# Paying for What Works

BC's experience with the Reference Drug Program as a model for rational policy making

by Alan Cassels • March 2002



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# **Summary**

GOVERNMENTS AROUND THE WORLD FACE SIMILAR DILEMMAS IN TRYING TO control the escalating cost of pharmaceutical benefits for their citizens. In Canada there have been few drug policy changes more controversial yet better studied than British Columbia's Reference Based Pricing (now called the Reference Drug Program or RDP), which began in 1995. Under RDP, if more than one drug for the same condition has been proven equally effective, the less expensive drug is identified as the "reference drug," and only its price is fully covered. If, however, a patient does not tolerate reference drugs, physicians can apply for "special authority" for another drug of the same class to be fully funded.

RDP was adopted as a means of reining in the rising cost of BC's Pharmacare program, which in the early 1990s was rising at a rate of 16 per cent per year. In Canada, most provinces tend to control rising drug plan costs either by shifting greater costs onto patients and private insurers (through increasing co-payments, premiums and deductibles) or by restricting which drugs will be covered (a process called formulary management). RDP is a formulary management program that reduces the profits of pharmaceutical manufacturers and, consequently, its implementation in BC caused a vigorous, multi-faceted and at times vitriolic response from the drug industry and its surrogate consumer groups. Opposition to RDP led to the BC Ministry of Health commissioning several rigorous evaluations of the policy's impact, resulting in some of the most thorough drug policy research in the Canadian health care system.

BC's Reference Drug Program, which applies to only five categories of drugs, is estimated to save the provincial Pharmacare program \$44 million each year. After seven years of experience, and several independent evaluations of RDP in BC, there is no evidence of adverse impacts on health outcomes, such as increased hospitalizations or deaths, nor is there evidence of increased costs to other parts of the health care system.

Establishing better communications with physicians, pharmacists and consumers would improve the feasibility and effectiveness of any expansion of RDP. Jurisdictions considering implementing or expanding reference-pricing programs can learn from the experience of British Columbia, where reference pricing has proved to be a workable model of rational policy making that can save money without harming patient care.

# Introduction

"The probable effect on drug costs of any public (or private) reimbursement policy can be gauged by the tone and vigour of the industry's response."

- Stephen Lewis et al. 1997

IN 1995, PHARMACARE, THE PUBLICLY-FUNDED DRUG INSURANCE PROGRAM operated by the British Columbia Ministry of Health, introduced the Reference Drug Program (RDP), initially called Reference-Based Pricing. The development and implementation of RDP grew out of a number of other cost-containment policies and were adopted to address the rising cost of BC's Pharmacare program, which in the early 1990s was increasing at a rate of 16 per cent per year. These kinds of cost escalations were paralleled nationally: Canada's overall drug expenditure grew an average of 12.1 per cent per year from 1985 to 1992.<sup>1</sup>

The rationale behind RDP is simple: if there is no evidence that a newer, more expensive drug is therapeutically superior to a cheaper, equally effective treatment, the taxpayer should fund the least expensive alternative first.

In BC, the Reference Drug Program applies to only five classes of drugs: non-steroidal antiinflammatory drugs (NSAIDs), used for the treatment of arthritis; histamine-2 receptor antagonists for the treatment of heartburn; oral nitrates for angina; angiotensin-convertingenzyme (ACE) inhibitors to treat high blood pressure; and dihydropyridine calcium-channel blockers, also used to treat high blood pressure. If a patient meets certain criteria, such as having a condition that could lead to an adverse effect from the reference drug, physicians can apply for an exemption from the policy by submitting a "special authority" form. Some specialists are exempt from the policy. Patients not exempted from the policy who wish to have a more expensive drug can pay the difference over the cost of the reference product.

The evidence of risks and benefits of new pharmaceuticals is routinely assessed before they are approved for marketing in Canada. In BC, RDP is an example of policy makers attempting to apply an evidence-based approach to drug coverage decisions. Maclure et al., in an exhaustive paper on research and policy making cycles at work in BC Pharmacare, said: "RDP can be viewed as a funding mechanism that incorporates evidence and opinions from clinical advisors, researchers, physicians and pharmacists, concerning the question 'What medicines are medically necessary to cover?"<sup>2</sup>

Looking closely at a drug's benefits in comparison to other treatments and making funding decisions based on that evidence is one way to control drug costs, but it is certainly not the only way and has met with stiff criticism from industry and lobby groups. A more popular trend in Canadian provinces is "ability-to-pay" policies or other cost sharing schemes that do not curb cost growth, but

With RDP, evidencebased coverage
decisions were
formalized into a
program. What
ensued was not a
battle but a war
between government
and industry, as the
drug industry
struggled to prevent
formal reference
pricing from gaining
a legitimate foothold
in Canada.

rather shift it onto patients, forcing them to carry a larger share of their drug costs.

Cost sharing drug benefit programs provide a helpful contrast to RDP. Drug manufacturers are less likely to oppose cost-shifting schemes than referencing-type systems, which hurt drug company profits directly. In Ontario and Quebec, where premium and user-pay systems are on the rise, criticism from industry has been muted. In contrast, when jurisdictions like BC refuse to pay for more expensive drug products with no clear evidence of superiority, they attract the full lobbying and public relations energies the manufacturers can muster. Government-industry skirmishes over provincial drug coverage happen all the time, as both sides debate the evidence when considering the inclusion of new drugs onto the provinces' lists of covered drugs. With RDP, however, these evidence-based coverage decisions were formalized into a program. What ensued was not a battle but a war between government and industry, as the drug industry struggled to prevent formal reference pricing from gaining a legitimate foothold in Canada. That war forms a backdrop to the experience of reference pricing in British Columbia.

The purpose of this paper is to examine the experience of RDP in BC in terms of drug cost containment and health outcomes, and to explore the parameters of the debate that ensued. The paper is organized into four sections:

- A background that sets out the policy framework and explains the rationale and origins of RDP in BC;
- An examination of evaluations of the financial and health care impacts of RDP policy in BC;
- A discussion section that examines the political context of RDP implementation in BC, the nature of the opposition to RDP, and the various criticisms levelled against it; and
- A conclusion summarizing the main findings of this paper and setting out recommendations for further drug policy concerning RDP.

### PART 1

# Background

### Pharmacare cost pressures

Like most drug benefits plans in the industrialized world, BC Pharmacare must contend with serious and mounting cost pressures. Over the last 10 years, Pharmacare's budget has more than doubled, from \$214 million in 1989/1990 to \$569 million in 1999/2000.<sup>3</sup> It is likely the 2001/2002 budget will exceed \$750 million.

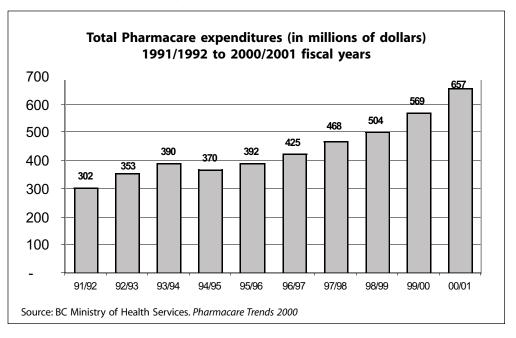
Federally, the introductory price of new drugs is regulated by the Patented Medicines Prices Review Board (PMPRB). The board reviews drug prices against international standards, and prohibits new drugs of moderate or no therapeutic improvement from being priced beyond the maximum price of other drugs in their class. Although the PMPRB may prevent some excessive pricing of new drugs in Canada, several key factors, such as the increased utilization of drugs and the rapid rate at which newer drugs replace older drugs, ensure that public drug benefit plan costs continue to rise.

To put this in its proper context, the rising cost of BC Pharmacare is part of a national and world-wide phenomenon. According to the Canadian Institute for Health Information, in 1997 spending on drugs overtook spending on physician services for the first time since comparable detailed expenditure data have been compiled (1975). Drug expenditures grew from 8.4 per cent of total health expenditure in the late 1970s, to 14.5 per cent in 1997. Today, drugs are the second largest expenditure category (after hospitals) with a share of approximately 15.2 per cent of all health care spending. 4 Spending on physician services ranks third.

The drivers behind drug cost increases have been extensively analyzed.<sup>5</sup> Some of the main factors in rising drug plan costs are the costs per prescription, the rising number of prescriptions, increases in the number of plan beneficiaries (i.e. more seniors), and overall population growth.

A recent study of BC Pharmacare cost drivers found that overall plan costs rose by 97 per cent from 1990/1991 to 1998/1999. The key drivers were found to be utilization and drug costs. During that period, the number of beneficiaries to the plan increased by 42 per cent; the number of prescriptions dispensed rose by 47 per cent; and the average cost per prescription increased by 34 per cent.<sup>6</sup> At the same time, the population of the province rose by only 22 per cent.

The rising cost of BC
Pharmacare is part of
a national and worldwide phenomenon.
In 1997 spending
on drugs overtook
spending on
physician services for
the first time since
comparable detailed
expenditure data
have been compiled.



### The rationale for RDP

In many ways, implementing a Reference Drug Program in British Columbia in 1995 represented a bold new approach to control public drug expenditures in Canada.

The Reference Drug Program is one of a range of cost containment policies that have been enacted in BC. It is seen by some as the logical extension to the Low Cost Alternative Program (LCA), a policy also known as "generic substitution," which mandates Pharmacare to pay for the least expensive alternative when chemically identical drugs are supplied by different companies. The goal of both RDP and LCA is essentially the same: to provide similar coverage for similarly effective drugs without increasing other health service costs or adverse health events.

Pharmacare keeps its administrative costs to around 1 per cent of its overall budget; the majority of the program spending goes to drug ingredient costs and dispensing fees. Pharmacare also employs other policies to help control drug costs, including:

- Reducing the maximum supply for shortterm therapy drugs to 30 days, a strategy to reduce waste from unused large prescriptions
- Dispensing certain costlier medications in "trial" prescriptions (enough for a 14 day supply). BC, in fact, was the first province to introduce a trial prescription program. A national analysis of trial prescription programs showed they can be acceptable to patients and, if focussed on specific medications, can reduce costs associated with drug waste.<sup>7</sup>
- PharmaNet, the province-wide pharmacy computer network established in 1995, helped to lower administrative costs and deliver faster adjudication of claims. Routine audits of PharmaNet transactions for fraud and abuse help reduce fraudulent transactions and recover costs.

In many ways, implementing a Reference Drug Program in British Columbia in 1995 represented a bold new approach to control public drug expenditures in Canada. When jurisdictions try to shift growing costs onto consumers or private insurance plans, they sometimes sacrifice equity (where the poorest tend to suffer the most) for cost savings. RDP, in contrast, does not focus on patients' ability to pay, but rather, on the evidence of a drug's benefits.

A recent examination of drug policies in seven developed countries, including Canada, showed that all countries make use of some kind of consumer cost-sharing for pharmaceuticals.<sup>8</sup> There is evidence, however, that programs relying on cost shifting, such as user co-payments, can affect utilization of essential medications and have a heavy impact on the poorest patients. A recent study of Quebec's drug policy changes showed that the rate of drug-related adverse experiences among the elderly and welfare recipients more than doubled after the Quebec cost-sharing scheme was introduced.<sup>9</sup>

The opposite tack to cost shifting is restricting how drugs are covered on the formulary. This is essentially what hospital formularies and programs such as RDP do. While physicians resent being restricted in the drugs they can prescribe, almost every drug benefits plan in the world employs some form of formulary management. However, despite over 40 years of experience from Canadian hospitals in using restrictive formularies, no large-scale, rigorously evaluated studies have looked at what happens in hospitals if patients, having a condition with a number of equally effective treatments, are provided only the least expensive alternative. The larger sample sizes involved in the implementation of RDP in British Columbia made this scenario much easier to study, as is set out in the evaluation section.

Any drug benefits plan that manages a list of drugs it is willing to pay for must rely upon unbiased and scientifically valid assessments of the added benefits of new drugs. If new drugs cannot justify their additional cost, both private and public drug insurance plans would be acting irrationally to pay for them. As Malcolm Maclure et al. discussed in an analysis of the rationale for RDP in BC, "If there is no evidence that a higher price buys better effectiveness or fewer toxicities,

then the extra cost should not be covered in a publicly funded insurance program."<sup>10</sup>

In 1994, the Therapeutics Initiative (TI) was established at UBC to create an independent source of scientific expertise and a body of evidence upon which to base drug benefits policy. This group of physicians and pharmacists reviews published evidence of the clinical effectiveness of new drugs and provides its evaluations to Pharmacare's Drug Benefit Committee and to BC health professionals. While the TI is funded by the BC Ministry of Health, it operates at arms length and makes no funding decisions regarding drug coverage. The sole authority for making decisions on drug listings lies with Pharmacare and its Drug Benefit Committee. <sup>11</sup>

### **RDP program details**

The reference drug program came to be applied to five classes of drugs, implemented in the following order beginning in 1995.

**H2-antagonists** (the histamine-2 receptor antagonists), used in the treatment of non-ulcer dyspepsia or upper gastrointestinal tract complaints, became effective October 1, 1995. The rationale behind applying RDP to this category of drugs was that, in terms of efficacy and safety, the evidence suggested only minor and very subtle differences among H2-antagonists for the treatment of heartburn. The TI reviewed H2 antagonists in 1994 and found little difference between the various agents other than cost. 12 Huge savings were anticipated if the referenced drug, cimetidine, was used the majority of the time as the first line agent. Pharmacare saved \$700,000 in the first 12 days of October 1995 when RDP was applied to H-2 antagonists. This was due to omeprazole, the most expensive heartburn medication (selling for \$2.40 per pill), being replaced by cimetidine, which cost \$0.14 per pill.

**Nitrates**, used in the treatment of angina, became effective October 1, 1995. The BC Office of Health Technology Assessment found no evidence to distinguish between regular release

isosorbide dinitrate (ISDN) and oral nitroglycerine (SR-NG) in terms of efficacy, effectiveness, development of tolerance, patient compliance, significant side effect profile, drug interactions or influence on quality of life. <sup>13</sup> The most significant difference between the two was the 10-fold higher cost of SR-NG against the generic ISDN, per usual dosage regimen.

Non-steroidal anti-inflammatory drugs (NSAIDs), used in the treatment of osteoarthritis and rheumatism, became effective November 27, 1995. The NSAID class consists of many apparently therapeutically equivalent products with large differences in price. No specific NSAID has been shown to have superior efficacy or lower overall toxicity. Experience with a prior authorization program for NSAIDs as part of Medicaid in Tennessee enabled managers to reduce NSAID expenditures by 53 per cent over the following two years for an estimated savings of \$12.8 million.14 The reduction in expenditures resulted from the increased use of generic NSAIDs, as well as from a 19 per cent decrease in overall NSAID use.

A TI review in February 1995 identified relatively few clinical trials comparing the effectiveness of different NSAIDs. These trials have not demonstrated any consistent superiority of one NSAID over another. Differences reported in publications can often be explained by the fact that the studies did not use equivalent doses.

**Angiotensin Converting Enzyme (ACE) inhibitors**, used in the treatment of hypertension (high blood pressure), became effective January 1, 1997. Any ACE inhibitor will control blood pressure in 50 to 70 per cent of patients. There are few clinically significant differences between ACE inhibitors.<sup>17</sup>

**Calcium Channel Blockers (CCBs)**, also used in the treatment of hypertension (high blood pressure), became effective January 1, 1997. Any one CCB will effectively control blood pressure in 60 to 70 per cent of patients.<sup>18</sup>

Any drug benefits plan that manages a list of drugs it is willing to pay for must rely upon unbiased and scientifically valid assessments of the added benefits of new drugs. If new drugs cannot justify their additional cost, both private and public drug insurance plans would be acting irrationally to pay for them.

# RDP evaluations

"It is particularly important that the Reference Drug Program be independently evaluated to assess its impact on health outcomes and overall health care costs."

— Office of the Auditor General of British Columbia, 1999

Evaluations directed by leading scholars at Harvard, McMaster and the University of Washington have made RDP in BC the most thoroughly evaluated referencepricing program in the world. ONE OF 10 RECOMMENDATIONS FROM A PHARMACARE AUDIT CONDUCTED IN 1998 by the BC Auditor General was that Pharmacare "encourage independent reviews of the Reference Drug Program and report the results to key stakeholders." <sup>19</sup> Critics of the policy continually claimed that RDP was never properly evaluated; demands for evaluation came from physicians' organizations and the drug industry, keenly interested in evidence to support their hypothesis that the policy was unworkable.

An initial study funded by the Pharmaceutical Manufacturers Association of Canada (PMAC) in 1999 also echoed the Auditor General's report. The study concluded that, despite initial and dramatic declines in annual expenditures on drugs affected by RDP, "a more comprehensive and longitudinal evaluation of reference-based pricing is needed and should take into account a wide range of non-cost impacts, the most important of which are the effects on health outcomes."<sup>20</sup>

Early commentary on reference pricing in BC, while largely lacking in substance, added to the call for a proper policy evaluation. (For an examination of some of the criticisms used to attack RDP on the basis of drug interchangeability, see Appendix A.) The Fraser Institute, a conservative think tank, summed up its opposition to the policy by calling RDP a "dangerous and costly mistake." The Fraser Institute claimed that reference pricing had repeatedly "exhibited two fundamental flaws, one medical and the other economic. From a medical viewpoint it is associated with increased illness. From an economic standpoint it increases health care costs substantially."<sup>21</sup>

Fortunately, the province saw beyond the ideological assertions and chose to fund proper evaluations of the impact of British Columbia's experiment with RDP. Pharmacare was encouraged to support independent scientific evaluation of its RDP policies and provided seed money to do so. The evaluations that followed, directed by leading scholars at Harvard University, McMaster University and the University of Washington, have made RDP in BC the most thoroughly evaluated reference-pricing program in the world.

Any drug policy change in BC could have at least three main potential impacts. The first and most obvious is the fiscal impact on the Pharmacare budget. If the policy saves more money than it costs to administer, either by reducing the rate of increased spending or keeping program spending static, it could be deemed at least partly successful. (Provided, of course, that the impact on health outcomes remains neutral.)

The second potential impact is on health outcomes and other health services. To monitor the policy's impact on health services utilization, researchers linked BC PharmaNet data

with hospital and Medical Services Plan data. To demonstrate an overall positive impact, it must be proven that the policy has not led to poorer health outcomes, measured by increased utilization of other health services such as doctor visits and hospitalizations, or deaths. If there are increases in physician visits (as was seen in the experience of ACE-inhibitors), those increased costs would have to be more than offset by the drug cost savings to Pharmacare, as was indeed the case with referencing ACE-inhibitors.

The third potential impact is on BC's investment climate. Since reference pricing would affect the profits of pharmaceutical companies, there stood the possibility that RDP would cause pharmaceutical companies to restrict investment in BC, due to what might be perceived as an unfavourable investment climate, and that this would have an adverse effect on university and other research programs.<sup>22</sup>

So, how did the program rate on these three impacts?

# Impact on Pharmacare expenditures

With respect to the first potential impact, Pharmacare estimates that since its implementation in 1995, the Reference Drug Program has saved it approximately \$161 million. Ministry of Health documents indicate the policy likely saved the province approximately \$44 million in 1999 alone.<sup>23</sup> Outside assessments by independent researchers (see below) verified some of the savings, notably with ACE inhibitors, H2 antagonists and nitrates. An early study of RDP in BC confirmed that there

were "dramatic declines in annual expenditures for drugs within referenced categories (from \$42 million the year before reference-based pricing was introduced to \$23.7 million the year after)," but the authors said a comprehensive evaluation of reference-based pricing was needed to examine its potential for noncost impacts such as health outcomes.<sup>24</sup>

In a more recent critique of the RDP, a Fraser Institute author claims that public spending on drugs in BC dramatically increased compared to the rest of Canada since the introduction of RDP.<sup>25</sup> This article, however, assumes that public spending in the rest of Canada didn't contract relative to that in BC, yet it clearly did. This was due to cost-shifting policies in other provinces for which the author fails to account. A change in drug policy in Quebec, for example, introduced co-payments in the mid 1990s, downloading about \$400 million in annual drug costs from the provincial plan to individual consumers.<sup>26</sup>

Some analysts found that reference pricing "exerted increased pressure on the suppliers of innovative drugs, causing them to lower their price to the RP [reference price] level almost without exception."<sup>27</sup> In Germany, between 1991 and 1992, pharmaceutical firms decreased the price of products covered by the reference system by 1.5 per cent, but increased the price of unaffected products by 4.1 per cent.<sup>28</sup> In BC, the cost of the more expensive nitrates came down after RDP was introduced, an indication that increasing price competition might force manufacturers to lower prices to the reference level.

Evidence of savings seen by BC Pharmacare is paralleled by the experience of reference-pricing programs in other jurisdictions. Prior

Evidence of savings by BC Pharmacare is paralleled by the experience of reference-pricing programs in other jurisdictions. In New Zealand, for example, the Reference Drug program and other cost-saving measures have achieved cumulative savings of around \$219 million, and drug expenditure growth has slowed to 5.6 per cent per year. to the introduction of reference pricing in New Zealand in 1993, for example, the drug expenditure budget was growing at a rate of 10 to 12 per cent per year. The New Zealand Reference Drug Pricing program and other costsaving measures have since achieved cumulative savings of around \$219 million (Canadian). Most noteworthy is that New Zealand's drug expenditure growth has slowed to 5.6 per cent per year, and the reference-pricing program has expanded to include more therapeutic categories.<sup>29</sup>

Reference-pricing programs were also implemented in the Netherlands and Denmark and, while each country used a different approach, both were able to say that the program was successful in producing drug plan savings.<sup>30</sup>

In one paper critical of reference pricing, the authors noted that price control systems are a bad idea because they "rarely generate the effect desired by regulators." The pharmaceutical industry often claims that RDP fails where it is implemented because it rarely contains the growth rate of drug costs at or near inflation levels. The shortcoming in this kind of critique is that it fails to distinguish correlation from causation: although drug expenditures continue to climb even in jurisdictions with reference-based pricing, one has to compare that growth to the steeper costs curves that would have resulted had reference-based pricing not been in effect.

The reality is that no developed country, regardless of whether it has RDP in place, has been able to hold public drug costs close to inflation. Controlling drug plan expenditures has proven difficult everywhere in the world. Increased utilization of drugs, higher-cost drugs replacing lower-cost drugs, and new

drugs entering the market every year at premium prices have all contributed to escalating costs

### Impact on health care utilization

With respect to the second potential impact — that of shifting costs to other sectors of the health care system — none of the evaluations of RDP in BC could detect any cost shifting. Although many commentators have raised the cost-shifting argument, or warned that referencing of drug categories would cause patients to cease treatment, none have yet been able to provide any evidence that RDP in BC has caused such impacts.

Upon the introduction of RDP, Pharmacare monitored its effect on hospitalizations and physician visits and saw no adverse impacts on these markers. McGregor echoed this finding in the *Canadian Journal of Cardiology*, concluding that in British Columbia "there has been no increase in physicians' office visits or in the rates of hospitalization of seniors associated with any of the sentinel illnesses" since the introduction of RDP in 1995.<sup>32</sup>

Evaluations of the health care utilization impact of RDP have been conducted for four of the five affected drug categories.

### **H2** antagonists

The Pharmaceutical Outcomes Research and Policy Program at the University of Washington, under Dr. Thomas Hazlet, analyzed the impact of BC's RDP on H2 antagonists. He reported to a Drug Information Association conference in Seattle in May 2000, that their analy-

sis shows "RDP of H<sub>2</sub>RAs in BC caused no increases in office visits, ER visits or hospitalizations." <sup>33</sup>

### Nitrates, ACE inhibitors and calcium channel blockers

Paul Grootendorst and his colleagues at the Centre for Evaluation of Medicines at McMaster University studied the impact of referencing nitrates, ACE inhibitors and CCBs. They estimated that the BC policy "was associated with a reduction in expenditures on its seniors drug plan in the order of \$24 million as of May 1999."34 These savings have to be weighed against additional expenditures on physician consultations, which were estimated to be under \$1 million. The researchers "found no evidence of an increase in rates of mortality associated with cardiovascular or renal disorders after RDP was applied to the nitrates, ACE inhibitor and CCBs drug classes."35 Additionally they found "no evidence of an increase in the rates of long-term care admissions after reference pricing was applied to the nitrates, ACE inhibitor and CCBs drug classes."36

Sebastian Schneeweiss of Harvard Medical School examined the impact of RDP on drug switching with ACE inhibitors. He found that the BC policy saved \$6.7 million in the first 12 months, although many patients did not stop taking the more expensive non-reference ACE inhibitor. Dr. Schneeweiss, in a landmark publication in the *New England Journal of Medicine*, reported that "we found little evidence that when reference pricing for ACE inhibitors was introduced in British Columbia, patients stopped treatment for hypertension or that health care utilization and costs increased."<sup>37</sup>

### Impact on investment

As for the third potential impact, the policy's effect on overall pharmaceutical industry research and development in BC, there is no evidence that the Canadian brand name drug industry places a high priority on investing in BC, whether RDP is in place or not. Even though the Canadian brand name drug industry threatened to withdraw R&D funding in the province due to unfavourable provincial policies, no significant decrease in R&D spending has been seen. BC gets a perennially low share of national pharmaceutical R&D investment, and that level remained unchanged, before, during and since RDP was introduced.<sup>38</sup>

British Columbia has roughly 13 per cent of Canada's population, yet receives only 3.3 per cent of national pharmaceutical research and development spending, an amount that has not changed in percentage terms since 1988.39 The truth is that BC has never really been on Canada's pharmaceutical R&D map. In the year 2000, total drug R&D spending in BC amounted to \$26.2 million for the year an amount equivalent to about 13 days of Pharmacare spending.40 Some might argue that, at the very least, pharmaceutical industry research investment in this province should be at a level commensurate with BC's population. In short, the pharmaceutical industry, despite complaining that BC Pharmacare policies are akin to saying "we don't value your innovation,"41 has never invested enough in BC for the prospect of withdrawal of that investment to pose a meaningful economic threat.

No significant decrease in R&D spending has been seen. BC gets a perennially low share of national pharmaceutical R&D investment, and that level remained unchanged, before, during and since RDP was introduced. BC has roughly 13 per cent of Canada's population, yet receives only 3.3 per cent of pharmaceutical R&D spending, an amount that has not changed in percentage terms since 1988.

### PART 3

# Debating the merits

The fact that the
United States is
looking to reference
pricing to curb drug
cost growth seems a
clear sign that this
kind of formulary
management program
is not a phenomenon
that will disappear
anytime soon.

REFERENCE PRICING IS ONLY ONE OF A NUMBER OF POLICIES USED TO contain drug costs. Despite its effectiveness in lowering drug plan costs in British Columbia and other jurisdictions, RDP is no panacea for slowing the escalation of drug budgets. True, all jurisdictions employing reference pricing have had to develop additional strategies to complement it. But that said, there are no solid reasons to conclude that RDP is a failure.

New Zealand, a nation demographically similar to BC, probably leads the world in its ability to contain drug costs through reference based pricing, competitive bidding, and negotiating good prices with manufacturers. This has not led to restricted access to drugs for New Zealanders. On the contrary, according to PHARMAC, New Zealand's national drug subsidization program, access has actually increased.<sup>42</sup>

As of March, 2002, there are over a dozen countries and jurisdictions in the world employing some form of price referencing or similar policies that pay only for the least expensive therapeutically equivalent drug. Program reforms proposed in the United States for Medicare and Medicaid include a more widespread use of reference-pricing-type strategies to provide drug coverage for U.S. citizens. These strategies include generic substitution, therapeutic substitution and prior authorization programs, nearly identical to the LCA, RDP and special authority programs in place in British Columbia. 43 The fact that the United States is looking to reference pricing to curb drug cost growth seems a clear sign that this kind of formulary management program is not a phenomenon that will disappear anytime soon.

Any drug policy that restricts formulary access based on price, such as RDP, will al-

ways be controversial, because it frustrates a key strategy of pharmaceutical manufacturers: profit maximization by creating and marketing higher-priced patented formulations. For the drug industry to maintain high rates of return for shareholders, new products must continually flow through the research pipeline, and those new products must bring premiums in price. If, however, new products bring little innovation to what exists already on the market, governments will be increasingly unwilling to pay the higher prices.

The condemnation of British Columbia's Reference Drug Program by the Pharmaceutical Manufacturers Association of Canada (PMAC, which represents brand-name manufacturers and is now called Rx&D) was swift and pre-emptive. Four months before the policy came into effect, PMAC initiated a series of ads in major BC newspapers in an attempt to discredit the policy. PMAC's full-page newspaper ads proclaimed: "The Provincial Government wants to change your medication" and "RBP has begun. Where will it end?" The provincial government countered with equal invective. One newspaper headline read "Minister condemns drug manufacturers. Greedy multinational firms trying to terrorize British Columbians "44

The extent to which average British Columbians felt allegiance toward one side of

the debate or the other was examined as part of a study on the impact of RDP on seniors. Researchers evaluating government and industry media messages concluded that the fiscal merits of RDP seemed more authentic to the public than the drug industry's arguments. The authors concluded that the pharmaceutical industry's campaign was generally unsuccessful because the drug manufacturers' tactics generated a high degree of scepticism, while "Pharmacare's messages resonated more effectively with seniors' views on public health policy."

Unable to win in the court of public opinion, PMAC attempted to bring an end to RDP in the courtroom. On December 18, 1995, PMAC and seven of its member companies filed suit in the Supreme Court of BC to stop the Minister of Health and Pharmacare from implementing all reference drug policies. The court ruled in the government's favour, as did the BC Court of Appeal. In February 1998 the Supreme Court of Canada denied PMAC leave to appeal the case further.

Although the government won the legal battle, the war was far from over. Strong industry lobbying continued, including consumer groups advocating for discontinuation of RDP. Groups such as the Canadian Association of Retired Persons (CARP), the Canadian Arthritis Society and the little-known "Better Pharmacare Coalition" vocally opposed the policy on the grounds that it would harm patients by interfering with physicians' ability to deliver the best pharmaceutical care. <sup>46</sup>

One of the main criticisms of RDP was the way in which it was perceived to involve the Ministry of Health in prescribing decisions. In October 1996, the Canadian Cardiovascular

Society delivered a position paper criticizing RDP on the grounds that physicians were being second-guessed by ministry bureaucrats. RDP's escape clause was the "special authority" process, whereby physicians could fax a request to Pharmacare to have a more expensive product covered. Not only did many physicians see RDP as an infringement on their prescribing, they likely also resented a further imposition of paperwork for which they were not compensated.<sup>47</sup>

Under scrutiny, however, it appeared that the primary criticism from the professions wasn't the perception of bureaucratic influence on prescribing, but a sense on the part of physicians that they were not adequately consulted in the creation or implementation of the policy. This sentiment was supported by one study that found that clinicians felt that the policy had been imposed on them without consultation, creating a situation whereby they must promote a policy in which they had no say and have no confidence.

Any policy change that creates more work for those having to carry it out – physicians and pharmacists – without appropriately compensating them will be met with opposition. While RDP did pay pharmacists for their extra time in some cases, the perceived increase in paperwork, which coincided with a greater level of chaos than normal (the beginning of RDP occurred at the same time as the start of PharmaNet, BC's pharmacy computer network), added to the administrative burden.

All of these factors may explain why RDP in British Columbia continues to be controversial, and may explain why a program of reference pricing has not been adopted in other provinces.

For the drug industry to maintain high rates of return for shareholders, new products must continually flow through the research pipeline, and those new products must bring premiums in price. If, however, new products bring little innovation to what exists already on the market, governments will be increasingly unwilling to pay the higher prices.

# recommendations

Due to the rigour of the studies and the size of the populations studied, the evaluations of BC's RDP will impact drug formulary policies throughout the world.

SEVEN YEARS OF EXPERIENCE AND SEVERAL SOLID EVALUATIONS HAVE definitively shown that BC's Reference Drug Program has resulted in significant cost savings to Pharmacare with no evidence of negative impact on patient health.

The policy attracted a high degree of controversy and criticism, and this resulted in a higher number of evaluations, with greater thoroughness, than perhaps would have otherwise resulted. Due to the rigour of the studies and the size of the populations studied, the evaluations of BC's RDP will impact drug formulary policies throughout the world. Dr. Schneeweiss, the pharmaco-economics expert at Harvard University who recently published an evaluation of BC's ACE-inhibitor policy in the *New England Journal of Medicine*, <sup>50</sup> has called the implications of his evaluation "huge" for the creation of a Medicare drug benefit in the United States. <sup>51</sup>

The BC experience suggests that jurisdictions considering implementing or expanding reference pricing should consider the following recommendations:

 Consult effectively with physicians and pharmacists on procedures to handle exemptions and on the overall administration and management of the program.

- Plan assertive public relations campaigns to educate the public about the interchangeability of the drugs involved, the actual cost savings experienced in BC (and the ability of the drug program to reinvest those savings in expanding coverage), and RDP's impact on patient health compared to other cost-shifting programs.
- Carefully weigh projected cost savings against the projected social costs involved in carrying out the program prepare for the likely lobbying activities of the pharmaceutical industry, including threats of withdrawal of investment.
- Learn from the experience of managers in British Columbia, New Zealand and other jurisdictions, who have effectively managed reference-drug programs.

The work of Dr. Schneeweiss and other researchers has demonstrated that reference pricing in British Columbia is a model of rational drug policy, well worthy of replication in other jurisdictions.

### **APPENDIX A**

# RDP health impact evaluations

There are many criticisms of reference-pricing programs, but the principal of these is that if the policy affects drugs that are not basically the same (i.e. interchangeable), then shifting patients between different drugs may lead to adverse effects. Several examinations of "interchangeability" are often held up by policy critics to discredit reference-pricing programs. One of the major limitations of those studies is that, while they may be held as examples of why RDP is wrong, they don't actually measure what happened in BC in terms of hard outcomes. A few of these studies deserve brief examination.

### 1. Thomas, M. 1999. "The change of cost: Reference-based pricing of the statins." *The Canadian Journal of Cardiology*, 15:535-538.

In this study, Thomas claims that patients who switched between different cholesterol lowering drugs suffered from inferior care. This conclusion is based on an analysis of patient cholesterol levels, rather than on actual measurements of illness or mortality. Furthermore, the differences in changes in cholesterol levels attributed to different drugs may have nothing to do with the drug involved. The differences might have been wholly attributable to other factors, such as differences in the size of the doses used. In any event, cholesterol-lowering drugs were never referenced in BC.

### 2. Boulet, A.P. and Tessier, G. 1997. "Reference-based pricing in British Columbia: implications for cardiologists. An analysis." *Canadian Journal of Cardiology*, 13:46-51.

The authors discuss the scenario where hypertensive and angina patients receiving diltiazem once a day are switched to diltiazem tablets, and then conclude that because switching patients between these two forms of diltiazem would inevitably lead to inappropriate drug therapy for some patients, reference pricing is flawed. Boulet and Tessier claim that a "wealth of data converge to the same conclusion: price controls and restricted access to drugs do not reduce prescription drug expenditures but actually increase health care costs." The authors present only an untested hypothesis, however, without data to support these conclusions.

## 3. Bourgault, C.; Elstein, E.; Le Lorier, J.; and S. Suissa. 1999. "Reference-Based Pricing of Prescription Drugs: Exploring the Equivalence of Angiotensin-Converting-Enzyme Inhibitors." CMAJ, 161:255-60.

Based on an analysis of ACE inhibitor use in Saskatchewan, the authors conclude that patients initially prescribed captopril used health care services more than those initially prescribed enalapril or lisinopril and, therefore, these ACE inhibitors may not be therapeutically equivalent. This study is flawed for several reasons. At the time of the study, captopril was likely available on all the hospital formularies and hence was prescribed simply because of its availability (few hospitals included lisinopril or enalapril on their formularies). This would mean that more seriously ill patients would have been more likely to be prescribed captopril. When challenged, the authors actually concluded that, "our study had several methodological limitations…and there may be other plausible explanations for the observed differences."<sup>52</sup>

## **APPENDIX B** The RDP debate at a glance

The Reference Drug Program in British Columbia: The pros, the cons and the evidence

The pro (what the policy defenders say)	The con (what the critics say)	The evidence (what the literature and experience say)
"RDP saves money."	"RDP doesn't save money, it costs money." (Fraser Institute)	Since RDP implementation in 1995, the program has saved Pharmacare approximately \$161 million. While annual public drug costs continue to rise, from 1994 to 1997, when RDP was implemented, the rate of growth levelled out. One must ask where our drug budget would be now if we had not implemented RDP.
"RDP has worked in other jurisdictions – hospitals even use similar approaches."	"RDP has failed wherever it has been tried." (Fraser Institute)	RDP is one of many types of policy measures used to control drug expenditures. All forms of drug price controls "fail" to some degree, but that has not stopped RDP from being implemented in the Netherlands, Sweden, Denmark, New Zealand, Poland, Slovenia, Spain, USA, British Columbia, Italy and Australia. The basic concept of paying for the lowest cost treatment, when you have two or more equally effective treatments, is a principle in use in every hospital in Canada and nearly every health jurisdiction in the world.
"RDP doesn't harm patients."	"It [RDP] sacrifices optimal patient care to the cheapest patient care, putting patient's health at risk." (Rx&D)	There has been no evidence of adverse effects (hospitalizations, increased mortality and morbidity) from three major studies of the impact of RDP in British Columbia. The only effect seemingly "at risk" is the growing profits of brand name drug manufacturers.
"RDP is acceptable to patients." (Journal of Applied Gerontology)	"These are real people with real health problems that are being compounded, not eased, by this government's restrictive drug policy." (CARP president Lillian Morgenthau)	A three-year study of RDP on seniors in British Columbia showed a high degree of policy acceptance. "The majority of seniors expressed support for RDP as they disapprove of excess profits for pharmaceutical corporations." Groups such as the Canadian Association of Retired Persons and the Better Pharmacare Coalition, acted as anti-RDP industry surrogates. CARP, surprisingly, claimed it opposed the policy because of "the demands of our members," yet this opposition was being voiced more than four months before the policy was implemented, i.e. before any seniors in BC had actually been affected by RDP.

"The only adverse impact is on the profit margins of the brand name drug industry." (BC government press release, 1998)

"This [RDP] reduces the economic incentive for companies to invest in research and will limit research funding opportunities." (Rx&D) There is no evidence that RDP has reduced investment in pharmaceutical R&D in BC. Between 1988 and 1999, Rx&D Canada reported a "398 per cent increase in pharmaceutical investment in BC"D—hardly an adverse effect of RDP. BC has always had a low share of national pharmaceutical R&D investments—before, during and since the implementation of RDP. Furthermore, the discussion of R&D investments are moot when you consider that the drug industry's spending priorities are on advertising and marketing, not R&D. Fortune 500 drug companies dedicated 30 per cent of revenues to marketing and administration in the year 2000, and just 12 per cent to R&D.<sup>E</sup>

"Doctors still decide what is best for the patient" (BC government press release) "It interferes with physician's treatment based on individual patient needs. (Rx&D)

A "special authority" process exists for doctors to override RDP for patients. Some specialists are automatically exempt from the policy for some drugs. Special authority requests are approved 98 per cent of the time. In the end, it is ultimately the physician who decides on a patient's treatment.

"This will not shift costs to other areas."

"Total healthcare costs may increase as a result of additional doctor and hospital visits." (Rx&D)

There is no evidence of increased hospitalizations and only marginal increases in physician visits. Expenditures on antihypertensives saw a savings of \$6.7 million in the first year. Factoring in a 42 per cent increase in service costs during the transition period, first-year savings came to \$6 million. Service costs included expenses such as patient assessment and dispensing fees. So, for ACE inhibitors, even if physician visits temporarily increase, the policy saves money.

"It is evidencebased policy." "It does not adhere to the principles of evidence-based medicine. (Rx&D) If two or more drugs are equally effective and there is no evidence of superiority, it is not economically rational to pay for anything other than the least expensive drug.

"This is a policy that pays for what works." "This will create two-tier medicine." (Rx&D)

Patients are always free to make irrational health choices – including paying extra for a medication that isn't any more effective or safer than an older, cheaper medication. Because the policy covers what the physician believes to be medically necessary, the only tier is between cost effective and non-cost effective treatments.

#### **Notes**

- <sup>A</sup> BC Ministry of Health and Ministry Responsible for Seniors, 2000a.
- <sup>B</sup> Lopez-Casasnovas, G. and Puig-Junoy, J., 2000.
- <sup>c</sup> Mullett, J. and Coughlan, R., 1998.
- D Rx&D, 2000.
- <sup>E</sup> Young, B. and Surrusco, M., 2001.

### **Endnotes**

- <sup>1</sup> Canadian Institute for Health Information, 2001.
- <sup>2</sup> This most recent analysis of BC's experience with RDP was originally presented at an international symposium organized by the Milbank Memorial Fund and the Cochrane Collaboration in Cape Town South Africa in October, 2000. (See Maclure, M. et al., 2001, p. 39.)
- <sup>3</sup> B.C. Ministry of Health, *Pharmacare Trends* 2000, p. 20.
- <sup>4</sup> Canadian Institute for Health Information, 1999.
- <sup>5</sup> Figures are available only up to the 1998/99 fiscal year. This information is drawn from the Federal/ Provincial/Territorial Task Force on Pharmaceutical Prices, *Study 5: Cost Driver Analysis of Provincial Drug Plans*, *British Columbia 1990/91-1998/99* (see also the Patented Medicines and Prices Review Board, www.pmprb-cepmb.gc.ca).
- <sup>6</sup> Ibid.
- <sup>7</sup> Paterson, J.M. and Anderson, G.M. (forthcoming).
- <sup>8</sup> Willison, D. et al., 2000.
- <sup>9</sup> Tamblyn, R. et al., 2001. This well-known study shows a clear line between increasing user fees for the poor and the elderly and their discontinuing life-saving drugs. Most people who stop taking their prescriptions will probably not suffer much because the drugs do very little in the first place. But people who need essential drugs, such as insulin, and stop taking them because they feel they can't afford them can suffer serious harm.
- <sup>10</sup> Maclure, M. et al., 2001.
- This is a crucial distinction. The TI is often criticized as being the architects of RDP, yet it makes no funding decisions. Pharmacare relies on expert opinion from the TI about drug effectiveness, but must make coverage decisions based on a number of factors (political implications, costs, side effects, etc.), not just therapeutic benefits.
- <sup>12</sup> Therapeutics Initiative, 1994.
- <sup>13</sup> Bassett K. and Rhone M., 1994.
- <sup>14</sup> Agency for Health Care Policy and Research, 1997.

- <sup>15</sup> Therapeutics Initiative, 1995.
- <sup>16</sup> Rochon, P.A. et al., 1994.
- <sup>17</sup> Grootendorst, P. and Holbrook, A., 1999.
- <sup>18</sup> B.C. Ministry of Health and Ministry Responsible for Seniors, 2000a.
- <sup>19</sup> Morfitt, G., 1998.
- <sup>20</sup> Narine, L. et al., 1999.
- <sup>21</sup> McArthur, W., 1997.
- <sup>22</sup> Pallarito, K. 2000.
- <sup>23</sup> B.C. Ministry of Health and Ministry Responsible for Seniors, 2000a.
- <sup>24</sup> Narine L. et al., 1999.
- <sup>25</sup> Graham, J.R., 2000.
- <sup>26</sup> This is one of the side effects of the Quebec solution, for which there were excess deaths and hospitalizations due to cost shifting to the poor and elderly (see Tamblyn, R. et al., 2001).
- <sup>27</sup> Zweifel, P. and Crivelli, L., 1996.
- <sup>28</sup> Lopez-Casasnovas, G. and Puig-Junoy, J., 2000.
- <sup>29</sup> New Zealand PHARMAC, 1999.
- <sup>30</sup> Selke, G.W., 1994; New Zealand PHARMAC, 1999; Jacobzone, S., 2000.
- <sup>31</sup> Zammit-Lucia, J., 1995.
- <sup>32</sup> McGregor, M., 1998.
- <sup>33</sup> Hazlet, T.K. and Blough, D.K., 2000. The researchers have a paper currently in production for the U.S. journal *Medical Care*.
- <sup>34</sup> Grootendorst, P. et al., 2001.
- 35 Ibid.
- <sup>36</sup> Ibid.
- <sup>37</sup> Schneeweiss, S. et al., 2002.
- <sup>38</sup> Rx&D, in its provincial fact sheets, reported in December 2001 that pharmaceutical R&D in BC has increased 498 per cent since 1988. By contrast, investment in Ontario over the same timeframe increased 454 per cent and Quebec 417 per cent. If these rises are true, it is hard to imagine how much better BC would have fared without RDP.

- <sup>39</sup> B.C. Ministry of Health, *Pharmacare Trends* 1997, p. 38.
- <sup>40</sup> Rx&D, 2000.
- <sup>41</sup> Duffy, A.A., 2000. Henry McKinnell, international president of Pfizer and a BC native, said in a *Vancouver Sun* interview that his company felt unwelcome in BC mainly due to government policies that wouldn't pay for some newer and more expensive medications.
- <sup>42</sup> New Zealand PHARMAC, 2001.
- <sup>43</sup> See Huskamp, H.A. et al., 2000, and other articles in this edition of *Health Affairs*, which is entirely devoted to a discussion of Medicare and managed care reforms to improve drug access in the U.S. The term "incentive pricing" is drawn from the lead article describing future Medicare drug coverage directions.
- <sup>44</sup> Vancouver Sun, June 21, 1995, p. A3.
- <sup>45</sup> Brunt, J.H. et al., 1998.

- <sup>46</sup> Except for lobbying against reference pricing, the coalition has been virtually inactive in all other policy matters pertaining to Pharmacare. The coalition was originally composed of the Arthritis Society, the BC Pharmacy Association, Canadian Association of Retired Persons, Internal Medicine Specialists of Nanaimo, and the First Association of Nephrologists of BC. The BC Pharmacy Association and the Arthritis Society later dropped out.
- <sup>47</sup> Woollard, R.F., 1996.
- <sup>48</sup> See Kent, H., 2000. This is a constant refrain from both physicians and pharmacists that they agree with the policy, philosophically, but the implementation seemed heavy-handed and was carried out without consultation.
- <sup>49</sup> Mullett, J. and Coughlan, R., 1998.
- <sup>50</sup> Schneeweiss, S. et al., 2002.
- <sup>51</sup> Pallarito, K., 2000.
- <sup>52</sup> Bourgault, C. and Suissa, S., 2000.

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