Approved: March 31, 2004
Date

MINUTES OF THE SENATE WAYS AND MEANS COMMITTEE

The meeting was called to order by Chairman Stephen Morris at 10:40 a.m. on February 11, 2004, in Room 123-S of the Capitol.

All members were present.

Committee staff present:
Alan Conroy, Director, Kansas Legislative Research Department
J. G. Scott, Chief Fiscal Analyst, Kansas Legislative Research Department
Melissa Calderwood, Kansas Legislative Research Department
Amy Deckard, Kansas Legislative Research Department
Susan Kannarr, Kansas Legislative Research Department
Jill Wolters, Senior Assistant, Revisor of Statutes
Judy Bromich, Administrative Analyst
Mary Shaw, Committee Secretary

Conferees appearing before the committee:
Chris Ward, President, Ward Health Strategies

Others attending:
See Attached List.

Bill Introduction

Senator Downey moved, with a second by Senator Helgerson, to introduce a bill relating to the comprehensive transportation program concerning the financing thereof (3rs1915). Motion carried on a voice vote.

Chairman Morris welcomed Chris Ward, President, Ward Health Strategies, Ontario, Canada, who gave a briefing on the economic importation of pharmaceuticals (Attachment 1) and (Attachment 2). Mr. Ward explained that his interest in healthcare stems from his involvement in the Ontario Legislature.

Mr. Ward explained that prescription drugs prices in Canada are fundamentally different than what they are in the United States as are the prices for all other healthcare services. Mr. Ward noted that the price differentials that exist between the two countries for health services and supplies because of:

1. Legislated Price Controls.
   The following was explained: Prescription drug prices in Canada are price controlled and legislated by the national government. A drug product launched in Canada can be sold for no more than an existing drug in the same therapeutic class or the average price of that drug in America and six other European countries. This is done through federal legislation called the Patent Medicine Prices Review Board.

2. Differences in the economy of the United States and Canada.

3. Differences in product liability laws.

Detailed information regarding the safety of the drug supply system and keeping control over drug prices is found in Mr. Ward's written testimony. He explained, in reference to when people say that they are only going to import FDA-approved drugs from Canada into the United States, it is impossible to sell an FDA-approved drug in America at Canadian prices. Mr. Ward noted that, legally, the only person that can export a product from one country to another is the manufacturer itself.

Mr. Ward noted that the Canadian government is on record as indicating that it does not guarantee the safety of drugs imported for personal use. It advises its own citizens against importing drugs, primarily out of concerns for safety and efficacy.

MINUTES OF THE SENATE WAYS AND MEANS COMMITTEE at 10:40 a.m. on February 11, 2004, in Room 123-S of the Capitol.

Copies of the Kansas Legislative Research Department Budget Analysis Report for FY 2004 and FY 2005 were distributed to the committee.

Subcommittee report on:

Kansas Department of Health and Environment (Attachment 3)

Subcommittee Chairman Adkins reported that the subcommittee on the Kansas Department of Health and Environment concurs with the Governor's recommendation in FY 2004 and concurs with the Governor's FY 2005 recommendations with changes and comments.

Senator Adkins moved, with a second by Senator Downey, to adopt the subcommittee budget report on the Kansas Department of Health and Environment in FY 2004 and FY 2005. Motion carried on a voice vote.

Chairman Morris called the committee's attention to discussion of:

SB 257--Authority for the animal health department to increase certain fees

Chairman Morris explained that **SB 257** had a substantial hearing during the 2003 session.

The Revisor explained a balloon amendment (Attachment 4). Senator Downey moved, with a second by Senator Helgerson, the balloon amendment for **SB 257** to give the agency authority to raise the fees 50 percent and remove $1.00 surcharge per pet. Motion failed on a voice vote.

Senator Kerr moved, with a second by Senator Downey, to amend the bill to give the agency authority to raise the fees 25 percent, remove the $1.00 surcharge and recommend **SB 257** favorable for passage as amended. Motion carried on a roll call vote.

The meeting adjourned at 12:05 p.m. The next meeting is scheduled for February 12, 2004.

SENATE WAYS AND MEANS COMMITTEE
GUEST LIST
DATE February 11, 2004

NAME	REPRESENTING
[illegible]	DOB
[illegible]	DOB
Chuck Westhoff	
Betty Westhoff	
Doug Bowman	Coordinating Council on Early Childhood
THOMAS BURLINGHAM	KDA
Janice Marcotte	
Eric King	K-FED
Mary Tobley	SRS
Brad Byrne	Cessna A.C.
[illegible]	KNFP
Christina Collins	KMS
Jerry Slaughter	KMS
Kelly Finney	Ks. Public Health Assn.
Teresa Schwab	Oral Health Kansas
Paula Tunnell	KAMU
M Hellebust	TFKC
Nancy Zogleman	Pfizer
Kathy Damron	Damron Assoc.
[illegible]	Hein Law Firm
Diane Bolin (Diane Bolin)	KDHE
Tom Hammerschmidt	KDHE

SENATE WAYS AND MEANS COMMITTEE
GUEST LIST
DATE February 11, 2004

NAME	REPRESENTING
Lorna Phillips	KDHE
Dave Mayfield	Extension
Mary Jane Stankiewicz	KGFA/KARA
Brad Smoot	Pfizer
Patrick Hubbell	Pharma
Brian Lungs	PhRMA
Debra Duncan	KHHD
Midge Grinstead	Governor's Pet Advisory Board
Graham Crosby	KDHE
Susan Kang	KDHE
Dick Morrissey	KDHE
Don Francuz	KDHE
Sharon Munk	Ks Pet Industry
Betty Westhoff	Ks Pet Industry
Chuck Westhoff	Ks. Pet Industry

The Economic and Policy Implications of Re-importation
A Canadian Perspective
University of Michigan
October 30, 2003
By Christopher Ward

Drug prices are lower in Canada than in the U.S primarily because of government-imposed price controls in Canada, differences in exchange rates and differences in product liability laws between the two countries. A growing number of Canadian Internet pharmacies are taking advantage of these lower prices to ship prescription drugs to Americans at higher prices than they can charge Canadian patients. While this may benefit American uninsured or under-insured seniors and others struggling with high drug prices in the U.S. free market, this practice threatens the ability of both Canadian and American governments to ensure the safety of their drug supply systems. It also jeopardizes Canadian patient access to new medicines as Canada is beginning to suffer from shortages of drugs and pharmacists as this questionable but profitable business detracts human resources and supplies from Canadian patients.

The Safety of the Drug Supply System

In Canada, the federal government is responsible for the safety and efficacy of the drug supply system. New drugs must go through a review and approval system. Marketing and advertising practices are regulated to prevent direct-to-consumer advertising and ensure that claims made regarding a product correspond to published scientific evidence. Records of prescribed drugs are kept and recall mechanisms are in place to remove from distribution any drug found to have unanticipated adverse effects or defects. Strict packaging and labeling requirements are also enforced. The provinces provide additional protection for drug consumers by regulating the standards for safe prescribing and dispensing of prescription drugs. The importation of pharmaceuticals via the Internet circumvents all of the above safeguards.

The import and export of prescription drugs is strictly regulated. Canada is a net importer of drugs, and importers must be licensed and work within with federally negotiated mutual recognition agreements with other nations about pharmaceutical manufacturing processes. Canada has mutual recognition agreements with 18 countries (1).

Senate Ways and Means
2-11-04
Attachment 1

The equivalency of good manufacturing processes (GMP) compliance programs is determined through a documentation review of each country's regulatory agencies and an evaluation of processes and procedures involving on-site evaluations. In this way, the Canadian government ensures that any pharmaceutical product dispensed to Canadians meets with federal requirements and standards.

A prohibition on commercial parallel trade or unregulated importation of prescription drugs has existed in Canada and the U.S. since 1988 to prevent potentially unsafe re-packaging and minimize exposure to drug-counterfeiting. However, exemptions to the prohibition exist for the importation of drugs by individuals for personal use. The proliferation of Internet marketing has permitted technically "personal" use to explode as American consumers can now easily order their drugs by Internet. Pressure created by increased spending on prescription drugs and the inability to resolve the issue of coverage for low-income elderly and uninsured populations has made such purchases ever more appealing. It is estimated that nearly $1 billion worth of medicines is now flowing from Canada to the U.S. each year.

Government agencies in Canada and the U.S. do not attest to the safety of drugs imported under the loophole opened up by the personal use exemption. "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter," said Diane Gorman, Assistant Deputy Minister of Health at Health Canada in a letter to the Washington Post in May, 2003. Her American counterpart, William K. Hubbard, Senior Associate Commissioner at the U.S. FDA echoed the lack of responsibility for foreign drug supplies in his testimony before the Senate Committee on Commerce, Science and Transportation in September 2001. "A growing number of Americans are obtaining their prescription medications from foreign locations," said Hubbard. "They often seek out Canadian suppliers, or sources that purport to be Canadian. As we have said in the past, the FDA cannot ensure the safety of drugs purchased from foreign sources."

Despite the similar high manufacturing standards upheld in both Canada and the U.S., the assumption that drugs marketed in Canada are identical to those in the U.S. is flawed. There are often important differences in formulation and in manufacturing processes, and Canadian prescription drugs have Canadian labeling and prescribing information that is never identical to U.S. labeling and prescribing information. Concerns about safety increase, however, with the prospect that many of the drugs making their way from Canadian suppliers to American consumers are of neither Canadian nor American origin. According to Industry Canada data, pharmaceutical/medicinal product imports into Canada during the period from January to August 2003, increased by 24% over the same period the previous year. And since 1998 the proportion of total Canadian imports from the U.S. is dropping, from 60% in 1998 to 48% in 2002. While the total value of Canadian pharmaceutical imports from the U.S. continues to increase, imports of drugs to Canada from other countries are increasing.

With the growth in mail order pharmaceutical exports to the U.S., Canada has become an important market for imported pharmaceuticals. Between January and August 2002 and the same period in 2003, 36 countries exported $500,000 or more in medicines to Canada, despite the fact that Canada has Mutual Recognition Agreements for pharmaceutical Good Manufacturing Processes with only 18 countries. Up until August of 2003, imports from China to Canada increased over 38% over the previous year, imports from South Africa increased 98%, from Ecuador 292%, from Argentina 176%, and from Iran 327%. (Industry Canada, Trade Data Online, www.strategis.ic.gc.ca).

As the end consumers in this chain, Americans have to deal with the safety issues that arise with unregulated importation. U.S. FDA spot checks at several mail facilities revealed that there were safety concerns regarding nearly 90% of mail order imported drugs coming in to the U.S. In a pilot project to inspect drugs imported through the mail, it was determined that less than 4% of the intended recipients had valid prescriptions, drugs not approved for use by the FDA or removed from the market for safety reasons were making their way into the hands of consumers, as were drugs with serious contra-indications and interactions. As long ago as July 2001, the FDA brought these concerns forward through testimony before various Congressional committees.

Perhaps most important is the elimination of real consultation with physicians and pharmacists in the process of obtaining drugs. Professional organizations representing physicians and pharmacists across Canada and the U.S. overwhelmingly agree that mail order importation puts patients at risk. College of Physicians and Surgeons of Manitoba argues that "with no face-to-face contact between the co-signing doctor and the U.S. patient, Internet drug delivery is breaching the College's standards of practice" (Pills, profits and perils, Maclean's, September 2002).

Keeping Control over Drug Prices

While it is primarily American patients who may suffer from the use of sub-standard, wrongly prescribed or wrongly labeled drugs, Canadian patients may soon feel the effects of unregulated importation and exportation in their pocketbooks and in the quality of their health-care system. Currently, the federal government imposes price controls on all patented drugs in Canada, essentially setting the manufacturer's price through the Patented Medicines Prices Review Board (2). A breakthrough drug in Canada can be sold for no more than the price of existing drugs in the same therapeutic class or the median price of the same drug in seven other countries (U.S., U.K., Switzerland, Sweden, France, Germany and Italy).

Canadian drug prices are not freely negotiated by pharmaceutical companies. And while a company may delay the launch of a new drug in Canada because of price controls or other market restrictions, if it refuses to market a product in Canada altogether it risks losing patent rights through compulsory licensing. Similar mechanisms are used to control drug prices in European countries.

Prescription drugs are not covered under Canada's Medicare system, nor is there a federal mandate for the provinces to provide drug coverage. But every province has established a drug benefit program that limits the exposure to drug costs to a certain extent for seniors and other vulnerable populations. Provinces benefit from federal price controls as well as negotiations with drug suppliers in the price they pay to fulfill their coverage plans, which, as every health care report in recent years has shown, keep climbing steadily upwards. Spending on prescription drugs in Canada grew 13% between July 2002 and July 2003 attributable, according to a recent study by the PMPRB, primarily to increased utilization of prescription drugs.

We can expect spending on drugs to continue rising even if the PMPRB continues to be able to keep drug prices in Canada artificially lower than in the U.S. where dictates of a free market prevail and pharmaceutical companies are free to set prices according to market conditions. In Canada the government has been able to impose price control mechanisms on drugs for Canadian consumption in a country which represents only 2% of the global pharmaceutical market on the assumption that those prices will apply only to Canadian consumers. But if Canadian price controls continue to cut into the U.S. market, which represents 40% of the global pharmaceutical market, through the diversion of drugs manufactured and priced for the Canadian market, Canada may become subject to trade actions that could threaten the sustainability of its prescription drug price controls. At a time when Canada is looking into ways of providing drugs more cheaply to developing countries in dire need, unregulated exports and imports through Internet pharmacies in Canada are generating enormous profits for a small group of entrepreneurs at the expense of Canadian patients.

Finally, the Internet drug supply business is acting as a powerful draw on our country's pharmacists. In Manitoba, 200 of the 1000 pharmacists licensed to practice in the province have shifted from serving Canadians to serving the U.S. Internet business. As a result, pharmacies across the province are reducing their opening hours, the remaining pharmacists are severely strained and at least one rural pharmacy has been forced to shut down because of the acute pharmacist shortage. Pharmacists may not be part of the Medicare system, but are becoming increasingly important to Canadian patients in an era when ambulatory care and pharmacotherapy are replacing hospital and physician care for many conditions. The drug regimens for patients with chronic

conditions such as heart disease and diabetes (whose numbers are growing at alarming rates as our population ages) are complex and require monitoring and advice, most effectively and most cheaply provided by their pharmacist. The health care system is also growing increasingly dependent on pharmacists to control health care costs by ensuring that prescriptions are properly used and advocating the use of less expensive alternative where appropriate. The health care system will not be able to count on pharmacists to play an ever more important role in health care if their ranks are decimated by the lure of Internet pharmacy exports and the remaining pharmacists are left struggling to provide basic service for Canadian patients.

The supply of prescription drugs themselves is also in jeopardy. Drug manufacturers ship the volume of medicines needed to treat Canada's population. If these medicines are diverted to the U.S. market, Canada's supply falls short. A pharmacy adjacent to the Winnipeg Health Sciences Centre recently fell short of essential drugs used to treat brain cancer and leukemia, forcing the pharmacist there to appeal to the manufacturer for emergency release supplies to meet the patients' urgent needs. These same drugs were, on the same day, available on the Web sites of several Manitoba-based Internet pharmacy sites to American patients who could pay a higher price.

A number of pharmacist groups are beginning to take a stand on the issue. The Nova Scotia College of Pharmacists issued a statement in 2002 that clearly sets out cross-border dispensing as a breach of practice (Pharmacy Post, October 2002). As well, the New Brunswick College of Physicians and Surgeons suspended the license of a New Brunswick physician, also licensed in Maine, who was co-signing American prescriptions for a Manitoba Internet pharmacy (Pharmacy Post October 2002). In Manitoba, where most of Canada's Internet pharmacy business is based, concern over shortages of pharmacists and drugs prompted a group of pharmacists to form the Coalition for Manitoba Pharmacy in June 2003. They believe that international Internet pharmacy poses a threat to access to an adequate supply of prescription medicines, access to the care of a pharmacist, and maintenance of lower drug prices in Canada relative to the U.S. The Coalition successfully opposed regulatory changes that would have institutionalized cross-border pharmacy through the Manitoba Pharmaceutical Association. The Manitoba government, however, officially supports the cross-border Internet pharmacy trade and has therefore taken no measures to either track drug shortages in the province or impose controls on these businesses.

Without action at the federal level, the unregulated import and export of prescription drugs will only expand. Most schemes abuse the personal importation exemption as a mechanism to allow commercial mail order suppliers to provide lower cost drugs and to ignore drug quality safeguards. National state and provincial

governments in both Canada and the U.S. are responsible for establishing a framework of laws and regulations that protect patients by setting standards for the safe and appropriate prescribing and dispensing of drugs. In its submission to the Standing Committee on Health, the Coalition for Manitoba Pharmacy advocated that the federal government urge provincial governments to pass regulations prohibiting the export of Canadian prescription drugs. The Coalition points to measures New Zealand adopted when faced with a similar challenge, such as requiring that pharmacists fill prescriptions legitimately signed only by New Zealand physicians, and forbidding a doctor from writing a prescription for a patient unless they have physically examined that patient. Import permits and export controls could also be invoked at a federal level to deal with the problem.

As a final challenge, cross-border Internet pharmacies are encouraging less than ethical behavior from a number of vital players in our health care system, by seeking out doctors willing to co-sign a prescription for an American patient they have never seen, and by enticing pharmacies to order more products than they need and pass on the extra for a premium to an Internet pharmacy. Any practice that encourages the erosion of professional values with financial reward merits close examination from Canadian legislators.

(1) Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden. United Kingdom, Switzerland, Iceland, Lichtenstein and Norway

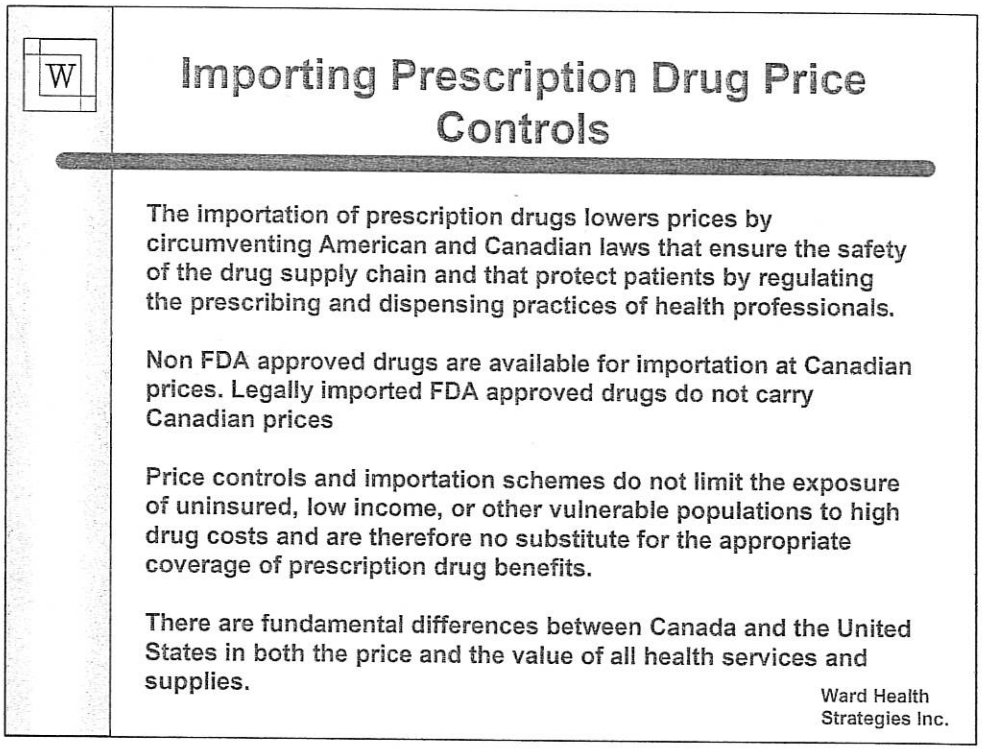
(2) Generic drug prices are not subject to Canadian controls and are, on average, higher than in the U.S. Nearly half of the prescriptions in the U.S. are for generic drugs.

The assumption that the drugs marketed in Canada are identical to those in the United States is flawed. In fact, there are often important differences: The formulation of Canadian drugs may differ from their U.S. counterparts; differences can occur through the use of different manufacturing processes; and Canadian prescription drugs have Canadian labeling and prescribing information that is never identical to the US labeling and prescribing information.

Both Canadian and American laws protect the safety of the drug supply by regulating imports and exports and allowing only manufacturers to legally export drugs commercially.

Personal use exemptions provide a loophole for legitimate and illegitimate. Simply changing U.S. law over-ride this safety standards or to attempt regulate Canadian commercial activity will have no effect in Canada.

Senate Ways and Means
2-11-04
Attachment 2



In both the United States and Canada the national government is responsible for ensuring the safety of the drug supply chain by setting standards for the manufacture of prescription drugs and by establishing safeguards that ensure that both domestic and foreign manufactured products meet these standards.

Government agencies in Canada and the United States do not attest to the safety of drugs illegally imported into the United States.

"The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter."

Diane Gorman
Assistant Deputy Minister, Health Canada
Letter to Washington Post, May 9, 2003

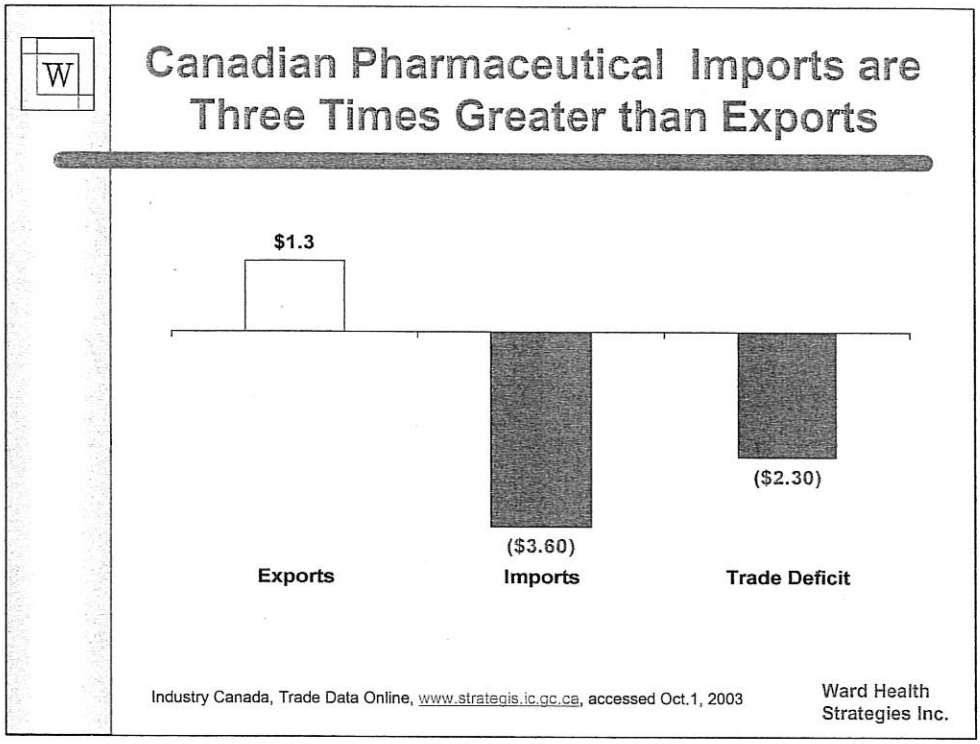
"A growing number of Americans are obtaining their prescription medications from foreign locations. They often seek out Canadian suppliers, or sources that purport to be Canadian. As we have said in the past, FDA cannot ensure the safety of drugs purchased from foreign sources."

Wm. K Hubbard
Senior Associate Commissioner FDA
Testimony Before Senate Committee on Commerce, Science and Transportation, Sept. 2001

Canada does not manufacture enough drugs to supply a Canadian market that is one/ twenty-fifth the size of the U.S. market. Although nearly one half of all Canadian drug imports are from the United States, when imports from the United States are added to total Canadian pharmaceutical production the combined total is barely enough to supply the Canadian market.

Pharmaceutical exports to Canada and from the United States represented nearly 60 percent of total Canadian imports in 1999 and 2000. Due to an increase in drug exports from other countries imports the percentage of drug imports from the U.S. has declined to 51 percent in 2001 and 48 percent in 2002 and 2003 to date. There is no indication of any decline in U.S. pharmaceutical exports to Canada.

There simply are not sufficient quantities of prescription drugs in Canada to supply the US market. Therefore there can be little doubt that much of the pharmaceutical product imported to the United States through Canada is manufactured somewhere other than Canada.



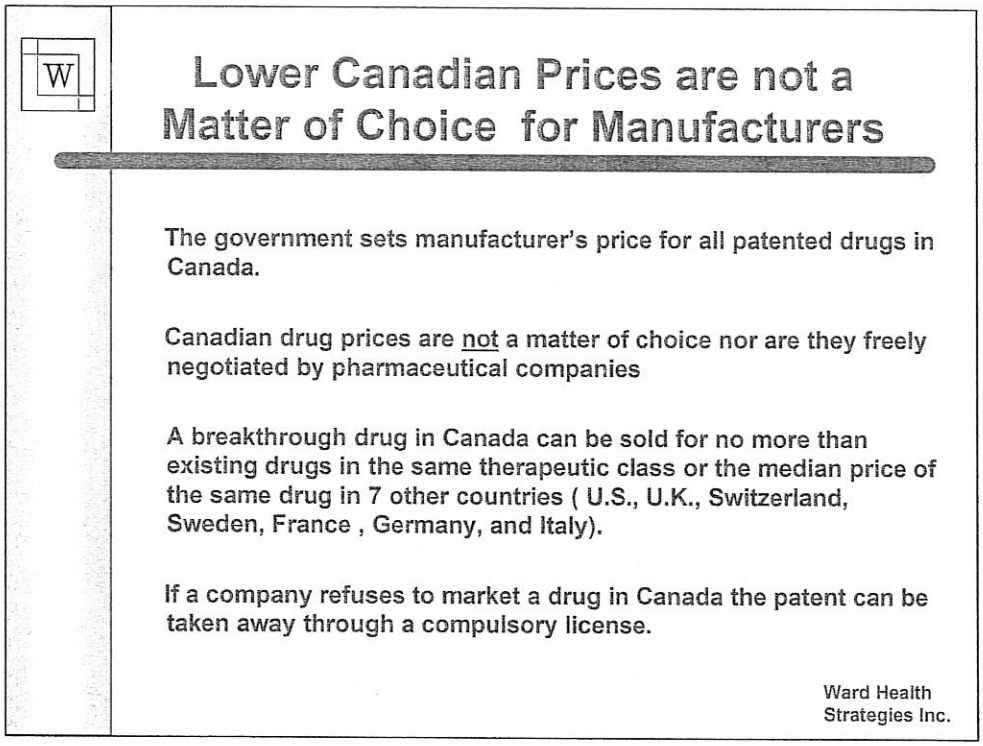
Prescription drugs imported by Canada can be easily distributed to the United States via mail order using the personal use import exemption.

According to Industry Canada data pharmaceutical/medicinal product imports have increased 24 % from January to August 2003, twice the 12% rate of increase in imports experienced in 2002.

Last year, according to Canadian government data, imports of pharmaceuticals and medicines into Canada was three times greater than exports.

So far this year (to August 2003) forty nine countries have exported $US 1,000,000 or more in medicines to Canada. The number of countries exporting $500,000 or more numbers 64.

Canada has Mutual Recognition Agreements for pharmaceutical GMP with only 17 countries.



The government of Canada imposes price controls on all patented drugs in Canada. Generic drugs are not subject to Canadian price controls and are, on average, substantially higher – priced than generic drugs in the United States. Nearly half of all prescriptions in the United Sates are for generic drugs.

Companies often delay the launch of new drugs in Canada because of market conditions that include price controls and other drug access restrictions. However a company does not have the option of refusing to market a product in Canada because a refusal to launch a product could result in the loss of patent rights through compulsory licensing.

Canadian price controls apply to ex-factory prices. In Canada, there are no rebate programs similar to the discounts that exist in the United States for Medicaid and other large purchasers.

The Trans - Shipment of Pharmaceutical Imports

Increase in Canadian Imports of Pharmaceuticals from Selected Countries Jan.- Sep. 2002 vs. Jan.- Sep. 2003)

COUNTRY	2002 to 2003 INCREASE	
Singapore	$13.8 TO $17.9 m	30%
Ecuador	$.74 TO $2.2 m	198%
China	$24.9 TO $35.5	43%
Iran	$.049 to $1.41 m	2,753%
Argentina	$.22 TO .72 m	221%
South Africa	$.28 TO $.51	84%
Thailand	$.61TO $.92 m	52%

Industry Canada, Trade Data Online, www.strategis.ic.gc.ca, accessed Novt.20, 2003

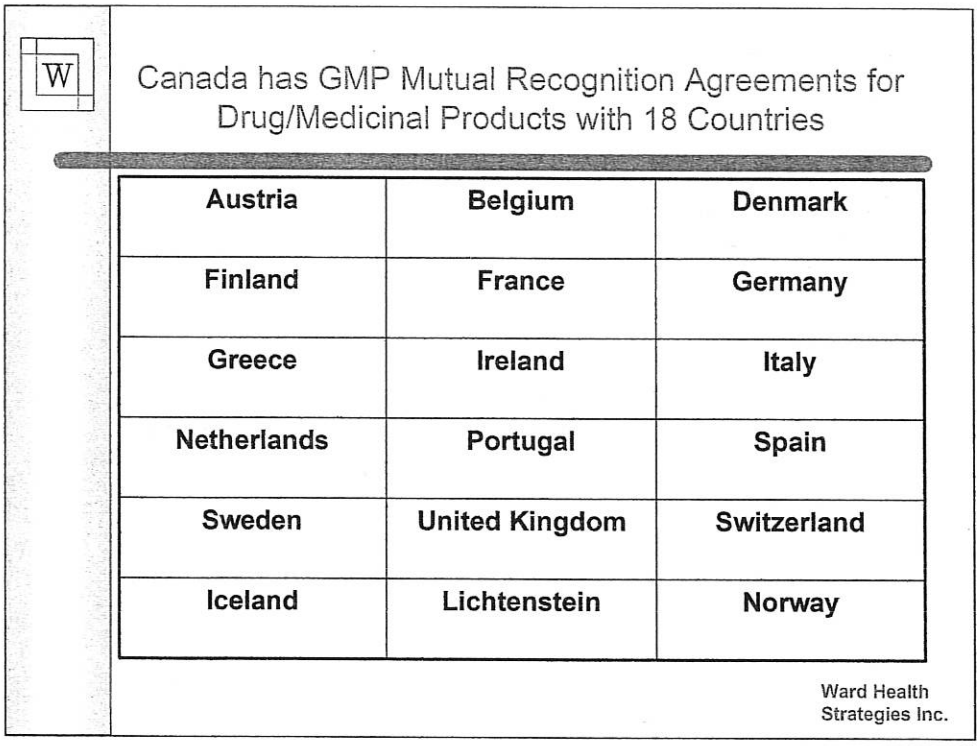
Ward Health Strategies Inc.

During the first eight months of 2003 pharmaceutical imports into Canada have increased by 22 percent over the same period last year.

With the growth in mail order pharmaceutical exports to the United States Canada has become an important market for imported pharmaceuticals. So far this year (to September 2003) thirty-eight countries have exported $US 500,000 or more in medicines to Canada.

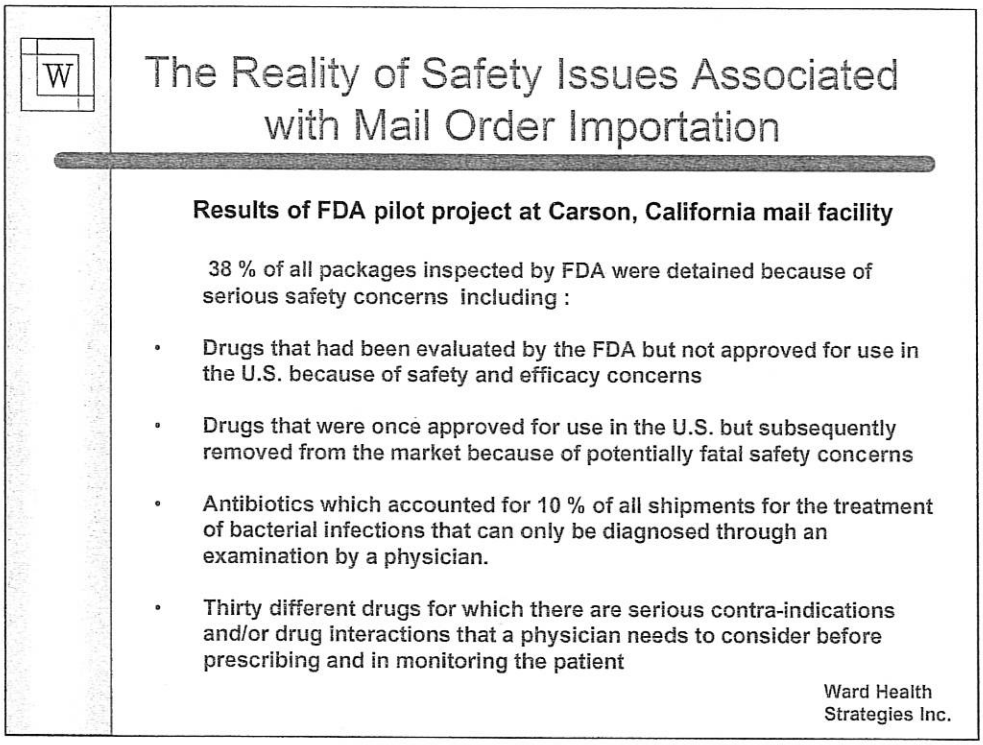
Canada has Mutual Recognition Agreements for pharmaceutical GMP with 17 countries.

None of the above listed countries have a pharmaceutical GMP mutual recognition agreement with Canada.



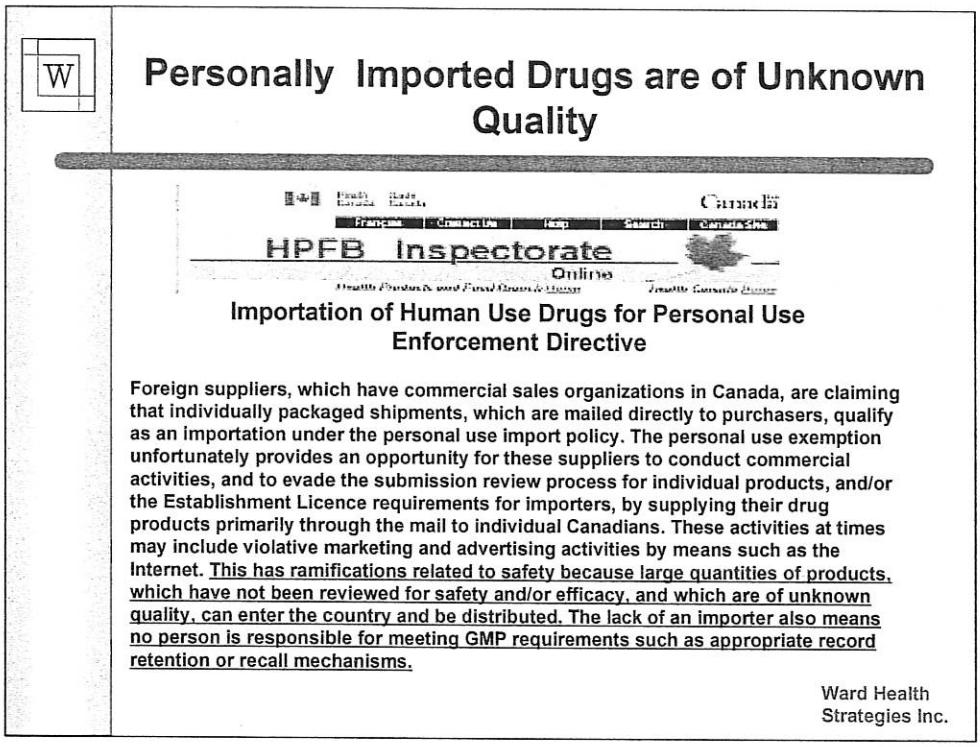
Approximately 7 % of medicinal imports to Canada are from countries other than the U.S. or those with an Mutual Recognition Agreement for with Canada for pharmaceutical GMP.

The equivalency of GMP compliance programs is determined through a documentation review of the involved regulatory agencies in each country and an evaluation of processes and procedures involving on-site evaluations.



Recently the FDA reported that spot checks at several mail facilities revealed that there were safety concerns regarding nearly 90 percent of mail order imported drugs coming in to the United States. As long ago as July 2001, the FDA brought these concerns forward through testimony before various Congressional committees.

Proponents of mail order importation argue that no one is harmed by the practice, yet the evidence of investigations such as the one in Carson California reveals that Americans are exposed to not only sub-standard but dangerous products when drugs are imported outside of the safeguards that exist to protect America's prescription drug supply. Less than 4 percent of the intended recipients of packages detained by the FDA in Carson, California had valid prescriptions.



Personally Imported Drugs are of Unknown Quality

HPFB Inspectorate Online

Importation of Human Use Drugs for Personal Use Enforcement Directive

Foreign suppliers, which have commercial sales organizations in Canada, are claiming that individually packaged shipments, which are mailed directly to purchasers, qualify as an importation under the personal use import policy. The personal use exemption unfortunately provides an opportunity for these suppliers to conduct commercial activities, and to evade the submission review process for individual products, and/or the Establishment Licence requirements for importers, by supplying their drug products primarily through the mail to individual Canadians. These activities at times may include violative marketing and advertising activities by means such as the Internet. This has ramifications related to safety because large quantities of products, which have not been reviewed for safety and/or efficacy, and which are of unknown quality, can enter the country and be distributed. The lack of an importer also means no person is responsible for meeting GMP requirements such as appropriate record retention or recall mechanisms.

Ward Health Strategies Inc.

The Canadian government is on record as indicating that it does not guarantee the safety of drugs imported for personal use. In fact it advises its own citizens against importing drugs, primarily out of concerns for safety and efficacy.

Health Canada is responsible for ensuring that drugs produced in Canada meet the manufacturing standards established by Health Canada for domestically produced products and international GMP (good manufacturing practices) for imported products.

Health Canada acknowledges that commercial sales organizations in Canada are using the personal use import policy " to evade the submission review process for individual products "and/or the Establishment Licence requirements for importers" .

Senate Ways and Means

Subcommittee Report on the

Kansas Department of Health and Environment

FY 2004 and FY 2005

David Adkins

Senator David Adkins, Chair

Jean Schodorf

Senator Jean Schodorf

Christine Downey

Senator Christine Downey

Senate Ways and Means
2-11-04
Attachment 3

Senate Subcommittee Report

Agency: Kansas Department of Health and Environment | **Bill No.** | **Bill Sec.**

Analyst: Kannarr | **Analysis Pg. No.** | **Budget Page No.**

Expenditure Summary	Agency Est. FY 04	Governor's Recommendation FY 04	Subcommittee Adjustments
All Funds:			
State Operations	$ 116,635,012	$ 116,412,793	$ 0
Aid to Local Units	43,774,607	43,796,826	0
Other Assistance	28,500,000	29,500,000	0
TOTAL	$ 189,909,619	$ 189,709,619	$ 0
State General Fund:			
State Operations	$ 16,731,046	$ 16,531,046	$ 0
Aid to Local Units	9,581,482	9,581,482	0
Other Assistance	0	0	0
TOTAL	$ 26,312,528	$ 26,112,528	$ 0
FTE Positions	894.0	894.0	0.0
Non FTE Uncl. Perm. Pos.	158.5	158.5	0.0
TOTAL	1,052.5	1,052.5	0.0

Agency Estimate/Governor's Recommendation

The **agency** estimates operating expenditures of $189,909,619 in FY 2004, an increase of $21,662,169 from the amount approved by the 2003 Legislature. The request includes: State General Fund spending of $26,312,528, an increase of $71,485 from the approved amount due to reappropriations; expenditures of $1,550,000 from the **Children's Initiative Fund**, the same amount as approved by the 2003 Legislature; expenditures of $3,469,453 from the **State Water Plan Fund**, an increase of $44,620 from the approved amount, representing a reappropriation of the same amount; and 894.0 **FTE positions**, an increase of 5.5 FTE from the approved amount. The request includes $127,057,931 for **Health** functions (Administration, the Center for Health and Environment Statistics, the Division of Health and the Homeland Security Program are included in this function) and $62,850,688 for **Environment** functions (Division of Environment and Health and Environment Laboratories are included in this function).

The remainder of the change from the approved budget is from agency fee funds, federal funds and trust fund accounts, none of which have set expenditure limitations. Major items included in these changes are the State Homeland Security Program - $17,554,336 in federal funds for the State Homeland Security Program; Federal Immunization Grant Funds - $2,191,870 increase in expenditures due to the availability of additional federal funds; Health Resources and Services Administration (HRSA) - Emergency Medical Services for Children (EMSC) Partnership grant - $1,017,856 in new federal funds to support the enhancement of the capability of the EMS system

to handle the unique needs of children in emergency situations; Underground Petroleum Storage Tank Release Trust Fund - $2,005,965 increase in expenditures; Federal Women/Infants/Children Health Program Fund - $4,979,452 decrease in expenditures due to changes in demand for services.

The **Governor** recommends expenditures of $189,709,619, including $26,112,528 from the State General Fund, and 894.0 FTE positions. The recommendation is a decrease of $200,000 SGF in state operations from the agency estimate. The recommendation includes $126,634,635 for **Health** functions, including $16,809,183 from the State General Fund, an all funds decrease of $423,296, 0.3 percent, from the agency estimate and $63,074,984 for **Environment** functions, including $9,303,345 from the State General Fund, an all funds increase of $224,296, 0.4 percent, from the agency estimate.

Senate Subcommittee Recommendations

The Senate Subcommittee concurs with the Governor's recommendation.

Senate Subcommittee Report

Agency: Kansas Department of Health and Environment | **Bill No.** | **Bill Sec.**

Analyst: Kannarr | **Analysis Pg. No.** | **Budget Page No.**

Expenditure Summary	Agency Request FY 05	Governor's Recommendation FY 05	Senate Subcommittee Adjustments*
All Funds:			
State Operations	$ 116,382,063	$ 116,534,962	$ (1,272,272)
Aid to Local Units	42,682,376	42,204,595	0
Other Assistance	30,500,000	30,500,000	0
TOTAL	$ 189,564,439	$ 189,239,557	$ (1,272,272)
State General Fund:			
State Operations	$ 18,220,763	$ 17,507,953	$ (263,661)
Aid to Local Units	9,638,568	9,160,787	0
Other Assistance	0	0	0
TOTAL	$ 27,859,331	$ 26,668,740	$ (263,661)
FTE Positions	894.0	894.0	1.0
Non FTE Uncl. Perm. Pos.	157.5	157.5	0.0
TOTAL	1,051.5	1,051.5	1.0

* Includes a reduction of $1,322,272, including $313,661 from the State General Fund, for deletion of the Governor's recommended pay plan adjustments.

Agency Request/Governor's Recommendation

The **agency** requests an FY 2005 budget of $189,564,439 including $27,859,331 from the State General Fund. The request is a net decrease of $345,180 from the agency's revised FY 2004 estimate with a State General Fund increase of $1,546,803. The request includes:

- **State Water Plan Fund** spending of $3,424,833, a decrease of $44,620 from the FY 2004 estimate;
- **Children's Initiative Fund** spending of $1,550,000, the same amount as in FY 2004. This amount includes an increase of $300,000 added by the 2003 Legislature beginning with FY 2004;
- **Enhancement Package** of $1,153,948 from the State General Fund detailed below. Absent the enhancement, the FY 2005 request is a net all fund decrease of $1,499,128 including an increase of $392,855 from the State General Fund.;
- **Health** function expenditures of $124,242,172 (Administration, the Center for Health and Environment Statistics, the Division of Health and the Homeland Security Program are included in this function); and
- **Environment** function expenditures of $65,322,267 (Division of Environment and Health and Environment Laboratories are included in this function).

The **Governor** recommends expenditures of $189,239,557, including $26,668,740 from the State General Fund. The recommendation is an all funds increase of $470,062 from the FY 2004 recommendation and a decrease of $324,882, 0.2 percent, from the agency request. The Governor's State General Fund recommendation is an increase of $556,212 from the FY 2004 recommendation and a decrease of $1,190,591, 4.2 percent, from the agency request. The recommendation includes:

- **Adjustments** for the statewide pay plan, BEST reductions and motor vehicle moratorium detailed below;
- A **reduction of $375,184 State General Fund** for part of the agency's suggested reduced resource package which converts funding for 11.0 clerical positions in the Division of Environment from State General Fund to special revenue funds;
- Funding of **$557,843 from the State General Fund** to allow the Division of Environment to proceed with the Stream Segment II enhancement described below;
- **A reduction of $425,000 from the State General Fund** in the Division of Health including $300,000 due to the elimination of the Pregnancy Maintenance program and $125,000 from contractual services in the Administration program;
- **State Water Plan** spending of $3,192,667, a reduction of $232,166, 6.8 percent, from the agency estimate. Of this amount, $75,000 was the result of a natural resources sub-cabinet agreement on the allocation of State Water Plan funds;
- **Children's Initiative Fund** expenditures of $1,550,000 which matches the agency request;
- **Health** function expenditures of $124,264,811, including $16,908,412 from the State General Fund, an all funds increase of $22,639, 0.01 percent, from the agency request; and
- **Environment** function expenditures of $64,974,746, including $9,760,328 from the State General Fund, an all funds decrease of $347,521, 0.5 percent, from the agency request.

Budget Efficiency Savings Teams (BEST) Reductions

The FY 2005 Governor's recommendation for executive branch agencies includes savings of $26.7 million (including $6.5 million from the State General Fund) anticipated to be realized by recommendations of the BEST teams. These amounts are related to information technology and purchases. To determine the FY 2005 reductions, expenditure object codes related to those two categories were identified, and four years of actual expenditures for each object code by agency were obtained. This allowed for the identification of a four-year average expenditure amount. The reduction recommended by the Governor is equivalent to 10 percent of that four-year average amount. The special revenue fund reductions will be transferred to the State General Fund. It is the recommendation of the Governor that these savings be used to offset the State General Fund portion of the Governor's recommended 3.0 percent salary increase for all state employees. **For this agency, the recommended BEST reduction totals $369,420, including $95,824 from the State General Fund.**

Statutory Budget Submission

KSA 75-6701 requires that the budget submitted by the Governor and the budget ultimately approved by the Legislature provide for a State General Fund ending balance of at least 7.5 percent of expenditures for FY 2005. To comply with this provision, Volume 1 of the Governor's Budget

Report includes a "statutory budget" designed to provide for a 7.5 ending balance. In general, this requires a 14.8 percent reduction to the FY 2005 State General Fund executive branch budget recommendations submitted by the Governor. That reduction has not been applied to school finance funding in the Department of Education or to the Board of Regents and its institutions. **For this agency, the reduction to the Governor's recommended FY 2005 State General Fund budget would total $3,949,693, including $1,445,524 for Environment and $2,504,169 for Health.**

New Vehicle Moratorium

On November, 13, 2003, The Governor imposed a moratorium on the purchase of new vehicles for the next two years (with the exception of certain law enforcement vehicles). Due to the deadline for budget submission, funds to purchase these vehicles had already been included in the agencies' budget submissions. Therefore, the requested moneys were removed from agency budgets by reducing $415,562 in State General Fund appropriations and by reducing expenditure authority and transferring $2,745,750 from special revenue funds. **For this agency, the reduction totals $25,788 of which $12,139 is from the State General Fund. All of the reduction is the Environment Division.**

Senate Subcommittee Recommendation

The Senate Subcommittee concurs with the Governor's recommendation with the following changes and comments:

1. **Pay Plan Adjustment**—Delete $1,322,272, including $313,661 from the State General Fund, to remove pay plan funding recommended by the Governor (a 3.0 percent base salary adjustment for all state employees) for consideration in a separate bill.

2. **State Dental Office—**Add $50,000 State General Fund and 1.0 FTE to support the creation of a State Dental Office. The Subcommittee continues to believe in the importance of improving oral health in Kansas and that the absence of a state dental director hinders such efforts. Kansas is consistently ranked near the bottom of states for children's oral health, heavily influenced by the fact that it does not have a state dental director or a state dental office, one of only seven states. Oral health status has been shown to have a strong link to overall health and well-being throughout life and especially for children where it has been linked to school performance. United Methodist Health Ministries Fund (UMHMF) has a continued belief in the value of a state oral health program and has offered to provide $150,000 over three years to support the activities of an Oral Health Office at KDHE. This money will assist the Department in drawing down additional matching dollars and is contingent upon state funds being appropriated for this purpose.

   Below are the Department's anticipated cost estimates associated with an oral health program according to the Department:

State Oral Health Program Cost Estimate	Year 1	Year 2
Salaries and Wages:		
Dental Director (6 mos. in year 1)	$ 46,000	$ 93,000
Assistant Dental Director	47,674	52,295
Fringe Benefits @ .12	11,241	17,499
Subtotal - Salaries and Wages	$ 104,915	$ 162,794
Other Operating Costs:		
Communications	$ 2,400	$ 2,400
Printing	500	500
Travel	4,000	4,000
Professional dental supplies	3,000	3,000
Office Supplies	500	500
Equipment	5,000	0
Contractual services - Oral Health Survey, Kansas 3rd Graders	52,879	0
	$ 173,194	$ 173,194
Financing:		
United Methodist Health Ministries Fund	$ 49,972	$ 50,000
Federal		
Medicaid	$ 23,250	$ 46,500
Maternal and Child Health	50,000	26,722
State General Fund	49,972	49,972
	$ 173,194	$ 173,194

3. **Fetal Alcohol Syndrome Diagnostic and Prevention Network Pilot Programs** The 2001 Legislature passed H.B. 2059 (codified as K.S.A. 65-1,216) which established the Fetal Alcohol Syndrome Diagnostic and Prevention Network Pilot Programs initiative within the Kansas Department of Health and Environment. The provisions of this legislation will expire on July 1, 2004 under current law. Due to the early success of this initiative and the perceived interest of additional communities in establishing such programs, the Subcommittee recommends that the Department continue to support the initiative beyond the statutory expiration date using the program guidelines set out in K.S.A. 65-1,216. The Subcommittee further recommends that funding of up to $100,000 be made available in FY 2005 for grants to existing or future programs with grants of no less than $20,000 per program.

4. **Community Water Fluoridation Legislation**—The Subcommittee recommends that legislation be introduced this session to encourage cities in Kansas to fluoridate water systems. The Legislation should include provisions that require communities fluoridate water when funding is available to do so. Community water fluoridation has been cited as one of the ten greatest public health achievements of the 20th Century. Since its introduction in 1945, water fluoridation has consistently been shown to be a safe, cost-effective way to reduce the incidence of dental carries particularly among children whose teeth are developing. Fluoridation has been credited with reducing tooth decay by 18-40

percent in recent years according to the CDC. Of the 50 largest US cities, 43 have community water fluoridation, Wichita is one of the 7 that does not. The CDC has set a goal to have 75 percent of people using public water systems receiving fluoridated water by 2010. Kansas is currently at about 63 percent and 26 states and the District of Columbia have met the goal. Opponents of fluoridation have challenged its safety and effectiveness but the claims have not been scientifically validated. The Subcommittee notes information received which indicates that fluoridation may also be a useful way of reducing medical expenditures, especially in programs like Medicaid as low-income people are less likely to receive regular dental care. Community water fluoridation has been cited as favorable to other prevention methods because no individual investment or choice has to be made. The CDC estimates that every $1 spent on community water fluoridation saves $7 to $42 in treatment costs, depending on the size of the community. The annual per capita cost of fluoridation averages $.50 to $3.00 with smaller communities having a higher per capita cost according to information received by the Subcommittee. States have used a variety of methods to encourage fluoridation of public water systems which are generally managed locally. According to the CDC, 11 states currently mandate community water fluoridation through statutes, regulations or local initiatives while others have attempted to use public referenda or funding incentives. The Subcommittee endorses legislation that consitutes a mandate when funding is available.

5. **Public Water Supply Funding and Fluoridation**—The Subcommittee requests that the Department return at Omnibus with an identification of public water supply funding sources to communities that could be conditioned upon fluoridation.

6. **Childhood Immunizations**—The Subcommittee requests that the Department **return at Omnibus** with specific recommendations and performance measures for improving childhood immunization rates. Further, the Department should provide a thorough assessment of the resources (state, federal, local and private) needed to meet the performance measures. The Subcommittee received testimony that immunization rates are falling relative to other states and that Kansas currently ranks among the lowest six to ten states according to the Centers for Disease Control and Prevention Immunization Survey for some immunizations. The Subcommittee believes that immunizations are a cost-effective investment in the health of Kansans and finds the Department's performance unacceptable.

7. **Immunizations**—The Subcommittee commends the Department's efforts to add immunizations for Varicella and Hepatitis B to the list of immunizations required for school entry. The Subcommittee recommends a **review at Omnibus** to consider adding additional funding to the Department to support these immunization efforts.

8. **Food Inspection Transfer**—The Subcommittee notes Executive Reorganization Order No. 32 which transfers food inspection activities from KDHE to the Department of Agriculture. The Subcommittee wishes to emphasize the importance of communication between all parties. Further, the Subcommittee hopes that the transfer does not negatively impact the intensity of the inspections

as they are an important piece of the state's responsibility to protect the public's health.

9. **Food Insecurity and Hunger**—The Subcommittee notes a recent report from the Kansas Health Institute on the issue of food insecurity and hunger in Kansas. According to the report one out of every ten Kansas households experiences food insecurity and nearly two-thirds of those household have at least one full-time worker in the family. Further, only half of the food-insecure, low-income Kansas families receive assistance from Food Stamps, WIC, or school meal programs and even fewer access community resources like food pantries and emergency kitchens. The agency indicated a willingness to explore options for new initiatives and to work with the Health and Human Services Cabinet team to assess ways to enhance access to food services and reduce the prevelance of food insecurity. The Subcommittee agrees with testimony from KDHE that this is not an issue one agency can address alone and that it will take a coordinated approach among state agencies, community organizations and other partners to address food insecurity and hunger in Kansas, especially among children.

   The Subcommittee encourages the creation of a central point of leadership on the issue with the expectation that all state government efforts at reducing food insecurity and hunger will be coordinated effectively. Ultimately, the Subcommittee does not want government created barriers getting in the way of children receiving the nutrition they need. The Subcommittee acknowledges efforts among cabinet agencies in other areas to try and work together to address issues in the form of Sub-Cabinet level groups and encourages such cooperation on this issue.

10. **Infant - Toddler (Tiny K)** - The Subcommittee notes its continuing support of early childhood education and service programs. Under the Infant-Toddler (Tiny-K) program (Part C of the Individuals with Disabilities Education Act), the state is federally mandated to provide early intervention services to children aged birth to three years with or at risk of developmental disabilities/delays. While the subcommittee is encouraged by the fact that funding has now been re-stabilized after suffering cuts in the allotment process in FY 2003, it notes that the number of children who must be served continues to increase resulting in fewer dollars being available per child as illustrated by the chart below. Note that this chart does not show all funding for the Infant-Toddler program, only the amounts that go to local networks.

Aid to Local Units for Infant-Toddler Programs
FY 2000 - FY 2005

	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Children's Initiatives Fund	$ 500,000	$ 500,000	$ 500,000	$ 500,000	$ 800,000	$ 800,000
State General Fund	1,992,000	1,992,000	1,992,000	1,871,305	1,992,000	1,871,305
Subtotal - State Funding	$ 2,492,000	$ 2,492,000	$ 2,492,000	$ 2,371,305	$ 2,792,000	$ 2,671,305
Allotment reduction & restoration adjustments	-	-	-	120,695	(120,695)	-
Adjusted subtotal - State funding	**$ 2,492,000**	**$ 2,942,000**	**$ 2,492,000**	**$ 2,492,000**	**$ 2,671,305**	**$ 2,671,305**
Federal	2,764,859	3,042,831	3,414,224	3,499,633	3,199,639	*
TOTAL	$ 5,256,859	$ 5,984,831	$ 6,356,224	$ 5,991,633	$ 5,870,944	*
Children Served	1,884	2,187	2,485	2,738	2,828	*
Funding per Child	$ 2,790	$ 2,530	$ 2,377	$ 2,144	$ 2,119	*
Percent funding per child change from previous year	10.6%	(9.3)%	(6.0)%	(9.8)%	(1.2)%	*

* This information is unknown at this time.

Note: Of the FY 2004 State General Fund amount, $120,695 is actually state funding used to restore the allotment reduction for FY 2003 and the remaining $179,305 is an increase to state funding. The practical effect of these adjustments is shown on the Allotment restoration adjustments line. The total state funding amount is maintained for FY 2005.

11. **Primary Health Care Clinics** -The Subcommittee notes that although state funding for primary health care clinics (*e.g.*, Community Health Centers) has not been reduced, they are being asked to do more with less, particularly as the number of people without health insurance increases.

The Subcommittee commends the Department's efforts to work cooperatively with other groups to address this critical issue and undertake an effort to maximize Kansas's share of additional federal resources made available by the Bush administration. In January, two dozen stakeholders participated in a round-table discussion on expanding the health care safety net in Kansas. Out of that meeting, convened by the Kansas Health Institute and the Kansas Association for the Medically Underserved, with support from the Sunflower Foundation, a task group was selected to develop a set of immediate activities to maximize potential for successful applications by Kansas communities to receive federal Section 330, Community Health Center funding for new or expanded clinical operations. A six member task group was identified to begin identifying the potential grantee communities with both the evidence of unmet health care need and the readiness develop new health center sites or expanded services. Future tasks will include the design and implementation of plans to provide technical assistance, consultation from experts, tools, templates and other resources that can be used by communities in planning of local health care projects and preparation of federal grant applications. The work of the task group is also the foundation for planning future health care safety net growth.

As Amended by Senate Committee

Session of 2003

SENATE BILL No. 257

By Committee on Ways and Means

3-10

AN ACT concerning the Kansas animal health department; relating to pet animal act fees; amending K.S.A. ~~2003~~ Supp. 47-1721 and repealing the existing section.

2003

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. ~~2003~~ Supp. 47-1721 is hereby amended to read as follows: 47-1721. (a) Each application for issuance or renewal of a license or permit required under K.S.A. 47-1701 *et seq.*, and amendments thereto, shall be accompanied by the fee prescribed by the commissioner under this section. Such fees shall be as follows:

(1) Except as provided in paragraph (5), for a license for premises of a person, ***an animal breeder, retail breeder or research facility also*** licensed under public law 91-579 (7 U.S.C. § 2131 et seq.), an amount not to exceed ~~$150~~ ~~$225~~ ~~$187.50~~ $225

(2) For a license for the premises of a distributor, an amount not to exceed $500.

~~(2)~~ ***(3)*** Except as provided in paragraph (5), for a license for any other premises, ***a retail breeder or pet shop***, an amount not to exceed ~~$300~~ ~~$150~~ ~~$225~~ $450

~~(3)~~ ***(4)*** For a temporary closing permit, an amount not to exceed ~~$75~~ ~~$112.50~~ ~~$94~~ $112.50

~~(4)~~ ***(5)*** For an out-of-state distributor permit, an amount not to exceed ~~$500~~ $750.

~~(5)~~ ***(6)*** For a hobby breeder license or a kennel operator license an amount not to exceed ~~$75~~ ~~$112.50~~ ~~$94~~ $112.50

~~(6)~~ ***(7)*** A late fee of ~~$50~~ ~~$63~~ shall be assessed to any person whose permit or license renewal is more than 45 days late. $75

~~***(8) In addition to the fees prescribed by this section, upon application for a license, each animal breeder, retail breeder or hobby breeder shall conduct a full inventory of their premises and pay a fee of $1.00 for each dog and cat housed on the premise.***~~

(b) The commissioner shall determine annually the amount necessary to carry out and enforce K.S.A. 47-1701 *et seq.*, and amendments thereto, for the next ensuing fiscal year and shall fix by rules and regulations the

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et seq., and amendments thereto.

Sec. 2. K.S.A ~~2002~~ Supp. 47-1721 is hereby repealed. 2003

Sec. 3. This act shall take effect and be in force from and after its publication in the Kansas register.