REPORT FROM THE STATE AUDITOR:
DRUG REIMPORTATION IS A VIABLE CHOICE

September 28, 2004

WORKING TOGETHER TO REDUCE KENTUCKY’S
PRESCRIPTION DRUG COSTS

CRIT LUALLEN
AUDITOR OF PUBLIC ACCOUNTS
The Auditor Of Public Accounts Ensures That Public Resources Are Protected, Accurately Valued, Properly Accounted For, And Effectively Employed To Raise The Quality Of Life Of Kentuckians.
Report From the State Auditor: Drug Reimportation is a Viable Choice
Working Together to Reduce Prescription Drug Costs for Kentuckians

Background
Americans pay the highest prescription drug prices in the world. Last year we spent $250 billion which represents half of drug manufacturers worldwide revenue. Prescription cost and utilization continue to accelerate. Drug costs are the fastest growing segment of healthcare expenditures in the U.S. On average drug costs are 40% less in Canada as compared to the U.S. However, the price differential can range from 30% to 80% less on specific drugs. Last year prices for brand name prescription drugs rose at more than 3 times the rate of inflation (1.9%) according to a report released by AARP and the consumer group, Families USA. Prices increased between 6.9% and 9.9% last year for the 5 leading drugs in sales: Lipitor, Plavix, Fosomax, Norvasc and Celebrex.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, signed by President Bush in December, contained language allowing drug reimportation from Canada with an important safety concept: The Department of Health and Human Services (HHS) must certify that drugs can be safely reimported. This provision, as in previous legislation, has effectively served as a legal barrier to implementation. In addition, the legislation directed the Secretary of HHS to convene a task force to study reimportation. Secretary Tommy Thompson convened the task force in March 2004, and hearings have been held. Several pieces of reimportation legislation are pending in the U.S. Congress and enjoy bi-partisan support. However, no federal legislation has been enacted at this time. Secretary Thompson has stated he would advise the President not to block any new legislation on reimportation of drugs from Canada.

Introduction
Drug companies can import and reimport drugs, but American pharmacists and distributors are prohibited from purchasing Food and Drug Administration (FDA) approved drugs at the much lower prices available in other countries. Pharmaceutical manufacturers imported $14.7 billion into the U.S. in 2001. A significant number of drugs are manufactured in foreign countries today and are on the U.S. market.

Canada’s regulation of prescription drugs closely mirrors U.S. safety standards. The FDA has designated 25 countries including Canada as having oversight comparable to our system of regulation. The FDA inspects 900 foreign manufacturing plants annually.

States and other government entities have experienced escalating costs for health insurance for their employees and retirees. Medicaid programs are deficit ridden nationally and have become the second largest component of states budgets after education. There were 82 million uninsured Americans in 2003, which represents a 14.6% increase from 2002. Health expenditures are exploding and there are insufficient financial resources to address the cost.

Many states and municipalities are debating and embracing reimportation as a means to reduce health care expenditures. Many view reimportation as a viable option to help defray the cost of prescription drugs. Four (4) states have state sponsored web sites for consumers to order drugs and reimport from Canada: Illinois, Minnesota, New Hampshire and Wisconsin.

At least five (5) states Illinois, New Hampshire, Oregon, Maryland and Vermont have sought waivers from HHS to reimport drugs from Canada. The FDA has denied their waiver requests.

As a consequence the state of Vermont has sued the FDA for failure to approve its waiver request. In addition a class action suit has been filed by 2 residents of Illinois to contest the FDA’s denial of the state’s waiver request. Illinois has announced plans to implement its reimportation plan in September 2004 without an approved waiver from the FDA.

Kentucky Facts
The overall poor health, low income and high rate of prescription use ranks Kentucky 3rd in the U.S. in terms of “drug cost burden.”

….The average Kentuckian has 14.6 prescriptions per year vs. U.S average of 10.6.

….Kentuckians spend an average of $750 each or about 2.8% of their income on drugs compared with the national average of 1.8%.

….Kentucky had 552,000 citizens in 2003 who were uninsured or 13.8% of the population.

….Kentucky is 8% above the U.S. average on its share of residents 65 or older.
Currently, 672,000 Kentuckians are enrolled in Medicaid. The National Conference of State Legislatures, which tracks state health insurance programs, identifies Kentucky state employees as paying the highest premium in the Nation: $540.80 per month on average for family coverage. The $286 per month state contribution was 2nd lowest in the Nation in 2003.

In 2002, Kentuckians purchased 59,564,000 prescriptions costing $2.9 billion. 63% of Kentuckians favor reimportation according to the Bluegrass Poll taken in May 2004.

What Could Reimportation Potentially Do For Kentucky?

Help lower cost of drugs for all Kentuckians.

Help Kentucky’s uninsured/underinsured purchase prescription drugs at more affordable prices.

Help lower premiums and co-pays for employees and employers.

Help state and local governments stabilize explosive costs for health care related expenditures.

We analyzed the 2003 drug expenditures for the Top 100 brand drugs by volume for the Kentucky State Employee Health Insurance Plan and Medicaid. The following is an example of the cost comparisons:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Purpose</th>
<th>Supply</th>
<th>Strength</th>
<th>Plan Ingredient Average</th>
<th>Canadian Ingredient Average</th>
<th>Potential Monthly Savings</th>
<th>% Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacid</td>
<td>Acid Reflux Disease</td>
<td>30</td>
<td>30 mg</td>
<td>$117.81</td>
<td>$65.15</td>
<td>$52.66</td>
<td>45%</td>
</tr>
<tr>
<td>Lipitor</td>
<td>Cholesterol Lowering</td>
<td>30</td>
<td>20 mg</td>
<td>$80.66</td>
<td>$59.63</td>
<td>$21.03</td>
<td>26%</td>
</tr>
<tr>
<td>Celebrex</td>
<td>Pain Relief</td>
<td>30</td>
<td>200 mg</td>
<td>$83.71</td>
<td>$42.62</td>
<td>$41.09</td>
<td>49%</td>
</tr>
<tr>
<td>Nexium</td>
<td>Persistent Heartburn</td>
<td>30</td>
<td>40 mg</td>
<td>$103.10</td>
<td>$74.73</td>
<td>$28.37</td>
<td>28%</td>
</tr>
<tr>
<td>Zoloft</td>
<td>Depression</td>
<td>30</td>
<td>100 mg</td>
<td>$56.40</td>
<td>$36.80</td>
<td>$19.60</td>
<td>35%</td>
</tr>
</tbody>
</table>

The cost comparison for drugs under the Kentucky State Employee Health Insurance Plan and Canada yielded a 32% average cost savings for the Top 20 drugs plus all drugs costing the plan $1 million or more.

If the cost savings on average saved 30%, the plan could have potentially saved $36.5 million in 2003 on ingredient costs alone. In addition to ingredient savings, public employee members would have savings associated with co-pays. Members of the plan paid “out-of-pocket” $33.8 million in co-pays in 2003.

The comparison of the Top 20 Medicaid drugs to Canadian pricing found Canadian prices on average 39% less expensive even after adjusting Medicaid’s cost for a 20% rebate factor.

If the 39% savings held across all brand drugs Kentucky potentially could have saved $37.3 million in state dollars.

Boston University’s, School of Public Health estimated Kentuckians could save approximately $663 million or 39% a year based on 2001 spending of $1.7 billion on brand name drugs if reimportation had been available. Kentucky’s drug cost burden makes the issue of reimportation an urgent concern.

Summary

The Auditor is vested with the responsibility and authority to protect taxpayer’s resources and has an obligation to explore or encourage strategies which promote efficiency and economy in government. We prepared this white paper outlining issues surrounding drug reimportation which includes an analysis of price comparisons to determine if reimportation is a viable way to reduce Kentucky’s drug costs. After careful analysis we concluded that drug reimportation is a viable option for Kentucky.

Action Steps

- Urge Governor Fletcher to submit a waiver authorizing drug reimportation to the FDA for consideration.

- Encourage Kentucky’s Congressional Delegation to support reimportation/bulk-purchasing legislation. The Auditor will share this data and report with the Congressional Delegation.

- Urge the Kentucky General Assembly to hold hearings and take testimony from stakeholders and experts to explore reimportation for Kentucky prior to the 2005 Session of the General Assembly. Hearings should focus on the following:
  - Mechanics of a reimportation program
  - Cost to implement a reimportation program
  - Review of safety standards
  - Review of Kentucky’s laws/regulations
  - Consumer education

- Urge the Attorney General to examine legal opportunities for Kentucky to reduce prescription drug costs by litigating or pursuing other legal remedies.

- Urge Kentucky Mayors and County Judges to explore reimportation for their health care plans. The Auditor will share information with the Kentucky League of Cities and the Kentucky Association of Counties.
Footnotes:

1 Associated Press, State Ranks Third in Drug Costs, July 18, 2004

2 U.S. Newswire, U.S. Senate Committee Debates Drug Reimportation, 5-20-04


4 Families USA, http://www.familiesusa.org

5 Boston University School of Public Health, Poorer States Face Much Heavier Prescription Drug Cost Burdens, Alan Sager, Ph.D. and Deborah Socolar.

6 Boston University School of Public Health, States Projected Spending on Brand Name Prescription Drugs and Savings if the U.S. Paid Canadian Prices in 2001, asager @ bu.edu, dsoco/ar@bu.edu
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BACKGROUND AND ANALYSIS

Introduction

1. Reimportation: The practice of allowing Americans to purchase U.S. drugs from Canada and other countries.

2. Legalizing the reimportation of drugs from Canada would help lower the cost of drugs which would:
   - Allow Medicare recipients dollars to go further;
   - Help the Uninsured/Underinsured; and,
   - Help lower premiums and co-pays for employers/employees.
   - Help States/Municipalities with Health Care Expenditures, i.e. Health Insurance and possibly Medicaid.

3. Canada’s regulation of drugs closely mirrors U.S. safety standards.

4. Even though drug companies can import and reimport drugs, American pharmacists and distributors are prohibited from purchasing Food and Drug Administration (FDA)-approved drugs at the much lower prices available in other countries. Pharmaceutical manufacturers imported drugs totaling $14.7 billion into the U.S. in 2001.

5. The top 10 drug companies spent nearly 3 times more on marketing, public relations and administration than they did on Research & Development in 1999.
   A. Advertisement expenditures grew from $791 million to $2.5 billion in 2000.
   B. Employed 70,000 sales reps, a ratio of 1 salesperson to every 10 doctors. Source: The Fight for Affordable Prescription Drugs
   C. Approximately, 12.5% of drug manufacturers revenues are committed to research and development. Source: Robert B. Reich, Double Payment, October 29, 2003

<table>
<thead>
<tr>
<th>Prescription Drugs as a Share of National Health Expenditure</th>
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<tbody>
<tr>
<td></td>
<td>4.9</td>
<td>5.5</td>
<td>5.8</td>
<td>6.9</td>
<td>7.6</td>
<td>8.5</td>
<td>9.4</td>
<td>12.9</td>
<td>14.7</td>
</tr>
</tbody>
</table>
Drug costs impact over-all health care costs. Drug costs are the fastest growing segment of medical expenditures in the U.S.

6. There are only 2 ways to reduce “drug cost burden”:
   a. Reduction of Prices
   b. Reduction in Utilization

   **Issue**

The Medicare Prescription Drug Improvement and Modernization Act of 2003, signed by President Bush in December, contained language allowing drug reimportation from Canada with an important safety concept: The Department of Health and Human Services (HHS) must certify that drugs can be safely imported. This provision as in previous legislation has effectively served as a legal barrier to implementation. Secretary of Health and Human Services Tommy Thompson has declined to certify the safety of drug reimportation.

   **Status**

The Task Force to Study Safety Issues of Drug Reimportation was convened by Secretary Thompson in March 2004. The outgoing FDA Commissioner Mark McClellan was to serve as Chair. The task force’s work is ongoing and has met several times. It is important to note that Mr. McClellan has recently been confirmed as the Director of the Center for Medicare and Medicaid Services (CMS) and is no longer Chairman. Secretary Thompson on Mar 5, 2004 stated that he would advise the President not to block any new legislation on drug reimportation from Canada. However, no federal legislation has been enacted at this time.

In Washington, a bipartisan group of Senators led by Senator Byron Dorgan (D-N.D.) and Senator Olympia Snowe (R-Maine) along with co-sponsors such as Senator Trett Lott (R-Miss.) and John Kerry (D-Mass.), claim they have up to 60 votes to get a prescription drug reimportation bill through the Senate. Several members of the Senate have sent correspondence to Senator Frist urging him to schedule the reimportation legislation for a vote. Majority Leader Bill Frist (R-Tenn.) still expressed concern about the safety issue, and some suggest that it will be difficult to get 60 Senators to back this type of bill. Republican leaders in both houses of Congress are concerned about reimportation. The White House strongly opposed a reimportation bill that passed out of the House of Representatives in 2003, but Senator Olympia Snowe (R-Maine) believes President Bush would not veto a measure with broad support.
National Facts

1. Americans pay the highest drug prices in the world, last year spending $250 billion half of drug manufacturers worldwide revenue. Source: Boston University School of Public Health, Poorer States Face Much Heavier Prescription Drug Cost Burdens, Alan Sager, Ph.D. and Deborah Socolar.

2. Americans bought about $1 billion in pharmaceuticals from Canada last year, saving up to 70% over the cost of drugs in the U.S. Source: Detroit Free Press.

3. Ernst & Young reports that the average cost of drugs in 2002 cost about 77% more in the U.S. than Canada, England, Germany, France, Italy, Sweden and Switzerland. The U.S. is the only developed nation in the world with no price controls. Source: “Ernst & Young, Source: US Drug Prices, Controls Likely, “ Reuters, 6-23-04”.

4. American Association of Retired Persons (AARP) and the consumer group Families USA released report studies in May, 2004, that show prices for brand name prescription drugs rose at more than 3 times the rate of over-all inflation last year and that the rate of growth has accelerated in recent years.

5. Drug prices increased between 6.9% and 9.9% last year for the 5 leading drugs in sales:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipitor</td>
<td>Cholesterol Reducing Drug</td>
</tr>
<tr>
<td>Plavix</td>
<td>Blood Thinner</td>
</tr>
<tr>
<td>Fosomax</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>Norvasc</td>
<td>High Blood Pressure</td>
</tr>
<tr>
<td>Celebrex</td>
<td>Pain Reliever</td>
</tr>
</tbody>
</table>

*Note: Inflation for the same period was 1.9%.*
6. The gap between inflation and price increases is especially significant for older Americans who rely on social security income. Social Security increases are based on the Consumer Price Index. As the gap widens seniors’ purchasing power has been diminished. The Medicare Drug Card Program has been confusing and savings have been minimal due to drug price increases prior to the June 1, 2004, implementation of the program.

7. 82 million Americans were uninsured in 2003 which represents a 14.6% increase from 2002. Source: Families USA Foundation.

8. U.S. vs. World: Prescription drug prices based on each Nation’s average price of drugs:

<table>
<thead>
<tr>
<th>Country</th>
<th>U.S.</th>
<th>France</th>
<th>Switzerland</th>
<th>England</th>
<th>Germany</th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price</td>
<td>$1.00</td>
<td>.51 cents</td>
<td>.65 cents</td>
<td>.64 cents</td>
<td>.60 cents</td>
<td>.60 cents</td>
</tr>
</tbody>
</table>

Source: Congressman Bernie Sanders Homepage
http://bernie.house.gov/

   a. Canada utilizes price controls and negotiates with manufacturers.
   b. The drug manufacturers are required to file the initial price of a newly patented drug with Canada’s Patented Medicines Prices Review Board (PMPRB) 60 days before the initial sale.
      1. PMPRB at the time of filing or at any other time may conduct a review to determine if the price is comparable to other drugs offering the same therapeutic value.
      2. Breakthrough drugs are limited to the average price in France, Germany, Italy, Sweden, Switzerland, England and the U.S.
      3. Price increases for all other approved drugs cannot increase more than CPI on an annual basis.
   c. Once the prices are established by the PMPRB wholesalers negotiate with manufacturers; and, pharmacies in turn negotiate with the wholesalers.

9. Pharmaceutical companies profits are 4 to 5 times greater than the average Fortune 500 Companies.
10. On April 22, 2004, the Centers for Medicare and Medicaid Services (CMS) approved the first-ever multi-state purchasing pool arrangement for Medicaid prescription drugs. Under this structure, Michigan, Vermont, New Hampshire, and Alaska will pool their collective purchasing power for 900,000 Medicaid beneficiaries to gain drug discounts. CMS has announced that it will soon provide guidance to states on forming pools and joining existing pools. This allows the states to use their respective volume to help negotiate with manufacturers. The effort is in its infancy and data is not available to access effectiveness.

11. When asked to name the primary factors contributing to the accelerated growth rate of state health care expenditures in 2003, 40 states identified prescription drugs. Regardless of where drug costs rank on their list of cost drivers, all 50 states have been actively working on plans to curtail the growth of their spending on pharmaceuticals. Source: Governing Special Issue, Health Care.

In the House, Congressman Gil Guthknecht (R-Minn.) has introduced a bill that would allow reimportation from 25 industrialized countries that have FDA-approved facilities and require the use of technology to prevent counterfeiting. Source: Drug Reimportation Remains Illegal, Heathland Institute, 2-04. On June 23, 2004, the House Appropriations Committee approved an agricultural bill containing language that forbids the Food and Drug Administration from enforcing the ban on reimportation. It is believed that the measure is unlikely to survive in the Senate should it get that far. “Health Biz: Drug Import Battle Heats Up,” UPI, 6-24-04

**Political Momentum**

1. Reimportation is now backed or conditionally endorsed by a growing number of Republicans and Democrats.

2. Recently, Governor Jeb Bush shut down 12 “storefront” businesses that helped patients fill their prescriptions through Canadian pharmacies. The state is now making it easier for the “storefronts” to operate as registered “mail order pharmacies”. Governor Bush reacted to the public outcry when the “storefronts” were closed.

3. Drug companies sharply raised many drug prices before the Medicare bill that was passed last November took effect. Thus, the Medicare drug cards offered no relief or limited relief to seniors.

4. Health care tied with the war in Iraq as the 2nd most important issue for most in the Presidential campaign after the economy. Source: New York Times/CBS News Poll, June 23-27
5. Governor Tim Pawlenty (Republican), Minnesota’s Governor plus at least 5 other Governor’s have written a letter to Congress urging it to pass legislation allowing the reimportation of prescription drugs from Canada and other industrial nations. The other five (5) states are New Hampshire, Illinois, Wisconsin, West Virginia and North Dakota.

6. Vermont has sued the FDA for failure to approve its FDA waiver request. For seven years, state health organizations, local governments and Vermont itself have found ways to help consumers buy drugs across the border. The practice has made drugs more affordable and has proved safe. Source: Courier Journal, Vermont’s Solid Case

**Who is in favor**
1) Consumers especially the frail elderly
2) The poor and underinsured and uninsured
3) States/Municipalities

**Governments Debating/Embracing Reimportation**

<table>
<thead>
<tr>
<th>States</th>
<th>Oregon</th>
<th>California</th>
<th>Municipalities/Counties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maine</td>
<td></td>
<td></td>
<td>Springfield, MA</td>
</tr>
<tr>
<td>Minnesota</td>
<td></td>
<td></td>
<td>San Francisco, CA</td>
</tr>
<tr>
<td>Wisconsin</td>
<td></td>
<td>Vermont</td>
<td>Los Angeles, CA</td>
</tr>
<tr>
<td>New Hampshire</td>
<td></td>
<td>Rhode Island</td>
<td>Washington, D.C.</td>
</tr>
<tr>
<td>Illinois</td>
<td></td>
<td>Florida</td>
<td>Boston, MA</td>
</tr>
<tr>
<td>Indiana</td>
<td></td>
<td></td>
<td>Montgomery, ALA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Montgomery County, MD</td>
</tr>
</tbody>
</table>

Note: This is not an exhaustive listing but what has been reviewed to date.

Nine (9) states legislatures considered reimportation bills in 2003 and 2004:

<table>
<thead>
<tr>
<th>Maine</th>
<th>Oregon</th>
<th>Rhode Island</th>
<th>California</th>
<th>Massachusetts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vermont</td>
<td>Maryland</td>
<td>Illinois</td>
<td>Florida</td>
<td></td>
</tr>
</tbody>
</table>

Four (4) states have state sponsored web sites for consumers to order drugs and reimport through Canada: Illinois, Minnesota, New Hampshire and Wisconsin.

Five (5) states Illinois, New Hampshire, Oregon, Maryland and Vermont have sought waivers from Health and Human Services to reimport drugs from Canada. Some of these states were going to leverage drug purchasing for their health insurance programs for public employees and Medicaid. These waivers were directed to the FDA and have been denied.
The state of Illinois and 2 citizens filed suit against the FDA in February 2004. Litigation is pending. The Governor appointed a panel of experts to draft a plan for reimportation of drugs from Canada for state employees and retirees. Taxpayers in Illinois paid $340 million last year to cover prescription costs for state employees and retirees which covered 230,000 individuals.

Governor Rod Blagojevich announced on August 17, 2004 that Illinois will go forward with a reimportation program despite opposition and non-approval of the state’s waiver request by the FDA.

Implementation is scheduled for September 2004 and will be targeted to Illinois residents with no prescription coverage. The state will reimport drugs from Canada, Ireland and Great Britain. Illinois will contract with a Pharmacy Benefits Manager (PBM) and the broad program outline is as follows:

- A patient would receive a prescription from a U.S. physician.
- A 30-day supply of the medication would be filled by a U.S. pharmacy
- After tolerating the medication, the patient would file a prescription refill from the original physician with the clearinghouse. At that time, the patient would also choose which vetted pharmacy he or she would like to utilize based on price (the clearinghouse would allow patients to calculate their best price based on the combination of ordered medications).
- The clearinghouse would enter the information into a database, make certain that the prescribed medication was appropriate for the patient’s medical history, and ensure that no drug interactions would take place. Any questions would be referred to the prescribing physician.
- The clearinghouse would then forward the prescription to a contracted physician in the country in which the participating pharmacy is located, and the prescription would be rewritten according to local requirements.
- The prescription would be forwarded to the participating pharmacy, which would fill it and send it directly to the customer.
- Participating pharmacies would bear the burden of cost related to inspection.
- Administration costs for the program are estimated around $3 to $4 million.
- Subscribers of the state health plans targeted by the prescription reimportation
  will be given the incentive to participate by waiving shipping and co-payments.

Source: Chicago Sun Times, State Defying Feds, Importing Drugs, August 17, 2004

Vermont’s Governor and Attorney General announced on August 10, 2004 that they would sue the FDA for failing to approve their plan to reimport drugs and to promulgate regulations pursuant to the Medicare Modernization Act of 2003.

The lawsuit was filed August 19, 2004, in U.S. District Court in Burlington, Vermont, which alleges the government wrongly denied Vermont’s waiver request to establish a reimportation program and failed to implement the Medicare Prescription Drug Improvement and Modernization Act of 2003.
The FDA indicated they would vigorously defend the litigation. It is important to note that Attorney General William H. Sorrell of Vermont is also President of the National Association of Attorneys General.

Attorney General Sorrell has urged and encouraged other Attorneys General to review the issue of reimportation: “I want to encourage my colleagues to further explore the issue of rising drug costs from a consumer protection perspective. As Attorneys General, we need to better understand this complex public policy.” Source: The National Association of Attorneys General, Presidents Message, http://www.nnag.org

The Congressional Budget Office estimated a savings of $40 billion over the next decade for the Medicare prescription benefit if reimportation becomes a reality.

**Proposed Federal Legislation**

A. **Pharmaceutical Market Access and Drug Safety Act** (Democrat-sponsored)

1. The FDA has 90 days to create rules permitting drug reimportation from passage of the act. U.S. pharmacies and drug wholesalers can reimport drugs from Canada in the first year and 19 other countries thereafter. Individuals would receive shipped prescriptions via mail order from FDA-approved Canadian pharmacies.

2. It is unlawful for drug makers to limit supply or alter drugs to purposely fail FDA standards. This provision is aimed at manufacturers so they can’t limit supplies to foreign countries, which in effect would make reimportation a non-viable option. In addition they would be barred from changing drug composition so it would fail U.S. standards.

3. A 1% user fee is imposed to fund FDA inspections.

4. Exporters to individuals would have to post a bond that they would forfeit if they exported unsafe drugs to Americans.

B. **Safe Importing of Medical Products and RX Therapies Act** (Republican-sponsored)

1. The FDA has one year to make safety recommendations before permitting imports from Canada and up to three years for 15 European Union countries. The FDA could ban drugs from some nations.

2. There are no provisions making it unlawful to reduce supply or alter drugs in such a way as to fail FDA standards.
3. A new, uncapped user fee program is established and FDA inspections are paid for by all foreign and domestic businesses engaged in reimportation.

4. Licensing requirements and penalties are established for all online pharmacies that illegally conduct or solicit U.S. business.

Senate hearings on the bills have been postponed until after the Labor Day recess.

**Pressures for Drug Reimportation**

1. Lack of prescription drug coverage. At any given time, 20% of Americans are uninsured or underinsured.

2. Medicare’s prescription drug benefit was estimated to cost $400 billion over the next 10 years. This estimate has ballooned to $535 billion.

3. Inflationary growth on prescription costs and the high overall cost of drugs in this country. On average, drugs costs 40% less in Canada with the price differential ranging from 30% to 80% less. For example, 30-200 mg capsules of Celebrex cost $100.99 in New Hampshire whereas a 90-day supply costs $147.97 in Canada. Celebrex is a pain relief drug utilized by individuals having arthritis.

4. Americans are already reimporting drugs without any government control to protect the quality and safety of drugs being reimported. Last year it is estimated that drugs totaling $1 billion were reimported from Canada to this country in calendar year 2003. Americans are using the internet, bus trips, visits, etc., to acquire Canadian drugs.

5. States and other governmental entities have experienced tremendous cost overruns on health insurance for employees and retirees. This type of cost cannot be sustained on a go forward basis. There are insufficient resources to address the costs. In addition, Medicaid programs are deficit ridden nationally. Prescription cost and utilization continue to accelerate. Medicaid is the second largest component of states’ budgets after education.

6. The FDA has designated 25 countries as having oversight comparable to our system of oversight. A significant number of drugs are manufactured in foreign countries today. The FDA inspects 900 foreign manufacturing plants annually. For example Lipitor is manufactured in Ireland and Prevacid is manufactured in Japan. The drug industry is global in nature. Of the Top 10 drug companies, five (5) are European: Glaxo Smith Kline, Astra Zeneca, Aventis, Roche and Norvartis.
7. In order for states/municipalities to monitor/manage drug reimportation and ensure safety they must do the following:
   
   a. Identify production facilities;
   b. Inspect and vet foreign pharmacies prior to approval;
   c. Conduct random drug inspections;
   d. Limit people /transportation route’s; and
   e. Involve Pharmacists to supervise/provide guidance to consumers.

8. The Kaiser Family Foundation released its 2004 Annual Employer Health Benefits Survey on September 9, 2004. The survey found employer sponsored health insurance premiums increased an average of 11.2% in 2004. This percentage growth is less than 2003 however it is the fourth consecutive year of double-digit growth.

<table>
<thead>
<tr>
<th>Type of Coverage</th>
<th>Annual Cost of Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Coverage</td>
<td>$9,950 ($829 per month)</td>
</tr>
<tr>
<td>Single Coverage</td>
<td>$3,695 ($308 per month)</td>
</tr>
</tbody>
</table>

The survey found that premiums for family coverage have risen 59% since 2001.

61% of workers receive health coverage from their employer which is down from the peak of 65% in 2001. There are at least 5 million fewer jobs providing health insurance in 2004 than 2001. Source: 2004 Annual Employer Health Benefit Survey, Kaiser Family Foundation, September 9, 2004

**Kentucky Facts**

1. Ky. ranked 3rd among states in “drug cost burden” which is the percentage of income that people spend on prescription medicine.
   
   A. Kentuckians spent an average of $750 each- about 2.8% of their income in 2002, compared with the national average of 1.8%.
   
   B. The average income in Kentucky is $25,494.

2. The overall poor health of Kentucky’s population, low income and high rate of prescription use combined to rank the state 3rd, in drug cost burden after Tennessee and West Virginia.
   
   A. Kentucky has high rates of asthma, heart disease, diabetes, obesity and cancer and other chronic conditions.
   
   B. Kentucky has more adult smokers that any other state in the Nation.
3. Kentucky ranks 3rd in the use of prescription drugs with an average of 14.6 scripts per year vs. U.S. average of 10.6 scripts per year.

4. 73% of Kentucky retirees with incomes of $15,000 or less say they cannot afford their medical expenses and over 52% of all retirees report having financial concerns relative to medical expenses. Source: Kentucky’s Long Term Policy Center, Prescription Drug Coverage May 21, 2004.

5. In 2003, Kentucky had 552,000 citizens without health insurance.

   A. The financial burden is highest on those without insurance because they pay the highest retail prices while private insurance companies and Medicaid negotiate better prices based on volume. Source: Courier Journal 7-12-04 Discounts and Rebates

   B. During 2003 approximately 29% of Kentuckians had no health insurance at some point during the year. Source: Families USA Foundations

   C. A Bluegrass Poll conducted May 5-11, 2004 by the Courier Journal showed 63% of people surveyed favored making it easier to buy cheaper drugs from other countries but only 4% said they or someone in their household had purchased drugs across U.S. borders.

   D. Average price for retail prescriptions in 2002:

<table>
<thead>
<tr>
<th></th>
<th>Kentucky</th>
<th>US</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$48.90</td>
<td>$54.58</td>
</tr>
</tbody>
</table>

6. Experts estimate Kentuckians could save approximately $663 million a year based on 2001 spending of $1.7 billion on brand name scripts if reimportation been available. Source: Boston University School of Public Health, September 5, 2001
7. The Commonwealth has had a difficult time balancing expenditures to available revenues for health related items, health insurance, Medicaid, etc.

Kentucky State Employee Insurance

A. The Kentucky Personnel Cabinet administers the State Employee Health Insurance Program.

Number and types of non-single contracts:
14,788 Contracts for Families
9,931 Couples
18,947 Parent Plus
43,666

Rate of Growth for Select State Expenditures
2001-2003

B. Total enrollment in State Plans on average in 2003 was 226,000, which includes employees, teachers, retirees and their families.

<table>
<thead>
<tr>
<th>State Health Insurance</th>
<th>Average 2002</th>
<th>% of Total 2002</th>
<th>Average 2003</th>
<th>% of Total 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>State Employees</td>
<td>57,750</td>
<td>25.6%</td>
<td>55,765</td>
<td>24.6%</td>
</tr>
<tr>
<td>School Boards</td>
<td>116,038</td>
<td>51.4%</td>
<td>113,135</td>
<td>50.0%</td>
</tr>
<tr>
<td>Health Depts.</td>
<td>4,091</td>
<td>1.8%</td>
<td>4,130</td>
<td>1.8%</td>
</tr>
<tr>
<td>KERS</td>
<td>23,895</td>
<td>10.6%</td>
<td>26,301</td>
<td>11.6%</td>
</tr>
<tr>
<td>KTRS</td>
<td>16,842</td>
<td>7.5%</td>
<td>17,554</td>
<td>7.8%</td>
</tr>
<tr>
<td>KCTCS</td>
<td>3,157</td>
<td>1.4%</td>
<td>3,604</td>
<td>1.6%</td>
</tr>
<tr>
<td>Quasi/Local Govt.</td>
<td>2,834</td>
<td>1.3%</td>
<td>4,757</td>
<td>2.1%</td>
</tr>
<tr>
<td>COBRA</td>
<td>988</td>
<td>.4%</td>
<td>1,144</td>
<td>.5%</td>
</tr>
<tr>
<td>Average Covered Lives:</td>
<td></td>
<td></td>
<td>225,959</td>
<td></td>
</tr>
<tr>
<td>Source: Kentucky Group Health Insurance Board, Power Point, July 27, 2004</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


The Following plans were available:

1. Preferred Provider Organization (PPO)- Co-payments for prescription drugs do not apply to the out-of-pocket limits. Co-pay applies to each 1-month 30-day supply. Preauthorization may be required for certain drugs.

   Options A & B
   $10 Generic
   $15 Brand
   $30 Non-Formulary

2. Health Maintenance Organization (HMO)- Co-payments for prescription drugs do not apply to the out-of-pocket limits. All other co-pays apply to out-of-pocket limits. Co-pay applies to each 1-month 30-day supply. Preauthorization may be required for certain drugs.

   Options A & B
   $10 Generic
   $15 Brand
   $30 Non-Formulary
3. Point of Service (POS)- Co-payments for prescription drugs do not apply to out-of-pocket limits. All other co-pays do apply. Co-pays apply to each 1 month 30 day supply. Preauthorization may be required for certain drugs.
   Options A & B
   $10 Generic
   $15 Brand
   $30 Non-Formulary

4. Exclusive Provider Organization (EPO)- Co-payments for prescription drugs do not apply to out-of-pocket limits. All other co-pays do apply. Co-pay applies to each 1-month 30-day supply. Pre-authorization may be renewed for certain drugs.
   $25 Generic
   $35 Brand
   $50 Non-Formulary

D. Kentucky Group Health Prescription Drug Utilization

<table>
<thead>
<tr>
<th></th>
<th>Average Scripts per Person</th>
<th>% Change 2002 to 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2000</td>
<td>2001</td>
</tr>
<tr>
<td>Scripts per Person</td>
<td>14.9</td>
<td>16.05</td>
</tr>
<tr>
<td>Single Source Brand</td>
<td>6.98</td>
<td>8.44</td>
</tr>
<tr>
<td>Multi Source Brand</td>
<td>2.00</td>
<td>1.16</td>
</tr>
<tr>
<td>Generic*</td>
<td>5.68</td>
<td>6.20</td>
</tr>
</tbody>
</table>

Source: Kentucky Group Health Insurance Board, PowerPoint Presentation, July 27, 2004

*Excludes those not classified in one of these groups.

Important Note: Average script per member exceed the average Kentucky resident in number of prescriptions. The average Kentuckian has 14.6 prescriptions vs. the Kentucky Health Insurance member who has 18.08 prescriptions. The U.S. average is 10.6.
E. COMMONWEALTH GROUP HEALTH EXPERIENCE

<table>
<thead>
<tr>
<th></th>
<th>2001</th>
<th>% Change</th>
<th>2002</th>
<th>% Change</th>
<th>2003</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Claims</td>
<td>$399,320,673</td>
<td>12.4%</td>
<td>$453,556,171</td>
<td>13.6%</td>
<td>$515,011,299</td>
<td>13.5%</td>
</tr>
<tr>
<td>Rx Claims</td>
<td>$104,247,320</td>
<td>20.6%</td>
<td>$123,337,035</td>
<td>18.2%</td>
<td>$145,208,960</td>
<td>17.7%</td>
</tr>
<tr>
<td>Total</td>
<td>$503,567,993</td>
<td>14.0%</td>
<td>$576,893,206</td>
<td>14.6%</td>
<td>$660,220,260</td>
<td>14.4%</td>
</tr>
<tr>
<td>Premium</td>
<td>$558,002,180</td>
<td>9.1%</td>
<td>$627,827,924</td>
<td>12.5%</td>
<td>$694,293,552</td>
<td>10.6%</td>
</tr>
<tr>
<td>Covered Lives</td>
<td>225,623</td>
<td>(0.1%)</td>
<td>225,784</td>
<td>0.0%</td>
<td>226,399</td>
<td>0.3%</td>
</tr>
<tr>
<td>PMPM Medical</td>
<td>$147.49</td>
<td>12.5%</td>
<td>$167.40</td>
<td>13.5%</td>
<td>$189.57</td>
<td>13.2%</td>
</tr>
<tr>
<td>PMPM Rx</td>
<td>$38.50</td>
<td>20.8%</td>
<td>$45.52</td>
<td>18.2%</td>
<td>$53.45</td>
<td>17.4%</td>
</tr>
<tr>
<td>PMPM Total</td>
<td>$185.99</td>
<td>14.1%</td>
<td>$212.92</td>
<td>14.5%</td>
<td>$243.02</td>
<td>14.1%</td>
</tr>
<tr>
<td>PMPM Premium</td>
<td>$206.10</td>
<td>9.2%</td>
<td>$231.72</td>
<td>12.4%</td>
<td>$255.56</td>
<td>10.3%</td>
</tr>
</tbody>
</table>

Source: Kentucky Group Health Insurance Board Power Point Presentation, July 27, 2004


The data reflects prescriptions dispensed to members of the Commonwealth’s Public Employee Health Insurance program in calendar year 2003, based on claims paid through March 31, 2004.

The data was derived from the database that MEDSTAT designed for the Commonwealth, based on data submitted by the Commonwealth’s insurance carriers.

The data was produced using the unique National Drug Code (NDC) for each drug, in order to distinguish varying strengths, dosages and/or packaging for a particular drug.

It was assumed that each script was for a 1-month period.

The data excludes dispensing fees and co-pays.
Any discounts taken by the carrier have also been taken into account.
Summary Calendar Year 2003
Top 100 Brand Name/Other Prescriptions for State Plan

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Plan Payments</th>
<th>No. of Scripts</th>
<th>Average Net Pay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>$121,886,343.28</td>
<td>2,252,942</td>
<td>$54.10</td>
</tr>
<tr>
<td>Generic</td>
<td>$19,783,286.05</td>
<td>1,763,265</td>
<td>$11.22</td>
</tr>
<tr>
<td>Other</td>
<td>$1,801,401.65</td>
<td>43,569</td>
<td>$41.35</td>
</tr>
<tr>
<td>Over-the Counter</td>
<td>$559,347.47</td>
<td>12,603</td>
<td>$44.38</td>
</tr>
<tr>
<td>Missing</td>
<td>$1,105,437.09</td>
<td>18,580</td>
<td>$59.50</td>
</tr>
<tr>
<td>TOTALS</td>
<td>$145,135,815.54</td>
<td>4,090,959</td>
<td>$35.48</td>
</tr>
</tbody>
</table>

Note: This data was revised by the Personnel Cabinet on August 4, 2004.

*Brand drugs costs the group $121.9 million in 2003 which represents 84% of all dollars expended. However, brand drugs represented 55% of all prescriptions filled or 2.3 million prescriptions of 4.1 million system wide.*

The following chart identifies the price comparison between the plan’s cost and Canada.
## G: Kentucky State Employee Health Insurance/Canadian Prices-Calendar Year 2003

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Purpose</th>
<th>Supply</th>
<th>Strength</th>
<th>State Employee Ingredient Average</th>
<th>Canadian Ingredient Average</th>
<th>Potential Ingredient Monthly Savings per Script</th>
<th>No.of Scripts in 2003</th>
<th>Total Costs in 2003</th>
<th>Potential Ingredient Savings in 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacid</td>
<td>Acid Reflux Disease</td>
<td>30</td>
<td>30 mg</td>
<td>$117.81</td>
<td>$65.15</td>
<td>$52.66</td>
<td>33,891</td>
<td>$ 4 M</td>
<td>$1.8 M</td>
</tr>
<tr>
<td>Allegra-D:</td>
<td>Allergies</td>
<td>30</td>
<td>120 mg</td>
<td>$43.78</td>
<td>$23.13</td>
<td>$20.65</td>
<td>17,938</td>
<td>$.8 M</td>
<td>$.4 M</td>
</tr>
<tr>
<td>Lipitor</td>
<td>Cholesterol</td>
<td>30</td>
<td>10 mg</td>
<td>$48.31</td>
<td>$45.57</td>
<td>$2.74</td>
<td>56,649</td>
<td>$2.7 M</td>
<td>$.2 M</td>
</tr>
<tr>
<td>Lipitor</td>
<td>Cholesterol</td>
<td>30</td>
<td>20 mg</td>
<td>$80.66</td>
<td>$59.63</td>
<td>$21.03</td>
<td>33,333</td>
<td>$2.7 M</td>
<td>$.7 M</td>
</tr>
<tr>
<td>Lipitor</td>
<td>Cholesterol</td>
<td>30</td>
<td>40 mg</td>
<td>$80.58</td>
<td>$64.31</td>
<td>$16.27</td>
<td>13,346</td>
<td>$1.1 M</td>
<td>$.2 M</td>
</tr>
<tr>
<td>Zyrtec</td>
<td>Allergies</td>
<td>30</td>
<td>10 mg</td>
<td>$27.72</td>
<td>$24.90</td>
<td>$2.82</td>
<td>39,093</td>
<td>$1.1 M</td>
<td>$.1 M</td>
</tr>
<tr>
<td>Singulair</td>
<td>Asthma</td>
<td>30</td>
<td>10 mg</td>
<td>$66.18</td>
<td>$64.83</td>
<td>$1.35</td>
<td>28,342</td>
<td>$1.5 M</td>
<td>$.1 M</td>
</tr>
<tr>
<td>Neurontin</td>
<td>Epilepsy</td>
<td>30</td>
<td>300 mg</td>
<td>$95.71</td>
<td>$26.07</td>
<td>$69.64</td>
<td>10,030</td>
<td>$1 M</td>
<td>$.7 M</td>
</tr>
<tr>
<td>Premarin</td>
<td>Estrogen Replacement</td>
<td>1.25 mg</td>
<td>$12.93</td>
<td>$10.19</td>
<td>$2.74</td>
<td>20,750</td>
<td>$.3 M</td>
<td>$.1 M</td>
<td></td>
</tr>
<tr>
<td>Zoloft</td>
<td>Depression</td>
<td>30</td>
<td>100 mg</td>
<td>$56.40</td>
<td>$36.80</td>
<td>*$19.60</td>
<td>22,413</td>
<td>$1.3 M</td>
<td>$.4 M</td>
</tr>
<tr>
<td>Zoloft- (2 kinds)</td>
<td>Depression</td>
<td>30</td>
<td>100 mg</td>
<td>$65.11</td>
<td>$36.80</td>
<td>*$28.31</td>
<td>22,094</td>
<td>$1.4 M</td>
<td>$.6 M</td>
</tr>
<tr>
<td>Fosamax</td>
<td>Osteoarthritis</td>
<td>This drug is more expensive</td>
<td>$53.10</td>
<td>*$56.71</td>
<td>23,287</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Celexa</td>
<td>Depression</td>
<td>30</td>
<td>20 mg</td>
<td>$56.73</td>
<td>$44.43</td>
<td>$12.30</td>
<td>21,985</td>
<td>$1.2 M</td>
<td>$.3 M</td>
</tr>
<tr>
<td>Flonase</td>
<td>Allergies</td>
<td>50 mcg</td>
<td>$40.71</td>
<td>$34.97</td>
<td>$5.74</td>
<td>24,177</td>
<td>$1 M</td>
<td>$.1 M</td>
<td></td>
</tr>
</tbody>
</table>

* 2004 Price List

Continued on Page 18
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Purpose</th>
<th>Supply</th>
<th>Strength</th>
<th>State Employee Ingredient Average</th>
<th>Canadian Ingredient Average</th>
<th>Potential Ingredient Monthly Savings per Script</th>
<th>No. of Scripts in 2003</th>
<th>Total Costs in 2003</th>
<th>Potential Ingredient Savings in 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allegra</td>
<td>Allergies</td>
<td>30</td>
<td>180 mg</td>
<td>$46.19</td>
<td>$54.95</td>
<td>*</td>
<td>53,982</td>
<td>more expensive</td>
<td></td>
</tr>
<tr>
<td>Ortho-Tricycline</td>
<td>Oral Contraception</td>
<td>30</td>
<td>-</td>
<td>$19.99</td>
<td>$16.87</td>
<td>*</td>
<td>33,508</td>
<td>$.7 M</td>
<td>$.1 M</td>
</tr>
<tr>
<td>Protonix</td>
<td>Acid Reflux GERD</td>
<td>30</td>
<td>40 mg</td>
<td>$88.49</td>
<td>$53.10</td>
<td>*</td>
<td>22,757</td>
<td>$.2 M</td>
<td>$.8 M</td>
</tr>
<tr>
<td>WellButrin SR</td>
<td>Anti-Depressants</td>
<td>30</td>
<td>150 mg</td>
<td>$82.87</td>
<td>$30.23</td>
<td>*</td>
<td>19,426</td>
<td>$1.6 M</td>
<td>$1 M</td>
</tr>
<tr>
<td>Evista</td>
<td>Osteoporosis</td>
<td>28</td>
<td>60 mg</td>
<td>$56.42</td>
<td>$50.40</td>
<td>*</td>
<td>17,074</td>
<td>$1 M</td>
<td>$.1 M</td>
</tr>
<tr>
<td>Zithromax-Z Pak</td>
<td>Antibiotic</td>
<td>No Comparable Drug Found</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexium</td>
<td>Persistent Heartburn</td>
<td>30</td>
<td>40 mg</td>
<td>$103.10</td>
<td>$74.73</td>
<td>*</td>
<td>16,118</td>
<td>$1.7 M</td>
<td>$.5 M</td>
</tr>
<tr>
<td>Effexor-XR</td>
<td>Depression</td>
<td>30</td>
<td>75 mg</td>
<td>$100.97</td>
<td>$42.34</td>
<td>*</td>
<td>16,066</td>
<td>$1.6 M</td>
<td>$.9 M</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>150 mg</td>
<td>$91.94</td>
<td>$52.07</td>
<td>*</td>
<td>10,521</td>
<td>$1 M</td>
<td>$.4 M</td>
</tr>
<tr>
<td>Zocor</td>
<td>Cholesterol lowering drug</td>
<td>30</td>
<td>20 mg</td>
<td>$101.62</td>
<td>$68.75</td>
<td>*</td>
<td>9,784</td>
<td>$1 M</td>
<td>$.3 M</td>
</tr>
<tr>
<td>Advair Diskus</td>
<td>Asthma</td>
<td>N/A</td>
<td>250 mcg</td>
<td>$118.92</td>
<td>$100.00</td>
<td>*</td>
<td>8,181</td>
<td>$1 M</td>
<td>$.2 M</td>
</tr>
<tr>
<td>Celebrex</td>
<td>Arthritis Pain Relief</td>
<td>30</td>
<td>200 mg</td>
<td>$83.71</td>
<td>$42.62</td>
<td>*</td>
<td>15,513</td>
<td>$1.3 M</td>
<td>$.6 M</td>
</tr>
</tbody>
</table>

*2004 Price List

TOTAL: $33 M $10.6 M

Top 20 Brand Prescriptions for the Commonwealth's Public Employee Health Insurance Program, and Drugs costing the plan $1 million or more in 2003, Commonwealth's Public Employee Health Insurance Program. Source: Kentucky Department of Personnel data supplied on 8-4-04; and, all 2003 prices on Canadian drugs captured from the state of Illinois: The Fight for Affordable Prescription Drugs. The 2004 Canadian prices represent an average derived by pricing the comparable drug through 3 internet pharmacies.
Analysis on Cost Comparison

1. $10.6 million represents a potential ingredient savings of 32%.
2. The plan expended $121.9 million for brand drugs in 2003 if 30% had been saved the total ingredient savings to the plan would have been $36.5 million.
3. In addition, to the plan savings you would have member savings because of co-pays. Co-pays go towards the ingredient cost of the drug.
4. Members/Plan would have costs associated with reimported drugs but not $15 per script.
5. Members had 2,252,942 prescriptions x $15 =$33,794,130.

Potential Savings to the plan and members if the drugs had been reimported from Canada:

- Potential 30% savings would total: $36.5 million
- Potential Members savings: $33.8 million
- Total Potential Savings: $70.3 million

The potential savings are based on 2003 utilization and assumes all drugs would be appropriate for reimportation, and, that all co-pays would be saved which would be contingent on the reimportation plan.

The Commonwealth’s Employee Health Insurance Plan for 2005

1. Plans for 2005 will include wellness initiatives and incentives for employees to make healthy lifestyle choices. Non-smokers will receive a discount on their premium contribution. They are estimating the plan will have 229,000 participants.

2. The Commonwealth is transitioning from an illness model to a wellness model and the following outlines the plans available:

   a. Salary will dictate what premium contribution state employees and teachers are responsible for relative to their health insurance coverage.
   b. Three (3) PPO plans will be offered to members of the plan.
      1. Commonwealth Essential;
      2. Commonwealth Preferred; and,
   c. Under all three (3) plans members will pay co-insurance, deductibles and co-pays. Out-of-pocket prescription costs will not be counted towards an individual’s deductible.
   d. On average state employees would pay $17 per month over the states contribution (smokers would pay $32). Parent/Plus Child coverage would cost an average state employee $127 per month (smokers would pay $157) and Family coverage would cost on average $486 per month (add $516 per month for smoking members).
3. The National Conference of State Legislatures, which tracks state health insurance programs, said Kentucky state employees in 2003 paid the highest premium in the nation $540.80 per month on average for family coverage under a standard benefits package. The $286 per month state contribution was the second lowest in the nation. Source: Courier Journal, Premiums Would Go Up for Some Workers, Down for Others, September 8, 2004.

4. There will be one (1) exclusive carrier per region. The carriers are: Anthem Blue Cross, Bluegrass Family Health, CHA Health and United Healthcare.

5. State employees and teachers would receive a 2% cost of living increase and an additional 1% beginning in January 2005, to help off-set the cost of health insurance.

6. State employees and teachers are dissatisfied with the plans and out-of-pocket costs associated with the plans and coverage available. There is widespread sentiment that costs have increased and coverage has been reduced.

7. Governor Fletcher has called a Special Session of the General Assembly, to begin October 5, 2004 to deal with the health insurance plan. Open enrollment for teachers, state employees and retirees has been suspended.

**Kentucky Medicaid Background**

1. Kentucky’s state share of Medicaid expenditures increased from $259 million in FY1990 to $1.2 billion in FY2003.

   1990- 370,000 eligibles
   2003- 650,000 eligibles

   Note: There were more Kentuckians eligible and participating in Medicaid in 2003 than children enrolled in Kentucky’s schools. The number of children enrolled in schools totaled 642,000. The 2004 numbers for school enrollment will not be available until October 2004.

2. Pharmacy costs alone have increased almost 350% from 1992-2003, more than 10 times the over-all inflation rate. Kentucky’s state share of pharmacy costs in FY2003 was $200 million.
3. Kentucky’s Medicaid recipients had an average of 23 prescriptions each compared to the national Medicaid average of 12.

   A. Medicaid Drug Rebate Program requires drug manufacturers to enter into a legally binding agreement with the U.S. Department of Health & Human Services before they can receive federal funding for outpatient drugs dispensed to Medicaid recipients. 49 States (Arizona does not participate) and 500 Drug Manufacturers participate in the agreement.

   B. There is a history of “pay and chase” on rebate collections. Rebate collection is time intensive but on average it reduces Medicaid expenditures by 18%-20%.

   C. A drug rebate is an amount that by federal law must be returned to the state by a pharmaceutical company for the privilege of making its drugs available to Medicaid recipients.

   D. The National Governors Association has estimated state Medicaid programs could save 10% to 15% with an aggressive supplemental rebate program. Kentucky’s Medicaid program has contracted to build a supplemental rebate program to compliment its Preferred Drug Lists/Formulary efforts. They are estimating supplemental rebates could net an additional $32 million this fiscal year. Source: June 16, 2004, Department for Medicaid Services (DMS) PowerPoint.

4. Eligibles in Kentucky during the last quarter FY2004 were as follows:

   April  671,195
   May    670,732
   June   672,981

5. 22% of Kentucky’s budget expenditures are due to Medicaid.

6. Explosive growth in eligibles and inflationary increases in costs of services while the budget has been essentially flat funded for 2 biennia’s has made for difficult decisions on the part of the Department to balance the budget.

   Pharmacy Expenditures

<table>
<thead>
<tr>
<th></th>
<th>FY2001</th>
<th>FY2002</th>
<th>FY2003</th>
<th>FY2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$579.3M</td>
<td>$651.4M</td>
<td>$693.5M</td>
<td>$779.1M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Expedited Payment Cycle to advantage the Commonwealth due to enhanced match rate authorized under federal fiscal relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Average Annual # of Eligibles

<table>
<thead>
<tr>
<th></th>
<th>FY2001</th>
<th>FY2002</th>
<th>FY2003</th>
<th>FY2004</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>602,932</td>
<td>626,440</td>
<td>653,959</td>
<td>• 672,981</td>
</tr>
</tbody>
</table>

• June 2004 Eligibles not annual average

7. Governor Fletcher has announced a Medicaid Modernization Plan to stabilize and reduce spending. The strategy has 3 major components:
   A. Care Management;
   B. Benefit Management; and,
   C. Technology.

The Benefit Management component includes an aggressive pharmacy initiative:
   1. Retain Pharmacy Benefit Manager- Contract was scheduled for approval August 4, 2004.
   2. Amend 907 KAR1:019 to bolster effectiveness of Pharmacy & Therapeutics Committee.
   3. Actions taken by P&T Committee to date:
      a. Recognized drug classes increased from 12 to 53 which create more opportunities for supplemental rebates.
      Source: DMS Power Point by: Health and Welfare Committee, June 16, 2004

Other pharmacy initiatives under consideration by Medicaid:
   1. More drugs to be prior authorized;
   2. Prior approval for any scripts over and above an identified cap;
   3. Restructure over-the-counter benefit;
   4. Increasing the co-pay; and,
   5. Mail order for scripts.


Medicaid claims history data on prescriptions provided by Medicaid for Calendar 2003.

1. Kentucky Medicaid data is by volume of prescriptions and does not adjust for dosage, strength. The dispensing fee is not included.
   A. Medicaid traditionally dispenses drugs for a 30-day period.
   B. The average cost was derived by subtracting dispensing fee and dividing the number of scripts into the dollars expended.
   C. Estimated rebate of 20% has been taken into account.

2. See the chart of Kentucky Medicaid/Canadian Prices for calendar Year 2003 on the next page, 2.A.
## 2. A. Kentucky Medicaid/Canadian Prices - Calendar Year 2003

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Purpose</th>
<th>Supply</th>
<th>Strength</th>
<th>Medicaid Ingredient Average After Rebate</th>
<th>Canadian Ingredient Average</th>
<th>Potential Ingredient Monthly Savings per Script</th>
<th>No. of Scripts in 2003</th>
<th>Total Ingredient Costs in 2003</th>
<th>Potential Ingredient Savings in 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Prevacid</td>
<td>Acid Reflux Disease</td>
<td>30</td>
<td>N/A</td>
<td>$105.42</td>
<td>$64.94</td>
<td>$40.48</td>
<td>17,412</td>
<td>$2.3 M</td>
<td>$ .7 M</td>
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<tr>
<td>Lipitor</td>
<td>Cholesterol</td>
<td>30</td>
<td>N/A</td>
<td>$63.51</td>
<td>$56.50</td>
<td>$7.01</td>
<td>279,654</td>
<td>$22.2 M</td>
<td>$ 2 M</td>
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<tr>
<td>Zyrtec</td>
<td>Allergies</td>
<td>30</td>
<td>N/A</td>
<td>$31.74</td>
<td>$24.90</td>
<td>$6.84</td>
<td>91,944</td>
<td>$3.6 M</td>
<td>$ .6 M</td>
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<tr>
<td>Singular</td>
<td>Asthma</td>
<td>30</td>
<td>N/A</td>
<td>$62.58</td>
<td>$58.21</td>
<td>$4.37</td>
<td>149,194</td>
<td>$11.7 M</td>
<td>$ .7 M</td>
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<tr>
<td>Neurontin</td>
<td>Epilepsy</td>
<td>30</td>
<td>N/A</td>
<td>$95.92</td>
<td>$23.07</td>
<td>$72.85</td>
<td>127,556</td>
<td>$15.3 M</td>
<td>$9.3 M</td>
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<tr>
<td>Risperdol</td>
<td>Antipsychotic</td>
<td>30</td>
<td>N/A</td>
<td>$135.62</td>
<td>$62.50</td>
<td>$73.12</td>
<td>124,237</td>
<td>$21.1 M</td>
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<tr>
<td>Premarin</td>
<td>Estrogen Replacement</td>
<td>30</td>
<td>N/A</td>
<td>$24.06</td>
<td>$8.90</td>
<td>$15.16</td>
<td>84,687</td>
<td>$2.5 M</td>
<td>$1.3 M</td>
</tr>
<tr>
<td>Paxil</td>
<td>Depression Anxiety</td>
<td>30</td>
<td>N/A</td>
<td>$65.82</td>
<td>$52.60</td>
<td>$13.22</td>
<td>76,177</td>
<td>$6.3 M</td>
<td>$1 M</td>
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<tr>
<td>Zoloft</td>
<td>Depression</td>
<td>30</td>
<td>N/A</td>
<td>$61.66</td>
<td>$36.80</td>
<td>$24.86</td>
<td>171,721</td>
<td>$13.2 M</td>
<td>$4.2 M</td>
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<tr>
<td>Vioxx</td>
<td>Pain Relief Arthritis</td>
<td>30</td>
<td>N/A</td>
<td>$59.74</td>
<td>$48.92</td>
<td>$10.82</td>
<td>51,673</td>
<td>$3.8 M</td>
<td>$.6 M</td>
</tr>
<tr>
<td>Fosamax</td>
<td>Osteoporosis</td>
<td>No Comparable Drug Located.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Celexa</td>
<td>Depression</td>
<td>30</td>
<td>N/A</td>
<td>$55.50</td>
<td>$45.18</td>
<td>$10.32</td>
<td>72,708</td>
<td>$.5 M</td>
<td>$.8 M</td>
</tr>
<tr>
<td>Flonase</td>
<td>Allergies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synthroid</td>
<td>Underactive Thyroid</td>
<td>30</td>
<td></td>
<td>$9.45</td>
<td>$5.90</td>
<td>$3.55</td>
<td>148,539</td>
<td>$1.8 M</td>
<td>$.5 M</td>
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<tr>
<td>Depakote</td>
<td>Epilepsy</td>
<td>30</td>
<td></td>
<td>$85.24</td>
<td>$15.29</td>
<td>$69.95</td>
<td>63,886</td>
<td>$6.8 M</td>
<td>$4.4 M</td>
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<tr>
<td>Protonix*</td>
<td>Acid Reflux</td>
<td>30</td>
<td>N/A</td>
<td>$79.10</td>
<td>$45.36</td>
<td>$33.74</td>
<td>106,324</td>
<td>$10.5 M</td>
<td>$3.6 M</td>
</tr>
<tr>
<td>Zyprexa*</td>
<td>Psychotropic</td>
<td>30</td>
<td>N/A</td>
<td>$241.95</td>
<td>$125.89</td>
<td>$116.06</td>
<td>104,967</td>
<td>$31.8 M</td>
<td>$12.2 M</td>
</tr>
</tbody>
</table>

Continued on Page 24
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Purpose</th>
<th>Supply</th>
<th>Strength</th>
<th>Medicaid Ingredient Average After Rebate</th>
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<th>Potential Ingredient Monthly Savings per Script</th>
<th>No. of Scripts in 2003</th>
<th>Total Ingredient Costs in 2003</th>
<th>Potential Ingredient Savings in 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plavix*</td>
<td>Helps Prevent Blood Clots</td>
<td>28</td>
<td>N/A</td>
<td>$82.41</td>
<td>$76.62</td>
<td>$5.79</td>
<td>97,878</td>
<td>$10.1 M</td>
<td>$.6 M</td>
</tr>
<tr>
<td>Ultracet*</td>
<td>Pain Relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Searched 6 Canadian Pharmacies Could Not Locate Price Quote</td>
</tr>
<tr>
<td>Norvasc*</td>
<td>Antihypertensive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Medicaid Less Expensive than Canada</td>
</tr>
<tr>
<td>Lexapro*</td>
<td>Depression</td>
<td>30</td>
<td>N/A</td>
<td>$48.21</td>
<td>$47.46</td>
<td>.75 cents</td>
<td>75,002</td>
<td>$4.5 M</td>
<td>$.1 M</td>
</tr>
<tr>
<td>Toprol XL*</td>
<td>Beta Blocker, Hypertension, Angina, Congestive Heart Failure</td>
<td>30</td>
<td>N/A</td>
<td>$21.66</td>
<td>$20.75</td>
<td>.91 cents</td>
<td>86,871</td>
<td>$2.4 M</td>
<td>$.1 M</td>
</tr>
<tr>
<td>Celebrex*</td>
<td>Arthritis Pain Relief</td>
<td>30</td>
<td>N/A</td>
<td>$62.95</td>
<td>$33.54</td>
<td>$29.41</td>
<td>88,824</td>
<td>$7 M</td>
<td>$2.6 M</td>
</tr>
<tr>
<td>Seroquel*</td>
<td>Antipsychotic</td>
<td>30</td>
<td>N/A</td>
<td>$134.06</td>
<td>$66.85</td>
<td>$67.21</td>
<td>93,010</td>
<td>$15.6 M</td>
<td>$6.3 M</td>
</tr>
</tbody>
</table>

*2004 Prices

TOTAL= $196.10 M $61.3 M

Source: Cabinet for Health & Family Services supplied data on Top 100 brand name drugs by volume for calendar year 2003 from the MMIS on June 4, 2004. The data is not adjusted for dosage or days supplied. Zithromax was deleted because no comparable drug could be located.

Note: $196.10 million total for top 20 + drugs by volume of prescriptions
$39.22 million 20% adjustment for rebate
$156.88 million
Analysis on Cost Comparison

1. If Canadian pricing had been available for the Top 20 + drugs $61.3 million could have been saved which represents a potential savings of 39% after the total of $196.10 million is adjusted by 20% for the rebate factor.

2. Medicaid expended $398,799,135 (ingredient costs absent dispensing fee) on 5,034,476 brand prescriptions in 2003, which represents Medicaid’s top 100 list of brand drugs by volume. This total must be adjusted by the 20% rebate factor which results in a revised total of $319,039,308. If the 39% savings held across the population of top 100 brand drugs it would result in a potential savings of $124,425,330 to the Medicaid program. Under Medicaid’s match formula this would equate to $37,327,599 in state funding.

ACTION STEPS TO REDUCE DRUG COSTS FOR KENTUCKIANS

1. Urge Governor Fletcher to submit a waiver to reimport drugs to the FDA for their consideration and action.
   a. Potential State Health Plan Savings: $36.5 million
   b. Potential Member Savings: $33.8 million
      Total= $70.3 million
   c. Potential Medicaid Savings: $37.3 Million (State share of $124.4 Million)

2. Urge the Kentucky General Assembly and Governor Fletcher to work with the Auditor in actively encouraging the Kentucky Congressional Delegation to support and actively pass legislation, which would allow reimportation.

3. Urge the Kentucky General Assembly to hold hearings with experts and stakeholders to explore mechanisms for Kentucky to reimport drugs. The hearings should be held prior to the 2005 Session of the General Assembly and should address the following issues related to a potential reimportation plan which would allow Kentucky to take advantage of low prices, protect Kentucky’s citizens and maintain patient relationship with physician and pharmacists.
   1. Mechanics of the plan
   2. Safety Review
   3. Consumer Education
4. Review of Kentucky’s Laws/Regulation
5. Utilize expertise from Government and Public sector
6. Involvement of all stakeholder groups
   a. KMA/KNA
   b. Executive Branch Agencies
   c. Board of Pharmacy
   d. Kentucky Pharmacists Association
   e. Citizens

4. Urge the General Assembly to convene a working group after hearings are held and charge the group to develop a report for the 2005 General Assembly’s consideration and action if deemed appropriate.

   A. Reimportation/Bulk Purchasing Options
      1. State Employee Health Group
      2. State Facilities
         a. Prisons
         b. Hospitals
         c. Facilities
      3. Medicaid
         a. Feasibility
         b. Complex Program with subtle issues with multi-million dollar impact.
            1. Waiver
            2. Rebate Agreement
            3. Supplemental Rebates

4. Urge the Attorney General to explore legal opportunities for Kentucky to reduce its prescription drug cost burden by possibly joining in other states litigation or pursuing other independent legal remedies.

6. Urge Cities and Counties to explore drug reimportation for their health related expenditures.

7. Pursue education campaign for citizens
   A. Reduce Utilization through Wellness Programs/Disease Management
   B. Utilize Reimportation
Contributors To This Report

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Marcia R. Morgan, Director, Division of Performance Audit

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Services Offered By Our Office

The staff of the APA office performs a host of services for governmental entities across the state. Our primary concern is the protection of taxpayer funds and furtherance of good government by elected officials and their staffs. Our services include:

Financial Audits: The Division of Financial Audit conducts financial statement and other financial-related engagements for both state and local government entities. Annually the division releases its opinion on the Commonwealth of Kentucky’s financial statements and use of federal funds.

Investigations: Our fraud hotline, 1-800-KY-ALERT (592-5378), and referrals from various agencies and citizens produce numerous cases of suspected fraud and misuse of public funds. Staff conduct investigations in order to determine whether referral of a case to prosecutorial offices is warranted.

Performance Audits: The Division of Performance Audit conducts performance audits, performance measurement reviews, benchmarking studies, and risk assessments of government entities and programs at the state and local level in order to identify opportunities for increased efficiency and effectiveness.

Training and Consultation: We annually conduct training sessions and offer consultation for government officials across the state. These events are designed to assist officials in the accounting and compliance aspects of their positions.

General Questions

General questions should be directed to Jeff Derouen, at (502) 573-0050 or the address above.