Approved: February 24, 2004
Date

MINUTES OF THE HOUSE APPROPRIATIONS COMMITTEE

The meeting was called to order by Chairman Melvin Neufeld at 9:00 a.m. on February 11, 2004 in Room 514-S of the Capitol.

All members were present except:
Representative Dean Newton- excused

Committee staff present:
Alan Conroy, Legislative Research
J. G. Scott, Legislative Research
Amy VanHouse, Legislative Research
Michele Alishahi, Legislative Research
Audrey Dunkel, Legislative Research
Jim Wilson, Revisor of Statutes
Mike Corrigan, Revisor of Statutes
Nikki Feuerborn, Administrative Analyst
Shirley Jepson, Committee Secretary

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

Others attending:
See Attached List.

- Attachment 1 Biography for Chris Ward, Ward Health Strategies, Ontario, Canada
- Attachment 2 Presentation by Chris Ward, Ward Health Strategies, Ontario, Canada
- Attachment 3 House Social Services Budget Committee's report and recommendations on Developmental Disabilities Institutions for FY 2004 and FY 2005
- Attachment 4 Statistical information presented by Representative Shriver on Developmental Disabilities Institutions
- Attachment 5 House Social Services Budget Committee's report and recommendations on the Mental Health Institutions for FY 2004 and FY 2005

Representative Feuerborn moved to introduce legislation concerning Emergency Medical Services (EMS) and certification. The motion was seconded by Representative Minor. Motion carried.

Representative Landwehr moved to introduce legislation concerning prohibiting legislators from receiving a salary for special sessions. The motion was seconded by Representative Pottorff. Motion carried.

Representative Ballard introduced members of the leadership class from her legislative district who were visiting in the gallery.

Chairman Neufeld welcomed Chris Ward, President of Ward Health Strategies, to the Kansas Legislature and the Committee (Attachment 1). Mr. Ward gave a presentation on the economic and policy implications of re-importation of drugs from Canada into the United States (Attachment 2). Mr. Ward stated that federal legislation regulates the price and production of prescription drugs sold to residents in Canada; however, drugs sold to citizens of the United States by Canadian firms are not required to meet these regulations nor are they approved by the Federal Drug Administration (FDA). Mr. Ward stated that research by FDA noted that approximately 88 percent of the drugs coming into the United States from Canada, are not approved by the Canadian regulations or FDA. In further comments, Mr. Ward indicated that products coming into Canada designated for export, are not subject to Canada's regulations. In addition, he noted that an actual prescription is not required to get drugs over the internet. Mr. Ward stated that the three things that impact the price differential and health care between the two countries are:

- the differences in economy and rate of exchange
- different systems and price controls
- difference in product liability laws.

Because of the unregulated shipment of drugs, the Committee voiced a concern about who would have the responsibility for liability on the drugs.

Representative Henry, member of the House Social Services Budget Committee, presented the Budget Committee report on the Governor's budget recommendation for the Development Disabilities Institutions for FY 2004 and moved for the adoption of the Budget Committee recommendation for FY 2004 (Attachment 3). Motion was seconded by Representative Landwehr. Motion carried.

Representative Henry, member of the House Social Services Budget Committee, presented the Budget Committee report on the Governor's budget recommendation for the Development Disabilities Institutions for FY 2005 and moved for the adoption of the Budget Committee recommendation with observations for FY 2005 (Attachment 3). Motion was seconded by Representative Bethell.

Representative Shriver presented a data sheet to the Committee on the DD institutions showing the number of unserved and under served DD population and the number served at Kansas Neurological Institute (KNI) and Parsons State Hospital (Attachment 4). The Budget Committee stated that they plan to review the information contained in a March 15, 2004, report to be presented by Social and Rehabilitation Services (SRS). The Committee voiced concern about the number of abuses reported at the KNI and requested that the Budget Committee review this information.

Representative Shriver moved to adopt the Budget Committee recommendation on the Parsons State Hospital FY 2005 budget and delay action on the Budget Committee recommendation on the KNI FY 2005 budget until the Budget Committee has reviewed the SRS report of March 15, 2004. The motion was seconded by Representative Feuerborn. Motion failed.

The Budget Committee stated their intention to review the March 15, 2004, SRS report. The Budget Committee requested that favorable action be taken at this time to pass the DD institutions FY 2005 budget in order for the budget process to proceed, noting that further action can be taken at a later date. The Committee concern was reiterated and felt that aggressive action needed to be taken on the KNI issue in the near future. Because the numbers on the report, distributed by Representative Shriver, did not total, the Committee asked for clarification.

Representative Henry renewed the motion for the adoption of the Budget Committee report on the recommendation with observations for the Development Disabilities Institutions for FY 2005 (Attachment 3). Motion was seconded by Representative Bethell. Motion carried.

Representative Henry, member of the House Social Services Budget Committee, presented the Budget Committee report on the Governor's budget recommendation for the Mental Health Institutions for FY 2004 and moved for the adoption of the Budget Committee recommendation for FY 2004 (Attachment 5). Motion was seconded by Representative Bethell. Motion carried.

Representative Henry, member of the House Social Services Budget Committee, presented the Budget Committee report on the Governor's budget recommendation for the Mental Health Institutions for FY 2005 and moved for the adoption of the Budget Committee recommendation with adjustments for FY 2005 (Attachment 5). Motion was seconded by Representative Landwehr. Motion carried.

Representative Pottorff moved to approve the minutes of the January 29, February 3 and February 5 Committee meetings as written. The motion was seconded by Representative Feuerborn. Motion carried.

The meeting was adjourned at 10:40 a.m. The next meeting of the Committee will be held at 9:00 a.m. on February 12, 2004.

Melvin Neufeld, Chair

HOUSE APPROPRIATIONS COMMITTEE

February 11, 2004
9:00 A.M.

NAME	REPRESENTING
JAN SIDES	SEAK/AARP
MIKE LACKEN	DEPT OF ADMIN
Jeff Bottoms	Merck
Patricia Hubbell	Pfizer
Joyce Jackson	TILRC
Carolyn Middendorf	Ks St Nurses Assn
Daniel Murray	Federico Consulting
CRAIG KABERLINE	KHA
Mike Hammond	Assn. of Cmtys of KS
Roxane Mulenex	AdvancePCS
Konnie Lefler	DOB
Brian Langs	PhRMA
David McCandless	Intern for Gatewood
Nancy Zoglemann	Pfizer

Chris Ward
President
Ward Health Strategies

Chris Ward has had a lengthy involvement in public policy both in the private and public sectors including six years as a lawmaker in the Province of Ontario, Canada.

During his time as a legislator he served as Parliamentary Assistant to the Minister of Health, in 1985, and had responsibility for carrying the legislation that established the Ontario Drug Benefit Program through legislative and public hearings. In 1987 he was appointed Ontario's Minister of Education and in 1990 became Government House Leader.

Prior to establishing his own consultancy practice, in Bridgewater, New Jersey and Hamilton, Ontario, Canada, Chris was Vice President of Strategic Planning and Communications for *Canada's Research- based Pharmaceutical Companies (Rx&D),* the innovative pharmaceutical industry association in Canada, and the equivalent to PhRMA in Canada.

Drawing on his experience as a former lawmaker and his familiarity with issues relating to patient access to new medicines, Chris Ward has participated in public forums, media tours, and advocacy workshops throughout Canada and in over 30 states. He has provided briefings to legislators throughout the United States and has testified on issues related to patient access to pharmaceutical innovation at legislative hearings in California, South Dakota, Pennsylvania, New Mexico, North Dakota, Minnesota, Hawaii, Michigan and Wyoming.

Chris has also been an invited speaker for the Council of State Governments, the U.S. Chamber of Commerce, the American Association of Family Physicians, the Nevada College of Pharmacy, the American Association of Physicians and Surgeons, the International Foundation of Employee Benefit Plans, the Massachusetts College of Pharmacy, the Healthcare Executives Club of New York and many other health - related organizations throughout the United States and Canada.

HOUSE APPROPRIATIONS

DATE 2-11-2004
ATTACHMENT 1

Ward Health Strategies

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).

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.

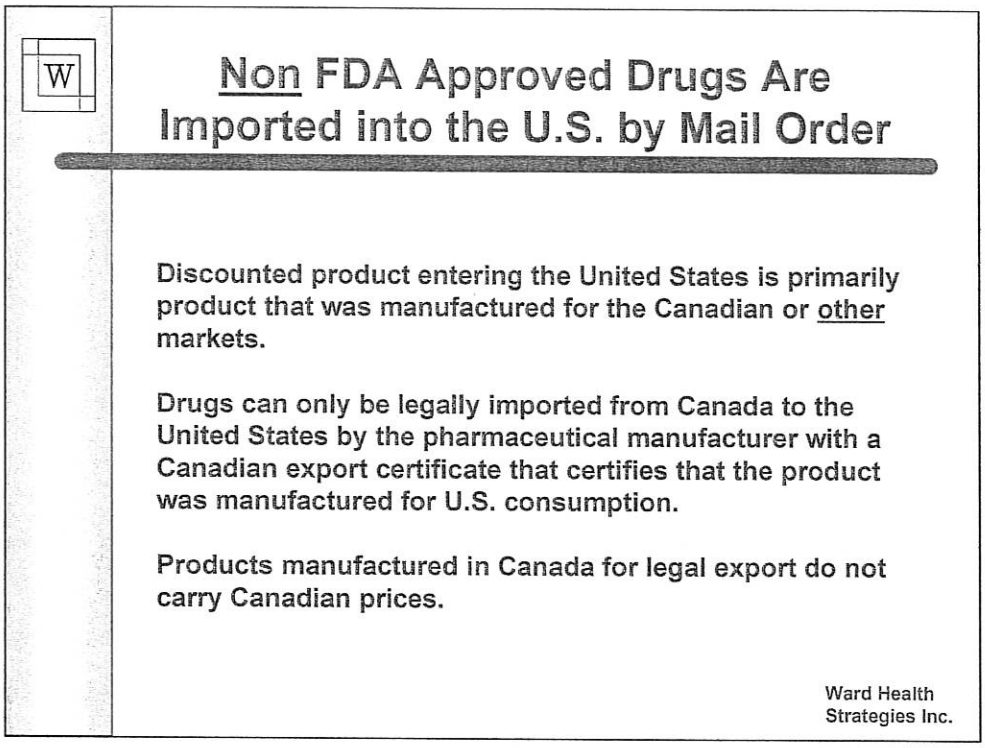
Without action at the federal level, the unregulated import and export of prescription drugs will only expand. Most schemes abuse the personal importation exemption as a mechanism to allow commercial mail order suppliers to provide lower cost drugs and to ignore drug quality safeguards. National state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

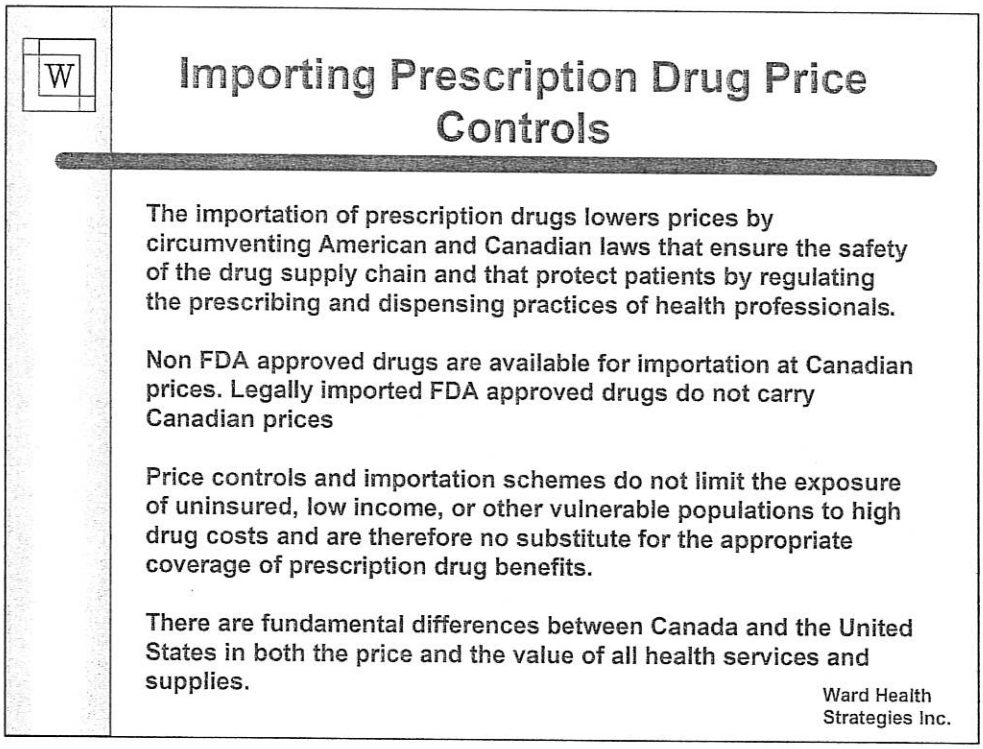
(2) Generic drug prices are not subject to Canadian controls and are, on average, higher than in the U.S. Nearly half of the prescriptions in the U.S. are for generic drugs.



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.



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

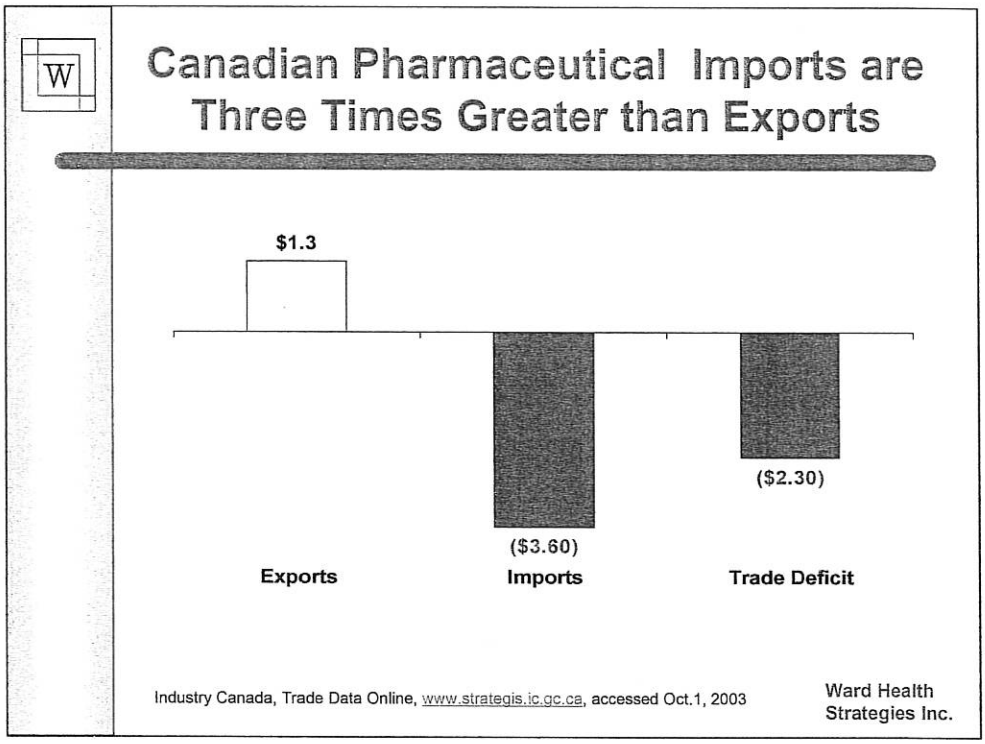
"A growing number of Americans are obtaining their prescription medications from foreign locations. They often seek out Canadian suppliers, or sources that purport to be Canadian. As we have said in the past, FDA cannot ensure the safety of drugs purchased from foreign sources."

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.



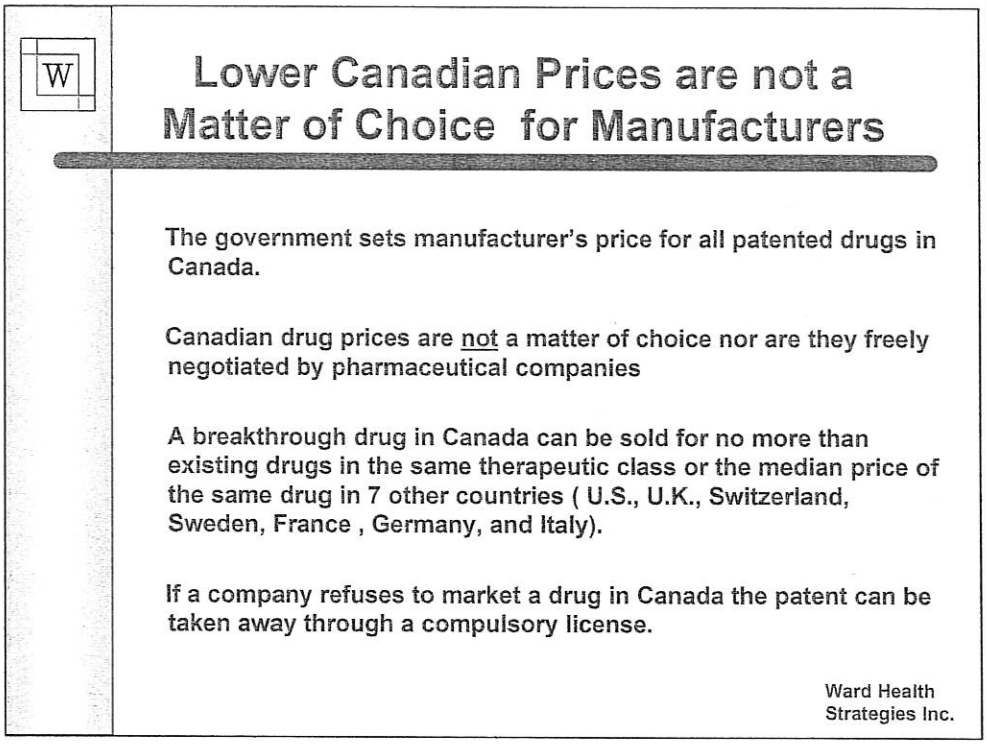
Prescription drugs imported by Canada can be easily distributed to the United States via mail order using the personal use import exemption.

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

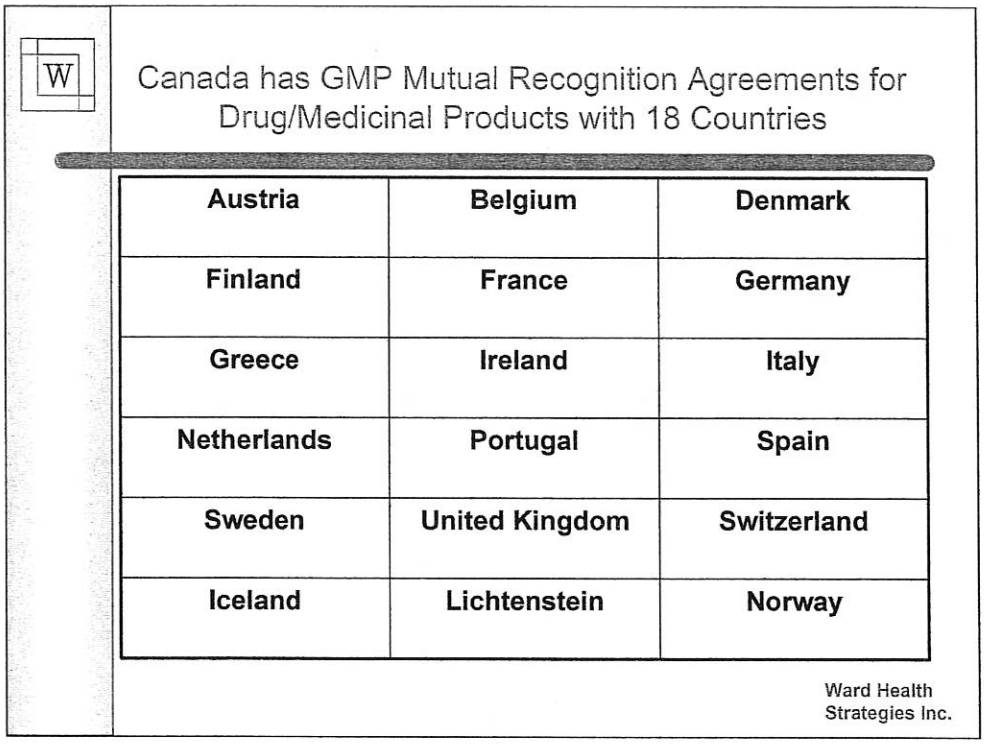
Ward Health Strategies Inc.

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.

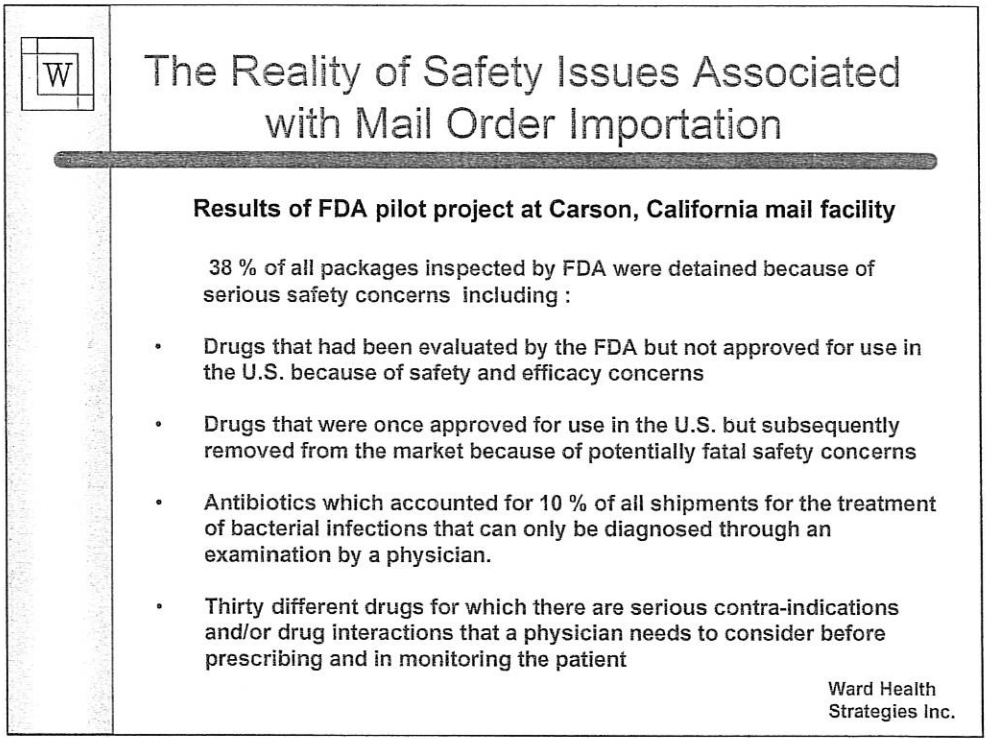
Canada has Mutual Recognition Agreements for pharmaceutical GMP with 17 countries.

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

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" .

FY 2004 and FY 2005

House Social Services Budget Committee

Developmental Disabilities Institutions

Representative Brenda Landwehr, Chair

Representative Barbara Ballard

Representative Bob Bethell

Representative Eric Carter

Representative Willa DeCastro

Representative John Edmonds

Representative Jerry Henry

Representative Melvin Neufeld

Representative Jerry Williams

HOUSE APPROPRIATIONS

DATE 2-11-2004

ATTACHMENT 3

House Budget Committee Report

Agency: Developmental Disabilities Institutions (DD Hospitals) **Bill No. --** **Bill Sec. --**

Analyst: Dunkel **Analysis Pg. No.** **Budget Page No.**

Expenditure	Agency Est. FY 04	Governor Rec. FY 04	House Budget Committee Adjustments
Kansas Neurological Institute			
All Funds	$ 24,695,014	$ 24,641,966	$ 0
SGF	10,022,788	10,023,740	0
FTE Positions	588.2	588.2	0.0
Parsons State Hospital and Training Center			
All Funds	$ 20,552,640	$ 20,552,640	$ 0
SGF	6,923,703	6,923,703	0
FTE Positions	467.2	467.2	0.0

Agency Estimate

Kansas Neurological Institute

The agency estimates FY 2004 expenditures of $24.7 million all funds, $10.0 million State General Fund, an increase of $264,072 or 1.0 percent all funds and $209,541 or 2.1 percent State General Fund and 58.2 FTE positions. The increase includes supplemental requests totaling $54,000 all funds for laundry services and internal agency adjustments shifting $20,493 State General Fund from other resources in the Department of Social and Rehabilitation Services (SRS) and the addition of $190,000 State General Fund and 58.2 FTE positions reflecting a shift of positions between the state hospitals to meet staffing needs while remaining within budget.

Governor's Recommendation

The **Governor** concurs with the agency request, but does not recommend the supplemental request.

Parsons' State Hospital

The **agency** estimates FY 2004 expenditures of $20.2 million all funds and $6.9 million State General Fund, an increase of $14,077 or 0.1 percent all funds and $10,888 or 0.2 percent State General Fund. There is an addition of 43.0 FTE positions over the amount approved for FY 2003, reflecting a re-allocation of positions from within the state hospital system. The agency request

includes internal adjustments of $14,077 all funds, $10,888 State General Fund and 43.0 FTE positions. The funding changes reflect an increase of $3,189 of Title XIX funds, and a shift of $10,888 to Parson's from SRS. The additional 43.0 FTE positions reflect a reallocation of positions within the hospital system.

Governor's Recommendation

The **Governor** concurs with the agency estimate for FY 2004.

House Social Services Budget Committee

The Budget Committee concurs with the Governor's recommendation.

House Budget Committee Report

Agency: Developmental Disabilities Institutions (DD Hospitals) **Bill No. --** **Bill Sec. --**

Analyst: Dunkel **Analysis Pg. No.** **Budget Page No.**

Expenditure	Agency Req. FY 05	Governor Rec. FY 05	House Budget Committee Adjustments
Kansas Neurological Institute			
All Funds	$ 26,587,940	$ 25,930,761	$ 0
SGF	11,387,203	11,048,774	0
FTE Positions	614.2	588.2	0.0
Parsons State Hospital and Training Center			
All Funds	$ 21,811,430	$ 21,490,225	$ 0
SGF	7,421,545	7,245,227	0
FTE Positions	483.2	467.2	0.0

Agency Request

Kansas Neurological Institute

The **agency** requests FY 2005 expenditures of $26.6 million all funds, $11.4 million State General Fund, an increase of $1.9 million or 7.7 percent all funds and $1.4 million or 13.5 percent State General Fund. The increase reflects enhancements totaling $1.0 million all funds, $375,000 State General Fund.

Governor's Recommendation

The **Governor** recommends FY 2005 expenditures of $25.9 million all funds, $11.0 million State General Fund, an increase of $1.3 million or 5.2 percent all funds and $1.0 million or 10.2 percent State General Fund from the FY 2004 recommendation. This includes $1.3 million all funds, $1.1 million State General Fund for the Governor's pay plan and BEST reduction of $65,890 all funds, $79,902 State General Fund.

The Governor's recommendation is a reduction of $657,179 or 2.5 percent all funds and $399,629 or 3.5 percent State General Fund from the agency request. The Governor does not fund the agency enhancement requests.

Under the Governor's FY 2005 **statutory budget** recommendation, the Governor's recommendation for this agency's budget would have to be reduced by an additional $1,636,345 State General Fund.

Parsons State Hospital and Training Center

Agency Request

The **agency** requests FY 2005 expenditures of $21.8 million all funds, $7.4 million SGF, an increase of $1.3 million or 6.1 percent all funds and $497,842 or 7.2 percent SGF from the FY 2004 estimate. The increase reflects the enhancement request for $630,000 SGF and 16.0 FTE positions to restore positions eliminated during FY 2002 from the Development and Training program and re-open a residence cottage.

Governor's Recommendation

The **Governor** recommends FY 2005 expenditures of $21.5 million all funds, $7.2 million SGF, an increase of $437,585 or 2.1 percent all funds and $321,524 or 4.6 percent SGF from the FY 2004 recommendation. The recommendation includes the Governor's pay plan adjustments and BEST reductions.

The recommendation is a decrease of $821,205 or 3. 8 percent all funds and $176,318 or 2.4 percent SGF from the agency request. It does not include the enhancement request.

Under the Governor's FY 2005 **statutory budget** recommendation, the Governor's recommendation for the agency's budget would have to be reduced by an additional $1,073,032 State General Fund.

House Social Services Budget Committee Recommendation

The House Budget Committee concurs with the Governor's recommendation with the following observations:

1. The Budget Committee requests that the Department of Social and Rehabilitation Services (SRS) report back to the 2004 Legislature on March 15, 2004 with recommendations for alternative use of intermediate care facilities for the mentally retarded (ICF/MR's) and state developmental disability institutions and how services will be provided for the residents of those facilities.

2. The Budget Committee recommends that if further budget reductions should become necessary, the state hospitals budgets should be exempted, each having contributed more than their fair share in addressing the budget crisis.

HOUSE APPROPRIATIONS
DATE 2-11-2004
ATTACHMENT 4

State
Developmental Disabilities Data
State Fiscal Year 2004

Developmental Disabilities Waiting List Numbers
As of January 22, 2004

Unserved DD Population

Adults	627
Families with DD children	548
Total	**1175**

Underserved DD Population

Adults	924
Families with DD children	537
Total	**1461**

Grand Total both Lists= 2636

Developmental Disabilities Hospitals Data

Agency	Average Converted Score	Licensed Capacity	% Lic Capacity	Current Population	Openings	More Severe - - - - Less Severe Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	ICF Rate as of 3/1/03	Projected SFY 04 Costs at Lic capacity	Annualized Total for Day/Res Services	Difference ICF rate vs HCBS rate
KNI	161.55	454	38.30%	174	279	89	37	36	20	2	$369.00	$23,499,396	$10,541,997.40	$12,957,398.60
PSH	119.7	226	56.50%	190	146	34	36	48	56	18	$309.00	$21,487,860	$8,487,057.90	$13,000,802.10
		680		364	425	123	73	84	76	20		$44,987,256	$19,029,055.30	**$25,958,200.70** **Potential Savings**

FY 2004 and FY 2005

House Social Services Budget Committee

Mental Health Institutions

Representative Brenda Landwehr, Chair

Representative Barbara Ballard

Representative Bob Bethell

Representative Eric Carter

Representative Willa DeCastro

Representative John Edmonds

Representative Jerry Henry

Representative Melvin Neufeld

Representative Jerry Williams

HOUSE APPROPRIATIONS

DATE 2-11-2004

ATTACHMENT 5

House Budget Committee Report

Agency: Mental Health Institutions **Bill No.** **Bill Sec.**

Analyst: Dunkel **Analysis Pg. No.** **Budget Page No.**

Expenditure	Agency Est. FY 04	Governor Rec. FY 04	House Budget Committee Adjustments
Larned State Hospital			
All Funds	$ 37,309,488	$ 37,128,488	$ 0
State General Fund	27,657,044	27,476,044	0
FTE Positions	801.2	798.2	0.0
Osawatomie State Hospital			
All Funds	$ 19,927,060	$ 19,927,060	$ 0
State General Fund	8,367,622	8,367,622	0
FTE Positions	398.6	398.6	0.0
Rainbow Mental Health Facility			
All Funds	6,908,318	6,908,318	0
State General Fund	3,891,400	3,891,400	0
FTE Positions	115.0	115.0	0.0

Larned State Hospital

Agency Estimate

The **agency** requests $37.3 million all funds and $27.7 million SGF for FY 2004, an increase of $2.3 million or 6.6 percent all funds and an increase if $2.0 million or 6.1 percent SGF. The increase in total expenditures is reflected in contractual services and commodities for the agency. The increase in SGF is a reflection of decreased availability of Title XIX funds for the agency. This is seen throughout the hospital system.

Governor's Recommendation

The **Governor** recommends FY 2004 expenditures of $37.1 million all funds, $27.5 million SGF for Larned State Hospital, an increase of $4.9 million or 15.1 percent all funds and $15.6 million or 131.9 percent SGF from FY 2003. The difference in all funds expenditures reflects the shift to State General Fund as revenues from the hospital fee fund and Title XIX decline and Intergovernmental Transfer (IGT) funds are no longer available

Osawatomie State Hospital

Agency Estimate

The **agency** reqests expenditures $19.9 million all funds and $8.4 million SGF for FY 2004, an increase of $195,602 or 0.9 percent all funds and an increase if $3.0 million or 58.4 percent SGF. The increase in SGF is a reflection of decreased availability of Title XIX funds for the agency. This is seen throughout the hospital system.

Governor's Recommendation

The **Governor** concurs with the agency estimate for FY 2004.

Rainbow Mental Health Facility

Agency Request

The **agency** estimates FY 2004 expenditures of $6.9 million all funds, $3.9 million SGF, an increase of $46,662 or 0.6 percent all funds and $9,603 or 0.2 percent SGF, with the addtion of 2.9 FTE positions. The SGF increase reflects a reallocation of SGF funds by the Department of Social and Rehabilitation Services to address agency expenditures.

Governor's Recommendation

The **Governor** concurs with the agency FY 2004 estimate.

House Social Services Budget Committee Recommendation

The Budget Committee concurs with the Governor's recommendation.

House Budget Committee Report

Agency: Mental Health Institutions **Bill No.** **Bill Sec.**

Analyst: Dunkel **Analysis Pg. No.** **Budget Page No.**

Expenditure	Agency Est. FY 05	Governor Rec. FY 05	House Budget Committee Adjustments
Larned State Hospital			
All Funds	$ 41,652,950	$ 35,925,662	$ 1,057,600
State General Fund	31,452,280	26,216,315	449,600
FTE Positions	921.7	707.2	19.0
Osawatomie State Hospital			
All Funds	$ 21,521,670	$ 20,768,542	$ 0
State General Fund	9,108,026	8,035,978	0
FTE Positions	422.6	398.6	0.0
Rainbow Mental Health Facility			
All Funds	$ 7,062,434	$ 7,174,008	$ 0
State General Fund	3,811,769	3,841,426	0
FTE Positions	115.0	115.0	0.0

Larned State Hospital

Agency Request

The **agency** requests an FY 2005 $41.7 million all funds, $31.5 million State General Fund for operations, an increase of $4.3 million or 11.6 percent all funds and $3.8 million or 13.7 percent State General Fund. The increases are primarily in salaries and wages and reflects enhancements totaling $5.4 million State General Fund.

Governor's Recommendation

The Governor recommends FY 2005 expenditures of $35.9 million all funds, $26.2 million State General Fund, a reduction of $1.2 million or 3.2 percent all funds and $1.3 million or 4.6 percent State General Fund. The reduction reflects the Governor's pay plan and BEST reductions, as well as the elimination of services for children 12 and under.

In addition, the agency base budget request did not include funding for the 72.0 FTE positions added for the Sexual Predator Treatment Unit in the FY 2004 recommendation. The funding was included in the agency enhancement package of $3.8 million to add 51.0 FTE to the SPTP program in FY 2005. The Governor did not fund the enhancement request.

Under the Governor's FY 2005 **statutory budget** recommendation, the Governor's recommendation for this agency's budget would have to be reduced by an additional $3,882,688 State General Fund.

Osawatomie State Hospital

Agency Request

The **agency** requests FY 2005 expenditures of $21.5 million all funds, $9.1 million State General Fund for operations, an increase of $1.6 million or 8.0 percent all funds and an increase of $740,404 or 8.8 percent State General Fund. The increases are primarily in salaries and wages, and include enhancement requests totaling $1.2 million State General Fund

Governor's Recommendation

The **Governor** recommends FY 2005 expenditures of $20.8 million all funds, $8.0 million State General Fund, an increase of $841,482 or 4.2 percent all funds and a reduction of $331,644 or 4.2 percent State General Fund from the FY 2004 recommendation. This reflects the Governor's pay plan increase, as well as the BEST reductions.

Under the Governor's FY 2005 **statutory budget** recommendation, the Governor's recommendation for this agency's budget would have to be reduced by an additional $1,190,144 State General Fund.

Rainbow Mental Health Facility

Agency Request

The **agency** requests an FY 2005 $7.0 million all funds, $3.8 million State General Fund for operations, in increase of $154,116 or 2.2 percent all funds and a decrease of $79,735 or 2.0 percent State General Fund from FY 2004 estimates.

Governor's Recommendation

The **Governor** recommends FY 2005 expenditures of $7.2 million all funds, $3.8 million State General Fund for operations, an increase of $265,690 or 3.8 percent all funds and a reduction of $49,974 or 1.3 percent State General Fund. The change in State General Fund expenditures reflects higher estimate revenues from the agency fee fund and the Title XIX fund.

Under the Governor's FY 2005 **statutory budget** recommendation, the Governor's recommendation for this agency's budget would have to be reduced by an additional $568,923 State General Fund.

House Social Services Budget Committee Recommendation

The House Social Services Budget Committee concurs with the Governor's recommendation with the following adjustments:

1. The Budget Committee notes that the Governor does not fund the 72.0 FTE positions approved in the FY 2004 recommendation for the Sexual Predator Treatment Program in FY 2005. In the event that this was merely an oversight on the part of the Governor, the Budget Committee would recommend review of the program prior to Omnibus.

2. The Budget Committee expresses concern regarding the projected growth of the Sexual Predator Treatment Program, which the agency estimates will grow by 3 persons per month, or 36 persons annually and requests a Post Audit of the program.

3. The Budget Committee notes the concerns of the advocates regarding the elimination of services for children 12 and under at Larned State Hospital, which are as follows:

   a. No additional funding was provided for the Severely Emotionally Disturbed (SED) Waiver to address treatment of these children in the community.

   b. There are a limited number of psychiatric beds for children in Kansas, and the elimination of these services would further limit available resources.

   c. Closure of the beds will force some families to seek treatment for their children far from home, where the family members cannot be part of the treatment process.

   d. Some children who are sent to LSH for treatment have already been receiving the full range of community based services, but could not be stabilized in a community based setting.

4. The Budget Committee recommends the restoration of the Governor's reduction of $449,600 State General Fund, $1,057,600 all funds which would eliminate services for children under 12 at Larned State Hospital (LSH). The Governor recommended the reduction because while the bed capacity for the program is eight, the average daily census for the program is four. The Budget Committee is not convinced that community services will be adequate to meet the needs of the children who would otherwise be served at LSH and recommends funding the restoration from the HCBS/SED Waiver program in SRS.

5. The Budget Committee recommends that if further budget reductions should become necessary, the state hospitals budgets should be exempted, each having contributed more than their fair share in addressing the budget crisis.