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The Ottawa Citizen

Saturday, January 19, 2002

A nation's costly addiction

Canada's soaring prescription costs – 15 per cent of our \$100-billion health care-budget and climbing – are forcing a clash between an aging population's insatiable demand for new and better drugs and society's ability to pay

Canadians last year spent an estimated \$15 billion on pills for headaches, high blood pressure, high cholesterol, depression, arthritis, asthma, impotence, hyperactivity and other maladies. The fastest-growing component of health-care expenditures, drug costs have grown at an average rate of more than 11 per cent over the past five years.

That double-digit growth is, in part, a function of Canada's stunning drug addiction.

Every man, woman and child filled an average of 9.5 prescriptions in 2000, up from eight in 1996, according to IMS Health Canada, an independent health research firm. With a total of 294 million prescriptions dispensed, the average Canadian spent \$360 on medicine, a per-capita expenditure that is among the highest in world.

Governments in Canada pay about 43 per cent of those costs. The rest is shared by private insurance companies and individual Canadians. Today, all three parties are struggling to afford their part.

Dr. Ted Boadway, director of health policy for the Ontario Medical Association, calls it "a staggering problem. You've got more people getting more prescriptions," he says. "And we've got very expensive drugs. Most of the drugs ... are extremely useful, but they have prices which I once thought would be imaginary."

Indeed, many experts warn of an inevitable clash between the public's demand for new and better drugs and the government's ability to afford them. Sometime soon, they say, governments will no longer be able to pay for every new and wondrous drug that comes along.

"We're definitely going to have to make choices," says Dr. Anne Holbrook, a specialist in the evaluation of prescription drugs and the director of clinical pharmacology at McMaster University's medical school.

Dr. Holbrook believes provinces will have to further restrict what types of drug therapies they'll cover, or enter into more and larger cost-sharing arrangements with patients: "There are many ways of cutting, but it is going to get increasingly difficult; I don't think there's any doubt about it."

Most provinces, for instance, are now wrestling with whether to add expensive new drugs, such as Gleevec and Remicade, to their list of medicines eligible for provincial insurance coverage. Both drugs were approved last year for use in this country by Health Canada. Gleevec, a drug to treat chronic leukemia, costs \$35,000 to \$52,000 a year depending on the dosage, while Remicade, used to treat rheumatoid arthritis and Crohn's disease, costs about \$18,000 a year.

Ontario Health Ministry officials are also trying to decide whether to add the breakthrough drug Visudyne to the roster of pharmaceuticals covered by the drug insurance plan. Experts estimate the drug, which can slow the onset of age-related blindness, will add \$20 million to \$30 million a year to the provincial drug bill.

Visudyne costs about \$7,500 a year per patient. It was approved for use by Health Canada in June 2000, and five provincial insurance plans now pay for the drug. Ontario is under intense pressure to do the same by people such as Tom Wainman, 78, a retired paper worker from St. Catharines whose eyesight is failing.

"It would be a great help," he says, "if the government would pay for this." Mr. Wainman, whose

private insurance covers three-quarters of his drug costs, has undergone three Visudyne treatments; he's paid \$1,875 out of his own pocket.

"It's almost like we're being asked to play God," one senior ministry official said. "You have all of these drugs which can be very helpful to different people for different things, but we can't afford them all. So how do you choose?"

Increasingly, provinces are using complicated cost-effectiveness criteria to assess new drugs. But the decisions they face will not get any easier.

With the human genome mapped and with more understood each day about human biology, more remarkable new drugs such as Visudyne are being pioneered. Others are being fine-tuned. Harmful side-effects are being reduced; drugs once delivered in hospital through IVs have been replaced by pills. But it all has a price.

"We really haven't seen anything yet compared to the enormously expensive products that are coming," warns Dr. Holbrook, a member of the expert committee that assesses the cost effectiveness of new drugs in Ontario.

Red flags have already been raised at provincial legislatures.

Last summer, Ontario Health Minister Tony Clement suggested affluent seniors may lose free medication under the province's drug insurance plan, which is expected to cost taxpayers \$2.3 billion this year -- a one-year increase of 17 per cent.

In Quebec, where drug costs rose 15.5 per cent in 2000-2001, the beleaguered drug insurance plan is expected to run a deficit of \$169 million. Public consultations on the plan's future will begin later this year. Quebec Finance Minister Pauline Marois, the former health minister, has suggested the province could simply scrap the plan altogether.

Meanwhile, in Alberta, where drug plan costs increased by 18.9 per cent last year to \$300 million, Premier Ralph Klein wants to re-examine what services, and drugs, the government pays for as part of a health-care overhaul.

In B.C., the province that offers the most extensive drug insurance coverage in the country, the annual drug bill jumped 15 per cent last year. Earlier this month, deductibles were raised for everyone covered by the plan, including seniors. B.C. Health Services Minister Colin Hansen has called the \$700-million plan the most generous in Canada, and one the province can no longer afford.

Canada's burgeoning drug expenditures are the obvious result of a growing and aging population that demands more and better medicines. But demographics are not the only explanation.

Indeed, government officials, private insurers and health economists have undertaken a raft of studies to understand the complex new drug market and the forces driving public expenditures. The answers are both complicated and troubling; some defy conventional wisdom. Consider:

Canada's Drug Prices are Not as Low as Most People Think

Everyone has heard the stories about busloads of American seniors crossing the border to buy Canada's cheap pharmaceuticals, about the successful mail-order services delivering cheap drugs to U.S. patients. And there's no doubt that Canada's drugs are cheaper than those in the U.S., where prices are the highest in the world.

Yet Canadian prices do not compare as favourably with those in other countries.

A recent study by the Australian Productivity Commission, for instance, concluded that drug prices in Australia were "much lower" than those in Canada. The study, which examined prices for 150 key pharmaceuticals, revealed that prices in Australia were 48 per cent to 51 per cent lower than prices in Canada, Britain and Sweden. Australian prices were more in line with drug prices in France, Spain and New Zealand, all of which boasted drug prices considerably lower than those in Canada.

Australia takes a national approach to listing the drugs eligible for insurance coverage and uses a system called reference-based pricing, in which limits are set on the amount that can be

reimbursed for a drug within a given family of drugs. The government decides what medicines it considers effective for heartburn, for instance; if patients want a different product, they have to pay the difference.

Just about every government on Earth is exploring ways to similarly rein in drug prices.

Even in the U.S., the spiritual home of the free market, the appetite for price controls has grown considerably during the past two years. Florida, for instance, is now forcing drug companies to offer special rebates under its Medicaid program, while Michigan has turned to a reference pricing system. Private insurers such as Daimler-Chrysler, meanwhile, have teamed up with other companies to win better deals from drug companies.

In Canada, drug prices are controlled primarily by a little-known federal agency called the Patented Medicine Prices Review Board. It reviews drug prices to see that they do not vault beyond inflation and ensures the prices of most new drugs are in line with the most expensive, existing drugs in their class. (It means pricing the first drug in the class is critical since all other drugs that fall into the same category will be similarly priced. The review board, to establish that initial price, examines the cost of the drug in seven OECD countries; the median figure becomes the Canadian price.)

The board is generally credited with keeping the price of drugs in Canada below those of the U.S. and in line with many European countries.

Yet with the continual introduction of new drugs, the average cost of prescriptions in Canada has been steadily on the rise, despite the review board's best efforts.

In 1996, according to IMS Health Canada, the average prescription cost \$29.64. Four years later, the average cost had jumped more than 20 per cent to \$37.79.

In Ontario, the average prescription price jumped 52 per cent between 1993 and 1999, even though the province froze prices for all existing products on its list of government-insured medicines.

Most provinces are taking further steps to restrict their drug costs and lower the prices they pay per prescription.

British Columbia, which has the lowest per-capita drug costs in the country, uses a reference pricing system and is quick to approve generic substitutes.

In Ontario, the government has recently entered into written agreements that require drug companies to forecast the net cost of a new product. Under terms of the agreements, manufacturers share some of the responsibility for managing drug expenditures by ensuring that their products are prescribed appropriately.

There are also nascent demands for a better public accounting by drug firms.

Dr. Andreas Laupacis, a member of the Ontario committee that assesses the cost-effectiveness of new drugs, is among those who believe drug companies should be made to better justify their prices. In two years on the committee, he says, there has never been a submission that explicitly justified the price of a drug.

"The price charged to my mind is a huge black box," he says. "It is driving a lot of this stuff."

But drug firms maintain prices are a small factor, that without new drugs the health-care system would be overwhelmed. Carlo Mastrangelo, a spokesman for drugmaker GlaxoSmithKline, says the increased use of medications, not prices, are driving costs. "Medications are paying a more pivotal role in the health-care system," he says. "We look at this as a very valuable contribution to health care. We have a profound impact on keeping people out of hospital."

Breakthrough Drugs are Few and Far Between

Reports commissioned by Canada's health ministers have discovered that only a small fraction (between one per cent and five per cent) of provincial drug budgets are spent on honest-to-goodness breakthrough drugs.

Instead, new drugs classified as offering "moderate, little or no improvement" over existing medicines account for the largest share of pharmaceutical spending in Canada, ranging from 34 per cent in Ontario to 29 per cent in B.C. These drugs, sometimes called "me-too" drugs, are now the driving force behind escalating drug costs.

The drugs, such as Lipitor, Paxil, Zoloft, Celebrex and Vioxx, are usually sold to millions and millions of patients, at a cost of between \$500 and \$1,000 for a year's worth of prescriptions.

Me-too drugs have overwhelmed provincial drug budgets by sheer volume since many have immediate and enormous uptake by physicians and patients. The arthritis medication Celebrex for instance, became one of the top three selling drugs in Alberta and Quebec within two years of its introduction. Alberta last year spent \$26 million on Celebrex, at a cost of \$515 per patient, while Quebec spent \$29 million on the drug, which largely displaced the use of older arthritis medications that were half as expensive.

Incredibly, new drugs such as Celebrex can record blockbuster sales even when there's limited evidence that they're better than existing, cheaper medications.

Similar controversies dog many expensive new products.

Calcium channel blockers such as Norvasc, for example, are routinely prescribed to patients with mild hypertension, even though studies suggest cheaper beta blocker and diuretic drugs can work just as well. Similarly, there's an ongoing debate about the widespread use of cholesterol-lowering statin drugs such as Lipitor. (Lipitor is now Canada's best-selling drug, with \$536 million in sales). Some researchers contend there's no evidence that the drugs reduce mortality among patients who suffer only from elevated cholesterol levels; they argue the drugs should only be prescribed to people with known heart conditions.

Provinces concerned about the runaway costs are increasingly taking note of the debates. Ontario and B.C. have introduced measures to assess the cost effectiveness of new drugs -- and improve their use by prescribing doctors. Each province employs a committee of medical experts to assess new drugs and restrict the use of those that cannot prove their therapeutic benefit is worth the asking price.

But neither system has entirely controlled drug spending. Between 1995 and 1999, Ontario's drug costs increased by an average of 12 per cent a year, the highest rate in the country, while B.C.'s drug costs increased by eight per cent a year.

Patented Drugmakers are on a Roll

More drugs are being prescribed than ever before -- 25 per cent more per capita than just six years ago. And it's new, patented drugs that are driving that increase. Many of the new drugs work to control chronic problems, such as high cholesterol, high blood pressure and depression, which means they're being renewed again and again by individual patients.

"It's not like we're treating an infection with antibiotics for a week," says Dr. Laupacis. "We're talking about putting people on these drugs for a lifetime."

That has translated into immense profits for the world's largest drug companies. Since 1988, according to Business Week magazine, the return on equity of the five biggest U.S.-based drugmakers -- Merck, Eli Lilly, Pfizer, Pharmacia and Schering-Plough -- has averaged 30 per cent a year. Last year, it was 36 per cent.

Drug company executives maintain their prices and profit levels are needed to finance innovation since bringing a new drug to market can cost \$1.3 billion. Thousands of chemical molecules are examined for every one that makes it far enough to be tested in animals. After that, successful drugs must be tested in clinical trials to prove they work better than placebos and they're safe for humans.

The whole process can take 10 years, sometimes more, and puts huge amounts of capital at risk.

In recognition of that, Canada protects new drugs from direct competition through its patent laws, which afford drug companies 20 years of market exclusivity from the time they file a patent.

Pharmaceutical companies are relentless in their efforts to protect and embroider those patents while generic competitors are equally determined to poke holes in them. Every day in Canada's Federal Court, drug companies fight a rear-guard action against generic drug manufacturers.

Some of the cases have lasted years, such as the one that involves the best-selling ulcer medication, Losec. The generic drugmaker Apotex has been in court for 12 years trying to market a generic version of the drug. The case continues today, almost three years after the expiry of drugmaker AstraZeneca's main patent on Losec capsules.

While Canadian politicians have been reluctant to discuss the role of patents and patent abuse in the inflation of the nation's drug bill (former health minister Allan Rock and former industry minister Brian Tobin refused to be interviewed on the subject), U.S. legislators have not been so timid.

In the U.S., 29 states are suing Bristol-Myers Squibb Co. for the millions they say was taken from consumers by the company's attempt to extend the patent protection on its anti-anxiety medication, BuSpar.

In Canada, brand-name drugmakers, at least for now, are winning the war of attrition with their generic rivals. Only a decade ago, generic drugs dominated the market in Ontario. Now, however, about 60 per cent of the province's drug budget goes toward patented medicines. (Canada's generic drugs are, on average, about half as expensive as their brand-name equivalents.)

The generic drug industry contends it's being squeezed out of the marketplace by Canada's brand-name companies, which have scored a long series of political triumphs in defence of patent laws.

The brand names have used "every trick in the book to protect their monopolies," charges Dr. Barry Sherman, chairman of Apotex, Canada's largest generic company.

He contends the regulatory regime maintained by the federal government allows drug companies to artificially extend protection on existing drugs. "What they're doing serves only the patent holders," he says. "But what's in the best interest of the health-care system?"

Canada's brand-name drugmakers, however, make no apologies. "We need these protections if there's going to be any kind of knowledge-based economy in this country," says Murray Elston, president of Rx and D, the pharmaceutical industry's Ottawa-based lobby group.

The brand-name companies regard their generic rivals as vultures feeding on their hard-earned intellectual property: "Putting a minimum amount of capital at risk, they take only the highest volume of products to make their money," Mr. Elston says.

"The generic business is a very valid part of the industry as soon as you get beyond the 20 years of patent protection," he added. "The problem is they keep trying to sneak back further and further by declaring that they have found a different way of making a product that doesn't violate patents."

Should Canadians Be Worried About the Nation's Ever-Increasing Drug Bill?

Canada's drug costs represent an estimated 15 per cent of the nation's overall \$100-billion health-care bill. That health-care bill represents about 9.4 per cent of the country's Gross Domestic Product (GDP), which means Canada spends more on health care in relation to the size of its economy than every country in the world, except the U.S. and Germany.

With so much money already going into health care, Canada does not have the economic might to swallow continual double-digit increases in its drug bill.

But What to Do?

Many experts believe that with more and more expensive new drugs hitting the market, each hyped for success, doctors must better target those patients who will benefit the most from them.

Dr. Andreas Laupacis, president of the Institute for Clinical Evaluative Sciences, a non-profit health care research organization in Toronto, insists doctors need to understand there's a difference between an effective drug and a cost-effective one. "I think there are very few drugs, if any, that we're paying for that are not effective. All of these drugs are effective," he says. "But in many of the

groups of patients we're providing them to, the benefit is relatively small, and therefore the cost effectiveness becomes prohibitive."

With that in mind, British Columbia has established what it calls the Therapeutics Initiative, a research body that examines evidence from clinical trials for new drugs and makes recommendations to doctors about how they should be prescribed. It is the only such agency in Canada and other jurisdictions, including Ontario, are studying the project closely.

"This isn't a knock on doctors," says Dr. Laupacis, "but if the patient doesn't have to pay for it, and the drug is slightly better, there's very little incentive to only prescribe it for that subgroup of patients in whom the drug is particularly cost-effective."

According to Ontario guidelines, for example, the ulcer medication Losec is only supposed to be prescribed to drug plan beneficiaries who complain of mild heartburn after cheaper drugs have proven ineffective.

Nonetheless, Losec is the province's second most prescribed medicine, costing the public drug insurance plan \$73 million in 2000.

Still, some doctors argue that money is well spent, saying it is the best ulcer medication on the market, and has all but eliminated expensive stomach surgeries.

And indeed, there's evidence that some drug expenditures reduce hospital and doctors' costs. The California-based health insurance company WellPoint Health Networks, for instance, set up a program in 1998 that taught asthma patients to monitor their symptoms and to use drug inhalers when their conditions deteriorated. The company found that although drug costs rose by 20 per cent, hospital admissions and emergency room visits decreased by 80 per cent. WellPoint cut in half its asthma-related expenses.

Yet more and better drugs do not always translate into long-term savings for the health-care system. Hospital admissions for heart failure, Dr. Laupacis notes, continue to climb even though there is a battery of new drugs, statins and ace-inhibitors, designed to reduce the amount of heart disease.

"I think some of us even in medicine have gotten the idea that we can prevent heart disease, for example," Dr. Laupacis says. "And I think that's just wrong. The word prevention was initially used for vaccines, which will truly prevent an infectious disease. But if you put a diabetic with high blood pressure on drugs to bring the blood pressure down and treat the diabetes, we're not frankly going to prevent the coronary artery disease that poor individual is going to get. We're going to delay it probably."

Tom Brogan, a health-care consultant and author of The Delta Report, an examination of the factors driving drug costs in Ontario that was published in 2000, says governments have to do a "whole lot of little things" to control drug costs. And most of those little things, he adds, involve better information for doctors.

"There's not one magic solution to control this," he says. "But I think more information has to get to physicians, feedback to them, to make sure they have the latest information so they're making the right choices and factoring cost into that choice."

As it now stands, many doctors rely on drug companies -- and studies funded by those same firms -- for information. In Canada, an estimated \$1.35 billion, or more than \$20,000 per physician, is spent on the marketing of drugs. In the U.S., some \$13 billion is spent on advertising, most of it targeted at doctors.

There's considerable evidence to show that money influences the way patients and doctors think about specific drugs. But what that is doing to public health -- and public expenditures on expensive new drugs -- is another matter.

"The market has a set of values and it does not operate in the interest of public health, it operates in the interest of making money," says Dr. Joel Lexchin, a Toronto emergency physician and the author of more than 40 papers on pharmaceutical-related subjects

Concerned that doctors are being unduly influenced, some medical schools and associations have

tried to limit contact between pharmaceutical representatives and medical students. And the practice of evidence-based medicine -- teaching medical students to critically assess drug studies and information sheets -- is fast taking root in medical schools.

Notes Dr. Lexchin: "What general practitioners should be getting is comparative information. Where does this drug fit into the spectrum of therapy? But it is often difficult to get this kind of information."

There are, however, moves afoot to put more information about prescription drugs into the hands of doctors and patients. This year, the federal government will require drug companies to provide more written information to patients. And the federal agency responsible for approving new drugs is about to launch a pilot project to post its findings on the Internet.

A debate will also unfold later this year about the merits of advertising drugs directly to patients -- a controversial practice that is disallowed by federal law.

The good news for Canadian taxpayers is that the price of many blockbuster drugs will soon be coming down.

The best-selling ulcer medication, Losec, is just one of a host of blockbuster drugs that will likely come off patent over the next four years. Other products that may lose their patent protection include the antibiotic Cipro, anti-depressants Paxil and Zoloft, and the best-selling allergy medication, Claritin. Generic drugmakers estimate that the Losec's replacement by a generic product will save Canadians about \$120 million a year.

Of course, expensive new blockbusters now awaiting approval could more than make up for those savings. Among them: Pharmacia and Pfizer's latest arthritis medication, Bextra, Schering-Plough's new allergy medication, Clarinex, AstraZeneca's new ulcer medication, Nexium, and its cholesterol reducer, Crestor.

The public's appetite for new drugs is seemingly bottomless.

There's considerable pressure to increase drug budgets in many provinces to cover more new products, including some expensive drugs designed for people with rare diseases.

The drug Prolastin, for instance, a drug used in the treatment of the rare Alpha-1 disease -- a genetic disease that produces a form of emphysema -- can cost \$50,000 a year. Some provinces cover the cost of the drug, while others, such as Ontario, do not.

That kind of inequity is a troubling feature of drug insurance coverage across the country. Each province now decides for itself which drugs it will cover. It means Canadians have access to different drugs in different provinces, while paying varying amounts of premiums, co-payments and deductibles.

A study, published last year in the journal *Medical Care*, found that access to prescription medications "differed widely" across Canada. The study's authors examined 58 drugs approved in 1996 and 1997 by Health Canada. They found that only five of the drugs were covered by all 10 provincial insurance plans.

The study concluded that it would be extremely difficult to create a national pharmacare program since each province has such a wide variety of drugs eligible for coverage. Former Saskatchewan premier Roy Romanow's health-care commission is now exploring the question of whether Canada needs -- or can afford -- a national pharmacare program.

Consider the situation faced by Canadians with rheumatoid arthritis. Most Canadians covered by private insurance have access to the latest "biologics," Enbrel and Remicade, drugs that block a chemical that inflames the joints. Both drugs cost more than \$15,000 a year.

For seniors who rely on provincial drug insurance plans, however, only those in Saskatchewan and Ontario have access to Enbrel and Remicade. And the residents of those provinces face much different co-payments and deductibles.

As it now stands, seniors and other Canadians who rely on government drug coverage are at the mercy of geography: In Saskatchewan, for instance, an elderly, single woman pays the first \$1,700

of her drug costs, plus 35 per cent of all other prescription costs. In Ontario, the same individual would pay the first \$100 of her drug costs, then \$6.11 per prescription.

Health care is governed by the Canada Health Act, which ensures that access to services are broadly equal across the country. But those rules do not apply to drugs, even though they are an increasingly important part of health care.

The price of government drug plans has forced the provinces to put their heads together: Later this week, premiers will meet in Vancouver to discuss a national strategy to contain drug costs. They'll consider a centralized approach to assessing the cost effectiveness of new products and measures to ensure all provinces are obtaining drugs at roughly the same price.

The Atlantic premiers have already circled the wagons. Earlier this month, the four provinces launched the Joint Expert Advisory Committee to assess new drugs and produce a common list of insured products. The provinces intend to use their unified buying power to push for better deals from drug manufacturers.

"There's only so much money we can put into health," says New Brunswick Premier Bernard Lord. "So the objective is to maximize the resources we have. There are always more drugs we can put on the formulary. The question is: How do we pay for them?"

No province has been able to adequately control its drug costs. For that matter, no other developed country has been able to wrestle drug costs to the ground.

"It's very frustrating. I've been watching this grow for years, and if I had an answer I'd be winning great awards and prizes," says Dr. Ted Boadway. "But you see the new drugs come on, like the one for Alzheimer's (Aricept). It's expensive.

"But I've got to tell you, if my Mom had Alzheimer's, I'd be lining up for it."

Top 10 Drugmakers

Pfizer

Headquarters: New York City

Canadian sales in 2000: \$891 million, 14.5-per-cent
increase over 1999

Top sellers: Lipitor, Norvasc, Zolof, Zithromax, Viagra

GlaxoSmithKline

Headquarters: Uxbridge, England

Canadian sales in 2000: \$758 million, 14.7-per-cent
increase over 1999

Best sellers: Paxil, Flovent, Flonase, Imitrex, Zyban

Merck Frosst

Headquarters: Whitehouse Station, New Jersey

Canadian sales in 2000: \$677 million, 22.5-per-cent
increase over 1999

Best sellers: Vioxx, Vasotec, Fosamax, Cozaar, Singulair

AstraZeneca

Headquarters: London, England.

Canadian sales in 2000: \$654 million, 16.8-per-cent
increase over 1999.

Best sellers: Losec, Zestril, Atacand, Pulmicort, Entocort
Johnson & Johnson

Headquarters: New Brunswick, New Jersey.

Canadian sales in 2000: \$503 million, 6.1-per-cent
increase over 1999

Best sellers: Tylenol, P

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