Creating Synergy

HEALTH COALITION OF ALBERTA

POSITION PAPER ON ALBERTA'S DRUG PROGRAM ACT (2009)

July 2009

INTRODUCTION

Creating Synergy is an Alberta voluntary health sector coalition of organizations and individuals who have identified a need to join together in speaking as a common voice on health care issues and decisions which impact Albertans. They desire to be proactive and become meaningfully engaged in relevant discussions with various levels of government concerning existing health care challenges or proposed health care reform that have impacted or will impact Albertans.

General Concerns of Albertans

Albertans are concerned that there is a lack of transparency and public accountability on the part of Alberta Health and Wellness, generally regarding the extensive recent reform of Alberta's health care system including the drug program. The reasons for the reform are clearly related to cost containment. Without a 'clear documented public plan' and the rationale for how this change will improve health care services and delivery and health outcomes, Albertans are confused by the emphasis being only on cost containment. In addition, it is not clear whether consideration has been given to the impacts of this reform on health care providers, and on equitable health care services access and availability by all Albertans. The reform planning did not involve any public consultation or meaningful engagement with key healthcare stakeholders including patients who, as public tax payers and voters, are directly impacted by the reform. Albertans are aware of the challenges facing the provincial government regarding aligning equitable distribution of key services and resources, but now there is uncertainty as to how this extensive reform including the change to one Alberta Health Services Board, will make things more equitable across urban and rural settings, or across priorities such as the Alberta Drug Program (Pharmaceuticals Strategy) , primary health care access, chronic disease management, health promotion and prevention strategies, public health as well as the other priorities identified in *Vision 2020: The Future of Health Care in Alberta* (2008), *Provincial Service Optimization Review: Final Report* (2008), the *Alberta Pharmaceuticals Strategy* (Updated May 2009), and other related documents and press releases such as "Alberta Health Services Restructures to Improve Access and Enhance Patient Care" (July 2008). [1]

[1] Information available at www.albertahealthservices.ca

Specifically, regarding pharmaceuticals, Albertans are concerned with the lack of transparency and accountability associated with the:

(1) decision-making processes involving the approved Drug Program Act (June 3, 2009). Neither the Alberta Pharmaceuticals Strategy nor the approved Drug Program Act (2009) had any open health stakeholder or public consultation or engagement regarding the strategy, related plans, the Act and their impacts on Albertans;

(2) approval, non-approval and delisting of drugs from the formulary. Information used in any of these decisions has not been made available to patients or their physicians and the general public. Consultations with experts including physicians, specialists or patients are currently not conducted by the Expert Advisory Committee on Drugs for drug review decisions and formulary recommendations for Alberta Health and Wellness;

(3) overall impact of aggressive containment of drug expenditures and healthcare costs on the health outcomes and societal benefits of maintaining healthy Albertans – consideration has not been given to the consequences, some of which can be seen in the failing reports and evidence from other provinces and countries.

The Issues Facing Albertans

Albertans have expressed concerns to Alberta Health and Wellness regarding specific drug review decisions which have impacted thousands of Albertans living with various chronic conditions. Some primary **Issues Facing Albertans** are that:

- The Drug Program Act was approved and received Royal Assent on June 4, 2009. The Act is vague and leaves open the possibility of having regulations which will be focused primarily on reducing healthcare services and access to drugs to decrease health care and drug expenditures.
- With some of the decisions already made, there is more indication that the government has more consideration for reducing health and drug expenditures and less regard for the health and wellbeing of Albertans or for improving their health outcomes. This is worrisome!
- Albertans are not being consulted or engaged on health care decisions that could compromise patient safety and have devastating outcomes.
- Cost pressures are impacting on formulary management.
- Cost-containment strategies such as bulk-buying, sole-tendering and reference-based pricing including generic or therapeutic substitution may save money in one area but limit choice for patients and their doctors and pose potential threats to patient safety and health outcomes and increased costs in other areas of the healthcare system.
- Pharmaceutical costs appear to be targeted the most and in isolation from overall healthcare costs or outcomes, and often without consideration of the evidence to support or reject decisions.
- Drug review and approval in Alberta is complicated, delays access to new treatments, lacks transparency, is not open to public consultation and does not account for decisions.
- Often drug rejection decisions have disregarded clinical practice guidelines, limited treatment options and appeared to put cost concerns ahead of patient safety or health outcomes.

Recent Background – What We Know

The number of challenges faced by Albertans in accessing the medicines they need have been increasing since the introduction of the national Common Drug Review and Alberta's revised review process. Formulary listings and drug coverage have been declining with the result that

Albertans are confronted with less choice in prescribed medicines, more acute health challenges, and in some cases, paying out of pocket for the medicines that work best for them. The inequity in all this is becoming obvious.

In December 2006, the Alberta Premier mandated the Minister of Health to develop a new pharmaceuticals strategy to 'improve management of drug expenditures' [2]. However, there has been no public consultation and no transparency around the development of this new strategy.

What we know:

- In May 2007, Alberta signed a *Memorandum of Understanding* with British Columbia to look at joint procurement [bulk purchases] of medications and medical devices to cut costs [3];
- Reports that a draft policy was sent back from caucus last June and may have included recommendations for means testing of seniors;
- Comments from then Minister of Health David Hancock in a September 2007 *Calgary Herald* article that he was concerned that "total drug spending [about $1 billion annually] has increased three times faster than physician and hospital spending…." Hancock also said the bulk-buying strategy was still in the works, with Alberta looking to some other buying groups in Canada to find the best-priced drugs; and that the government was looking at the pricing structure of generics [4];
- Confirmation from the Executive Director of Pharmaceuticals and Life Sciences, Steve Long in April 2008, that a new pharmaceuticals strategy is in development and that cost containment is a primary concern. [5]
- Release of the Alberta Pharmaceuticals Strategy and Drug Program Act, indicated that Seniors were intentionally targeted with having to pay more for premiums and cost-sharing. This puts seniors at risk if they are not able to afford their medications for any reason.

OVERALL GOALS OF CREATING SYNERGY

Members of Creating Synergy in Alberta are advocating

1. To participate in a meaningful way as the patient or public voice in the development of Alberta policy regarding pharmaceuticals;
2. To ensure that Albertans have optimal access to the right medicines for their disease or conditions when they need it most, whether for managing their disease and symptoms, or preventing disease onset or the potential complications from disease; and

[2] *Mandate Letter December 15, 2006.* Premier Stelmach to then Minister of Health and Wellness David Hancock – Management of drug expenditures one of four specific priorities.
[3] *Memorandum of Understanding – BC/Alberta.* Exploring bulk-purchasing arrangements. Criticism from the Canadian Diabetes Association//BC referenced in *BC Pharmaceutical Task Force Report* (April 2008, p.21).
[4] Lang, Michelle (September 4, 2007) Alberta revisits drug funding: Province plans strategy to deal with rising costs. *Calgary Herald,* News: A1(Front). [comments from then Health Minister Dave Hancock].
[5] Presentation by Steve Long to Alberta Creating Synergy Forum, April 14, 2008. Participants at forum included Alberta Health Charities, patients and consumers.

3. To ensure that health outcomes are not neglected over healthcare cost containment strategies in public health policy decision-making.

CREATING SYNERGY'S POSITION STATEMENTS ON THE ISSUES

Position Statement 1: A new, Alberta Drug Program Act has been approved but without much consultation with Albertans. It must be one that puts Albertans first, and is developed transparently, through meaningful public engagement and through consideration of the medical evidence and doctors' recommendations for disease treatment.

Position Statement 2: We need to consider the value and therapeutic benefits of medicines in the context of the health and well being of Albertans in addition to the total healthcare costs. Pharmaceuticals should be seen as a strategic investment in better patient outcomes including the prevention of complications.

Position Statement 3: Alberta can learn from recent negative experiences and application of cost containment measures in other jurisdictions. There is an opportunity to become a world leader in embracing new science to improve health outcomes and in long-term and holistic decision-making.

Position Statement 4: Consider other cost solutions than cost containment such as –

- Economic evaluation of pharmaceuticals within the whole of the healthcare system
- Health promotion campaigns on more effective use of medicine, disease prevention and management
- Enhanced roles for pharmacists and other health professionals in front-line interaction with patients
- Investigation of opportunities for cost management that does not directly impact health outcome – for example, negotiating the reduction of brand and generic drug prices.

Position Statement 5: We support a review and restructuring of Alberta's Expert Drug Review Committee and support the parallel development of an independent citizen's council, which could include:

- Meaningful patient participation in societal value issues/debates and other relevant review processes
- Meaningful disease-expert participation in the review process
- Open and transparent decisions
- Accountability for decisions
- Shortened timelines for decision-making
- Increased access to new improved therapies.

BACKGROUND CONTEXT FOR ISSUES AND POSITION STATEMENTS

Reform to Alberta's health system concerns all Albertans. Yet there is very little consideration given to the engagement of Albertans in discussions regarding the recent reform. The public tax dollar is an investment for which Albertans would like transparency and accountability reporting. This has not happened as evidenced by the employment of strategies which lack the foundation and necessary supports (e.g. Alberta's Third Way presentation in 2004/2005). Health reform

initiatives lack credibility because they are planned in isolation of the engagement of Albertans and particularly those with front line expertise. The recent reform in Alberta will be closely and critically watched and monitored – it has not passed the test as of yet. So the pressure will be on the present Health and Wellness Minister and his team, as well as the new Alberta Health Services organization, to demonstrate competence and credibility in the execution or implementation of a 'hidden' nontransparent and accountable plan.

There are several key areas of concern with Alberta's and Canada's health care systems, but with the focus of this position paper on pharmaceuticals, the following context will include the discussion around the obsession that exists for drug cost expenditures and cost containment, and drug review processes. Some potential cost solutions are also mentioned. Much of this discussion is based on the experiential lessons of patients and other stakeholders, research evidence, and jurisdictions across Canada and in other parts of the world.

1. COST CONTAINMENT

According to Steven Lewis there appears to be an unusual preoccupation or obsession with the financial sustainability of the public healthcare system as we know it. Lewis claims that there is compelling evidence to confirm that this is a "fundamental misdiagnosis". [6] The Canadian Health Services Research Foundation (December 2007) suggests the same as Lewis – that depending on what data is extracted, used and analyzed for measuring financial changes and sustainability, the snap-shot changes accordingly. "An analysis of estimated expenditures over time can be misleading when the figures are not adjusted for population growth, inflation and aging. For example, an analysis of estimated expenditures over a 27-year period in Alberta debunked hype over an unwieldy 900-percent spending increase. After initial adjustment, the increase was about 65 percent. With further correction for increases in average personal wealth, the figures dropped once again to a controllable 17.5 percent." [7, 8]

The same can be said regarding drug expenditures and containing these costs above all other health expenditure increases. One of the myths that has been put out into public documents and discussions is that "the costs of drugs is causing unsustainable growth in government health spending" [9] That this is a myth is backed by evidence released by the Canadian Institute for Health Information (2007) and the Patented Medicine Prices Review Board (2007). No one denies that the costs of drugs to the public and private payers as well as out-of-pocket costs to patients are increasing, but so are the other health care costs. However, no one is pointing at the escalating costs of other aspects of the health care system. Figure 1 shows the percentage of

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[6] Lewis, S. (2007) Can a Learning-Disabled Nation Learn Healthcare Lessons from Abroad? *Healthcare Policy* 3(2): 19-28. Quote is from Abstract, p.19.

[7] Canadian Health Services Research Foundation. (December 2007) Myth: Canada's system of healthcare financing is unsustainable. *Myth Busters*. Ottawa: CHSRF.

[8] Thompson, A.H. (2004) Healthcare costs in Alberta in context after corrections for inflation, population growth, and the aging population. *Longwoods Review* 2(4): 1-7.

[9] Skinner, B. (2008) *Myths and Facts: Drug Spending and Access in Canada.* Presentation at Alberta Creating Synergy Forum, April 14, 2008. (slide 2). Also found Rovere, M., Skinner, B (2008) Medicare's red herring: Prescription drug aren't to blame for unsustainable growth in government health spending. *Fraser Forum 06/08.* available at www.fraserinstitute.org.

government health expenditure in Canada in 2006, by use of funds. [10] Patented prescription drug expenditures totaled 6.3% of all health costs.

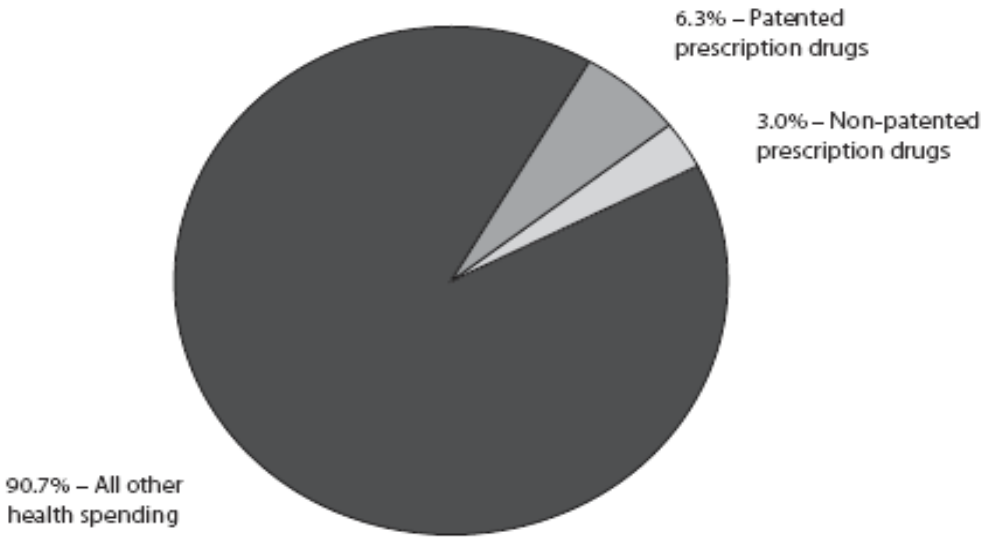

Figure 1 Percentage of government health expenditure in Canada including prescription drugs (patented and non-patented), by use of funds (2006 Data sources: Footnotes 9, 10 and 11).

The 90.7% for all other health spending includes hospitals (28.4%), health professionals (24.2%), other institutions (10.4%), administration (6.1%), and public health (5.8%). Most of the line items decreased in amount spent from the previous year.

Figure 2 shows the trend in government health expenditures in Canada from 1975 to 2007, by use of funds. [11] In this figure all prescription and non prescription drugs are combined when really only prescription drugs are paid by government to some extent. So, the statistics are presented in a way which does not accurately portray only government spending. The prescription drug expenditures are lower government costs compared with hospitals and institutions, health professionals and an ‘other ‘category.

[10] CIHI (2007) *National Health Expenditure Trends:1985 – 2006.* Ottawa: Author; and Patented Medicine Price Review Board (2007) *PMPRB 2006 Annual Report.* Ottawa: Government of Canada. Calculation for graph by Skinner, B. at Fraser Institute.
[11] CIHI (2008) *National Drug Expenditure Overview.* Ottawa: Author.

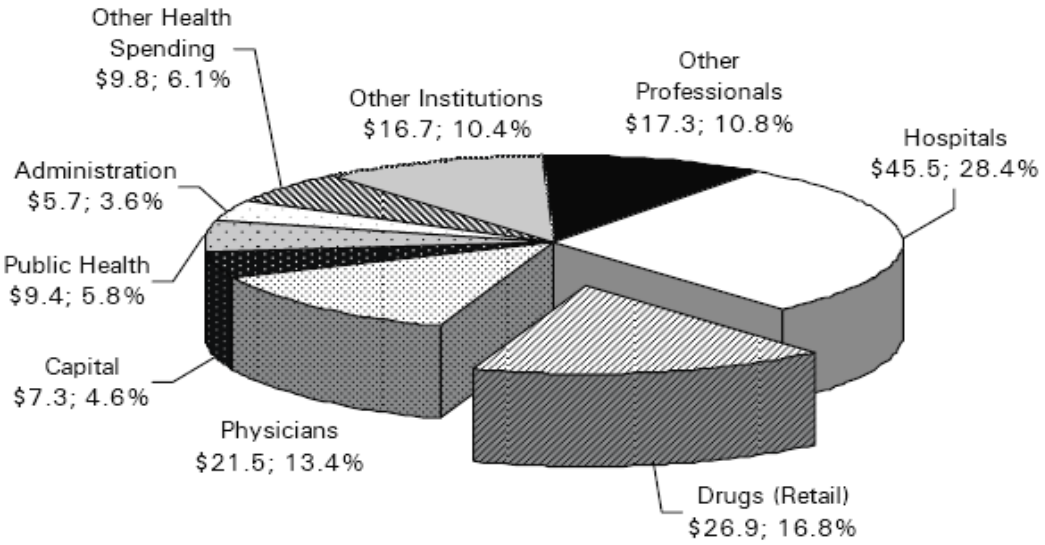

Figure 2 Health Expenditures in Canada from 1975 to 2007 (Footnote 9, 10, and 11). All are related to government spending except the Retail Drug total of $26.9 billion which includes non-prescription expenditures of $6.9 billion which is public out-of-pocket expenditures.

The overall trend in drug expenditures has shown a decline over the past three years but the health expenditures have gone up in the same time frame. For example, from 2005 to 2006 there was a drop in drug expenditures from 17.4% in 2005 to 16.7% in 2006. Prescription drugs were estimated at 9.3% of total government spending on health care in 2006, down from 9.6% in 2005 (footnote 10 – CIHI 2007). Expenditure on prescription drugs represents a growth rate of 8.1% in 2006 and 7.5% in 2007, whereas expenditure on non-prescribed drugs paid by the public shows an opposite growth rate of 5.0% in 2006 and 5.6% in 2007 (Footnote 11 – CIHI 2008).

Why is there such an obsession on only containing drug costs as compared with balancing all or other health care expenditure costs? There appears to be a silo approach to resolving the overall issue and concern of health care expenditures – focusing on only drug costs is not going to resolve overall health care expenditures or costs. The issue is that more focus and money is needed in the 'public health' area for health promotion, chronic disease management and risk prevention programs and services. Evidence in B.C. has shown that even with reference-based pricing cost containment measures in place and drug expenditures declining, the overall costs and expenditures of its healthcare has gone up. [12] Recent evidence about B.C.'s therapeutic substitution strategy, originally aimed at saving costs, points to an increase in adverse events, decrease in patient safety and liable health care consequences (Skimeret et al., 2009). So where are the savings? And at what cost to BC citizens who were able to demonstrate good health outcomes on the drugs they were taking before the changes? Can we learn from this experience? We need more research in B.C. and similar places looking at the mortality data of seniors (B.C. focus evidence supporting reference based pricing) and others to see if deaths were not due to adverse events from changing medications as a result of the drug plan. Where is the research looking at acute care utilization in balance with changes in drug plans?

[12] Ibid. CIHI (2008) p. 17.

Silo-budgeting
Alberta needs to address growing pharmaceutical costs – but they cannot be isolated as a cost silo in the healthcare budget or addressed at the expense of health outcomes. How is the government assessing the impact of pharmaceutical spending – or cost containment – on expenses elsewhere in the health system, or related to health outcomes and patient safety overall.?

We need to consider the value, or more specifically, the 'benefits' of medicines in the context of total healthcare costs. Pharmaceuticals should be seen as a strategic investment in better patient outcomes – Alberta appears to be focused on the cost of medications rather than the value or outcome benefits of medications. Access to medications improve health outcomes and generate savings through effective cost-utilization, enhanced quality of life and productivity of persons affected. Access to the right medication can reduce overall health costs by keeping people out of hospitals and in their communities as productive society members.

Bulk-buying & Sole-tendering
Bulk-buying of pharmaceuticals and sole-tendering mean limited choice for patients and their prescribing doctors. It is a 'one-size-fits-all' approach and yet we know that individuals have different health benefits and different side effects from the same drug -- one of the reasons we need options and choice. Bulk-buying may have appeal from a budgetary perspective, but it is regressive in terms of new medical science which is moving towards personalized medicine with the right medication, in the right dose, for the right person at the right time.

There are not only concerns for the recipient side of the procurement process which in this case is bulk-buying and sole tendering, but there are also risks for the drug plan regulator and purchaser or negotiator at the government level. Market constraints must be considered by each country and in this case, each province (e.g. volume, payment plans, etc.). Procurement planning is essential and must consider all the risks to all concerned. The World Health Organization (1999) published its *Operational principles for good pharmaceutical procurement* which included a strong recommendation that there should be efficient procedures in place to manage the procurement and distribution system long before implementation. Failure in following through with all the steps has led to "lack of access to appropriate drugs and to waste. In many public supply systems, breakdowns regularly occur at multiple points in this process…. If the procurement process is not managed in an efficient and transparent manner, interest among suppliers in competing for procurement contracts decreases, leading to fewer choices and higher prices for drugs".[13]

Reference-based pricing
This practice is in place in B.C. where reimbursement levels are associated with the cheapest medication in a class without consideration of health outcomes. The cheapest medication in a class is not necessarily the most effective for each patient with the same condition. There is no one medication in any class of drugs that will fit the needs of every patient with the same symptoms! To limit coverage to the cheapest in a class and make patients pay the difference to obtain drugs they need to stay well is setting precedence for inequity. In many cases,

[13] Essential Drugs and Medicines Policy Interagency Pharmaceutical Coordination Group (1999) *Operational principles for good pharmaceutical procurement.* Geneva: World Health Organization. (p.3)

unaffordable health care costs are imposed on patients. The only research evidence we have for this type of system is from B.C. where studies to date have only been on senior citizens, which does not reflect on the rest of the population. [14] Studies are beginning to appear in the general population, particularly with therapeutic substitution.

Therapeutic Substitution – a false image for health outcomes and reducing costs

We have an important lesson to learn from a policy decision in British Columbia regarding 'Therapeutic Substitution', which is a reimbursement policy based on a *false* assumption that drugs within the same therapeutic class are medically interchangeable, *incorrectly* implying that their health effects do not differ significantly, even between drug molecules that are not bio-equivalent.

A study published in April 2009, using the BC Health Linked database, showed medically unnecessary drug switching within a class of multiple brand name products, caused by compliance with Therapeutic Substitution policy, to be independently associated with higher overall healthcare utilization.[15] In fact, rather than saving the anticipated $42 million over three years, results show an increased cost to healthcare of $43.5 million over three years. Costs were attributed to more frequent visits to physicians and hospitals as well as more frequent use of diagnostic services and an increase in use of prescription medication within the entire class of medications to which the policy applied. The overall detriment was decreased patient health, increased costs in many areas of healthcare, and no net savings in the drug budget silo. In this study, the BC Ministry of Health Services provided all the linked data for each patient subjected to the Therapeutic Substitution policy, and all linked data were included in the analysis. Therefore, it offers the clearest picture of a real world Canadian experience of an attempt to save costs that, in the final analysis, took a huge toll on the system and patients. We strongly oppose Therapeutic Substitution as instituted by government who does not have a medical license to diagnose nor prescribe a therapeutically substituted medication to patients, and who could be found liable for compromising patient safety and practicing in an irrational unsafe manner. What a price to pay just to save costs!

Generic Substitution - does not work for every patient

As patents on brand name drugs end, there is a rush to bring in generic product to substitute. These are assumed to be the same in therapeutic effectiveness as the brand name product, and cheaper in cost. Therefore one can assume that making this switch would be beneficial for all concerned. However, evidence is now appearing to indicate the opposite for patients, some with severe chronic conditions such as stroke, epilepsy or depression. Physicians need to closely monitor patients who have been given generically substituted drugs. Otherwise, patients will be at risk of a reaction or adverse event and end up with increased emergency room visits or hospitalization, not to mention personal costs and suffering, lost work time and other quality of life concerns. [16] Pharmacists should not be allowed to substitute generic products for brand name

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[14] Aaserud, M., Dahlgren, A.T., Kosters J.P., Osman, A. D., Ramsay, C., Sturm, H. (2008) Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies (Review). *The Cochrane Collaboration.* Available at www.thecochranelibrary.com.

[15] Skinner BJ, Gray JR, Attara GP. Increased health costs from mandated Therapeutic Substitution of proton pump inhibitors in British Columbia. *Alimentary Pharmacology and Therapeutics.* 2009;29(8):882–891.

[16] Liow K. Understanding patients' perspective in the use of generic antiepileptic drugs: compelling lessons for physicians to improve physician/patient communication. *BMC Neurology* 2009; 9(11):1-10.

ones without the permission and knowledge of the physician attending to the patient. A program of action should be established to ensure that such substitutions are safer and less problematic for patients, than is currently the case. Several things need to be in place for safe substitution:

- Bioequivalence studies on generic drugs to ensure comparable effectiveness, efficacy and safety
- Health care providers and patients need to be educated about the risks and limitations associated with a generic substitution
- Follow up surveillance with physicians, pharmacists and patients is needed to collect data on generic drugs and their differences from brand name drugs.
- Both the physician and pharmacist must communicate about the substitution, and both have an obligation to inform the patient about the shift and any potential side effects. [17]

Although generic substitution is seen as a means to reduce drug expenditures overall, these savings should not be offset by increased hospitalization costs, and patients and their health should not be compromised in the process of experimenting to see if the substitution will work or not. Patients are not guinea pigs!

Learning from cost containment in other jurisdictions

Alberta can learn from recent experiences and application of cost containment measures, in other jurisdictions.

New Zealand is often held up as a model in reducing its pharmaceutical budget. In a decade of bulk-buying and sole-tendering, New Zealand has undoubtedly reduced its pharmacare costs. But there are many questions about its effects on the health of individuals. There is ongoing debate in New Zealand medical journals about the harmful – and costly – effects of switching stabilized patients to the bulk purchased medications, and concerns about shortages of pharmaceuticals, inferior quality of product, and increased costs in other parts of the healthcare system.

An article in the February 15, 2008 issue of the *New Zealand Medical Journal* says bulk-buying and sole-tendering pharmaceutical policies have been dangerous to New Zealanders' health. It cites a study from 1998-2004 – post New Zealand's adoption of the aggressive cost-containment strategies – that shows New Zealanders are 35% more likely to die of cardiovascular disease than Australians. The preeminent cardiologists who coauthored the study take direct aim at New Zealand's pharmacare policy, concluding that the government there has misguided pride in its cost-cutting achievements.

"PHARMAC's 15-year involvement in the New Zealand health care environment has been a difficult and sometimes dangerous experience for patients…Access to a number of CVS [cardiovascular] medications in recent years has been delayed or remains limited…In terms of statin availability and use, PHARMAC's delays in making available appropriate medications has probably caused more unnecessary death and major morbidity to New Zealanders than any other of their policies" [18]

[17] Borgherini G. The bioequivalence and therapeutic efficacy of generic versus brand-name psychoactive drugs. *Clinical Therapeutics* 2003; 25(6):1578-1592.

[18] Ellis, CJ, Hamer, AW. (2008) Cardiovascular health in New Zealand: areas of concern and targets for improvement in 2008 and beyond. *NXMJ* 121(1269):5-10.

British Columbia has implemented the most aggressive pharmaceutical cost containment measures in Canada: reference-based pricing in the mid-1990s, therapeutic substitutions, bulk-purchase agreements and most recently sole-tendering of products. Consumers have reacted with strong opposition, citing limited choice and poorer health outcomes as a result. In November 2007, the Minister of Health called for a Task Force on Pharmaceuticals which heard from patients and advocates, medical practitioners, pharmacists and the pharmaceutical industry.

In their submission to the BC Pharmaceutical Task Force, the Canadian Diabetes Association (CDA) expressed particular concern about the memorandum of understanding signed by Alberta and British Columbia, "…which indicates that the two jurisdictions would work together to explore the bulk purchase of glucose test strips with a view towards achieving significant cost savings to the public drug plans in both jurisdictions. The problem, from the CDA perspective, is that this was being done with little or no consultation with the key target patient groups and there was considerable concern that this move would:

- unreasonably limit patient choice;
- potentially result in the required use of test strips that correspond to inferior blood glucose monitors;
- lead to a possible decline in diabetes education currently available at the pharmacy level;
- cause further disruption and inconvenience for a patient group who already experience considerable disruption in their lives; and
- result in increased risk of adverse reactions or declines in quality of care or patient outcomes that would inevitably shift costs to other parts of the healthcare system."

The British Columbia Medical Association in "A Prescription for Quality: Improving Prescription Drug Policy in British Columbia," (July, 2007), said this: "As in any area of public policy, increased spending may be a prudent investment, with gains to be realized in the future. For example, clinical guidelines and chronic disease management programs have increasingly emphasized drug therapy as a cornerstone to improving health outcomes and controlling costs. Multiple clinical trials suggest that use of appropriate heart failure drug therapies may be the most effective way to reduce the cost of care while reducing morbidity and mortality: drug therapies can reduce hospitalization by 12% to 35%, depending on the drug. [19] Nonetheless, within finite budgets, increased spending in one area may also offset expenditures elsewhere in the healthcare system. The challenge for healthcare policymakers is to determine if and when the investment in prescription drugs – particularly in light of continued growth – is worth the expected return" (p. 14). [20]

Recommendation from the final report of the BC Pharmaceutical Task Force released in May 2008: "The PSD [Pharmaceutical Services Division] should adopt a cautious approach to broadened utilization of tendering processes. The process adopted should mirror tendering processes used in other areas of Government characterized by a process that is transparent, fair,

[19] Goldfarb, N. Weston, C., Hartmann, CW, Sikirica, M., Crawford, A., Hope, HE., et al. (2004) Impact of appropriate pharmaceutical therapy for chronic conditions on direct medical costs and workplace productivity: A review of the literature. *Disease Management* 6(1): 61-75.
[20] Also referenced in the B.C. Pharmaceutical Task Force Report, April 2008. p. 4.

open and includes understandable evaluation criteria. Increased tendering should provide for reasonable levels of patient choice, avoid the deployment of older inferior products and, where possible, arrangements that provide for participation of multiple suppliers." [21]

The report also recommended substantially enhanced, meaningful stakeholder – consumers and disease experts – engagement in the decision-making process around listing of therapies and products and greater transparency in all pricing agreements between government and manufacturers and distributors/pharmacies and pharmacists.

2. DRUG REVIEW, LISTING AND DE-LISTING DECISIONS FOR ALBERTA'S DRUG FORMULARY

We support a review and restructuring of Alberta's Expert Drug Review Committee and the establishment of the Citizens' Council for:

- Meaningful patient engagement in the drug review and decision-making processes
- Meaningful disease-expert participation in the review process
- Open and transparent decisions
- Accountability for decisions
- Shortened timelines for decision-making
- Increased access to new improved therapies
- Extensive assessment of any proposed therapeutic or generic substitution to determine risks before implementation

Currently, the drug review and approval in Alberta is multi-layered and complicated. It delays access to new treatments, lacks transparency, is not open to public consultation and does not account for decisions. Recent drug approval decisions have disregarded clinical practice guidelines, limit treatment options and appear to put cost concerns ahead of health outcomes.

We believe that patient experts and disease specialists are under-utilized in informing decision-making in the best interests of Albertans. Consumer involvement in health technology assessment is not new to the U.K. or other countries, but it is in Canada. Consumers have expressed interest in becoming involved in drug reviews and HTA. [22, 23] At a minimum, there should be two consumer representatives on the drug review committee such as exists in the Ontario Ministry of Health, Committee on Evaluating Drugs (CED). Although these patient/consumer members receive an orientation and training on reading and interpreting drug review documents, as full voting members of CED they also present their perspectives on the societal values and benefits to risks. In addition, the Ontario Ministry Drug Secretariat is putting

[21] B.C. Pharmaceutical Task Force (April 2008) *Report of the Pharmaceutical Task Force: The Report of Pharmaceutical Policy Recommendations for the Ministry of Health.* Victoria, B.C. : Author.

[22] Kovacs Burns, K. (Researcher and Primary Author). (July 2006). *The Voluntary Health Sector as Participants in the Public Health System: Defining the Role and Impact.* Report submitted to the Public Health Agency of Canada, National Voluntary Health Organizations. Sector Development Grant was provided to Researcher through the Best Medicines Coalition and The Arthritis Society of Canada.

[23] Pivik, J., Rode, E., Ward, C. (2004) A consumer involvement model for health technology assessment in Canada. *Health Policy* 69: 253-268.

into place a Citizen's Council which will be engaged in deliberative dialogue on very specific societal issues, the information of which will be valuable to CED. The BC Pharmaceutical Task Force report also has a recommendation that calls for three public members to be selected through a process external to the Pharmaceutical Service Division, and teams of disease-specific experts to be consulted as part of the approval process. There are other countries which have some similar models in place and have evaluated and adjusted them to better accommodate patients/consumers as experts in health care and pharmaceutical decision making. These other countries include the U.K., Australia and some of the European Countries. A Citizens' Council as proposed for the Alberta pharmaceuticals strategy will go a long way towards informing the drug decisions which involve societal values, ethical considerations and patients' real world experiences.

Transparency and full disclosure on listing decisions is needed following the Common Drug Review (CDR) model which publishes reasons for all its recommendations on its website. As Alberta has a record of upholding all CDR recommendations against listing; and deciding against CDR recommendations to list, it would be particularly helpful to understand the reasons behind the decisions.

There is also a need for improved consultation and communication with doctors and patients on any changes in formulary listings, such as changes in listing status from available to special authorization or de-listing of drugs. Changes made without prior consultation with all stakeholders are arbitrary and create unnecessary anxiety for patients. Access through special authorization is onerous and complicated, requiring burdensome paperwork and persistence on the part of the doctor. Not all patients have doctors who will advocate on their behalf.

We further recommend shortened timelines specifically for those drugs for which there are no comparator drugs, such as for rare disorders. Having a separate Drugs for Rare Disorders program for Alberta's pharmaceutical strategies is seen as the right way to go. Engaging patients and experts in this review process will be critical.

3. TRANSPARENCY OF DRUG PROGRAM ACT DECISIONS AND ACCESS SOLUTIONS

Transparency and accountability needs to exist at all levels of decision making related to the regulation of the Drug Program Act and its implementation. "Transparency in pharmaceutical policy-making would probably lead to increased confidence in the decision-making process and to better decisions". [24] With transparency comes interested independent analysts playing key roles in reviews of clinical trials which add to the confidence in decision-making, less impression that something is being hidden, and governments might receive more public trust. Transparency must begin with the research gathering evidence to support or reject a drug. There must be further discussions about the types of research needed that will produce the best evidence for making decisions about drug reviews.[25] Transparency must also be present through the review

[24] Dhalla, I., Laupacis, A. (2008) Moving from opacity to transparency in pharmaceutical policy. *CMAJ* 178(4): 428-431. p. 428.
[25] Hall, W.D., Lucke, J. (2007) Assessing the impact of prescribed medicines on health outcomes. *Australia and New Zealand Health Policy* 4:1-9.

of the drug, pricing, formulary review and listing, and advertising and promotion. It must also be present in all procurement proposals and activities to ensure that the drugs negotiated and purchased meet the needs of patients and are not only cost saving. [26]

Drug review and access solutions include the engagement of key stakeholders or experts including patients. The understanding and translation for the public as to why a drug is delayed in review or rejected or approved for formulary listing can be better achieved when there are patients as members of expert review committees who can substantiate the decisions made.

Costs will always be part of the discussion for pharmaceuticals and healthcare generally. Everyone is conscious of this. However, as Lewis points out, "…we need to declare a moratorium on the sustainability debate, become more adept at learning which features of international systems we can and cannot easily import, and recognize that what ails our system originates in design rather than the laws of nature". [27] This is supported by the Canadian Health Services Research Foundation which clearly believes that fiscal sustainability of programs and health services is a matter of government choice and also a choice of the public. But people must be involved in the decision regarding more or less taxes and how they should be spent across the health care system. [28]

The Seniors Drug Plan is an example where more transparency and engagement of seniors would have prevented the opposition to the proposed premiums and cost sharing model. Now seniors are forced may be forced to make decisions in their drug treatment programs which may not be in their best interest. Monitoring the results over the first year of this program will be the test!

In summary, the recommendations for improving pharmaceutical integration into the rest of the health care system include exploring or implementing:

- Economic evaluation of pharmaceuticals within the whole of the healthcare system
- Health promotion campaigns on more effective use of medicine, disease prevention and management
- Enhanced roles for pharmacists and other health professionals in front-line interaction with patients
- Investigation of opportunities for cost management that does not directly impact health outcome – for example, negotiating the reduction of brand name and generic drug prices
- Citizens' Council on which patients and citizens can be engaged to debate and provide insights to key societal value and ethical questions related to drug program decisions.

[26] Essential Drugs and Medicines Policy Interagency Pharmaceutical Coordination Group (1999) *Operational Principles for good pharmaceutical procurement.* Geneva: WHO.
[27] Lewis, S. (2007) Can a Learning-Disabled Nation Learn Healthcare Lessons from Abroad? *Healthcare Policy* 3(2): 19 – 28. (p.19).
[28] Canadian Health Services Research Foundation (2007) Myth: Canada's system of healthcare financing is unsustainable. *Myth Busters.* Ottawa: CHSRF.

CONCLUSION

As demographics shift to an increasingly older population who place increased demands on the health care system, there is a need for effective management to ensure sustainability of our system. However, we worry that pressures for cost containment dominate decision-making.

As medical science advances genome knowledge, there is a shift to personalized and targeted medicine that improves health outcome. We worry that cost-containment measures are biased towards cheaper, one-size-fits-all medicine which does not promote optimal health outcomes.

With a stated provincial government objective of developing a new pharmaceuticals strategy, we see this as an opportunity to get it right.

Alberta can learn from other jurisdictions. There is an opportunity to become a world leader in embracing new science to improve health outcomes and in long-term and holistic decision-making.

Albertans want to work with government on their health care – not to have government do it for them. The consumer/patient voice in health policy sharpens awareness of the moral debate. It is easier to make decisions without knowing first-hand, the implications in real life for families and communities.

Patients and consumers of healthcare are becoming more interested in, and more critical of, the processes used by decision-makers to decide on health services, technologies, service and product reviews and access, and health policies. They are also saying that they want to play a more significant role in discussing and deciding on health care initiatives and health policy decisions that impact them on a daily basis, sometimes with negative or harmful consequences.

GENERAL RECOMMENDATIONS

Consider the Alberta Pharmaceuticals Strategy as a priority initiative in Alberta. Put Albertans and health outcomes first, not cost containment.

Bring new thinking to pharmaceuticals policy with an advisory group comprised of patient experts and advocates, health professionals including disease specialists, researchers, economists and others with broad-based health and health care perspectives. Learn from all perspectives. Make stakeholder engagement meaningful. Bring the real, human element into the policy- and decision-making process

Foster a culture of consumer friendliness with plain language information, open and transparent process and full public disclosure and accountability. Albertans deserve this!

Consider other country experiences and evidence, both positive and negative, regarding pharmaceutical strategies. Don’t adopt one because it is convenient or ‘cheaper’.

Support research or evaluations of health care programs/ services including drug strategies and changes to existing plans, to ensure that what is proposed is making a positive impact and improving health outcomes. Gather information from the Albertans, particularly patients/consumers who utilize and access the health care system and drug plans regularly, and the health professionals who deliver the care and treatment.

Emphasize the public's health and well being with particular emphasis on how a pharmaceutical strategy is also preventative of complications and more disease burden. Pharmaceuticals also prevent disease and improve health outcomes.

Consider the education of health professionals in optimal prescribing and patients to take responsibility for following through on their care and treatment and reporting adverse reactions.

We want our government and Ministry of Health and Wellness to focus on health and wellness!

For additional information and comments please contact:

CREATING SYNERGY: *Health Coalition of Alberta*

Lk. Bonavista, PO Box 81121, Calgary, AB T2J 7C9

Email: ***creatingsynergy@telus.net***