



# A Prescription for Quality: Improving Drug Policy in BC

*A Policy Paper by BC's Physicians* | July 2007



# **A Prescription for Quality**

## Improving Prescription Drug Policy in British Columbia

**A Policy Paper by BC's Physicians**

July 2007



The BCMA Council on Health Economics and Policy (CHEP) reviews and formulates policy through the use of project oriented groups of practising physicians and professional staff. The Project Group for this paper includes:

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# Executive Summary

Concern over prescription drug policy in Canada is fuelled primarily by the growth in expenditures. Prescription drugs are the fastest growing component of Canadian health care expenditures. As drug costs escalate, questions have emerged about how to ensure the optimal use of medications, guarantee patient safety, and better manage public prescription drug benefits.

This policy paper offers recommendations on six areas of particular importance to physicians in British Columbia:

1. Prescription drug expenditures
2. BC's PharmaCare program
3. The promotion of prescription drugs (to both doctors and patients)
4. Information technology (and its relationship to patient safety)
5. Professional roles in prescribing
6. The National Pharmaceuticals Strategy

Twenty-four recommendations are offered.

The British Columbia Medical Association (BCMA) Prescription Drug Project Group conducted a review of the relevant peer-reviewed literature, a review of the literature produced by various stakeholders including governments and policy think tanks, and a survey of the BCMA membership in November 2006 on prescription drug policy. A description of the survey methodology is provided in Appendix A.

## Drug costs

Research on prescription drug costs reveals several interesting trends, often contrary to conventional wisdom:

- Public spending on prescription drugs is increasing at a rapid pace across Canada. In British Columbia, expenditure growth has increased faster than the national average, with average annual growth of 11.3% from 1986 – 2006 (versus 10.6% nationally).
- Most of the growth is not due to increases in manufacturers' prices or the aging of the population, but rather the volume and selection of drugs prescribed. Drugs classified by the Patented Medicine Prices Review Board (PMPRB) as "Category 3", i.e., a new drug or dosage form of an existing drug that provides moderate, little, or no improvement over existing drugs, are leading cost drivers.<sup>1</sup>
- Increases in prescription drug use and expenditures *per se* are not necessarily problematic. In many cases, the health of the population benefits from increased prescribing. In other cases, additional spending on prescription drugs may represent a poor investment. The challenge for health care policymakers is to determine if and when the investment in prescription drugs, particularly in light of continued growth, is worth the expected return.

<sup>1</sup> The PMPRB is the Patented Medicine Prices Review Board. It is "an independent quasi-judicial tribunal that limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive." (Patented Medicine Prices Review Board 2006).

## Lessons from Abroad

Canada is not alone in its efforts to control prescription drug expenditures. Nearly all OECD (Organisation for Economic Co-operation and Development) nations are spending significantly more each year on prescription drugs. We examined four countries whose public prescription drug programs contained elements similar to those found here: Germany, New Zealand, Australia, and the Netherlands. Several important lessons emerged:

1. Attempts by governments to impose solutions without the support of the medical profession (e.g., physician drug budgets in Germany) do not succeed. Efforts to control drug spending should be managed collaboratively by physicians and the government.
2. Both the Australian and Dutch experiences demonstrate the difficulty of achieving drug cost containment even with policies that have been successfully implemented elsewhere. Given the unique policy environment in each jurisdiction, one cannot assume that “one size fits all.”
3. Every country studied had adopted some form of physician education for prescribing. The BCMA believes that there may be opportunities for the programs like the Education for Quality Improvement in Patient Care (EQIP), which operate as partnerships of the Ministry of Health, the BCMA, and other relevant stakeholder organizations, to provide physicians with unbiased education on the efficacy, cost, and cost-effectiveness of prescription drugs.

Because of its high profile in recent policy discussions, the New Zealand experience merits particular attention. Elements of New Zealand’s policies, including direct negotiations with manufacturers on drug prices, may be useful in BC. However, caution should be taken in following New Zealand’s example of a capped budget for public prescription drug expenditures. Even with a special authority mechanism in place, a budget cap means that some medication decisions are based purely on fiscal, not clinical, considerations. This is not appropriate.

## BC’s PharmaCare Program

The lack of integration between hospital and outpatient drug formularies must be addressed. Failure to integrate hospital and outpatient formularies compromise patient care if prescriptions change upon hospital discharge or if patients receive new prescriptions upon discharge.

The BCMA is concerned about the lack of transparency in the PharmaCare formulary approval process. PharmaCare must ensure the transparency of drug coverage decisions, as specified in the 2005 PharmaCare Review Implementation Final Report. These decisions should be binding on the BC government. Moreover, all Canadian Expert Drug Advisory Committee (CEDAC) decisions should be brought forward to the PharmaCare Drug Benefit Committee for review.

The involvement of the University of British Columbia’s (UBC’s) Therapeutics Initiative (TI) in the formulary approval process is a unique feature of BC’s PharmaCare program. A significant minority (26%) of physicians did not agree with the statement, “I trust the TI to provide independent information on prescription drugs.” This is problematic. Common criticisms suggest that the TI is too closely tied to government to provide objective information and that there is a lack of transparency in the TI decision-making process as well as the appointment of its members. An independent review of the membership

appointments, decision-making processes, and the arms-length nature of the TI would help improve the profession's perception of it.

The BCMA supports, in principle, Reference-Based Drug Pricing (RDP) provided it is clinically focused, fiscally responsible, and patient sensitive. However, BC physicians remain concerned over the implementation of RDP, particularly with respect to the potential for negative clinical impacts and limited patient access to necessary medications. For these reasons, BCMA support for RDP in British Columbia is contingent on the following.:

1. Implementation of a transparent process for careful evaluation of the therapeutic equivalence of drugs in current and future reference drug categories. This process must be ongoing, include a thorough assessment of the peer-reviewed literature, and be conducted by a working group whose membership includes practising physicians, some of whom should be selected by the BCMA;
2. An assessment of the impact on health outcomes of RDP for all drug classes in the BC Reference Drug Pricing Program, both current and future, on a short- and long-term basis;
3. Creation of a working group whose membership includes practising physicians, some of whom should be selected by the BCMA for examining additional categories of reference-based drugs in the BC Reference Drug Pricing Program; and
4. Appropriate reimbursement for physicians for the completion of special authority forms.

### **Promotion of Prescription Drugs**

There is a palpable tension between prescription drug manufacturers and regulators over the proper role of advertising in the industry. The legitimate desire of manufacturers – who operate in a market and are accountable to shareholders – is to increase sales and market share. On the other hand, the equally legitimate desire of regulators and others is to curb excessively optimistic claims that could compromise patient safety. The BCMA recommends that:

- Direct-to-consumer advertising for prescription drugs be banned in Canada; and
- Health Canada appoint a watchdog to oversee and regulate drug manufacturers' promotional activities to the public and all health care providers and prescribers.

The BCMA supports the Canadian Medical Association (CMA) guidelines on appropriate relationships between physicians and the pharmaceutical industry and encourages other health care providers to adopt similar guidelines.

### **Patient Safety and Information Technology**

A number of information technology (IT) interventions have been introduced to reduce errors in medication management, including e-prescribing or computerized physician order entry (CPOE), clinical decision support systems, electronic medical records (EMRs), and automated dispensing. In British Columbia, the implementation of PharmaNet in 1995, and its more recent expansion to physicians' offices through the Medical Practitioner Access to PharmaNet (MPAP) program can facilitate further advances in e-prescribing. However, government should ensure that the integration and expansion of IT in



prescribing is accompanied by a greater level of standardization than currently exists, the privacy of patient information is protected, start-up and ongoing funding for physicians to use e-prescribing systems is available, and the provision of physician access to PharmaNet is at no cost to physicians.

### Professional Roles in Prescribing

In May 2006, the Alberta government approved the *Pharmacists Profession Regulation*, which allows for a greatly expanded scope of practice for pharmacists. Similar efforts are likely to follow in other provinces, and the implications for the practice of medicine are significant. The BCMA examined the legislation in Alberta, activities in British Columbia and elsewhere in Canada, and experiences abroad, and recommends the following policy on professional prescribing:

- The right to prescribe medications independently for medical conditions must be reserved for qualified practitioners who are adequately trained to take a medical history, perform a physical examination, order and interpret appropriate investigations, and arrive at a working diagnosis.
- The BCMA endorses a role for pharmacists to independently renew prescriptions on a short-term basis (maximum 30 days) under defined circumstances when a renewal cannot be readily obtained from the patient's physician. The pharmacist must notify the original prescribing physician and/or regular family physician of the prescription renewal, in writing, as soon as reasonably possible.
- Delegated professional prescribing is acceptable provided that:
  - It is part of a multidisciplinary practice (i.e., takes place in the physician's office or as part of a virtual team).
  - The multidisciplinary practice is led by a clinical team leader with ultimate responsibility for patient care and who is the best-trained generalist (in the majority of instances, this would be the GP).

### The National Pharmaceuticals Strategy

In 2004, the First Ministers established a Ministerial Task Force (MTF) to develop the National Pharmaceuticals Strategy (NPS). This task force is part of the larger 10-Year Plan to "Strengthen Health Care" and coordinates the efforts of federal, provincial, and territorial Health Ministers. In the two years since the creation of the MTF, stakeholders have expressed their views on the NPS through conferences and policy statements dedicated to exploring issues of pharmaceutical policy. Despite this interest from stakeholders, as well as the publicly-stated assurance from the MTF that "*key stakeholders including patient groups, health care providers, insurers and industry - will be engaged as part of the development and implementation process to ensure the long-term success and viability of a National Pharmaceuticals Strategy*", the development of the NPS has taken place without meaningful input from any stakeholder. The BCMA calls upon the NPS to honour its commitment to include meaningful physician input in the development of its policies and recommendations. Further, the BCMA recommends that the NPS expediently develop positions on the remaining four focus areas: (1) physician prescribing behaviour and optimal drug therapy; (2) e-prescribing; (3) generic drugs; and (4) improving analytic capability. The CMA's joint statement on the NPS, written with the Coalition for a Canadian Pharmaceutical Strategy, provides a framework for undertaking this task.

# List of Recommendations

## Prescription Drug Policy

**Recommendation #1.** PharmaCare should negotiate directly with wholesalers and drug manufacturers to secure the best prices for PharmaCare-insured drugs.

**Recommendation #2.** PharmaCare should involve practising physicians in the decision-making process behind policies to control prescription drug expenditures.

**Recommendation #3.** PharmaCare should not implement a strict budget cap on public drug expenditures.

**Recommendation #4.** The BCMA supports the provision of educational materials on the efficacy and cost of prescription medications to BC physicians. This must be done on a regular basis through a continually funded, collaborative organization such as the program for Education for Quality Improvement in Patient Care (EQIP) with representation from the BCMA, the Ministry of Health, and other relevant stakeholder organizations.

## British Columbia's PharmaCare Program

**Recommendation #5.** The BC Ministry of Health should improve the integration and harmonization of hospital and outpatient formularies.

**Recommendation #6.** PharmaCare should ensure the transparency of drug coverage decisions, as specified in the 2005 PharmaCare Review Implementation Final Report. These decisions should be binding on the BC government.

**Recommendation #7.** All Canadian Expert Drug Advisory Committee (CEDAC) decisions should be brought forward to the BC PharmaCare Drug Benefit Committee for review.

**Recommendation #8.** PharmaCare should, no later than December 31, 2007, implement a process for regularly assessing the cost-effectiveness of existing drugs in the formulary as recommended in the BC Auditor General's 2006 report on managing PharmaCare.

**Recommendation #9.** There should be an independent review of the membership appointments, decision-making processes, and the arms-length nature of the BC Therapeutics Initiative (TI), intended to improve transparency and objectivity, to be completed no later than December 31, 2007.

**Recommendation #10.** The BCMA supports, in principle, Reference-Based Drug Pricing (RDP) provided it is clinically focused, fiscally responsible, and patient sensitive. Support for the BC Reference Drug Pricing Program is contingent on the implementation of recommendations 11 – 14 below.

**Recommendation #11.** There must be a transparent process for evaluating the therapeutic equivalence of drugs in current and future reference drug categories. This process must be ongoing, include a thorough assessment of the peer-reviewed literature, and be conducted by a working group whose membership includes practising physicians, some of whom should be selected by the BCMA.

**Recommendation #12.** There must be an assessment of the impact on health outcomes of RDP for all drug classes in the BC Reference Drug Pricing Program, both current and future, on a short- and

long-term basis. This process must show that the application of reference-based drug pricing avoids significant negative clinical outcomes.

**Recommendation #13.** A working group whose membership includes practising physicians, some of whom must be selected by the BCMA, must be created for examining additional categories of reference-based drugs in the BC Reference Drug Pricing Program.

**Recommendation #14.** Physicians must be appropriately reimbursed for the completion of special authority forms.

### Promotion of Prescription Drugs

**Recommendation #15.** The prohibition on direct-to-consumer advertising for prescription drugs should continue and be enforced in Canada.

**Recommendation #16.** Health Canada should appoint a watchdog to oversee and regulate drug manufacturers' promotional activities to the public and all health care providers and prescribers.

**Recommendation #17.** The BCMA supports the CMA guidelines on appropriate relationships between physicians and the pharmaceutical industry and encourages other health care providers to adopt similar guidelines.

**Recommendation #18.** The BC Ministry of Health, in conjunction with the BCMA and other health professional organizations, including but not limited to the College of Registered Nurses of British Columbia, the College of Pharmacists of British Columbia, the Canadian Association of Chain Drug Stores, and the College of Physicians & Surgeons of British Columbia, should develop and provide accurate, unbiased prescription drug information to patients.

### Information Technology

**Recommendation #19.** The BC Ministry of Health should provide adequate start-up and ongoing funding for physicians to use e-prescribing systems as part of BC's e-health strategy and in support of the Physician Information Technology Office (PITO). The BC government must enable all physicians to have access to PharmaNet at no direct cost to physicians.

### Professional Roles in Prescribing

**Recommendation #20.** The right to prescribe medications independently for medical conditions must be reserved for qualified practitioners who are adequately trained to take a medical history, perform a physical examination, order and interpret appropriate investigations, and arrive at a working diagnosis.

**Recommendation #21.** The BCMA endorses a role for pharmacists to independently renew prescriptions on a short-term basis (maximum 30 days) under defined circumstances when a renewal cannot be readily obtained from the patient's physician. The pharmacist must notify the original prescribing physician and/or regular family physician of the prescription renewal, in writing, as soon as reasonably possible.

**Recommendation #22.** Delegated professional prescribing is acceptable provided that:

- it is part of a multidisciplinary practice (i.e., takes place in the physician's office or as part of a virtual team), and

- the multidisciplinary practice is led by a clinical team leader with ultimate responsibility for patient care and who is the best-trained generalist (in the majority of instances, this would be the GP).

### **National Pharmaceuticals Strategy**

**Recommendation #23.** The National Pharmaceuticals Strategy Ministerial Task Force must honour its 2004 commitment to include meaningful physician input in the development of its policies and recommendations.

**Recommendation #24.** The National Pharmaceuticals Strategy Ministerial Task Force must expediently develop positions on the remaining four focus areas: physician prescribing behaviour and optimal drug therapy; e-prescribing; generic drugs; and improving analytic capability.

# Introduction

Physicians, as the primary prescribers of prescription drugs, control access to the most common treatment modality in medicine. This role has brought attention from many quarters: drug manufacturers who work to persuade physicians to prescribe their product, patients who demand from their physicians access to the latest medicines, and governments that wish to control growing public expenditures on drugs.

To date, BC's physicians have not formally commented on BC prescription drug policy and the management of the public drug benefit plans beyond relatively narrow issues of reimbursement and coverage decisions.

Why should physicians involve themselves now? One reason is the growth of prescription drug expenditures. Prescription drugs are the second largest component of the Canadian health care system after hospital expenditures. In some cases, spending on prescription drugs is a wise investment; in others, it is not cost-effective. Growing drug budgets will affect the rest of the health care system and, by necessity, the practice of medicine.

Another reason for increased physician involvement is the role that physicians can play in the evolving debates on prescription drug policy. In contrast to other stakeholders – pharmacists, prescription drug manufacturers, retailers, and governments themselves – physicians have no direct financial interest in pharmaceutical policy. It is true that some doctors benefit from the promotional activities of prescription drug manufacturers (something we argue should be significantly curtailed). But for the vast majority of physicians, changes in prescription drug policies have no direct effect on their incomes. Physicians are uniquely able to offer an objective perspective on these policy questions, one that derives from their role as advocates for patients.

This report addresses seven areas: prescription drug expenditures, lessons from abroad, BC's PharmaCare program, the promotion of prescription drugs (to both doctors and patients), patient safety and information technology, professional roles in prescribing, and the National Pharmaceuticals Strategy.

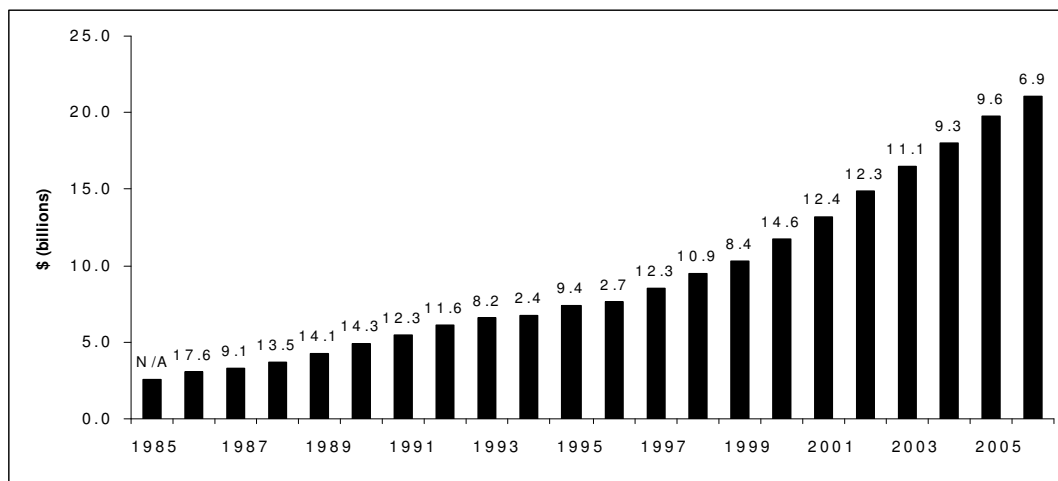
# I. Prescription Drug Expenditures

Concern over prescription drug policy in Canada is fuelled primarily by the growth in expenditures. Here we explore the nature of this growth, both its magnitude and its causes, across Canada and specifically in British Columbia.

## Prescription Drug Spending in Canada <sup>2</sup>

Prescription drugs account for nearly 84% of all drug spending in Canada, which itself is the second largest share of expenditures in the Canadian health care system after hospital expenditures (Canadian Institute for Health Information 2007).<sup>3</sup> The magnitude of this growth – \$2 billion per year – is enough to displace spending in other essential areas of health care. As one health policy analyst notes, “Freezing Canada’s prescription drug spending...for just one year would free up enough money to hire 8,000 new doctors or 20,000 new nurses” (Munro 2006).

**Figure 1: Prescription Drug Expenditures, Canada 1985 – 2006 \***



Source: CIHI (2007). *Drug Expenditure in Canada 1985-2006. National Health Expenditure Database. Ottawa, CIHI: 123.* Figures atop bars show percent change in expenditures from previous year. Data for 2005 and 2006 are forecasted.

<sup>2</sup> Data in this section come from the Canadian Institute for Health Information (CIHI). Other data sources, including IMS data, have been used in the literature to report drug class-specific expenditure information. Because they do not, therefore, provide an overview of Canadian and BC prescription drug spending, they have not been included in this analysis. Because CIHI data rely, in part, on provincial reports, estimates of prescription drug expenditures may include some non-prescription drug expenditures routinely covered by certain provincial drug plans (e.g., diabetes test strips). Further, as CIHI data reflect the final costs of drugs to Canadian consumers, the estimated cost of prescribed medicines could be reduced if costs for retail distribution (e.g., dispensing fees) and all non-prescription drug expenditures were removed from the total. Rx&D estimates that doing so would show that prescribed medicines account for only 8% of all health expenditures in Canada (Rx&D Analysis of data published by CIHI National Health Expenditure Trends 1975 – 2004).

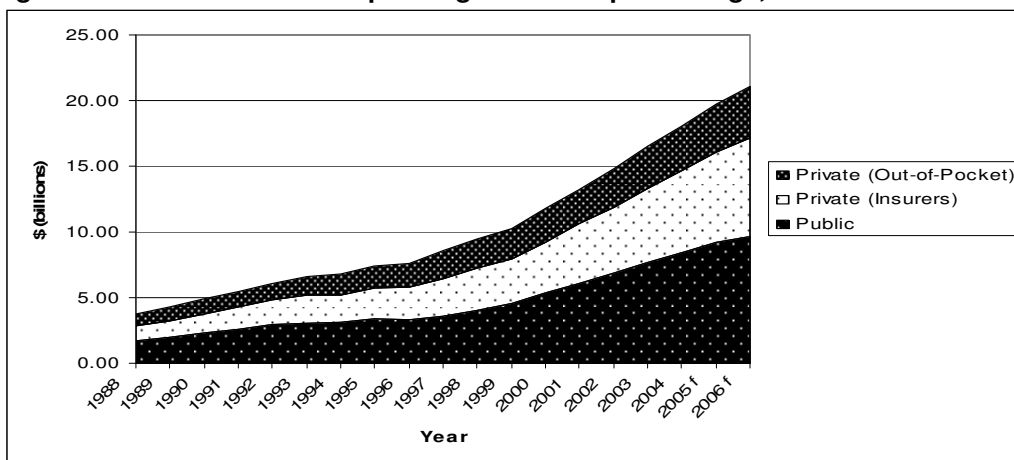
<sup>3</sup> The Canadian Institute for Health Information (CIHI) data on prescription drug expenditures come from the National Health Expenditure Database (NHEX). This database is created by CIHI, using information from public and private data sources. “Public” expenditures include any spending by provincial governments, the federal government, Workers’ Compensation Boards, and the Quebec Drug Insurance fund. Data on “private” drug expenditures come from not-for-profit insurance companies, the Canadian Life and Health Insurance Association, and Statistics Canada data on out-of-pocket drug spending. The total amount paid for any prescription drug can be a combination of contributions from these public and private sources. CIHI’s measures of prescription drug expenditures are based on the final costs to Canadian consumers and include dispensing fees, mark-ups, and taxes for medicines requiring a prescription. Unless otherwise noted, data reported here are for outpatient care only. Drug expenditures for hospitals and residential care facilities are considered in NHEX as institutional expenses. See section below on “Prescription Drug Expenditures in Hospitals”.

A closer look at these figures reveals rapid, sustained growth over the past two decades (Figure 1). Spending on prescription drugs has grown from \$3.0 billion in 1986 to \$21.1 billion in 2006, outpacing growth in the health care system overall (10.6% versus 6.5% per year since 1985) and in the consumer price index (2.8% per year since 1985, Canadian Institute for Health Information 2007). Only in five of the last 20 years did the increase in prescription drug spending fall below 9% per year, and between 2001-2006 annual growth averaged nearly 10% per year. Notably, 2006 marked a slowing of prescription drug expenditure growth, with spending at only 6.9% more than in 2005. The reasons for this may emerge over the next few years, as it becomes clearer whether 2006 represents the beginning of a new trend or an anomalous year.

As the portion of total prescription drug spending paid for by governments has remained fairly constant (in 2006, the public sector financed 46% of prescribed drug expenditure, up 2% from 1985), governments' drug bills have grown in tandem with those of the private sector (Figure 2). Since 1986, the public sector's average annual increase in spending on prescription drugs has been 10.9% per year, slightly more than the 10.4% average for the private sector.

Other measures of prescription drug expenditures reflect the overall growth trend. For example, prescription drugs have grown steadily as a portion of total drug expenditures.<sup>4</sup> In 1985, prescription drugs made up slightly more than one-third of the total, but by 2006 they accounted for more than 83%. Similarly, per capita spending on prescription drugs has grown substantially, reaching \$648 in 2006, more than double the amount in 1998 (\$314).

**Figure 2: Public and Private Spending on Prescription Drugs, Canada 1988 – 2006**<sup>5</sup>



Source: CIHI (2007). *Drug Expenditure in Canada 1985-2006*. National Health Expenditure Database. Ottawa, CIHI: 123.

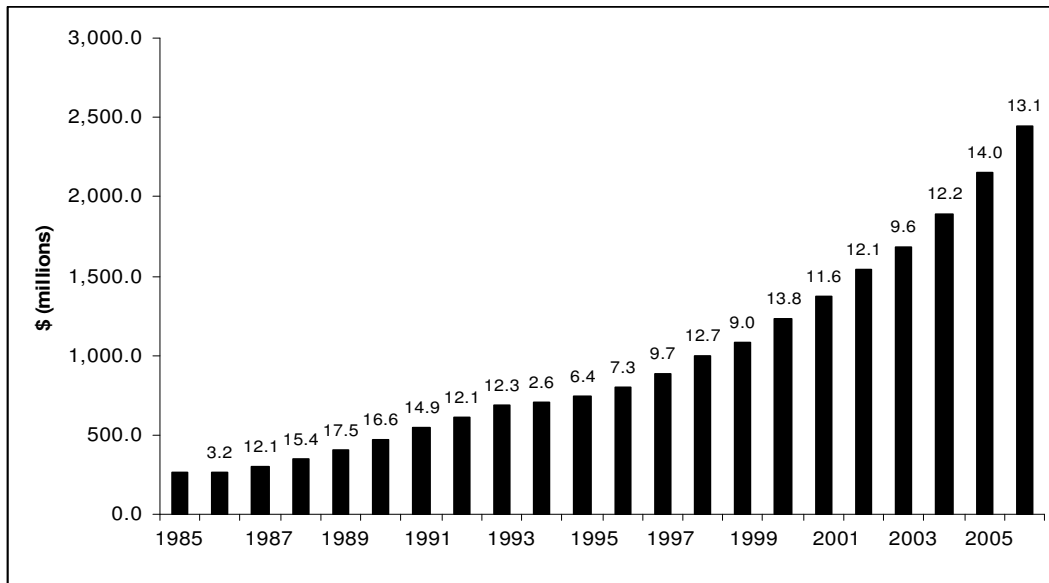
<sup>4</sup> Total drug expenditures includes prescription (i.e., prescribed) and non-prescription drugs. CIHI defines prescribed drugs as “a substance considered to be a drug under the Food and Drugs Act, and which is sold for human use as the result of a prescription from a health professional.” Non-prescribed drugs include “over-the-counter drugs (e.g., cold remedies, cough remedies, and headache remedies) and personal health supplies (e.g., anti-perspirants, dental floss, and disposable diabetic syringes).” CIHI acknowledges as a limitation of its data that “some over-the-counter drugs and personal health supplies that are covered under some drug benefit plans may be counted as prescribed drug expenditure.

<sup>5</sup> Data on private out-of-pocket and private insurer expenditures prior to 1988 are not available. “Private (Out-of-Pocket)” expenditures are those expenditures paid by patients. “Private (Insurers)” expenditures are paid by third-party, non-public insurers. “Public” expenditures include any spending by provincial governments, the federal government, Workers Compensation Boards, and the Quebec Drug Insurance Fund.

### Prescription Drug Expenditures in British Columbia

Similar to the national trends, prescription drug expenditures in British Columbia have also increased substantially (Figure 3), reaching \$2.4 billion in 2006 compared to just over \$1.2 billion in 2000 – a 100% increase. Growth in British Columbia has been faster than the Canadian average. Since 1986, the average annual percent increase in British Columbia has been 11.3% (versus 10.6% nationally). Over the last five years, average annual growth reached 12.2% in British Columbia (versus 9.8% nationally).

**Figure 3: Prescription Drug Expenditures, British Columbia 1985 – 2006 \***



Source: CIHI (2007). *Drug Expenditure in Canada 1985-2006. National Health Expenditure Database. Ottawa, CIHI: 123.* Figures atop bars show percent change in expenditures from previous year. Data for 2005 and 2006 are forecasted.

Funding for prescription drugs in British Columbia has shifted from government toward the private sector. The proportion of prescription drug expenditure funded by the public sector<sup>6</sup> fell from 53% (\$137.7 million) in 1988 to 42% (\$1.024 billion) in 2006. Likewise, the proportion of spending by the private sector increased from 47% (\$121.1 million) to 58% (\$1.42 billion) in 2006 (Canadian Institute for Health Information 2006).

Per capita, British Columbia spends less than the Canadian average on prescription drugs: \$567 versus \$648 per person per year in 2006. As total prescription drug expenditures rise, Canadian patients are paying more out of pocket for their drugs: \$120 in 2006 compared to \$84 in 2001 – a 43% increase over only five years (Canadian Institute for Health Information 2006).

<sup>6</sup> "Public sector" includes funding from the provincial government, federal programs, and the Workers' Compensation Board.



## Prescription Drug Expenditures in Hospitals

Expenditures for hospital drugs are also increasing. In Canada, drugs in hospitals are covered as part of hospital treatment under the Canada Health Act (Jacobzone 2000). In 2003, hospital drug expenditure in Canada was over \$1.5 billion, accounting for 3.9% of total hospital expenditure; British Columbia's share was 4.7%, at \$211 million. Among the provinces, the average hospital drug expenditures per inpatient day were \$60 in 2005, an increase of 8.3% from 2002. British Columbia's average was higher at \$76 in 2005, an increase of 6.2% from 2002 (Canadian Institute for Health Information 2006).

## Factors Affecting the Growth in Prescription Drug Expenditures

There are many causes for the rise in prescription drug expenditures, although researchers have identified the most significant (Morgan 2005) as being:

- **Volume effects** relate to rate and breadth of drug therapy. It is the change in the absolute volume of prescription drug therapy that a population receives (e.g., per capita volume of prescriptions, average size of the prescriptions).
- **Therapeutic choices** influence the cost of therapy through the type or form of drug per course of treatment (e.g., changes in the selection of drug types within a drug class or within therapeutic categories).
- **Price effects** influence the cost of therapy received by a population independent of the quantity or type of drug used (e.g., changes in drug prices, change in price paid due to use of generics).

Morgan analyzes the effects of these cost drivers in British Columbia and Canada (Table 1).

**Table 1**  
**Magnitude and Determinants of Change in Per Capita Expenditure<sup>7</sup> on Oral Solid Prescription Drugs in Canada and British Columbia, 1998 – 2004 \***

| Determinants                    | Canada | British Columbia |
|---------------------------------|--------|------------------|
| Volume effects                  | 8.4%   | 8.6%             |
| Therapeutic choices             | 3.9%   | 3.3%             |
| Price effects                   | - 0.3% | - 0.6%           |
| Total: average annual growth ** | 11.9%  | 11.4%            |

\* Adapted from Morgan, S. (2005). Drug Expenditure Trends in the Canadian Provinces: Magnitude and Causes from 1998 to 2004. University of British Columbia. Vancouver.

\*\* Figures do not total due to rounding.

Both Canada and British Columbia witnessed average annual growth of over 11% from 1998-2004. Most of this growth in BC (8.6% of the 11.4% average annual growth, or 75% of the total) was due to volume effects. Therapeutic choices and the selection of drugs from within that class (e.g., choice of a particular statin) accounted for the remaining growth. Contrary to popular belief, increases in manufacturers' prices

<sup>7</sup> Expenditure data include drug costs (public and private), retail markups, and pharmacists' fees. Data only include drug expenditures in retail pharmacies.

did not drive the cost increase. In fact, price effects were *negative* over the period under study. Morgan attributes this to the increased use of generic drugs, which reduced total expenditures. The aging of the population is likely responsible for less than 2% to the annual rate of expenditure growth for prescription drugs (Morgan 2005). While it is true that seniors use a proportionally greater share of prescription drugs than their younger counterparts, the growth in the population over the age of 65 has been too low to account for all but a small fraction of the total increase.

### “Category 3” Drugs

The Patented Medicine Prices Review Board (PMPRB), the federal body responsible for drug prices, classifies a new drug or dosage form of an existing drug that provides moderate, little, or no improvement over existing drugs as a “Category 3” drug. Between 1990 and 2003, the PMPRB classified only 68 (5.9%) of 1,147 patented drugs as breakthrough, or “Category 2” drugs<sup>8</sup> (Patented Medicine Prices Review Board 2004). In British Columbia, 80% of the increase in prescription drug expenditure between 1996 and 2003 was explained by the use of “Category 3” drugs (Morgan, Bassett et al. 2005).

**Table 2: British Columbia’s Use of Prescription Drugs and Expenditure by Product Classification, 1996-2003\***

|  | 1996 | 2003 |
|--|------|------|
| Use of Prescription Drugs accounted for by         |      |      |
| – Category 3 drugs                                 | 24%  | 44%  |
| – Breakthrough drugs                               | 1%   | 2%   |
| – Brand and generic drugs introduced before 1990** | 75%  | 54%  |
| Expenditure as accounted for by                    |      |      |
| – Category 3 drugs                                 | 41%  | 63%  |
| – Breakthrough drugs                               | 6%   | 10%  |
| – Brand and generic drugs introduced before 1990** | 53%  | 27%  |

\* Adapted from Morgan, S. et al. (2005). Breakthrough drugs and growth in expenditure on prescription drugs in Canada. *BMJ* 331 (7520):815-19.

\*\* PMPRB’s breakthrough assessments are not available for drugs first marketed before 1990.

Table 2 illustrates that Category 3 drugs are a leading cost driver in prescription drug expenditures. The rising cost of using Category 3 drugs at prices exceeding those of time-tested competitors deserves careful scrutiny. For example, \$350 million (26% of total expenditure on prescription drugs) would have been saved in British Columbia if half of the Category 3 drugs consumed in 2003 were priced to compete with older alternatives (Morgan, Bassett et al. 2005). Better approaches to drug pricing are needed so that Category 3 drugs are priced competitively with generics or earlier versions.

<sup>8</sup> A “breakthrough” drug is defined as the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drug products.

## Conclusion

Growth in prescription drug expenditures *per se* is not necessarily problematic. 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 (Goldfarb, Weston et al. 2004). Nonetheless, within finite government budgets, increased spending in one area may also offset expenditures elsewhere in the health care system. The challenge for health care policymakers is to determine if and when the investment in prescription drugs – particularly in light of continued growth – is worth the expected return.

## II. Lessons from Abroad

Canada is not alone in its experience with growing prescription drug expenditures. Spending on pharmaceuticals across OECD countries has increased by an average of 32% in real terms since 1998, reaching more than US \$450 billion in 2003 (Organisation for Economic Co-operation and Development 2005). Drug spending has taken an increasing share of health costs in many OECD countries and its growth has outpaced total health expenditures in most, making it target for cost containment efforts. In response, many countries have applied various policies to manage their drug budgets, including listing systems and formularies; patient co-payments; policies influencing prescribing behaviour (e.g., auditing, clinical guidelines, prescribing budgets); reference drug pricing; and direct price controls. In this section, we limit our analysis to four OECD countries with pharmaceutical policies comparable to those in BC.

### Germany

The pharmaceutical industry in Germany is among the largest in the world and contributes significantly to the national economy. Prescription drug prices are determined by manufacturers, largely without negotiations involving the payor. Cost containment has concentrated on the social health (public) insurance market, which accounts for 70% of total pharmaceutical expenditures. From 1998 to 2003, Germany's total pharmaceutical expenditure grew an average of 3.5% per year, much less than the OECD's average of 6.1%. Spending on pharmaceuticals in Germany in 2003 was 14.6% of total health expenditure, well below the OECD average of 17.7%. Policies in Germany to control drug spending include reference-based drug pricing (RDP), generic substitution, global budget caps, prescribing protocols and physician drug budgets, a bonus-rating plan, and prescription feedback/education (Busse 2005).

### New Zealand

In 1993, New Zealand established an independent crown agency, Pharmac, to manage the public drug benefits scheme. Initially, Pharmac was responsible for managing the public drug expenditures in community health care but it has since expanded its role into hospital pharmaceutical purchasing and demand management (Davis 2004). Pharmac is advised by a Pharmacology and Therapeutics Advisory Committee (PTAC), comprised of medical specialists and general practitioners. Pharmac also uses cost-utility assessments as part of its decision criteria when managing drug subsidies.

In contrast to every other OECD country, New Zealand has, through Pharmac, reduced the growth of public prescription drug expenditures to less than 3.0% per year since 1993, despite increased volume in prescribed drugs. Pharmac attributes this to the use of strictly capped budgets, reference drug pricing, tendering, and cross-product negotiations (Pharmac 2003). As of 2005, these policies led to savings of NZ\$894 million in the public drug budget (Pharmac 2005).

### Australia

Australia controls the supply and costs of drugs through the Pharmaceutical Benefits Scheme (PBS), which has been in operation since 1948. All drugs listed on the PBS are subsidized, and nearly three quarters of prescriptions from community pharmacies are covered under PBS. Hospital medicines (both

inpatient and outpatient) are funded by the states under a federal/state cost sharing arrangement with public hospitals (Hilless 2001).

Pharmaceuticals go through an exhaustive assessment process before listing on the PBS. The Pharmaceutical Benefits Advisory Committee (PBAC), a statutory committee established under the National Health Act of 1953, is charged with making recommendations to the Minister of Health and Aged Care about which drugs should be included in the PBS. The Committee's members include family and specialist medical practitioners, pharmacists, health economists, and a consumer representative. Because PBAC's decisions have a direct budgetary impact, cost of a new drug is part of the committee's deliberations. Since 1993, the PBAC has based its recommendations on both clinical- and cost-effectiveness, including comparisons to already listed products for the same or similar indications (Henry, Hill et al. 2005).

In 2004/05, PBS expenditure amounted to \$6 billion. The government's drug budget is not capped and has been increasing at an annual rate greater than the OECD average. Although PBS is the smallest component of public health expenditure at 16%, it has had the highest average annual rate of growth from 1994-2004 at 12.7% per year, compared to 6.2% per year for public hospital services and 4.9% per year for medical services (Harvey 2005). Measures to control PBS expenditures have included negotiated prices, RDP, increased generic drug use, price-volume contracts, patient co-payments, financial incentives to influence prescribing behaviour, and a specialty authority process.

### **Netherlands**

As elsewhere, the Netherlands has experienced a greater rise in pharmaceutical expenditure than in overall health care costs, but its growth is lower than most countries (excluding New Zealand). The average annual growth of pharmaceutical expenditures was approximately 5.0% from 1998 to 2003 in comparison to the OECD average of 6.1% (OECD, 2005). In 2003, the Netherlands' pharmaceutical expenditure as a percentage of total health expenditures at 11.4% was much lower than the OECD average (17.8%). The steady fall in the price of older drugs and a growth in generic prescribing have kept drug expenditures in check over the past decade (Mossialos, 2005).

The drug approval and reimbursement system in the Netherlands is highly centralized: the government employs a reimbursement system for pharmaceuticals covered by public insurance in the public sickness fund package, and stimulates market forces and competitive pricing in order to keep prices low as possible. The health minister has the authority to decide whether a new pharmaceutical is to be allowed into the basic public health insurance package and can remove obsolete pharmaceuticals from coverage (Exter, 2004). Since 2005, pharmaceutical companies have had to provide proof of relative efficacy (e.g., cost-effectiveness) of their product when requesting reimbursement for new drugs. Cost containment policies include RDP, price regulation, patient co-payments, generic substitution and prescribing, prescribing guidelines, and physician education programs.

### **Lessons for BC**

Each country has important lessons for BC as policymakers address the challenge of rising prescription drug costs. The German experience highlights that government's willingness for, and the futility of,

restrictions on physician prescribing behaviour without support from the medical profession. The transfer of financial risk for prescription drug costs to physicians through drug budgets left patients responsible for out-of-pocket payments and alienated the profession. While negotiated targets may be an improvement over physician drug budgets, the bonus-rating plan may compromise clinical judgement.

Because of its unique achievement among OECD countries of containing prescription drug expenditures, New Zealand serves as an interesting case study for other public prescription drug plans. Some of its policies reaffirm BC's experience, namely the success of RDP in shifting physician prescribing patterns to less expensive (but ideally, equally clinically effective) drugs. Other policies are worthy of study in BC. For example, New Zealand-style attempts to secure better prices for covered drugs by acting as a monopsony power and directly negotiating with manufacturers may be one way for PharmaCare to address the BC Auditor General's concerns that such efforts are lacking in the province (Auditor General of British Columbia 2006). Indeed, PharmaCare already has had some experience successfully negotiating with drug manufacturers to secure better prices. In 2003, PharmaCare entered into a cost-sharing arrangement with Schering Canada to provide Pegatron, a new drug for patients with chronic hepatitis C, which resulted in a price reduction of 33%, bringing the cost in line with that of the closest therapy alternative.

**Recommendation #1. *PharmaCare should negotiate directly with wholesalers and drug manufacturers to secure the best prices for PharmaCare-insured drugs.***

Caution should be taken, however, in following New Zealand's example of a capped budget for prescription drug expenditures. Even with a special authority mechanism in place, having a budget cap means that some special authorities are based purely on fiscal, not clinical, considerations. Moreover, any dollar figure set for the budget cap is inherently arbitrary. Rising prescription drug costs should be managed through clinically sensitive mechanisms to encourage cost-effective prescribing, not through something as blunt as a budget cap. The decision-making process behind PharmaCare's cost-containment policies should involve the medical profession.

**Recommendation #2. *PharmaCare should involve practising physicians in the decision-making process behind policies to control prescription drug expenditures.***

**Recommendation #3. *PharmaCare should not implement a strict budget cap on public drug expenditures.***

Finally, Australia and the Netherlands demonstrate the difficulty of achieving drug cost containment even with implementation of policies that have been successful elsewhere. The most notable feature of Australia's PBS – the cost-effectiveness requirements for subsidy listing – have not led to a meaningful reduction in prescription drug spending, and the high percentage of younger patients unable to obtain a prescription due to the cost of drugs raises concerns about the equity of the system. In the Netherlands, significant decreases in drug expenditures did not result from the introduction of RDP, but from direct price controls.

Common to all four countries reviewed is some form of physician education program and the expansion of transparent, objective education to physicians. Similar efforts in BC, perhaps through the recently created Education for Quality Improvement in Patient Care (EQIP) program, could be of value. EQIP was established in 2004 as a joint effort of the BC government and the BCMA to explore, evaluate, and implement appropriate initiatives aimed at optimizing effective prescribing. EQIP members include representatives from PharmaCare, BCMA, UBC, University of Victoria, the College of Physicians and Surgeons of BC, and the College of Pharmacists of BC. The goal of EQIP is to provide physicians with prescribing tools that enable evidence-based savings which will be reinvested into patient care. Such tools may include concise prescribing advice, drug price charts, and medical chart inserts that serve as patient handouts. This first intervention will focus on improving the prescribing of first-line thiazides diuretics for patients with few co-morbid conditions. Although it is too early to evaluate the impact of EQIP, research from BC suggests that providing physicians with targeted education, prescribing feedback, and appropriate incentives to optimize prescribing could result in sustained savings of over \$10 million per year (EQIP Working Group 2006). The BCMA believes that programs like EQIP, which operate as partnerships of the Ministry of Health, the BCMA, and other relevant stakeholder organizations, have significant potential to provide physicians with unbiased education on the efficacy, cost, and cost-effectiveness of prescription drugs.

**Recommendation #4. *The BCMA supports the provision of educational materials on the efficacy and cost of prescription medications to BC physicians. This must be done on a regular basis through a continually funded, collaborative organization such as the program for Education for Quality Improvement in Patient Care (EQIP) with representation from the BCMA, the Ministry of Health, and other relevant stakeholder organizations.***

### III. British Columbia's PharmaCare Program

This section reviews the formulary approval process for prescription drugs in Canada and more specifically in BC, followed by a discussion of the PharmaCare formulary and cost-saving mechanisms.

#### Formularies

Formularies are lists of drugs for which private or public insurance will pay (Levinson and Laupacis 2006). Not all drugs listed on a formulary are eligible for full reimbursement, nor are all non-listed drugs necessarily excluded from any reimbursement. Formularies vary in their approval process, co-payments, appeals process, patient eligibility criteria, and reimbursement levels. Formularies also vary by context. In BC, hospitals have their own formularies for inpatient care, while PharmaCare manages a province-wide formulary for out-patient care. Nonetheless, all formularies are an attempt by drug plans to balance costs versus care: for any two drugs of equal effectiveness, the one with the lower price is usually the one covered.

As prescription drug costs have increased, formularies have become tools – and targets – for health care stakeholders. Manufacturers need formulary approval for their drugs in order to reach a sizable market of patients. For payers, formulary approvals and denials translate into direct costs (or savings) to drug plans. Finally, once a drug is listed (or not), physicians deal with the consequences, either offering their patients the formulary-approved drug or helping them find alternatives.

PharmaCare's decision to restrict reimbursement has little consequence when prices are low and patients can afford to shoulder some or all of the drug's costs. But when a drug's price is high, these decisions become paramount. For all practical purposes, an unaffordable drug prescribed by a physician is the same as a drug never prescribed at all. In both cases, the patient does not – indeed, cannot – obtain the drug. The advent of some very high-priced drugs for chronic conditions, moreover, means that affordability may not be a problem for just the poor.

PharmaCare is, nonetheless, a *public* program. It is a steward of public dollars with a fiduciary duty to maximize value and manage funds responsibly. Seen in this light, a formulary can be a tool to determine how best to spend a limited, albeit growing, budget. The policy debate is, therefore, not whether patient X needs drug Y (a physician can determine that), but whether the money spent on patient X's drug would be better spent elsewhere, and if so, how and by whom should that decision be made?

Debates over the proper role of the formulary remain. Poorly constructed formularies can lead to undesirable clinical practice such as when physicians feel compelled to prescribe a less effective drug because it will be reimbursed. This can also lead to poor health outcomes (Levinson and Laupacis 2006). Moreover, the impact of formularies extends well beyond the individual drug plan. Provincial formularies may be used as a basis for coverage in private plans (Milne 2001), so a drug not covered by PharmaCare may also be excluded from private drug plans. Increasing numbers of high-priced pharmaceuticals, as well as increases in drug utilization for conventional drug therapies, will continue to place pressure on PharmaCare to restrict formularies.



Finally, the lack of integration between hospital and outpatient drug formularies should be addressed. Hospital formularies are managed by hospitals and are 100% publicly covered. In contrast, PharmaCare's formulary is limited to outpatient care and drug subsidies are income-dependent. Failure to integrate hospital and outpatient formularies not only can compromise patient care if prescriptions change upon hospital discharge, or if patients receive new prescriptions starting at the moment of discharge (Stuffken and Egberts 2004), but also raises equity concerns as when patients receive expensive drugs that are fully reimbursed in the hospital but then only partially covered in the out-patient setting.

**Recommendation #5. *The BC Ministry of Health should improve the integration and harmonization of hospital and outpatient formularies.***

### Drug Coverage Decisions

The BC Ministry of Health has conducted a review of the formulary approval process for PharmaCare and released a final report (Ali 2005). It remains unclear to what extent the report's recommendations have been implemented. The BCMA has some concerns over the transparency of the formulary approval process described therein:

- **Binding final PharmaCare decisions.** All final coverage decisions rest with PharmaCare, albeit with significant input from other entities (e.g., Canadian Expert Drug Advisory Committee, Drug Benefits Committee, Therapeutics Initiative). It is unclear, however, how the final coverage decision is made within PharmaCare and how this decision will remain binding and not subject to review at senior political levels. The BCMA proposes that PharmaCare Review Implementation (PRI) provide greater detail of the internal PharmaCare decision-making process and take measures to protect these decisions from review at senior political levels.
- **Mechanism for drug review.** It is unclear from the final report what mechanism exists for drugs to be reviewed by PharmaCare at the request of specific user groups, either professional or non-professional. The BCMA proposes that this process be outlined. In addition, the final report makes reference to reviews of "line extensions" and "generics" but not to a review of the existing drugs for current suitability or replacement by superior (new) therapeutic choices. The BCMA proposes that a mechanism for reviewing existing drugs be adopted.
- **Listing decisions.** The final report is focused on the "manufacturer relations" aspect of formulary management. However, the equally important area of listing decisions is not addressed, although it is the core of formulary management. Several questions remain:
  - How does a drug move from limited coverage to become an ordinary benefit as knowledge of the drug or its costs change?
  - How does a drug migrate to limited coverage from ordinary benefit should it become apparent that there are better drugs for general use?
  - How are limited coverage and partial coverage decisions made?

The process outlined does not appear to make listing decisions in the above-mentioned situations more transparent. The BCMA proposes that PharmaCare increase transparency by clearly defining processes by which these decisions are made.

- **CEDAC “no” decision.** The report notes that Canadian Expert Drug Advisory Committee “no” decisions will not go to the Drug Benefit Committee (DBC). Not sending these decisions to the DBC will eliminate the possibility of monitoring CEDAC’s “no” decisions or providing a different response. The BCMA proposes that this stipulation be abandoned.
- **Additional submission of proposals.** The final report indicates that when the DBC recommends “Yes with conditions,” the manufacturer may submit additional proposals. It is unclear whether there is any additional expert review or if this is purely a monetary consideration. The BCMA proposes that PharmaCare clarify this issue.

**Recommendation #6. PharmaCare should ensure the transparency of drug coverage decisions, as specified in the 2005 PharmaCare Review Implementation Final Report. These decisions should be binding on the BC government.**

**Recommendation #7. All Canadian Expert Drug Advisory Committee (CEDAC) decisions should be brought forward to the BC PharmaCare Drug Benefit Committee for review.**

### **Assessing Clinical and Cost Effectiveness of Pharmaceuticals**

Prior to the creation of the Common Drug Review in 2003, the Therapeutics Initiative (TI) provided a therapeutic assessment of the drugs submitted for approval by the pharmaceutical companies. Another organization, the Pharmaco-economics Initiative (PI), looked at the drug’s cost-effectiveness and pharmaco-economic advantage (e.g., whether a new drug would reduce a patient’s days lost at work, reduce the need for hospitalization or other drugs, or improve the patient’s quality of life); however, the PI has been disbanded. Currently, pharmaco-economic analyses of new drugs are carried out at the national level by the Common Drug Review, which PharmaCare uses in its assessment of drug inclusion in its formulary. However, PharmaCare does not have a process in place to assess the continuing cost-effectiveness of existing drugs on its formulary, as pointed out in the Auditor General’s report on PharmaCare (Auditor General of British Columbia 2006). Old drugs were added to the formulary before rigorous reviews were carried out, so there is a risk that some may have outlived their usefulness and should not be available for prescribing. The Auditor General recommends that PharmaCare consider adopting a fast-track review process and internal procedures for systematically assessing the cost effectiveness of existing drugs in the formulary.

**Recommendation #8. PharmaCare should, no later than December 31, 2007, implement a process for regularly assessing the cost-effectiveness of existing drugs in the formulary as recommended in the BC Auditor General’s 2006 report on managing PharmaCare.**

## The Therapeutics Initiative

BC physicians are ambivalent about the TI. According to the BCMA's 2006 Prescription Drug Policy survey, 26% of physicians do not trust it as an independent source of information. Among these physicians, the most common criticisms of the TI included:

- The TI is too closely tied to the payer (Ministry of Health) to provide objective information (80%).
- The TI's decision-making process is not transparent (56%).
- The TI's appointment process of members is not transparent (53%).

A fair process requires a clear, complete, and public statement about the rationales that play a part in decision making. Transparency must extend to the criteria for the selection of experts and other participants in the TI process. The TI's budget and financial arrangements must be in the public domain in order to answer questions about independence and bias. An independent review of the arms-length nature of the TI would add integrity to their drug assessment process.

**Recommendation #9. *There should be an independent review of the membership appointments, decision-making processes, and the arms-length nature of the BC Therapeutics Initiative (TI), intended to improve transparency and objectivity, to be completed no later than December 31, 2007.***

## PharmaCare Policies to Control Drug Expenditures

PharmaCare employs a variety of mechanisms to control costs:

- Maximum Days' Supply Policy. For short-term drug prescriptions (e.g., antibiotics, sedatives, sleeping pills and barbiturates that may become addictive) and first-time prescriptions for maintenance drugs (e.g., medications used for long-term conditions, such as diabetes), PharmaCare coverage is limited to a maximum 30 days supply.
- Trial Prescription Program. The Trial Prescription Program was implemented to encourage the dispensing of a small quantity (10-14 days supply) of expensive medications with known high incidence of side effects to discourage waste when the medication is not well tolerated. Examples of drugs in this category include Accupril, Cardizem, Naproxen, Vasotec, and Zantac.
- Low Cost Alternative. When several drugs contain identical active ingredients, PharmaCare provides coverage only for the lower priced drugs. Patients have the choice of obtaining either the full status low cost alternative(s), which will be fully recognized according to the guidelines of each PharmaCare plan, or the partial status low cost alternative(s) which is eligible for only partial coverage up to the low cost alternative price.
- Special Authority Process. A Special Authority grants full benefit status to a medication that would otherwise be a partial benefit or a limited coverage drug. Special Authorities are granted for a specific drug for an individual patient. In rare cases, however, a Special Authority exemption may be granted to a physician or physician specialty group. These exemptions provide coverage for specific drugs for all the patients of a physician or specialty group.

- Reference-Based Drug Pricing (RDP). Under the RDP, PharmaCare coverage is based on the cost of the reference drug or drugs in a therapeutic category. This is the drug(s) considered to be equally efficacious and the lowest priced in that category. The RDP currently applies to five classes of drugs: Histamine 2 receptor Blockers (H2 Blockers), Non-Steroidal Anti-inflammatory drugs (NSAIDs), Nitrates, Angiotensin Converting Enzyme Inhibitors (ACE inhibitors), and Dihydropyridine Calcium Channel Blockers (Dihydropyridine CCBs).

BC's RDP program is one of the most extensively studied pharmaceutical policy interventions in the world. In a separate review of research on RDP in British Columbia through 2002, Schneeweiss et al. concluded that RDP resulted in moderate to large savings in drug expenditures (Schneeweiss Nov 2002). Grootendorst et al. found that RDP for nitrates used for long-term prophylaxis led to a \$14.9 million reduction in expenditures on nitrates prescribed to senior citizens, with no compensatory increases in expenditures for other anti-anginal drugs (Grootendorst Oct 16, 2001). Schneeweiss et al. found that RDP for ACE inhibitors led to a 29% decline in the use of high-priced cost-shared ACE inhibitors, saving \$6.7 million in pharmaceutical expenditures over the first year of the program (Schneeweiss Mar 19, 2002). In a similar study of the effects of RDP on histamine-2 receptor antagonists (H<sub>2</sub>RAs), Marshall et al. likewise found an increase in use of the reference drug (generic cimetidine) and a decline in the use of other restricted H<sub>2</sub>RAs, which also lead to savings between \$1.8 and \$3.2 million for PharmaCare (Marshall 2002).

Despite the significant cost savings, aspects of RDP have been criticised. The program was poorly implemented, with little consultation with physicians, pharmacists, and patients (Kent 2000). Others question the whole premise of RDP, namely the underlying assumption that all drugs in a class are, in fact, interchangeable – that one ACE-inhibitor is the same as another ACE-inhibitor, despite the lack of randomized comparative trials of drugs within RDP classes (Anis 2002). But perhaps the most serious criticism focused more specifically on limitations of the cost studies. Without an explicit examination of changes in health outcomes attributable to RDP, it remained unclear whether the program's cost savings came at the price of patient well-being. Were patients being shifted from medications that worked for them to ones that were less expensive, but less effective? Did some patients stop taking medications altogether?

Schneeweiss et al. sought to answer these questions by examining medical claims data for patients using ACE-inhibitors before and after the implementation of RDP (Schneeweiss Mar 14, 2002). They compared patients who switched to the reference ACE-inhibitor during the first six months of RDP to patients who received only ACE inhibitors subject to cost sharing (the non-reference drugs). They found that RDP for ACE-inhibitors was not associated with changes in the rates of visits to physicians, hospitalization, admissions to long-term care facilities, or mortality. Similarly, Hazlet found no worsening of health outcomes (emergency room visits, hospitalizations, hospital length of stay, and vital statistics) following the implementation of RDP for histamine2 receptor antagonists (Hazlet 2002). Grootendorst et al. found no evidence of an increase in rates of mortality associated with cardiovascular or renal disorders, or an increase in long-term care admission rates after reference pricing was applied to the nitrates, ACE inhibitors, and calcium channel blockers drug classes. However, the effect of reference pricing on morbidity for these drug classes was not conclusive (Grootendorst Oct 4, 2001).

## BCMA Position

The most important step in Reference-Based Drug Pricing (RDP) is an effective, transparent process for establishing therapeutic equivalence. The BCMA supports, in principle, RDP provided it is clinically focused, fiscally responsible, and patient sensitive. Along with physician education, RDP can be an effective policy because it allows more people to receive effective prescription drugs at a lower cost. However, BC physicians remain concerned over the implementation of RDP in BC, particularly with respect to the potential for negative clinical impacts and limited patient access to necessary medications. For these reasons, BCMA support for RDP in British Columbia is contingent on the following.

- There must be a transparent process for careful evaluation of the therapeutic equivalence of drugs in current and future reference drug categories. This process must be ongoing, include a thorough assessment of the peer-reviewed literature, and be conducted by a working group whose membership includes practising physicians, some of whom should be selected by the BCMA.
- There must be an assessment of the impact on health outcomes of RDP for all drug classes in the BC Reference Drug Pricing Program, both current and future, on a short- and long-term basis.
- Support for RDP from the medical community requires that physicians have an ongoing opportunity to contribute to the development of the program. A working group whose membership includes practising physicians, some of whom should be selected by the BCMA, must be created for examining reference-based drugs in the BC Reference Drug Pricing Program.
- The BCMA has stated, as a matter of principle, that physicians must be appropriately compensated for their professional services. This is consistent with the mission of the BCMA “to promote a social, economic, and political climate in which members can provide the citizens of British Columbia with the highest standard of health care while achieving maximum professional satisfaction and fair economic reward.” To that end, BC physicians must be reimbursed for completion of the special authority forms. While physicians recognize that the special authority process is a necessary component of reference pricing to ensure drug coverage for those patients who react adversely to the reference drug and require another higher priced drug within the therapeutic class, the Government must in turn acknowledge that physicians incur significant administrative work when assessing and completing special authority forms.

**Recommendation #10.** *The BCMA supports, in principle, Reference-Based Drug Pricing (RDP) provided it is clinically focused, fiscally responsible, and patient sensitive. Support for the BC Reference Drug Pricing Program is contingent on the implementation of recommendations 11 – 14 below.*

**Recommendation #11.** *There must be a transparent process for evaluating the therapeutic equivalence of drugs in current and future reference drug categories. This process must be ongoing, include a thorough assessment of the peer-reviewed literature, and be conducted by a working group whose membership includes practising physicians, some of whom should be selected by the BCMA.*

**Recommendation #12.** *There must be an assessment of the impact on health outcomes of RDP for all drug classes in the BC Reference Drug Pricing Program, both current and future, on a short- and long-term basis. This process must show that the application of reference-based drug pricing avoids significant negative clinical outcomes.*

**Recommendation #13.** *A working group whose membership includes practising physicians, some of whom should be selected by the BCMA, must be created for examining additional categories of reference-based drugs in the BC Reference Drug Pricing Program.*

**Recommendation #14.** *Physicians must be appropriately reimbursed for the completion of special authority forms.*

## IV. Promotion of Prescription Drugs

There is a palpable tension between the prescription drug manufacturers and regulators over the proper role of advertising in the industry. On one hand, the legitimate desire of manufacturers – who operate in a market and are accountable to shareholders – is to increase sales and market share. On the other hand, the equally legitimate desire of regulators and others is to curb excessively optimistic claims that could compromise patient safety. This section reviews direct-to-consumer advertising and advertising to physicians for prescription drugs.

### Direct-to-Consumer Advertising (DTCA)

Three types of pharmaceutical advertisements are directed to consumers:

- **Help-seeking (disease-oriented) advertisements** do not mention a specific brand but discuss a condition, and suggest that consumers ask their doctor about an unspecified treatment. No risk information is required.
- **Reminder advertisements** include the drug's brand name, but no health claims about its use. No risk information is required.
- **Full product advertisements** include the drug's brand name, health claims and risk information.

The United States and New Zealand are the only countries that allow DTCA of prescription drugs through help-seeking, reminder, and full product advertisements. In Canada, reminder advertisements and help-seeking advertisements are permitted through policies set by Health Canada and through an amendment to the *Food and Drugs Act*. Full-product advertisements are prohibited. Canadians have been exposed, nonetheless, to full-product advertisements through the US media since 1997.

### Research Evidence on the Effects of DTCA

DTCA is controversial. Opponents claim that DTCA causes physicians to waste valuable time during encounters with patients and encourages the use of expensive and sometimes unnecessary medications. Proponents argue that DTCA increases consumers' awareness and knowledge about available medical treatments, enabling them to detect a possible disease at an earlier stage and become partners with physicians in their own health care (Brekke and Kuhn 2006).

Evidence suggests that DTCA increases patient demand for many prescription drugs – not just those specifically advertised (Gilbody, Wilson et al. 2005). DTCA campaigns can lead to more patient visits, more diagnoses for conditions treated by advertised drugs, and more prescriptions for those drugs (Basara 1996; Mintzes, Barer et al. 2002; Zachry, Shepherd et al. 2002; 't Jong, Stricker et al. 2004). Other studies examining the effect of unbranded disease-oriented advertising campaigns found that DTCA was effective in stimulating brand-specific sales (Basara 1996; 't Jong, Stricker et al. 2004). Also, branded full product advertisements may stimulate sales of similar drugs as well as the specific brand (Zachry, Shepherd et al. 2002).

There is conflicting evidence on whether DTCA influences the appropriateness of physician prescribing behaviour. According to the BCMA 2006 Prescription Drug Policy survey, many physicians have patients

that inquire about prescription medication that they have seen advertised – just under half (47%) of physicians said that, in the previous week, patients have asked about medications that they heard about through advertising. A Vancouver-Sacramento study found that if patients requested an advertised drug, the physician complied and prescribed that drug three-quarters of the time (Mintzes, Barer et al. 2002). A randomized controlled trial of physician responses to patient requests for antidepressants found that patient requests for advertised medicines strongly predict the decision to prescribe, with more than half of the patients who did not need an antidepressant nevertheless receiving a prescription for one if they asked for an advertised brand (Kravitz, Epstein et al. 2005). Brekke and Kuhn, however, have found no empirical evidence to support the argument that patients pressure physicians to prescribe unnecessary medication (Brekke and Kuhn 2006). Similarly, Iizuka and Jun found that DTCA prompts physician visits but has no influence on the physicians' choice among prescription drugs within a therapeutic class (Iizuka 2005).

There are no direct analyses of the effect of DTCA on health (Mintzes 2006). The pharmaceutical industry argues that DTCA acts as an additional source of quality health care information for patients. However, researchers who analysed the content of US magazine drug advertisements from 1989 to 1998 found the educational value to be minimal: 91% of advertisements omitted information about the likelihood of treatment success and 71% failed to mention any other possible treatments (Bell, Wilkes et al. 2000). Another content analysis of a systematic sample of 23 television advertisements found that individual statements of benefits received 30% more time than risk statements (Kaphingst and DeJong 2004).

Advertising does inform the public about a specific subset of treatments. Drugs with the highest advertising spending do not necessarily reflect therapeutic advantage and tend to be expensive drugs for chronic or intermittent long-term use by a large target audience (Mintzes 2006). Off-patent drugs are never advertised to the public even if they are superior in a specific indication (e.g., diuretics for uncomplicated high blood pressure).

### **Recent Policy Recommendations on DTCA**

In 2006, CanWest Media argued to the Ontario Supreme Court that the current ban on direct-to-consumer advertising violates the *Canadian Charter of Rights and Freedoms*. They maintain that the ban not only restricts freedom of expression, but is also ineffective since many Canadians receive full-product advertisements from US media (Canadian Broadcasting Corporation 2006). This view contrasts with a 2004 recommendation from the House of Commons Standing Committee on Health that Health Canada immediately enforce the current prohibition of all industry-sponsored advertisements on prescription drugs to the public and to ensure the provision of independent, unbiased and publicly financed information on prescriptions to Canadians (Standing Committee on Health 2004). The recent Health Council of Canada report on DTCA fully supported these recommendations, and also recommended: (1) better enforcement of regulations governing physician-oriented drug promotion, and (2) a ban on reminder advertisements (Mintzes 2006). Likewise, the CMA opposes direct-to-consumer prescription advertising in Canada and supports the provision of objective, evidence-based, reliable plain-language information for the public about prescription drugs (Canadian Medical Association 2003). In the BCMA 2006 Prescription Drug Policy Survey, four out of five BC physicians reported that they are against DTCA in Canada. The BCMA supports a complete ban on all DTCA for prescription drugs in Canada.



**Recommendation #15. *The prohibition on direct-to-consumer advertising for prescription drugs should continue and be enforced in Canada.***

### Physician Detailing

In 2000, promotion to physicians accounted for 85% of promotional spending in the US (Rosenthal, Berndt et al. 2002). According to the BCMA 2006 Prescription Drug Policy survey, two out of three physicians (67%) report visits from drug company sales representatives at least once per month, with 42% of GPs visited several times per week.

In Canada, drug promotion to health professionals is weakly regulated, with few incentives to comply with regulatory requirements, and low risk for prosecution when violated. Prescription drug advertisements targeting health professionals are subject to voluntary pre-screening by the Pharmaceutical Advertising Advisory Board (PAAB). The PAAB is a semi-autonomous organization with representation from the pharmaceutical and advertising industries, medical publishers, health professional associations, and consumers (Health Canada 2003). Rx&D, an association representing Canada's Research-Based Pharmaceutical Companies, has a detailed guideline entitled *Code of Marketing Practices* which describes principles that member companies must follow with respect to marketing practices, continuing health education programs, relationships with physicians, and other activities. However, adherence to the *Code* is voluntary, and penalties are minimal. The extent to which violations are reported is not known (Health Canada 2003). To ensure adequate oversight, free from any conflicts of interests, a new agency or watchdog appointed by Health Canada should be created to assume the responsibilities of the PAAB.

**Recommendation #16. *Health Canada should appoint a watchdog to oversee and regulate drug manufacturers' promotional activities to the public and all health care providers and prescribers.***

The Canadian Medical Association (CMA) has issued guidelines for relationships between physicians and the pharmaceutical industry (Canadian Medical Association 2001). The CMA's policy on physicians and the drug industry is that in the event of any conflict of interest between themselves and their patients resulting from interactions with industry, the physician should act in favour of their patients. In particular, they should avoid any self-interest in their prescribing and referral practices. Ultimately, relationships between physicians and the industry should be guided by the CMA's Code of Ethics. The BCMA fully supports the CMA's guidelines on physician relationships with the pharmaceutical industry (Appendix D).

**Recommendation #17. *The BCMA supports the CMA guidelines on appropriate relationships between physicians and the pharmaceutical industry and encourages other health care providers to adopt similar guidelines.***

### Better Information for Physicians and Patients

Physicians and patients need accurate, balanced information on prescription drugs in order to make informed decisions. However, there is no common, independent source of drug information readily available for patients and physicians. The CMA has developed principles for providing information about prescription drugs to consumers and has recommended that a review of current mechanisms, including mass media communications, be carried out for providing this information to the public (Canadian Medical Association 2003). The BCMA calls upon the BC government to work with health care providers, patient groups, and drug manufacturers to develop and provide accurate, unbiased prescription drug information to patients. To ensure that information is accurate and appropriate, drug information should be accredited by a reputable and unbiased body and be provided in a way as to minimize the impact of vested commercial interests on the content. Possible sources include health care providers or independent research agencies. Governments should provide appropriate sustaining support for the development and maintenance of up-to-date consumer drug information.

**Recommendation #18. *The BC Ministry of Health, in conjunction with the BCMA and other health professional organizations, including but not limited to the College of Registered Nurses of British Columbia, the College of Pharmacists of British Columbia, the Canadian Association of Chain Drug Stores, and the College of Physicians & Surgeons of British Columbia, should develop and provide accurate, unbiased prescription drug information to patients.***

Physicians likewise need better access to accurate, balanced drug information. Studies have demonstrated that the more physicians rely on commercial sources of information, the less likely they are to prescribe the medication of first choice for the condition the patient presents (Lexchin 1997). Quality prescribing practices need to be promoted through educational programs targeted to physicians, such as academic detailing. Academic detailing is a program of one-on-one interactive educational outreach provided by a clinician, either a pharmacist or physician, who has been trained to discuss prescribing decisions with physicians. The goal of academic detailing is to induce evidence-based change in prescribing behaviour. Numerous studies have shown that academic detailing can reduce inappropriate prescribing (Soumerai and Avorn 1990; Soumerai 1998; Ilett, Johnson et al. 2000; Solomon, Van Houten et al. 2001; Siegel, Lopez et al. 2003; Simon, Majumdar et al. 2005). British Columbia and other provinces are using academic detailing to varying degrees. For example, since 1993, a ministry-funded academic detailing pilot called the Community Drug Utilization Program (CDUP) has operated and involved family physicians on Vancouver's North Shore. A formal evaluation of the program is underway. A preliminary evaluation carried out on heart failure therapies showed an increase in the use of the recommended therapies over a two-year period (Auditor General of British Columbia 2006). According to the BCMA 2006 Prescription Drug Policy Survey, 50% of GPs and 34% of specialists would be interested in participating in an academic detailing program.

## V. Information Technology

Medication-related injuries are common, clinically significant, and costly (Bates, Boyle et al. 1995; Bates, Cullen et al. 1995; Leape, Bates et al. 1995; Bates, Spell et al. 1997). One study found 6.5 adverse drug events per 100 adult hospital admissions, of which 28% were preventable, with errors occurring at the stage of ordering (49%), transcription (11%), dispensing (14%), and administration (26%) (Bates, Cullen et al. 1995).

Although 75% of visits to general practitioners and internists are associated with the continuation or initiation of a drug, little data is available regarding consequences of medication use in the ambulatory setting (Kaushal and Bates 2002). In a study of four adult primary care practices using prescription review, patient survey and chart review of 1,202 patients, prescribing errors occurred in 7.6% of outpatient prescriptions. Errors in frequency (54%) and dose (18%) were common (Gandhi, Weingart et al. 2005).

A number of information technology (IT) interventions have been introduced to reduce errors in medication management:

**E-prescribing or Computerized Physician Order Entry (CPOE)** has been advocated as one way of improving the quality of prescribing in the first two steps (drug ordering and transcribing). E-prescribing is defined as the use of an automated data entry system to generate a prescription, rather than writing it on paper (California Healthcare Foundation 2001). Potential advantages of e-prescribing include:

- Improved patient safety through the generation of legible prescriptions that have been checked by the computer for possible harmful interactions.
- Reduced costs through improved efficiencies. Streamlined communication of prescriptions to pharmacies, resulting in receipt of clean, legible, formulary-adherent prescriptions, thus reducing calls back to physician offices to clarify inconsistencies.
- Improved patient satisfaction through rapid prescription fulfillment and fewer errors.

E-prescribing with advanced decision support can reduce medication errors 55-86% of the time in hospitals (Bates, Leape et al. 1998; Bates, Teich et al. 1999). Computerized clinical decision support substantially increases the error reduction capability of CPOE by providing basic computerized advice regarding drug doses, routes and frequencies, as well as more sophisticated data such as drug allergy, drug-laboratory values, drug-drug interactions, background checks and clinical guidelines (Bonnabry 2003). E-prescribing can also involve electronically transmitted prescriptions to pharmacies through integration with pharmacy software programs. Automated drug reviews can also be incorporated with CPOE to detect prescription errors resulting from duplication, excess dose, drug-disease, drug-drug, and drug-allergy contraindications. However, in ambulatory care, no information is typically available on current drugs, diseases or allergies that can be used for drug problem surveillance in Canada (Tamblyn; Tamblyn 2004).

In Quebec, the MOXXI project has launched a mobile electronic prescribing and integrated drug and disease management system that links physicians, pharmacists, patients, and external sources of information on drug monographs and alerts. Lacking a BC-like PharmaNet system, MOXXI created a centralized server and databases to manage drug claims. The MOXXI system was extended to physicians' offices, where participating doctors use handheld computers to view patient prescribing profiles and review decision support materials. The system is being evaluated in 32 GP practices and 29 pharmacies encompassing nearly 20,000 patients. The system has proven effective in several ways (Health Canada 2004):

- Reducing potential errors by providing menus for dose selection and treatment indication.
- Avoiding transcription errors by printing prescriptions.
- Allowing physicians to issue stop orders and change orders.
- Avoiding transcription errors by electronic retrieval and integration into pharmacy software.
- Automating tracking of patients' current prescriptions.
- Assisting physicians in resolving compliance problems.

**Clinical decision support systems (CDSSs)** help with the drug ordering step of prescribing. After viewing the recommendation, the physician may write the prescription by hand or electronically. Evaluations of CDSSs have shown that their use increases appropriate prescribing and reduces medication errors (Kaushal and Bates 2002).

**Computerization of the medication administration record** may assist in the transcribing stage. Combined with CPOE, computerization of the medication administration record may reduce errors by, for example, performing cumulative dose checking (Kaushal and Bates 2002).

**Automated dispensing** may reduce medication errors. In the inpatient setting, drugs are ordered, transcribed, and then dispensed by a robot. Robots have been found to decrease dispensing errors dramatically in adult inpatients (Weaver 1998). Similarly, automated drug distribution systems include computer controlled devices that package, dispense, and distribute medications. Bar coding of prescription drugs for easier identification, dispensing, and administering; "smart" intravenous devices, and computerized discharge prescriptions and instructions have also been associated with reducing medication errors (Kaushal and Bates 2002).

### **Drug information management technologies in BC**

PharmaNet. In September 1995, the BC Ministry of Health implemented PharmaNet, which linked community pharmacies, outpatient hospital dispensaries and emergency rooms to a common data-sharing network. Everyone issued a prescription in BC, including residents and non-residents, is registered with PharmaNet, which includes 14 months of all medications dispensed, adverse drug reactions, and clinical outcomes. PharmaNet supports drug dispensing, drug monitoring and claims processing and is designed to reduce errors in drug ordering (BCMA 2004).

In 2000, a pilot project was initiated to give 100 physician offices access to PharmaNet. In February 2005, the PharmaNet Patient Record Information Regulation was amended to provide all physicians province-wide access to PharmaNet (Auditor General of British Columbia 2006). After overcoming some legal issues, the Medical Practitioner Access to the PharmaNet database (MPAP) has been made available to all physicians as of December 2005. This move was supported by the College of Physicians and Surgeons of BC who urged physicians to apply for PharmaNet access (College of Physicians and Surgeons of BC 2006). According to the BCMA 2006 Prescription Drug Policy survey, only 21% of physicians have registered for PharmaNet. Common reasons for not registering for PharmaNet include: lack of awareness (25%), excessive cost (24%), lack of usefulness (23%), and difficult to use (18%). The cost of private sector software to gain PharmaNet access is still a concern to many BC physicians. Of those physicians who have registered for PharmaNet, 88% have found it useful.

It has been recommended that PharmaNet provide comparable up-to-date drug cost information for physicians in order to make prescribing more cost-effective. Physicians have reported that they have little knowledge of the cost of many drugs they prescribe and do not have ready access to this information (Auditor General of British Columbia 2006). In the BCMA 2006 Prescription Drug Policy survey, a large majority (84%) of physicians would use up-to-date drug cost information to inform their prescribing decisions if it was readily available. In addition, if PharmaCare provided up-to-date drug files with current Canadian Drug Identification Code numbers/products and unit cost pricing cost information on their website, electronic medical record users would have an accurate, comprehensive lookup that would assist with their initial prescribing decisions.

CPOE. The use of e-prescribing systems in BC hospitals and physician offices remains low, due largely to the costs involved and slow investment in baseline systems. The First Consulting Group in the US notes that for an average 500-bed hospital, CPOE systems cost \$7.9 million US to install, and about \$1.35 million US annual to maintain. It is important to note that in order to realize the true benefits of CPOE, such applications require an investment in baseline systems (e.g., PharmaNet). According to the BCMA 2006 Prescription Drug Policy survey, a substantial proportion of physicians (29%) are not sure whether or not they will implement e-prescribing in their practices, while 4% of physicians have already implemented e-prescribing. Only one in five physicians say that they are not likely to implement e-prescribing. These physicians' main reasons for not doing so include lack of necessity (55%), cost (42%), privacy concerns (33%), and lack of interoperability (26%).

As a component of the BC's e-Health strategy, the Ministry of Health established the e-Drug Project for the use of electronic medication information management across all care settings. One of its goals is the implementation of electronic prescribing (e-prescribing). The target is to have 50% of prescriptions to be electronically generated by 2008. Both provincial and federal resources, including funds from Canada Health Infoway, are available to support BC's eHealth initiatives. Infoway's current eHealth allocation for BC is \$120 million to 2008/09. Along with the health authority allocations, the Ministry expects to contribute approximately \$30 million to eHealth initiatives over the period 2005/06 to 2008/09.

### **Challenges in implementing prescribing technologies**

Need for greater standardization. Standards are required for defining and identifying all of the needed data elements and ensuring interoperability across IT systems. Some data elements required in

eliminating medical errors include a complete list of all medications a person is taking; prescription, over-the-counter, and herbal medications; and access to the person's diagnoses, height, weight, and certain laboratory data. Additional standards that affect e-prescribing are standards for defining clinical guidelines, clinical protocols, and functional standards for the electronic health record. To ensure interoperability with other e-health applications, a common set of data elements including name, definition, data type, terminology, units and value sets must be adopted (Hammond 2004). Designing common standards is a crucial and difficult step in ensuring the widespread use and effectiveness of prescribing technologies. For example, Alberta's Pharmaceutical Information Network, which provides an electronic record of the patient's medication to the physician, experienced problems interfacing the provincial database with the multitude of programs in physicians' offices (Haight 2005). In Australia, the Enhanced Divisional Quality Use of Medicines project highlighted the need for prescribing software standards in order to extract comparable drug utilisation data from different prescribing systems, to integrate clinical guidelines into prescribing systems, and to facilitate accurate and acceptable detection of drug-drug interactions (Harvey 2005).

Privacy of health information. Without confidence in the privacy of the information collected, stored, and transmitted electronically, patients and physicians may be reluctant to increase the use of information technologies. For example, the extension of PharmaNet into physician offices presents new privacy and enforcement challenges. For a physician to have access to PharmaNet, it is required that the physician sign the Medical Practice Access to PharmaNet Agreement. This agreement is established between the BC government and the individual physician, and includes confidentiality and security standards and the need for written patient consent.

Cost of systems. Depending on the practice size and technology in question, prescribing technology costs will be prohibitive for physician practice. The costs of purchasing and installing a system, training, annual operation and maintenance, and the opportunity costs are high and often limit the implementation process (Bonnabry 2003).

BC physicians have indicated that province-wide access to PharmaNet would benefit patient care (BCMA 2004). In BC, ongoing software and hardware costs are borne by the physician. This is not a practical approach to develop a province-wide integrated prescription information system or any other prescribing technologies such as e-prescribing. In the 2006 Letter of Agreement between the BC government and the BCMA, a total of \$107.8 million has been dedicated to cover initial and on-going costs associated with IT projects in physician practices till 2011/2012. This Letter of Agreement also specifies that access to PharmaNet will be included in early PITO/electronic medical record implementations where available. Additional content such as drug order entry will be made available as it is developed over the next 2–3 years.

**Recommendation #19. *The BC Ministry of Health should provide adequate start-up and ongoing funding for physicians to use e-prescribing systems as part of BC's e-health strategy and in support of the Physician Information Technology Office (PITO). The BC government must enable all physicians to have access to PharmaNet at no direct cost to physicians.***

## VI. Professional Roles in Prescribing

In May 2006, the Alberta government approved the Pharmacists Profession Regulation, which allows for a greatly expanded scope of practice for pharmacists. Similar efforts may follow in other provinces, and the implications for the practice of medicine are significant. This section examines the legislation in Alberta, developments in British Columbia and elsewhere in Canada, and experiences abroad.

### Developments in Alberta

Alberta's Pharmacists Profession Regulation permits pharmacists to prescribe Schedule 1 drugs, continue prescriptions made by other health practitioners, and administer injectable drug treatments, such as vaccines. As "enabling legislation," it only allows pharmacists the right to prescribe, but not the ability to do so until more detailed regulations are developed (e.g., define the additional training required for pharmacists who will be prescribing). Nonetheless, Alberta pharmacists are now entitled to one of the broadest scopes of practice in the world (see below). The Alberta government's primary argument for passing the legislation was to "provide better access to drug treatments" (Government of Alberta 2006).

The Alberta Medical Association (AMA) and the College of Physicians and Surgeons of Alberta (CPSA) had been in discussions with the Alberta government on this issue prior to the announcement in May 2006. Both groups provided comments on an earlier draft of the Pharmacists Profession Regulation, and both groups have substantial objections to the legislation.

The AMA stated that they cannot support independent prescribing by pharmacists (i.e., initial access prescribing, primary prescribing). The AMA's objections cover three areas (Hynydyk 2005):

1. Concern for patient safety/quality of care. "It has not been demonstrated that pharmacists anywhere receive appropriate training or assessment as competent clinicians for the purpose of providing independent pharmaceutical treatment with Schedule 1 drugs. This training would include the knowledge and skills to take a history, conduct a physical examination, make a diagnosis and assess options, including non-drug ones, for treatment."
2. Conflict of interest. "Physicians have always been restricted from having both a prescribing and dispensing role as this would create a conflict of interest. The potential conflict is just as relevant to pharmacists. There is concern that pharmacists will have an economic interest in the medication prescribed ... It is not clear how this potential conflict of interest will be monitored and enforced."
3. Further implications for Medicare. "Pharmacist prescribing means that more providers will perform a service that has (i) generally been provided by physicians, (ii) been considered a 'medically necessary' service, and (iii) been covered by Medicare. Physicians in the public system may not charge patients directly for this service, but no such restriction currently applies to pharmacists. If government wishes to give pharmacists the right to prescribe, it must then decide how pharmacists' services are dealt with in Medicare."

The CPSA's position on the issue has been to support "collaborative prescribing" by pharmacists, but not primary prescribing. The CPSA argues that "pharmacists have not to date provided evidence that they

have the appropriate training, expertise and hands-on experience to take on this responsibility [of primary prescribing].”

The Alberta Pharmacists’ Association (RxA) has countered the positions, stating they were “gravely concerned about how the AMA and CPSA have called into question the professionalism of Alberta pharmacists” and “the public has every reason to trust that their health and safety will be respected and protected by Alberta pharmacists.” RxA also objected to the “AMA’s speculation that a conflict of interest exists in Alberta pharmacists wanting prescribing authority due to commercial interests” (Pharmacists Association of Alberta 2006).

### **Developments in British Columbia and Elsewhere in Canada**

British Columbia. The BC government has not introduced legislation allowing an expanded scope of practice for pharmacists. The BC Pharmacy Association issued the following position statement in January 2007:

*The BC Pharmacy Association supports the principle of pharmacist prescribing contingent on the development of standards, limits and conditions in collaboration with the College of Pharmacists of BC and other health care professionals (BC Pharmacy Association 2007).*

The BC Pharmacy Association believes that pharmacists are underutilized and that allowing pharmacist prescribing under an expanded scope of practice will maximize pharmacists’ available training and skill.

Manitoba. The Manitoba government passed Bill 41, the *Pharmaceutical Act*, on December 4, 2006, giving pharmacists the ability to expand their scope of practice, including prescriptive authority and authority to order diagnostic tests. As specified in the *Act*, the College of Pharmacists of Manitoba will need to determine the qualifications and other requirements that a pharmacist must have in order to prescribe independently or collaboratively with other practitioners, the types of drugs that a pharmacist may prescribe, the circumstances in which a pharmacist may prescribe, and measures to address situations in which a pharmacist sells drugs that he/she is authorized to prescribe (Legislative Assembly of Manitoba 2007).

Nova Scotia. The *Continued Care Prescriptions Agreement* between the Nova Scotia College of Pharmacists and the College of Physicians and Surgeons of Nova Scotia has been in place since September 2004. The *Agreement* tells pharmacists that the College of Physicians and Surgeons of Nova Scotia will not, under certain conditions, consider the renewal of a prescription as the practice of medicine and therefore contrary to the *Medical Act*. The *Agreement* assumes that continued care prescriptions cannot and do not take the place of ongoing medical care and that pharmacists assume full responsibility for extending the refill (Nova Scotia College of Pharmacists 2004).

Northwest Territories. The Northwest Territories government passed Bill 7, a new Pharmacy Act, on November 2, 2006. Bill 7 allows pharmacists to issue prescriptions that modify the practitioner’s prescription by altering the dosage, formulation or regimen of the drug, or by therapeutically substituting a drug for the drug prescribed by the practitioner. Pharmacists are also allowed to renew prescriptions on a short-term basis if the patient has an immediate need for the drug and the patient cannot be attended by



a practitioner who is authorized to prescribe the drug. A pharmacist who issues a prescription must notify the practitioner who issued the original prescription with a written or faxed copy of the modified prescription and reasons for the modification (Legislative Assembly of the Northwest Territories 2007).

New Brunswick. According to the Canadian Taxpayers Federation, “the pharmacists of New Brunswick have announced they too want the same powers [as pharmacists in Alberta]” (Fliss 2006). However, no further mention of this has been made publicly.

Saskatchewan. In September 2003, prescriptive authority was granted to pharmacists according the Pharmacy Act (1996). Under the bylaws of the Saskatchewan College of Pharmacists, pharmacists can prescribe emergency contraception within conditions imposed on his/her license. The Saskatchewan College of Pharmacists has recently drafted a consultation paper advocating for expansion of pharmacists’ prescribing authority to include altering the formulation, dosage, or regimen of the drug prescribed, performing therapeutic substitutions, renewing prescriptions for patients in urgent or emergency situations when refills have run out and the prescriber is not available, and interdependent prescribing where a pharmacist can prescribe within formal protocols or collaborative practice agreements with prescribers. The Saskatchewan College of Pharmacists is not advocating, however, that pharmacists expand their scope of practice or prescribe independently (Saskatchewan College of Pharmacists 2006).

### **Pharmacist Prescribing Abroad**

Numerous models for pharmacists’ prescribing have been implemented internationally, varying in their dependency on protocols, formularies, and collaboration with physicians (Emmerton et al 2005). Independent prescribing occurs where the prescribing practitioner is solely responsible for patient assessment, diagnosis and clinical management and requires legally defined levels of knowledge and skill that are usually monitored through a licensing process. Similar to Alberta and Manitoba, the UK introduced independent prescribing by pharmacists in May 2006. A Pharmacist Independent Prescriber in the UK can prescribe any licensed medicine for any medical condition, with the exception of Controlled Drugs, provided the pharmacist has successfully completed an accredited education and training program (Department of Health April 2006).

Dependent prescribing incorporates more restriction on prescribing activities and can take many forms. Prescribing by protocol is the most common example and consists of a delegation of authority from an independent prescribing practitioner, usually a physician, via a formal agreement (protocol). In New Zealand, a pharmacist can enter into dependent prescribing arrangements with authorised prescribers under standing orders or protocols. In the USA, protocol-based prescribing had been successfully legislated in at least 25 states by 2001 (Emmerton et al 2005). Supplementary prescribing is another form of dependent prescribing and is defined as a voluntary prescribing partnership between the independent prescriber (usually a physician) and the pharmacist in order to implement an agreed patient-specific clinical management plan (Department of Health July 2006).

Collaborative prescribing requires a cooperative practice relationship between a pharmacist and a physician or practice group, with legal authority to prescribe medications. The physician diagnoses and makes initial treatment decisions for the patient, and the pharmacist selects, initiates, monitors, modifies and continues or discontinues pharmacotherapy as appropriate. Informally, hospital pharmacists in

Canada and the USA have practiced collaborative prescribing for the past 25 years (Emmerton et al 2005).

### **Canadian Medical Association**

Following the passage of the Pharmacists Profession Regulation in Alberta, the Canadian Medical Association passed the following motion at its 2006 annual meeting:

*“The Canadian Medical Association, in conjunction with its divisions and affiliates, without endorsing pharmacist independent prescribing strongly urges the Government of Alberta to require pharmacists who are given independent prescribing authority to:*

- *require explicit, informed consent from a patient;*
- *maintain a patient's record;*
- *provide 24-hour availability to the patient;*
- *carry appropriate coverage for legal liability;*
- *disclose any potential conflict of interest as both a prescriber and dispenser of medication; and*
- *if the pharmacist changes a physician's prescription, advise the physician of the change(s).”*

This motion highlights the difficulty in implementing legislation that grants pharmacists independent prescribing powers. Moreover, necessary mechanisms, such as audits of pharmacists' prescribing behaviours, should be in place to ensure the quality of their prescribing and optimal patient outcomes. Even with significant investments in infrastructure and the process re-design required to implement these recommendations, it remains unclear how pharmacists can demonstrate that they have the training and skills necessary to independently prescribe safely.

### **Canadian Pharmacists Association Position Statement**

In February 2004, the Canadian Pharmacists Association (CPhA) Board of Directors released a position statement on the cross-border drug trade. Although not addressing specifically the issue of pharmacist prescribing, the statement does have direct implications for such a policy:

*“CPhA supports the position of the Canadian Medical Association in its Statement on Internet Prescribing which states ‘It is incumbent upon the physician to obtain an adequate history and perform an appropriate physical examination to reach a diagnosis which will ensure that the prescribed medications are appropriate. It is not acceptable for a physician to sign a prescription without properly assessing the patient’”*  
(Canadian Pharmacists Association 2004).

It is difficult to understand how pharmacists can argue that, on one hand, it is unacceptable for a physician to prescribe a medication without having properly assessed the patient, while on the other hand, advocate for allowing pharmacists the privilege of doing so. A review of all pharmacy school curricula in Canada reveals that no school trains pharmacists to take a patient's medical history, perform a physical examination, or reach a medical diagnosis (see Appendix B).

## Policy Recommendations

The vast majority of BC physicians (95%) are strongly opposed to pharmacists prescribing medications independent of physician involvement. Ninety-five percent of BC physicians do not agree that pharmacists are adequately trained to prescribe independently. Ninety percent believe that independent pharmacist prescribing will have a negative clinical impact on patients. Furthermore, the vast majority of BC physicians (87%) believe that independent prescribing puts pharmacists in a conflict of interest if they are able to prescribe and dispense medications. No one without the professional training to obtain an adequate history, perform an appropriate physical examination, and reach a medical diagnosis can prescribe safely. Without evidence that pharmacists have the medical training to perform these functions, BC physicians cannot support independent prescribing by pharmacists.

However, BC physicians believe that there are circumstances in which pharmacists could prescribe, albeit with physician notification. Fifty-nine of physicians agree that pharmacists should be able to renew prescriptions (a “continued care prescription”), with notification to the physician, on a short-term basis (maximum of 30 days) under defined circumstances when a renewal cannot be secured from the patient’s physician. Pharmacists often extend prescription repeats or advance prescription drugs in urgent or emergency circumstances where the repeats have expired and the patient needs the drugs but the prescriber is not available. Continuity of care could be allowed under these circumstances provided that the patient is stabilized on the medication and providing the drugs would not put the patient at risk. The medication to be continued must only be for a chronic or long-term condition. The quantity dispensed would be sufficient to last the patient until they can see their physician and the original prescribing physician would be notified in writing as soon as reasonably possible by the pharmacist.

Pharmacists in BC have been informally renewing prescriptions for patients when their physician is unavailable but physicians are often not informed of these renewals. An agreement that outlines the conditions under which pharmacists could renew or refill prescriptions would provide greater transparency and accountability to patients, physicians, and pharmacists. Such an agreement would assume that continued care prescriptions cannot take the place of ongoing medical care and that pharmacists assume full responsibility for extending the refill. Physicians must be appropriately compensated for telephone prescription renewals and for the time spent in providing professional advice to pharmacists. Physicians continue to bear medical and legal responsibility for these decisions.

Delegated prescribing is acceptable provided that it is part of a multidisciplinary practice (i.e., takes place in the physician’s office or as part of a virtual team), and the multidisciplinary practice is led by a clinical team leader with ultimate responsibility for patient care and who is the best-trained generalist (in the majority of instances, this would be the GP). Prescribing protocols would have to be developed to ensure appropriate delegation.

**Recommendation #20.** *The right to prescribe medications independently for medical conditions must be reserved for qualified practitioners who are adequately trained to take a medical history, perform a physical examination, order and interpret appropriate investigations, and arrive at a working diagnosis.*

**Recommendation #21.** *The BCMA endorses a role for pharmacists to independently renew prescriptions on a short-term basis (maximum 30 days) under defined circumstances when a renewal cannot be readily obtained from the patient's physician. The pharmacist must notify the original prescribing physician and/or regular family physician of the prescription renewal, in writing, as soon as reasonably possible.*

**Recommendation #22.** *Delegated professional prescribing is acceptable provided that:*

- *it is part of a multidisciplinary practice (i.e., takes place in the physician's office or as part of a virtual team), and*
- *the multidisciplinary practice is led by a clinical team leader with ultimate responsibility for patient care and who is the best-trained generalist (in the majority of instances, this would be the GP).*

## VII. National Pharmaceuticals Strategy

In September 2004, the First Ministers established a ministerial task force (MTF) to develop the National Pharmaceuticals Strategy (NPS). This task force is part of the larger 10-Year Plan to Strengthen Health Care and coordinates the efforts of federal, provincial, and territorial health ministers. The MTF is responsible for nine actions:

1. Catastrophic drug coverage: develop, assess and cost options for catastrophic pharmaceutical coverage;
2. National drug formulary: establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness;
3. Drug approval process: accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
4. Post-approval surveillance: strengthen evaluation of real-world drug safety and effectiveness;
5. Purchasing and pricing strategies: pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
6. Physician prescribing behaviour and optimal drug therapy: enhance action to influence the prescribing behaviour of health care professionals so that drug are used only when needed and the right drug is used for the right problem;
7. E-prescribing: broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record;
8. Generic drugs: accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and
9. Improve analytic capability: enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies (Health Canada 2005).

In the two years since the creation of the MTF, stakeholders have expressed their views on the NPS through conferences and policy statements dedicated to exploring issues of pharmaceutical policy. Examples include the May 2006 health policy conference, “Toward a National Pharmaceuticals Strategy”, hosted by the University of British Columbia Centre for Health Services and Policy Research; a conference of physicians, pharmacists, and patient advocacy groups hosted by the Medical Post in March 2006; and various policy statements released by interested stakeholders. However, despite this interest from stakeholders, as well as the publicly-stated assurance from the MTF that “key stakeholders – including patient groups, health care providers, insurers and industry – will be engaged as part of the development and implementation process, to ensure the long-term success and viability of a National Pharmaceuticals Strategy” (Health Canada 2005), the development of the NPS has taken place without meaningful input from any stakeholder. In the absence of opportunities to express their views directly to the MTF, some groups released public statements explaining their positions. For example, the Coalition for a Canadian Pharmaceutical Strategy, whose membership includes the Canadian Medical Association, released a position statement detailing a number of general principles to guide the MTF (Appendix C).

The MTF released its first progress report to the public in September 2006. The progress report focuses on only five of the original nine actions identified by the First Ministers: catastrophic drug coverage,

expensive drugs for rare diseases, a national drug formulary, pricing and purchasing strategies, and real world drug safety and effectiveness. Two of these areas were the most frequently selected by BC physicians as the top areas to focus on: strengthening the evaluation of real world safety and effectiveness of drugs (59%), and a common national drug formulary (52%).

The recommendations of both the Coalition and the MTF are general, and neither proposes specific policies to be enacted. This is perhaps appropriate given that the MTF has not yet sought meaningful dialogue with stakeholders, which could lead to the development of more concrete strategies. The most developed policy area in the MTF progress is on the national drug formulary. The Coalition simply calls for a common definition of “catastrophic” coverage, but the MTF progress report presents two options (without endorsing one over the other): a fixed percentage definition of five percent (i.e., catastrophic coverage begins once a family has paid 5% of their household income) and a variable percentage definition (0%, 3%, 6%, 9%) that increases as family income increases. Costs for these proposals vary significantly and depend on whether the private insurers choose to continue offering coverage even with a national catastrophic plan. For example, a fixed percentage program where private payers continue to offer drug coverage would cost \$6.6 billion, but a variable percentage program without private payers’ involvement would cost \$10.3 billion.

An open and inclusive process for developing and discussing specific, detailed policy options – such as whether or not to have a fixed or variable percentage catastrophic drug benefit – is essential to creating a NPS that is both practical and supported by stakeholders. The BCMA is encouraged that the MTF progress report references, in many instances, the importance of stakeholder input. Although stakeholders have been excluded from the development of the NPS so far, we are nonetheless hopeful that ample opportunity for meaningful input will be provided in the near future.

**Recommendation #23. *The National Pharmaceuticals Strategy Ministerial Task Force must honour its 2004 commitment to include meaningful physician input in the development of its policies and recommendations.***

**Recommendation #24. *The National Pharmaceuticals Strategy Ministerial Task Force must expediently develop positions on the remaining four focus areas: physician prescribing behaviour and optimal drug therapy; e-prescribing; generic drugs; and improving analytic capability.***

## Conclusion

The 24 recommendations in this paper were developed as part of a comprehensive, deliberate process that incorporated findings from the peer-reviewed literature and the views of practising BC physicians. Taken together, they reveal two underlying themes. First, any policy change must begin by considering the impact on patient safety and the quality of care. The well-being of patients supersedes the interests of any stakeholder. Second, there are no shortcuts for effective pharmaceutical policy. The challenge of balancing cost and quality is too great to be remedied quickly and without making some difficult choices. However politically expedient or administratively simple some options might appear, they are bound to cause more harm than good if insufficient attention is paid to the practical consequences of their implementation. For example, reference drug pricing (RDP) that is not based on adequate scientific data could lead to severe negative clinical outcomes. Controlling costs by imposing a blunt budget cap on PharmaCare expenditures would result in unacceptable reductions in access to medicines. Implementing e-prescribing technologies without adequate funding or change management training would significantly limit buy-in from physicians. Expansions in scopes of practice that fail to reflect training and education would lead to poor quality prescribing and endanger patient safety.

The medical profession of BC believes these 24 recommendations collectively provide a path to improve the quality of health care for all British Columbians and urge their implementation.

## Appendix A: BCMA 2006 Prescription Drug Policy Survey

The BCMA conducted a survey on prescription drug policy issues to its members in November 2006 to help inform this report in areas such as prescribing by pharmacists, reference-based pricing, drug promotion, and prescribing technologies. After confirming that there were no significant differences on key database criteria between physicians with emails and physicians without emails in the BCMA member database, an online survey methodology was chosen. A total of 3,913 randomly selected BCMA members were emailed an invitation to complete the BCMA Prescription Drug Policy Survey. Two reminder emails were sent two and four weeks after the initial invitation.

### Response Rate

A total of 727 physicians completed the online survey. The margin of error associated with survey responses based on this sample size is +/- 3.6% at the 95% level of confidence.

The survey participants match the BCMA member population with respect to age, location of practice, GP/specialist distribution, and gender as shown in the table below:

| Characteristic       | Population/Survey Sample Comparison |                       |
|----------------------|-------------------------------------|-----------------------|
|                      | BCMA Member Population              | Survey Sample (n=727) |
| Average Age          | 50                                  | 49                    |
| Rural/Urban Practice | 18% / 82%                           | 17% / 83%             |
| GP/Specialist*       | 58% / 42%                           | 60% / 40%             |
| Male/Female          | 70% / 30%                           | 69% / 31%             |

\*Physicians from over 30 different specialties were represented in this survey.



## Appendix B: Review of Canadian Schools of Pharmacy Undergraduate Curricula

We examined the curricula of undergraduate pharmacy programs for all faculties of pharmacy in Canada, paying particular attention to course descriptions that indicated training relevant to independent prescribing practice. Pharmacy curricula were downloaded from the individual university's web site in August 2006, following up with phone calls in cases where the published curricula were unclear. We defined independent prescribing practice as the ability to take a medical history, perform a physical examination, order and interpret appropriate investigations, and arrive at a working diagnosis.

All pharmacy programs include some practical experience (i.e., pharmacy rounds, structured practicum, rotations in hospital or community pharmacies). It is unclear whether this practical experience provides opportunities for training in areas required to prescribe independently. With respect to required coursework, we found that (1) pharmacy students are not taught to conduct physical examinations; (2) no program includes training for making a differential diagnosis or ordering and interpreting appropriate investigations; and (3) all programs include some component of "patient counseling." This may be interpreted as training students to take a patient history. The table below summarizes the coursework in each university.

| University                          | Relevant Training  |
|-------------------------------------|--|
| University of British Columbia      | Program philosophy states "the diagnosis of a medical problem is the responsibility of the physician and the pharmacist's role is the identification and resolution of drug-related problems." Coursework includes 24-credit pharmacy practice course.   |
| University of Alberta               | Pharm 405: Introduction to Institutional Practice and Patient Counseling with the Emphasis on Non-Prescription Drugs   |
| University of Saskatchewan          | Pharm 365.5: Patient Care I: "...students will develop skills in patient care through interviewing..."   |
| University of Manitoba              | Clinical pharmacy I (course description: "develop the necessary assessment skills required to determine whether self-care is an appropriate option, or if referral to a physician/practitioner is necessary.")   |
| University of Toronto               | Pharmaceutical Care III (course description: "students will acquire and reinforce their skill at determining whether a patient's signs and symptoms are related to drug therapy and, if so, how they are related to drug therapy and what alterations are required in the patient's drug therapy to solve or prevent this problem.") |
| Universite Laval                    | No course descriptions indicate training relevant to independent prescribing   |
| University of Montreal              | No course descriptions indicate training relevant to independent prescribing   |
| Dalhousie University                | No course descriptions indicate training relevant to independent prescribing   |
| Memorial University of Newfoundland | PHAR 2102: Pharmacy Practice II-- Emphasis on communication and patient counseling<br>PHAR 4150: Pharmacy Skills-- students participate in dispensing and interview/counseling sessions  |

\* Assumes a 3-credit hour course in a 15-week semester, unless otherwise indicated by the University.

# Appendix C: Framework for a Canadian Pharmaceutical Strategy – Statement of the Coalition for a Canadian Pharmaceutical Strategy

## Preamble

The Coalition for a Canadian Pharmaceutical Strategy brings together five organizations – the Best Medicines Coalition, Canadian Medical Association, Canadian Nurses Association, Canadian Pharmacists Association and Canadian Health Care Association – who represent patients, health professionals, health system managers and trustees. Based on our knowledge and experience of the benefits and use of pharmaceuticals, we believe we can make important contributions to the development of a Canadian pharmaceutical strategy.

## Goal and Principles

The goal of a Canadian pharmaceutical strategy should be to ensure that every Canadian has timely access to safe and effective prescription drugs, and that no Canadian is deprived of needed prescription drugs because of inability to pay. To achieve this goal we propose the following principles to frame the strategy's development, implementation and evaluation:

- Canadians, no matter where they live, have equitable access to prescription drug coverage.
- Decisions are patient-centred, taking account of the unique needs and therapeutic outcomes of individual patients and respecting the relationship between patients and their health-care providers.
- All policy decisions, including drug approval and program coverage, are based on an impartial review of the best available scientific evidence and on the adoption of best practices nationally and internationally.
- All initiatives are carefully assessed in accordance with a comprehensive evaluation strategy.
- Pharmaceuticals are evaluated not in isolation but as an integral part of the health system. They are assessed in the context of the overall burden of illness, and of their impact on direct and indirect illness costs and health system sustainability.
- Health care providers and health organizations have access to the knowledge and information necessary to facilitate optimal and appropriate pharmacotherapy.
- Appropriate use is made of the knowledge and skills of physicians, nurses, pharmacists and other health care providers.
- The decision-making process is open, transparent and accountable, and incorporates the active, meaningful participation of patients, health professionals, and other relevant stakeholders including public and private insurers.

## Toward a Canadian Pharmaceutical Strategy

The above principles, and the following recommendations, apply broadly to any pharmaceutical strategy, including the nine-point National Pharmaceuticals Strategy (NPS) proposed by governments following the 2004 First Minister's Accord. The elements of a comprehensive Canadian pharmaceutical strategy are

interdependent and should be developed concurrently to ensure that the strategy is coherent and holistic. In addition, they should form part of a broader framework that encourages research and development of new medicines in Canada.

### **Drug Coverage**

- All Canadians should have access to prescription drugs for which evidence indicates effectiveness in the treatment, management and prevention of disease and/or significant benefits for quality of life.
- Public and private payers should conduct research to identify the current gaps in drug coverage and develop policy options for providing this coverage, focusing first on uninsured and underinsured patients.
- Coverage should be based on optimal and appropriate standards of treatment for all Canadians. It should be comparable across the country, minimizing disparities between provinces and territories.
- Coverage plans should include coverage for catastrophic drug costs. As a first step, governments should adopt a common operational definition of “catastrophic”.

### **Common Formulary**

- Governments should work toward national harmonization of formularies, based on optimal and appropriate standards of treatment.
- Decisions regarding inclusion of drugs in formularies should be based primarily on scientific evidence of their impact on health outcomes, and informed by evidence regarding their cost-effectiveness.
- A process should be in place for allowing patients to access non-formulary agents in cases of medical necessity.

### **Access to Drugs**

- The federal government should continue to reduce the time required for regulatory review to the fastest level consistent with ensuring optimal health outcomes and the safety of the drug supply.
- The drug review process should provide updates on status and the opportunity for stakeholder input. The rationale for decisions should be made apparent to all stakeholders, and an appropriate appeal mechanism should be provided.
- Health Canada should continue to apply a priority review process to drugs that demonstrate a substantial improvement over products already on the market.
- Canada should develop a comprehensive drug policy for rare disorders that includes clear rules for setting prices that are fair to patients, governments and the pharmaceutical industry.

### **Post-Approval Surveillance for Safety and Effectiveness**

- A strong, adequately-funded post-approval surveillance system is essential to ensuring drug safety and effectiveness. This system should include:
  - Simple, comprehensive and user-friendly reporting processes, to which health-care providers are encouraged to promptly report adverse drug reactions. User-friendly reporting processes should also be available to patients and the public;
  - Rigorous analysis of reports to identify significant threats to drug safety;

- Communications systems that produce useful information, distributed to health care providers and the public in a timely, easily understood manner; and
- Links to international post-approval surveillance systems.
- All newly approved products, either brand name or generic, should be evaluated with particular scrutiny in real-world practice.
- Post-approval surveillance should evaluate both the safety and the effectiveness of new drugs.
- Adverse drug reaction reports from patients and the public should be actively solicited.

### **Pricing and Purchasing**

- Purchasing and price control strategies should aim to better manage drug costs without compromising access to optimal and appropriate treatments.
- Strategies related to drug purchasing and distribution should ensure that the supply of prescription drugs is sufficient to meet Canadians' needs.
- Pricing strategies should include an examination of the trade-offs between relative costs and benefits for patients, consumers, drug developers, drug manufacturers, pharmacies and governments.
- Substitution strategies, when used, should respect the clinical independence of prescribers, the patient-prescriber relationship and the uniqueness of patients.

### **Optimal Drug Therapy**

- The federal government should fund a comprehensive program to promote optimal prescribing and drug therapy monitoring by health professionals. Such a program should:
  - be founded not on sanctions but on education, including objective academic detailing;
  - include use of information technology and practice tools;
  - be organized and implemented by professional and patient organizations;
  - include strategies to improve patients' knowledge of and adherence to drug regimens; and
  - be accompanied by the development and maintenance of reliable, up-to-date, impartial drug information for consumers.
- Direct-to-consumer advertising of prescription drugs should not be permitted in Canada. The regulatory loopholes that currently permit a limited amount of drug promotion should be closed.

### **e-Prescribing**

Governments should support the development of electronic communication networks, and work with health professional and patient groups to establish standards for electronic prescribing, taking into consideration patient privacy and confidentiality requirements.

### **Non-Patented Drugs**

Governments should work together to develop policies for regulating the prices of generic and off-patent drugs.

### **Analysis of Cost Drivers**

A pharmaceutical strategy must support ongoing research into the factors contributing to the rapid growth in drug expenditures, and identify strategies to manage these expenditures in a fiscally sustainable manner.

### **Conclusion**

Canada needs a strong nationwide pharmaceutical strategy to ensure that Canadians have access to safe, effective pharmaceuticals as an important and integral part of their health care. Building this strategy will require early, ongoing and meaningful consultation with all stakeholders, including health care providers and consumers. Our Coalition stands ready to work with governments and all other stakeholders to achieve this goal.

## Appendix D: CMA Guidelines on the Relationship Between Physicians and the Pharmaceutical Industry (Update 2001)

The history of health care delivery in Canada has been marked by collaboration between physicians and the pharmaceutical and health supply industries; this collaboration extends to research as well as to education. Because medicine is a self-governing profession, physicians have a responsibility to ensure that their participation in such collaborative efforts is in keeping with their duties to their patients and society. The following guidelines have been developed by the CMA to assist physicians in determining when a relationship with industry is appropriate. Although directed primarily to individual physicians, including residents, and medical students, the guidelines also apply to relationships between industry and medical organizations. These guidelines focus on the pharmaceutical companies; however, the CMA considers that the same principles apply to relationships between physicians and all commercial organizations, including manufacturers and suppliers of medical devices, infant formulas, health care products and informatics, and other service suppliers. These guidelines reflect a national consensus of medical organizations and are meant to serve as an educational resource for physicians throughout Canada.

### General principles

1. The primary objective of professional interactions between physicians and industry should be the advancement of the health of Canadians rather than the private good of either physicians or industry.
2. Relationships between physicians and industry should be guided by the CMA's Code of Ethics.
3. The practising physician's primary obligation is to the patient. Relationships with industry are appropriate only insofar as they do not negatively affect the fiduciary nature of the patient–physician relationship.
4. Physicians should resolve any conflict of interest between themselves and their patients resulting from interactions with industry in favour of their patients. In particular, they should avoid any self-interest in their prescribing and referral practices.
5. In any relationship between a physician who is not an employee of the pharmaceutical industry and the industry itself, the physician should always maintain professional autonomy, independence and commitment to the scientific method.

### Industry-sponsored research

6. A prerequisite for physician participation in industry-sponsored research activities is evidence that these activities are ethically defensible, socially responsible and scientifically valid. The physician's primary responsibility is the well-being of the patient.
7. The participation of physicians in industry-sponsored research activities should always be preceded by formal approval of the project by an appropriate ethics review body. Such research should be conducted according to the standards and procedures set out in the Tri-Council Policy Statement on

Ethical Conduct for Research Involving Humans as interpreted by the National Council on Ethics in Human Research.

8. Patient enrolment and participation in research studies shall occur only with the full, informed, competent and voluntary consent of the patient or his or her proxy, unless the research ethics board authorizes an exemption to the requirement for consent. The standards and procedures set out in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans should be utilized for structuring and obtaining the relevant consent or for determining that the requirement for consent can be waived. The enrolling physician is responsible for implementing these standards and procedures. In particular, the CMA Code of Ethics requires the enrolling physician to inform the potential research subject, or proxy, about the purpose of the study, its source of funding, the nature and relative probability of harms and benefits, and the nature of the physician's participation and to advise prospective subjects that they have the right to decline to participate or to withdraw from the study at any time, without prejudice to their ongoing care. Because the prospective research subject is in a dependent relationship to the physician and might be susceptible to consenting under duress, it is preferable that the informed consent be obtained by a qualified person who is independent of the patient-physician relationship. However, the responsibility of assuring that proper consent has been obtained remains with the enrolling physician.
9. The physician who enrolls a patient in a research study has an obligation to ensure the protection of the patient's privacy, in accordance with the provisions of CMA's Health Information Privacy Code. If this protection cannot be guaranteed, the physician must disclose this as part of the informed consent process.
10. Practising physicians should not participate in research studies unless they are assured by the sponsors that the results will be made public within a reasonable period.
11. It is acceptable for physicians to receive remuneration for enrolling patients or participating in approved research studies only if such activity exceeds their normal practice pattern. This remuneration should not constitute enticement. It may, however, replace income lost as a result of participating in a study. Parameters such as time expenditure and complexity of the study may also be relevant considerations. The amount of the remuneration should be approved by the relevant review board, agency or body mentioned previously. Research subjects must be informed if their physician will receive a fee for enrolling them in a study.
12. Incremental costs (additional costs that are directly related to the research study) should not be paid by health care institutions or provincial or other insurance agencies regardless of whether these costs involve diagnostic procedures or patient services. Instead, they must be assumed by the industry sponsor or its agent.
13. When submitting articles to medical journals, physicians should state any relationship they have to companies providing funding for the studies or that make the products that are the subject of the study whether or not the journals require such disclosure.

#### **Industry-sponsored surveillance studies**

14. Physicians should participate only in post-marketing surveillance studies that are scientifically appropriate for drugs or devices relevant to their area of practice.

15. Physicians considering participation in surveillance studies should avail themselves of appropriate resources to assist them in their decision-making. Research ethics boards that already exist in their community may serve in this capacity. The National Council on Ethics in Human Research is an additional source of advice.
16. When institutionally based research ethics boards are unavailable, participation in research and surveillance studies should be through national, regional, provincial or territorial coordinating agencies or bodies that can function as a resource for physicians in assessing the study's ethical acceptability and scientific value. Although these boards, agencies and bodies may be partially or completely funded at arm's length by industry, they should be under the direction of appropriately qualified health care professionals and researchers working independently from industry.

### **Continuing medical education / continuing professional development (CME/CPD)**

17. The primary purpose of CME/CPD activities is to address the educational needs of physicians and other health care providers in order to improve the health care of patients. Activities that are primarily promotional in nature should be identified as such to faculty and attendees and should not be considered as CME/CPD.
18. The ultimate decision on the organization, content and choice of CME/CPD activities for physicians shall be made by the physician-organizers.
19. CME/CPD organizers are responsible for ensuring the scientific validity, objectivity and completeness of CME/CPD activities. Organizers must disclose to the participants at their CME/CPD events any financial affiliations with manufacturers of products mentioned at the event or with manufacturers of competing products.
20. The ultimate decision on funding arrangements for CME/CPD activities is the responsibility of the physician-organizers. Although the CME/CPD publicity and written materials should acknowledge the financial or other aid received, they must not identify the products of the company(ies) that fund the activities.
21. All funds from a commercial source should be in the form of an unrestricted educational grant payable to the institution or organization sponsoring the CME/CPD activity. Upon conclusion of the activity, the physician organizers should be prepared to present a statement of account for the activity to the funding organizations and other relevant parties.
22. Whenever possible, generic names should be used rather than trade names in the course of CME/CPD activities. In particular, physicians should not engage in peer selling. If specific products or services are mentioned, there should be a balanced presentation of the prevailing body of scientific information on the product or service and of reasonable, alternative treatment options. If unapproved uses of a product or service are discussed, presenters must inform the audience of this fact. Faculty must disclose to the participants at CME/CPD events any financial affiliations with manufacturers of products or service providers mentioned at the event or with manufacturers of competing products or providers of competing services.
23. Negotiations for promotional displays at CME/CPD functions should not be influenced by industry sponsorship of the activity. It is preferable that promotional displays not be in the same room as the educational activity.



24. Travel and accommodation arrangements, social events and venues for industry-sponsored CME/CPD activities should be in keeping with the arrangements that would normally be made without industry sponsorship. For example, the industry sponsor should not pay for travel or lodging costs or for other personal expenses of physicians attending a CME/CPD event. Subsidies for hospitality should not be accepted outside of modest meals or social events that are held as part of a conference or meeting. However, faculty at CME/CPD events may accept reasonable honoraria and reimbursement for travel, lodging and meal expenses. Scholarships or other special funds to permit medical students, residents and fellows to attend educational events are permissible as long as the selection of recipients of these funds is made by their academic institution.

#### **Clinical evaluation packages (samples)**

25. The distribution of samples should not involve any form of material gain for the physician or for the practice with which he or she is associated.
26. Physicians who accept clinical evaluation packages (samples) and other health care products are responsible for ensuring their age-related quality and security. They are also responsible for the proper disposal of unused samples.

#### **Other considerations**

27. These guidelines apply to relationships between physicians and all commercial organizations, including manufacturers of medical devices, infant formulas and health care products as well as service suppliers.
28. Physicians should not dispense pharmaceuticals or other products unless they can demonstrate that these cannot be provided within a reasonable time frame by an appropriate other party, and then only on a cost-recovery basis.
29. Physicians should not invest in pharmaceutical manufacturing companies or related undertakings if knowledge about the success of the company or undertaking might inappropriately affect the manner of their practice or their prescribing behaviour.
30. Practising physicians affiliated with pharmaceutical companies should not allow their affiliation to influence their medical practice inappropriately.
31. Practising physicians should not accept a fee or equivalent consideration from pharmaceutical manufacturers or distributors in exchange for seeing them in a promotional or similar capacity.
32. Practising physicians should not accept personal gifts from the pharmaceutical industry or similar bodies.
33. Practising physicians may accept patient teaching aids appropriate to their area of practice provided these aids carry only the logo of the donor company and do not refer to specific therapeutic agents, services or other products (e.g., baby formula).

#### **Medical students and residents**

34. These guidelines apply to physicians-in-training as well as to practising physicians. Medical curricula should deal explicitly with the guidelines.

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