exemption granted to terminal cancer patients, DHHS provided an exempt to any patient with long term care eligibility, regardless of the condition being treated. All long-acting opioids other than the preferred agents are denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

Because the preferred products, methadone and extended-release morphine sulfate, are both generic, there are no supplemental rebates for these products. Cost avoidance or savings results only from

prescriber adherence to the PDL recommendations. As a result of the PDL implementation, the average cost per long-acting opioid prescription was reduced by 61 percent.

Interestingly, while some patients – including many classified as disabled for more than two years moved into Medicare Part D plans, there appeared to be an earlier, and even greater reduction in the number of patients being treated with long-acting opioids than would have been expected. It is not clear if these missing patients shifted their use to short-acting agents, or if they sought other ways to obtain their brand of choice. The EBRx Call Center became aware of several patients who managed to purchase their brand of choice with cash when it was no longer covered without prior authorization and some evidence why a trial of the preferred agent would be inappropriate. Table 7 demonstrates estimated savings based on the method previously described.

**TABLE 7 – Long-Acting Opioids Medicaid Prescription Costs**

	<b>Q4 05</b>	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$1,580,000	\$700,000	\$620,000	\$2,900,000
<b>Post-PDL Net Cost Estimate</b>	\$1,080,000	\$320,000	\$250,000	\$1,660,000
<b>Costs Avoided/Savings</b>	\$500,000	\$380,000	\$370,000	\$1,240,000

### **ACE INHIBITORS**

Angiotensin Converting Enzyme (ACE) Inhibitors are useful for treating high blood pressure, renal disease, and congestive heart failure. Review of these agents revealed differences in approved indications, but no significant differences among the agents for most indications. However, ramipril was better studied in patients with congestive heart failure than other agents by virtue of its inclusion in a long-term trial. Most of the ACE Inhibitors are available generically, and several have established Maximum Allowable Costs. The manufacturer of ramipril submitted a net cost bid which resulted in the potential for a supplemental rebate, but which was also competitive with the Maximum Allowable Costs for other generic agents in the category.

The ACE Inhibitor recommendations became effective November 16, 2005 with generic captopril and Altace® (ramipril) selected as preferred products. At the request of several pediatric subspecialists, lisinopril and enalapril were exempted from the PDL restrictions for patients under age 18. Ramipril is less well studied in children than the other agents, and captopril is not a once-daily product. DHHS chose to exempt all patients who were eligible for prescription coverage under Medicare Part D, as the PDL effective date was close to the start date for Part D plans. All other ACE Inhibitors now are denied at the point of sale and require prior authorization for Medicaid coverage of these medications. However, as elderly patients and those with end-stage renal disease are covered under Medicare Part D plans a large percentage of ACE Inhibitor patients were removed from the Medicaid covered population on January 1, 2006.

The Altace bid price is competitive with the costs of other agents, some and some cost avoidance may result from shifting market share to this brand. Additional cost avoidance may occur if the mandatory Altace CMS rebate results in a lower cost than the Medicaid Net price bid. Captopril is the least expensive option in the category, but requires more than once daily dosing. It was added to the PDL due to a unique indication in prevention of renal disease in insulin dependent diabetes. Table 8 summarizes the minimum potential prescription costs avoided. Additional specific information on quarterly CMS rebates would be required to present a more accurate estimate.

**TABLE 8 – ACE Inhibitor Medicaid Prescription Costs**

	<b>Q4 05</b>	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$1,040,000	\$370,000	\$320,000	\$1,730,000
<b>Post-PDL Net Cost Estimate</b>	\$880,000	\$280,000	\$250,000	\$1,400,000
<b>Costs Avoided/Savings</b>	\$160,000	\$90,000	\$70,000	\$320,000

**TRIPTANS**

Triptans are agents used to treat migraine headache. Prior to the PDL review of this category, DHHS instituted monthly quantity limits for this category of medicines. These limits are consistent with the use of these agents to abort a developing migraine, and previously resulted in significant cost savings in the category. The DRC review found marginal evidence that rizatriptan had a slight advantage over other agents on some clinical parameters. However, in general there are a variety of parameters which are measured in migraine studies, and it is not clear which are clinically most important. The DRC excluded two of the agents for lack of information on comparative effectiveness relative to the other agents. Additionally, the DRC recommended placing at least two triptan agents on the PDL as there was no definitively superior product, and some individuals may respond differently to different agents. The DRC also recommended that at least one of each of the delivery formulations should be available without the requirement of a prior authorization call.

The Triptan class was the first drug class to become effective in 2006. Unfortunately, only one net price contract bid was deemed acceptable by DHHS among these agents. The maker of the least expensive brand based on CMS net costs did not submit a net price bid, and this product was excluded from addition to the PDL. The manufacturer of Maxalt and Maxalt MLT (rizatriptan) submitted the only acceptable net price contract, and DHHS selected this brand as the sole preferred triptan for Arkansas Medicaid effective February 7, 2006. DHHS chose to keep existing quantity limits in place for this class of medications. Through the SmartPA program, DHHS created an elaborate set of rules which can grant an automatic prior authorization for non-preferred agents or alternative formulations providing the patient has had a recent trial of the preferred agent. Without a trial of a rizatriptan formulation, payment for other agents is denied at the time a prescription is submitted for payment.

The manufacturer of Maxalt provided a net price bid which resulted in a supplemental rebate. Cost avoidance/savings will result from moving market volume from more expensive triptan brands to the preferred agent. As a result of the PDL implementation, the average cost per Triptan prescription has been reduced by 30 percent. Table 9 provides the estimated medication costs avoided or saved for triptans in the previous two quarters.

**TABLE 9 – Triptan Medicaid Prescription Costs**

	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$260,000	\$220,000	\$480,000
<b>Post-PDL Net Cost Estimate</b>	\$200,000	\$160,000	\$360,000
<b>Costs Avoided/Savings</b>	\$60,000	\$60,000	\$120,000

## **ANGIOTENSIN RECEPTOR BLOCKERS (ARBs)**

In reviewing the ARB class, the DRC found little data on direct comparisons of the products. While none had a significant apparent advantage or disadvantage, individual products had specific data supporting their use in specific conditions. The DRC recommendation covered the product, indication, and patient population considerations relating to these agents. None of these agents is yet generically available. Several manufacturers submitted net price bids, though some were deemed not conforming to DHHS requirements.

Diovan (valsartan) and Cozaar (losartan) were selected as preferred products effective February 21, 2006. This effective date was after the start of the Medicare Part D benefit for dual eligible patients. A large percentage of ARB prescriptions in 2005 were for this population. DHHS elected to grant preferred status to Diovan HCT (valsartan & HCTZ) and Hyzaar (losartan & HCTZ) which are the preferred ARBs in combination with HCTZ. For its application in patients with congestive heart failure, Atacand (candesartan) was granted an exemption for these patients through the SmartPA programming. All other ARBs are now denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

The manufacturers of Diovan/Diovan HCT and Cozaar/Hyzaar provided net price bids which result in supplemental rebates. Medication costs are avoided by shifting to the use of the preferred agents which are less expensive than other options. The average price per ARB prescription has been reduced by roughly 33% through provider prescribing of the preferred agents. Table 10 summarizes the results to date.

**TABLE 10 – Angiotensin Receptor Blocker Medicaid Prescription Costs**

	<b>Q1 06</b>	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$290,000	\$220,000	\$510,000
<b>Post-PDL Net Cost Estimate</b>	\$220,000	\$150,000	\$370,000
<b>Costs Avoided/Savings</b>	\$70,000	\$70,000	\$140,000

## **SKELETAL MUSCLE RELAXERS**

Various agents used to treat muscle spasms and spasticity were reviewed as a group. While there was limited comparative trials of these agents, the DRC distinguished between muscle spasm, and spasticity. Muscle spasm is most often associated with injury or chronic complaints such as low back pain. Spasticity is a condition which affects individuals with some interruption of usual pathways in the brain or spinal cord for muscle control. The DRC emphasized safety concerns for one of the agents, Soma(carisoprodol), noting that marketing approval for the major metabolite of this product was rescinded by the FDA several years ago.

The skeletal muscle relaxer recommendations became effective March 20, 2006 with generic chlorzoxazone, cyclobenzaprine, and methocarbamol being selected as preferred agents for treating muscle spasm. Baclofen and tizanidine, both generically available, are preferred for patients with muscle spasticity. All other skeletal muscle relaxants are now denied at the point of sale and require prior authorization for Medicaid coverage of these medications.

All of the preferred agents are generically available, and most are subject to Maximum Allowed Cost limitation for pharmacy reimbursement. Cost avoidance/savings results from moving market share to the preferred products. As the PDL became effective so late in the First Quarter 2006, the savings generated was insignificant, and below the ability of our estimates to identify cost savings accurately. Table 11 summarizes the cost avoidance estimated in the Second Quarter 2006, and the Fiscal Year from March 1, 2006.

**TABLE 11 – Muscle Relaxer Medicaid Prescription Costs**

	<b>Q2 06</b>	<b>Fiscal Year 2006</b>
<b>Estimated Expected Costs</b>	\$290,000	\$440,000
<b>Post-PDL Net Cost Estimate</b>	\$200,000	\$340,000
<b>Costs Avoided/Savings</b>	\$90,000	\$100,000

### **ESTROGENS**

With the initiation of Medicare Part D coverage, between one half and two thirds of Medicaid’s previous prescription volume for estrogen products disappeared. Average net cost per prescription was below \$20 for these agents even prior to the PDL. Nevertheless, DHHS requested a review of estrogen replacement products. These agents are used primarily by women before and after menopause. Recent evidence indicates that taken long-term, these agents may have undesirable effects.

The DRC did not find significant differences among any of the agents, though there was very limited comparative data. The DRC recommended that a tablet and a topical formulation be included on the PDL. The manufacturer of the market leading product in this category did not submit a net cost bid to Arkansas Medicaid, and was consequently excluded from inclusion by DHHS.

On April 17, 2006 generic estradiol and generic estropipate became the preferred agents for Arkansas Medicaid. Topical estrogens are exempted for pediatric patients for the treatment of labial adhesions. With the exception of the topical products, the preferred agents are generically available, and subject to Maximum Allowed Cost limitations. These changes did result in further reduction of the average net cost per prescription, Cost avoidance/savings results from moving market share to the preferred products. Table 12 summarizes the cost avoidance estimated in the Second Quarter 2006 for Estrogens.

### **NEWER SEDATIVE HYPNOTICS**

The DRC did not find significant differences among any of the agents described as Newer Sedative Hypnotics. One of the agents reviewed had very limited data supporting its use, and virtually no direct comparative data, but it appeared to have robust data on safety. All of the manufacturers in this very competitive market segment provided net price bids to Medicaid. Ambien CR, Sonata, and Rozerem became the preferred drugs in this category effective May 9, 2006.

Due to the aggressive competition in this category, DHHS was offered bids which resulted in supplemental rebates. These rebates became effective at the beginning of April 2006, resulting in cost savings for Medicaid even before significant market share shift occurred. Table 12 summarizes the cost avoidance estimated in the Second Quarter 2006 for newer Sedative Hypnotics.

**TARGETED IMMUNE MODULATORS**

Targeted Immune Modulators are the newest agents used to control autoimmune diseases such as rheumatoid arthritis, inflammatory bowel disease, psoriasis, and other conditions. They are biotechnology products, and must be injected by the patient, or a health care provider. These agents are extremely expensive per patient, and are typically prescribed for long-term use after other agents have proven ineffective or too toxic for a patient. Prior to the DRC review, DHHS had a set of use controls in place on these agents, and only a small number of Arkansas Medicaid Recipients were treated with these products. In 2005, the peak number of patients treated was around 160 in the month of December. After January 2006, the number of patients treated ranged from 78 to 89 patients.

Due to the lack of comparative data on these products, the DRC could only review the effectiveness of each product compared to placebo. The DRC recommendations could not suggest if one product was superior to any other for the conditions treated.

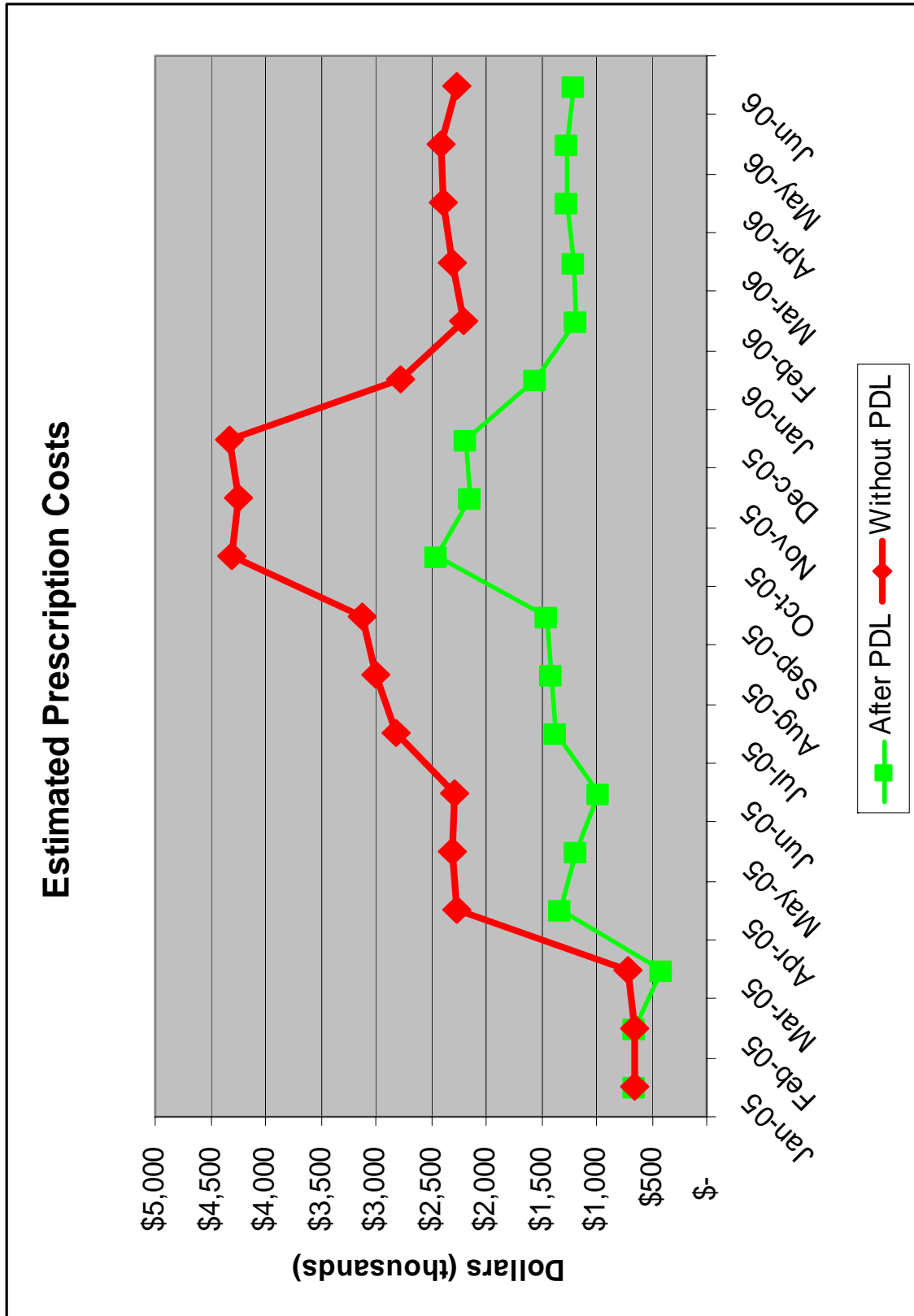
This is not a competitive drug category as the products are somewhat unique in the uses. Two manufacturers submitted net price bids, one of which appeared to offer the potential for supplemental rebates in the future. DHHS selected both of these products as preferred agents. Neither of the preferred products is approved for inflammatory bowel disease, and the previous use controls ratified by the Medicaid Drug Utilization Review board were left in place. Effective June 13, 2006, Enbrel and Humira became the preferred agents among Targeted Immune Modulators.

Assessing costs avoided in this category is especially challenging. Because of the high cost per prescription, and the small number of prescriptions dispensed, there is more volatility in the estimated net costs for Medicaid than desirable. Additionally, if the mandatory CMS rebate changes only a small percentage each quarter, this can result in large dollar fluctuations. It is unlikely that any real difference in net costs has been realized. However using the same approach to estimating the cost impact in other PDL classes, it appears that this PDL selection may have increased net costs by almost \$20,000 in the most recent quarter. More likely is the conclusion that this PDL selection has had no impact on Medicaid costs at this time. Table 12 summarizes the estimates for this class for the Second Quarter 2006.

**TABLE 12 – Second Quarter 2006 PDL Classes Medicaid Prescription Costs**

	<b>Estrogens</b>	<b>Newer Sedative Hypnotics</b>	<b>Targeted Immune Modulators</b>	<b>Total Second Quarter 2006 Classes</b>
<b>Estimated Expected Costs</b>	\$60,000	\$290,000	\$310,000	\$660,000
<b>Post-PDL Net Cost Estimate</b>	\$40,000	\$190,000	\$330,000	\$560,000
<b>Costs Avoided/Savings</b>	\$20,000	\$100,000	(\$20,000)	\$100,000

Graph 1



# MARKET SHARE IMPACT OF PDL RECOMMENDATIONS

---

## PRESCRIBER AND PATIENT COMPLIANCE WITH PDL SELECTIONS

---

The success of the PDL depends in large part on participation by prescribers with the recommendations of the Drug Review and Drug Utilization and Cost Committees. Prescribing compliance with the Preferred Drug List is monitored by EBRx. The following table presents data on the percentage of prescriptions that were filled for preferred product(s) in each of the therapeutic categories reviewed and implemented to date. This percentage is commonly called market share in the pharmaceutical industry. Outcomes and cost savings are maximized as market share approaches 100 percent compliance with the Preferred Drug List recommendations. However, it should be noted that complete compliance with the Preferred Drug List is unlikely as there remains individual variation in response to any medicine.

**Market Share of PDL Preferred Agents by Drug Class and Month**

	July 05	Aug 05	Sep 05	Oct 05	Nov 05	Dec 05	Jan 06	Feb 06	Mar 06	Apr 06	May 06	Jun 06
<b>NSAs</b>	88%	88%	88%	87%	86%	85%	86%	86%	86%	87%	86%	82%
<b>PPIs</b>	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
<b>Statins</b>	99%	99%	99%	99%	99%	99%	99%	99%	99%	99%	99%	99%
<b>CCBs</b>	<b>85%</b>	96%	96%	96%	96%	96%	96%	96%	97%	96%	97%	97%
<b>Beta Blockers</b>	75%	75%	75%	<b>86%</b>	92%	92%	91%	91%	92%	91%	92%	91%
<b>Long-acting Opioids</b>	28%	28%	32%	<b>37%</b>	68%	68%	77%	83%	81%	81%	83%	82%
<b>ACE Inhibitors</b>	17%	17%	18%	21%	<b>28%</b>	45%	77%	78%	78%	77%	78%	79%
<b>Triptans</b>	23%	22%	21%	24%	24%	28%	33%	<b>72%</b>	89%	90%	85%	88%
<b>ARBs</b>	72%	72%	72%	71%	72%	71%	72%	<b>75%</b>	100%	100%	100%	100%
<b>Skeletal Muscle Relaxers</b>	58%	58%	58%	58%	58%	57%	58%	59%	<b>68%</b>	99%	99%	99%
<b>Estrogens</b>	14%	15%	15%	15%	15%	16%	16%	15%	17%	<b>32%</b>	93%	93%
<b>Newer Sleep Aids</b>	5%	5%	5%	8%	12%	17%	21%	23%	28%	27%	<b>60%</b>	100%
<b>Targeted Immune Modulators</b>	91%	88%	91%	91%	89%	93%	78%	83%	86%	91%	84%	<b>87%</b>

Data in bold highlight the month PDL recommendations for the drug class became effective.

# 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 SFY 2006, which includes July 1<sup>st</sup> 2005 through June 30, 2006.

<b>PA Call Center Statistics</b>	<b>3Q 2005</b>	<b>4Q 2005</b>	<b>1Q 2006</b>	<b>2Q 2006</b>	<b>Total SFY 2006</b>
Incoming Calls from Healthcare Professionals	2505	4266	2182	3080	12033
Number of SmartPA Tickets Created	2432	4331	2221	3972	12956
Total Number of P.A. Request at the Call Center	1389	2363	1323	2806	7881
Total Number of P.A. Requests Approved at the Call Center	931	1593	835	2114	5473
Call Center P.A. Approval Percentage	67%	67%	63.1%	75.3%	69%
Point of Sale SmartPA Requests	5731	26931	26260	28511	87433
Point of Sale SmartPA Approvals	2944	10020	9961	13714	36639
Point of Sale SmartPA Approval Percentage	51%	37%	37.9%	48.0%	42%
Average Call Duration	2 min 46 sec	3 min 04 sec	2 min 48 sec	2 min 39 sec	

# Budget Update

---

## A GENERAL OVERVIEW OF THE PROGRAM BUDGET

---

The current budget status for the Arkansas Medicaid Evidence-based Prescription Drug Program is presented below. The second column in the table shows total State Fiscal Year budget allocation, and the third column shows program expenditures for July 2005 through June 2006. There are a number of personnel positions which remain empty; however, if demand arises the program will work within its budget to ensure that it can meet the demand. At the end of the third quarter of SFY 06, the program is approximately \$1,7000,000 under budget from July 1, 2005 through June 30, 2006.

	<b>SFY06 Budget</b>	<b>SFY06 Expenditures To Date</b> <small>(through June 30, 2006)</small>
<b>Personnel –(Salary and Fringes, includes DRC stipends)</b>	\$2,183,719	\$1,162,150
<b>Miscellaneous – (Supplies, Travel, etc)</b>	\$157,650	\$33,693
<b>Equipment – (computers, phones, furniture, renovation)</b>	\$0	\$0
<b>Indirect Costs</b>	\$1,264,339	\$645,755
<b>TOTAL</b>	<b>\$3,605,708</b>	<b>\$1,841,598</b>

# 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 been hired to help facilitate the evaluation of the data. It is our hope to begin providing some initial outcome data during the last quarter of SFY 06 or early SFY07.

Date: April 20, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 04/20/06 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, mometasone, and triamcinolone.

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 six 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 six drugs have been proven more effective for patients in the aforementioned three patient populations.
3. Although data are limited, at least one of the following inhaled corticosteroids should be available adults with COPD: beclomethasone, budesonide, fluticasone, and triamcinolone.
4. None of the six inhaled corticosteroids have been associated with fewer adverse events on the basis of sex, race, pregnancy, co-morbidities or concomitant use of other medications.
5. Due to considerations regarding potential growth retardation budesonide should be available for children.
6. None of the six drugs has been proven more effective on the basis of sex, race, pregnancy, comorbidities, or concomitant use of other medications.
7. At least one of the following delivery systems should be available given the varying capabilities of patients: dry powder inhaler, metered dose inhaler and nebulizer.
8. Triamcinolone should not be the sole agent available due to its relatively low potency.

Henry F. Simmons, Jr.  
April 20, 2006

Date: May 18, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 05/18/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of the agents for overactive bladders in adults.

Specifically considered were

Darifenacin (Enablex)

Flavoxate hydrochloride (Urispas)

Oxybutynin chloride (Ditropan)

Solifenacin succinate (Vesicare)

Tolterodine tartrate (Detrol)

Tropium chloride (Sanctura).

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 captioned agents is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration for adults with overactive bladders.
2. There is insufficient evidence to conclude that any of the captioned agents is superior in efficacy to the others in adults with overactive bladders.
3. Because oxybutynin ER, tolterodine ER and solifenacin produce relatively fewer adverse effects than the other agents, at least one should be available.
4. None of the captioned drugs have been associated with fewer adverse events to adults on the basis of gender, race, pregnancy, co-morbidities or concomitant use of other medications.
5. None of the six drugs has been proven more effective for adults on the basis of gender, race, pregnancy, comorbidities, or concomitant use of other medications.

Henry F. Simmons, Jr.

May 18, 2006

Date: June 15, 2006

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

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

At its 06/15/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of newer antiemetic agents in adults and children.

Specifically considered were

**Newer antiemetics under consideration (equipotent doses assumed)**

Aprepitant (Emend) [oral]

Dolasetron (Anzemet) [oral, injectable]

Granisetron (Kytril) [oral, injectable]

Ondansetron (Zofran) [tablet, orally disintegrating tablet, injectable]

Palonosetron (Aloxi) [injectable]

**Indications under consideration in adults and children**

Nausea, vomiting or retching in children and adults

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. The Committee elected not to discuss aprepitant at this time due to insufficient evidence. However, they felt that it should be available via the Prior Authorization Process.
2. None of the captioned agents is associated with clinically evident adverse events of sufficient severity or number to exclude it from further consideration for use in adults and children with the aforementioned problems.
3. There is insufficient evidence to conclude that any of the captioned agents is superior in efficacy to the others in children or adults with the aforementioned problems. However, at least one oral and one injectable formulation should be available.
4. There is insufficient evidence to conclude that any of the remaining agents differ to a significant degree either qualitatively or quantitatively in adverse effects.
5. None of the captioned drugs have been associated with significantly fewer adverse events on the basis of gender, race, pregnancy, co-morbidities or concomitant use of other medications.
6. Ondansetron should be available for children and for pregnant patients.

Henry F. Simmons, Jr.

June 15, 2006