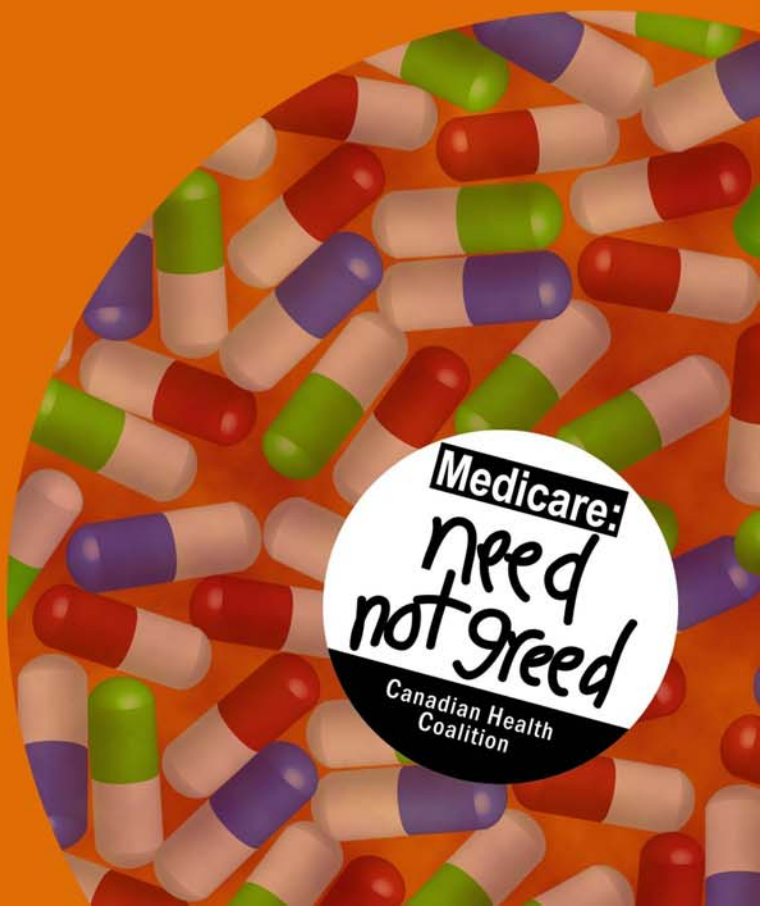
NURSES SUPPORT

A National Pharmacare Strategy



Canadian Federation of Nurses Unions
THE NATIONAL VOICE FOR NURSES

Forward

Most Canadians believe that Medicare should include Pharmacare. As governments discuss a national pharmaceutical strategy, organizations representing millions of Canadians have worked together to develop a vision of a national Pharmacare Program. We are proud to share that vision with you.

Canadian Health Coalition
Canadian Auto Workers Union
Canadian Federation of Nurses Unions
Canadian Labour Congress
Canadian Union of Postal Workers
Canadian Union of Public Employees
Communications, Energy and Paperworkers Union
Congress of Union Retirees of Canada
Medical Reform Group
National Anti-Poverty Organization
National Union of Public and General Employees
United Steelworkers

Acknowledgement

The Canadian Health Coalition would like to thank the following individuals for their contributions in the writing of this paper: Joel Lexchin, MD, Linda Silas, RN, Julie White, Irene Jansen, Mike Luff, Pat Kerwin, Jorge Garcia-Orgales, Teresa Healy, Geoff Bickerton, Kathleen Connors, and Michael McBane.

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Summary

This paper proposes a national Pharmacare plan for Canada that would provide equal access to prescription drugs, be publicly funded and controlled, and cover essential drug costs in the same way that Medicare now covers hospitals and physicians.

Our current patchwork of public and private drug plans is inequitable, because obtaining coverage for drug costs is not determined by need, but by where you live and work. The present system is also incapable of resisting the negative influence of pharmaceutical companies on cost and safety, and has not ensured that our use of drugs is safe and appropriate. We urgently need a new system that would be accessible, safe, and affordable.

Access

All Canadians should have access to the drugs necessary for healthy living. The goal of a public Pharmacare plan would be to provide essential drugs approved on a national formulary to all Canadians on a first dollar basis, that is, with all costs covered. Seniors, children, those with disabilities and those on low incomes should be immediately relieved of any drug costs. For a phase-in period, while cost-saving mechanisms would be coming into effect, others would contribute a limited proportion of their drug costs.

Safety

A public Pharmacare plan must include an independent agency to approve drugs on a more rigorous basis, set research standards and ensure that research findings are available to health care professionals and to the public. Post-marketing safety must also be strictly monitored. Drug company advertising and promotion to the public and to health care professionals must be replaced with more reliable and independent information.

Cost Controls

The proposals for safety would reduce costs by restricting new, more expensive drugs to situations where they offer a therapeutic advantage and by ensuring that drugs are used for appropriate and tested therapeutic reasons. We also need a national formulary of essential drugs, approved in a process that considers both safety and cost effectiveness. Patent laws need to be reviewed to allow the earlier introduction of cheaper generic drugs.

Affordable

A national, public Pharmacare plan would have the negotiating strength to obtain lower prices for drugs. It would also replace the more expensive private insurance plans, reducing administrative costs and eliminating profits, sales and commissions. The federal government contribution to drug costs should be increased from its current very low level. This change would both relieve the provinces' financial burden and make the federal government financially responsible for its decisions on drug approvals, patents and advertising. The substantial drug costs now paid only by those employers who provide work based plans, should be replaced by an equitable Pharmacare tax on all employers. A Pharmacare plan would benefit employers by removing responsibility for the health care of their workers to an equitable and cost-controlled public system.

Like Medicare, a national public Pharmacare plan would benefit all Canadians, be advantageous to employers and bring our health care services up to the standard that exists in every other developed country except the US.

Introduction

Pharmacare has long been envisioned as an essential step in the evolution of Medicare, and we have the opportunity to realize that vision. The First Ministers agreed in September 2004 to develop and implement a national pharmaceuticals strategy (Appendix A). A Task Force of representatives from federal, provincial and territorial governments has been meeting and will report its recommendations in June 2006.

In this paper, we offer a framework for a national public pharmaceutical plan that would meet the following criteria:

- Accessible
- Safe
- Cost effective
- Affordable

Canada and the United States are the only two industrialized countries without a national public drug plan. The expansion of Medicare to include universal drug coverage was recommended by Justice Emmett Hall in 1964. It is time to realize that vision and bring Canada up to par with other developed nations.

1. Cost Effectiveness and Controlling Drug Costs

What We Have

Escalating spending on drugs is undermining current drug plans and will threaten the sustainability of any system unless restrained. Prescription drug costs rose 62.3 percent between 1994 and 2004.[1] Adjusted for inflation, the amount that we spend on drugs is now increasing by between seven and eight percent each year – three times the rate of inflation.[2] We spent $15 billion on prescription drugs in 2002, expected to rise to $18 billion by 2004.

Drugs now rank second after hospitals in terms of share of total health care spending, having overtaken spending on physicians in 1997. The share of total spending going to drugs rose from 9.5 percent in 1985 to 16.2 percent in 2002. Spending on drugs is expected to hit 16.7 percent of total health care spending in 2004, while spending on physicians will be just 12.9 percent.[3]

The rapid rise in drug costs is primarily due to the ongoing substitution of newer, more expensive drugs in place of existing, less expensive products. The newer drugs, in the majority of cases, have no added benefit. Of the 117 drugs with new ingredients introduced in Canada between 1998 and 2002, only 15 provided a substantial improvement over existing drugs.[4] The rest are "me-too" drugs that offer little or no therapeutic advances over existing therapies but are responsible for 80 percent of the increased expenditure on drugs.[5]

Aggressive advertising by drug companies drives consumption of these me-too drugs.[6] Apart from advertising directly to consumers, drug companies spend approximately $30,000 per year for every doctor in Canada on drug samples, sales rep contact, conferences, trips and giveaways.[7] The influence of pharmaceutical companies on research, education and clinical practice has also been widely documented.[8] Both patients and doctors are influenced by the onslaught,[9] with the result that drug costs are skyrocketing but health outcomes are not necessarily improving.

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[1] Canadian Institute for Health Information (2004). *Drug Expenditure in Canada, 1985–2003*, Table A.2. Retrieved Nov. 22, 2005, from http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=PG_283_E&cw_topic=283&cw_rel=AR_80_E

[2] Lexchin, J. (2005). *50 Years of Waiting for Pharmacare is Long Enough - Fact sheet*. Ottawa: Canadian Federation of Nurses Unions. Retrieved Aug. 15, 2005, from http://www.nursesunions.ca/en/Press%20Releases/2005-08-11-Fact_Sheet_Lexchin.pdf

[3] Canadian Institute for Health Information (2005). *National Health Expenditure Trends, 1975-2004*, p. 19.

[4] Patent Medicine Prices Review Board (2003). *Annual Report.* Ottawa.

[5] Morgan, S.G. et al (2005). Breakthrough drugs and growth in expenditure on prescription drugs in Canada, *British Medical Journal*, Vol. 331, October 2005, pp. 815-816.

[6] Mintzes, B., Barer, M. L., Kravitz, R. L., Bassett, K., Lexchin, J., Kazanjian, A., Evans R. G., Pan, R., & Marion, S.A. (2003). How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *Canadian Medical Association Journal* 169(5): 405-412.

[7] Lexchin, Joel, "are Drugs too expensive in Canada?", in Canadian Family Physician, Vol. 52: May 2006, p. 573.

[8] Angell, M. (2004). Excess in the pharmaceutical industry. *Canadian Medical Association Journal,* 171(12): 1451-1453; Bordemier, T. (2000). Uneasy alliance: clinical investigators and the pharmaceutical industry. *New England Journal of Medicine,* 342: 1539-44; Choudhry, N. K., Stelfox, H. T., & Detsky, A. S. (2002). Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *Journal of the American Medical Association*, 287: 612-7; Lenzer, J. (2002). Alteplase for stroke: money and optimistic claims buttress the 'brain attack' campaign, *British Medical Journal*, 324: 723-9; Wazana, A. (2000). Physicians and the pharmaceutical industry. *Journal of the American Medical Association,* 283(3): 373-380; Ziegler, M. G. & Singer, B. C. (1995). The accuracy of drug information from pharmaceutical sales representatives, *Journal of the American Medical Association,* 273 (16): 1296-8.

[9] Kassirer, J.P. (2004). *On the Take: How Medicine's Complicity With Big Business Can Endanger Your Health*. Oxford University Press; Mintzes, B. (2001, July). Doctor, about that medicine I saw advertised…, *In Motion Magazine*; Schafer, A. (2005, March 14). Can your doctor be bought for a dinner? *Globe and Mail*, p. A13; Blackwell, T. (2005,

The federal Patented Medicines Prices Review Board (PMPRB) reviews the prices of patented drugs, limiting the introductory price to comparable products and tying increases to the consumer price index. However, these "controls" still leave new drugs with high introductory prices.[10] The PMPRB was established by the Mulroney government in 1987 to create the appearance of effective drug price controls when it granted increased monopoly patent protection for pharmaceutical products. The PMPRB's methodology is skewed to give the appearance of price controls while granting brand names drug companies high introductory drug prices. Once this high introductory price has been approved by the PMPRB, all future medicines in this therapeutic class will be priced at a similarly high level. The drug industry points to PMPRB reports and asserts that drug prices are declining. This deflects attention away from the real problem – the inflated introductory price.

The PMPRB is not mandated to regulate non-patented or generic drugs. However, Health Ministers agreed at their October 22-23, 2005 meeting to give the PMPRB responsibility to monitor and report on non-patented drug prices. Patent protections enjoyed by brand-name pharmaceutical companies continue to inflate drug costs. New drugs have patent protection for 20 years from the time a company files an application for a patent – effectively 12 to 13 years after they reach the market. Automatic extensions and legal battles extend this patent protection by several years further delaying the introduction of cheaper generic drugs. Brand name drugs are increasing their market share compared to generics by substituting newer, more expensive patented medications for older, less expensive nonpatented ones.[11]

The multiplicity and fragmentation of Canadian drug plans impedes better management of drug costs, including decisions on what drugs get funded and the ability to negotiate lower prices. Once new drugs are approved federally, they are assessed for placement on provincial drug formularies. Drugs are purchased separately by provincial governments, hospitals and individuals, which precludes bulk purchasing and undermines negotiation of lower prices. Australian government drug managers negotiate an acceptable price with manufacturers and pay about 10% less than what Canada pays. New Zealand achieved 50 percent savings using coordinated bargaining methods.[12] A national Pharmacare program would achieve significant savings.[13]

April 27). Wining, dining MDs. *National Post*, p. A1; Hensley, S., & Martinez, B. (2005, July 15). To Sell their Drugs, Companies Increasingly Rely on Doctors. *Wall Street Journal*, p.1, A1.

[10] Green Shield Canada (2002). A Focus on Drug Trends, *Canadian Health Care Manager*, Vol. 9, No. 4, P. 6.

[11] Lexchin, J. (2003). *Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go From Here?* Ottawa: Canadian Centre for Policy Alternatives.

[12] Ibid.

[13] Lexchin, J. (2001). *A National Pharmacare Plan: Combining Efficiency and Equity*. Ottawa: Canadian Centre for Policy Alternatives.

The Problems

We are paying for many expensive drugs when cheaper existing drugs would provide equivalent and sometimes better treatment. We are also spending on drug therapy when other types of treatment would be equally or more effective.[14]

Rising drug costs have placed both public and private drug plans under pressure. Provincial drug plans have been cut back in response to rising costs. These plans most commonly cover seniors on low incomes, social assistance recipients and those with high-cost medical conditions. In work place health benefit plans, drugs account for 70 to 80 percent of the cost, and premiums are rising by 15 percent each year. Employers are pressing to contain costs, and health benefits have become a major source of contention between unions and employers.

The fragmentation of drug plans and responsibility undermines effective and accountable planning. The federal government, for example, has control over drug approval, patents and advertising, while paying little towards drug expenditures. It therefore has no fiscal responsibility for the impact of its decisions.

What We Need

A national formulary of essential drugs

We need a national drug formulary that would focus on providing essential drugs that are both medically and cost effective. This would not cover all of the drugs on the current formularies, but would include essential drugs. The list would be decided by independent pharmaceutical experts on a national formulary committee governed by strict conflict of interest rules.

Some provinces are already using various methods to control costs. For example, reference based pricing means paying only for the lowest priced drug among drugs of the same type. Although the B.C. Reference Drug Program applies to only five categories of drugs, it has resulted in substantial savings.[15] Another approach is the first line system, which means prescribing a less expensive drug as a first treatment, and resorting to more expensive drugs only if necessary. These methods should be part of a national system.

Single-payer public system

Governments in Canada should assume the cost for essential drugs on the national formulary, introducing a single payer system. They would then have the power to negotiate lower prices for the large quantities of drugs they would be responsible for providing.

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[14] Antonuccio, D.O., Danton, W.G., DeNelsky, G.Y., Greenberg, R.P., Gordon, J.S. (1999). Raising questions about antidepressants, *Psychotherapy and Psychosomatics*, 68 (1): 3-14; "Treating hypertension with dietary modification: Therapeutics Initiative." Therapeutics Letter, Can blood pressure be lowered by a change in diet? Evidence from DASH trials. Issue 50, October – December 2003.

[15] Cassels, A. (2002, March). *Paying for What Works: B.C.'s experience with the Reference Drug Program as a model for rational policy making*. Ottawa: Canadian Centre for Policy Alternatives, p. 4.

No advertising

Drugs are not just another commodity like clothes or cars, and advertising is not designed to inform but to encourage purchase. Health Canada should enforce legislation that prohibits drug advertising to the Canadian public, including mandatory filtering out of broadcast ads from the United States. Drug company advertising, promotions and seminars directed at doctors and other health care providers must also be strictly controlled.

Safe and effective prescribing

A universal, public system would enable government to have more impact on prescribing practices, including the ability to inform doctors and others through expert opinion and medical research. Governments should develop a national, unbiased, evidence-based drug information system for all health care professionals and patients. This information system would include a single dispensing database and independent comparative information on drug and non-drug treatments. National coordination and the controlled listing of new drugs would help the government to regulate early use.

Improved prescribing would also be achieved by making better use of pharmacists, nurse practitioners, and other health professionals working together in teams.

Better regulation of drug prices

The Patent Medicine Prices Review Board must be revamped to make it publicly accountable, transparent, and effective. The government must change the regulations governing the PMPRB's methodology so that the introductory price of new drugs reflects the OECD average.

Patent reform

Granting monopoly pricing to pharmaceutical drugs through patent protection should be reviewed. Pending the outcome of the review, patents should be limited to 20 years with no extensions. The government should abandon proposed amendments to Food and Drug Regulations that offer increased data protection and extended monopolies.

2. Access to Prescription Drugs

What We Have

Obtaining drugs is a mix of public and private arrangements.

Drugs in hospitals are covered as publicly insured services under the Canada Health Act.

Provincial government plans cover drug costs for some people, based on age, income and medical condition. Eligibility rules and coverage vary between provinces. Some provinces subsidize the drug costs for patients receiving nursing care at home, but coverage is limited.

Work based plans, often negotiated by unions, cover 58 percent of workers and their families.[16] These workers are insured in group plans, most commonly through private insurance companies. The plans vary by how much workers contribute to the premiums, what percentage of drug costs are covered, and the deductibles charged.

Many Canadians get no help with the cost of drugs and must pay the full amount themselves.

The Problems

The impacts of our fragmented and inadequate drug plans are inequality between citizens, both between provinces and within provinces, and devastating health consequences for many Canadians. Further, people who cannot afford to take their prescriptions often experience deteriorating physical and mental health status and need more expensive health care interventions down the road, ultimately meaning higher costs for the health care system.

For many Canadians purchasing prescribed drugs represents a significant financial hardship. Almost one million Canadians (three percent) are uninsured, meaning that they would have to pay more than 4.5 percent of their gross family income for drugs. Another 2.4 million Canadians (eight percent) are underinsured, having to pay between 2.5 and 4.5 percent of gross family income for drugs.[17] Financial barriers to prescribed drugs are heightened as hospital stays are shortened and all health care services are shifted to community and continuing care settings, and ultimately to individuals.

The lack of drug plans in many low wage, part-time or temporary jobs is a major barrier for people on social assistance wanting to move into paid employment who would lose their drug benefits. There are many people now on social assistance who because of their medical condition, require prescription drugs, who could be working if they could get Pharmacare coverage.

Provincial plans provide different levels of coverage, with a complex mix of eligibility rules, deductibles and co-payments.[18] Coverage is especially limited in the Atlantic provinces.

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[16] Applied Management in association with Fraser Group and Tristat Resources (2000, March). *Canadians' Access to Insurance for Prescription Medicines, Volume 2*, submitted to Health Canada, p. 28.
[17] Ibid, Volume 2, pp. 91-93.
[18] Health Council of Canada (2005). Report to Canadians, Appendix A.5. Retrieved Nov.22, 2005, from http://hcc-ccs.com/report/Annual_Report/exec_sum/ExecSumGER.pdf

For example, take the case of a couple aged over 65 with an income of $35,000 and in need of $1,000 of drugs per year. This couple would pay the entire costs in New Brunswick and Newfoundland, two-thirds of the cost in Quebec, one-third in Ontario and B.C., and nothing in the Yukon or Northwest Territories.[19]

Those most likely to have inadequate insurance are 18 to 24 years old and 55 to 64 years old. These age categories are less likely to have drug coverage through work or be eligible for provincial plans.

Our multi-payer system of drug coverage and high reliance on out-of-pocket spending leads to neglected health needs and ultimately higher overall health care costs. Even small increases in individual payments for drugs among those on low incomes can discourage their use, leading to the need for more expensive health care services such as physician care, emergency department visits, and hospitalization.[20]

What We Need

Universal coverage for essential drugs in a public plan

All Canadians should be publicly insured for essential drugs, with the costs shared between the federal and provincial governments. The goal would be a universal plan, providing first dollar coverage to all Canadians. This means the entire cost of drugs on the formulary would be covered. There is a precedent for such a plan in the six drug benefit programs run by the federal government and the Northwest Territories' plan, which are all first-dollar universal public plans.

Such a plan would be a public plan similar to the provision of other health services, like visits to doctors and hospitalization, providing essential care to everyone. If necessary, first dollar coverage for all Canadians would be phased in. In this scenario, first dollar coverage would be provided for a broad definition of those most in need, including seniors, those on low incomes, people with disabilities, children and those with medical conditions requiring high-cost drugs. Others would pay a reasonable and affordable premium, adjusted for different income levels and exempting those with low income. This would provide for additional financing for the new system during its introductory period, while savings from the cost control mechanisms come into effect.

With such a public system, work-based plans would be unnecessary for basic drug coverage but could supplement the public service. This would be done in the same way as additional health services such as semi-private hospital rooms and physiotherapy are currently negotiated.

[19] Ibid, Volume 1, Appendix 4-11.
[20] Tamblyn et al. (2001). Adverse Events Associated with Prescription Drug Cost-Sharing Among Poor and Elderly Persons. *Journal of the American Medical Association*, 285 (4): 421-429.

Problems With Catastrophic Drug Coverage

The public Pharmacare plan we are proposing would not be a catastrophic drug plan. The Romanow Report proposed that the federal government share costs with the provinces for drugs that cost more than $1,500 per year, per person. While Canadians certainly need help in the event of very high drug costs, there are serious drawbacks to focusing on just catastrophic drugs.

Although federal government cost sharing for this component of drug costs would help relieve provincial finances nothing else would change. It is not a step towards a more fair and universal public system. Injecting more government financing without cost controls or quality measures would not improve the future prospects for drug coverage. More public money would be funneled to pharmaceutical companies, costs would continue to rise, and government drug plans might be further eroded.

Catastrophic coverage is essentially a deductible, where individuals pay $1,500 or some other rate before financial help is provided. Those who cannot afford to pay the deductible would receive no new support. Moreover, in order to obtain federal cost sharing, provincial health dollars might be diverted to catastrophic coverage and away from first dollar coverage for those now covered by provincial plans.[21]

Another critical concern is that the catastrophic coverage envisioned would only provide federal support to provincial plans, and does nothing for work-based plans. It would not relieve employers from their responsibilities for catastrophic drug coverage, or help reduce the pressure on the work-based plans that cover 16 million Canadians.

[21] Morgan, S.G., & Willison, D.J. (2004). Post-Romanow Pharmacare: Last-Dollar First… First-Dollar Lost? *Healthcare Papers*, 4(3), pp. 10-20.

3. Safe and Effective Drugs

What We Have

Health Canada's Therapeutic Products Directorate (TPD) determines the safety of drugs and approves their use. In 1995, a new "cost-recovery" approach meant that drug companies began paying fees for the approval process. Pharmaceutical companies now pay half the running costs of the agency that evaluates and approves their drugs. The percentage of new drug applications getting a positive decision has risen, and Health Canada is no longer enforcing the legislation that prohibits prescription drug advertising to the public.

Health Canada does not share the drug evaluation research with the public or with doctors, pharmacists and others in the health care profession. When a new drug is approved, there is often very limited information available to doctors.

The threshold for approvals is too low. In order to receive approval, a drug does not have to be better than an existing drug. It only has to be better than a placebo. The approval process does not consider cost-effectiveness.

As part of the Smart Regulation initiative, Health Canada is revising the Canada Food and Drugs Act. In this process, it is considering faster, not safer, ways of approving drugs.

The Problems

Health Canada approves expensive me-too drugs that provide no improvement over existing drugs.

Health Canada and its approval procedures are not adequately protected from influence by pharmaceutical companies. The Canadian Medical Association Journal has stated that Health Canada is biased towards approving drugs too quickly and without adequate proof of safety.[22]

Pharmaceutical industry influence also extends to research. Three leading medical journals issued a joint statement that market values were compromising medical science because huge grants from pharmaceutical companies to universities and research hospitals are biasing research outcomes.[23]

There is a remarkable lack of information about drugs, especially new drugs, even for the doctors who prescribe them. One doctor has described how "obtaining even the barest form of clinical information from the TPD about drugs is exceedingly difficult", even in

[22] Editorial (2005, January 4). Vioxx: Lessons for Health Canada and the FDA, *Canadian Medical Association Journal*, 172 (1).
[23] Schafer, A. (2002). *Medicine, Morals and Money: Dancing with porcupines or sleeping with elephants*. Manitoba: University of Manitoba Centre for Professional and Applied Ethics, University of Manitoba.

situations where the drug treatment is controversial.[24] Doctors are left to rely on drug companies for information.

Drug scandals are common. Millions of women were prescribed hormone drugs for menopause symptoms, often to be taken for life. These drugs are now recommended only in severe cases, at low doses and for the shortest possible time, since they are linked to increased risk of strokes, heart attacks, breast cancer, blood clots and gallstones.[25] The widely prescribed pain killers Vioxx and Bextra were found to cause heart attacks and strokes.[26]

Currently, the most prescribed drug in Canada is a cholesterol-lowering statin called Lipitor, at 9.7 million prescriptions per year.[27] Three million people, one out of every eight Canadians over 15 years old, are taking statins to lower cholesterol. While proven effective for people with actual heart problems, it is widely used as a preventative treatment. Its value for prevention is disputed. Health Canada has determined that potential side effects warrant warnings to consumers with each prescription.

Pre-marketing trials test drugs on selected groups of patients. However, when the products are released on the market they are aggressively promoted and often prescribed to patients with health conditions not covered by the clinical trials. This heavy prescribing takes place long before the full safety profile of new drugs is known, exposing patients to potentially serious problems. Half of the drug withdrawals in the United States between 1975 and 1999 occurred within the first two years of a drug being introduced.[28]

What We Need

Drug regulation that puts safety and efficacy first

We need an accountable and transparent regulatory agency to approve drugs, free of conflict of interest and with no funding from the pharmaceutical industry. The government should replace Health Canada's Therapeutic Products Directorate with this new agency, which would report to the federal Minister of Health and be guided squarely by the public interest, including cost effectiveness.

The new drug approval agency would also monitor and regulate the quality and effectiveness of pharmaceutical industry research to ensure independent analysis and publication of all results. National rules should be implemented to ensure ethical conduct in clinical trials and health research. Government should also establish mandatory registration before the clinical trials are started. Registration of clinical trials would identify: funders,

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[24] Lexchin, J. (2004, October). Transparency in Drug Regulation: Mirage or Oasis? Ottawa: Canadian Centre for Policy Alternatives, p. 8.
[25] Taylor, P. (2005, February). HRT: heart attacks, cancer and now, incontinence, *Globe and Mail*, p.A11.
[26] Goldstein, R. (2004, October 4). Drug Industry Scandal a Crisis. *Inter Press News Agency*, Canadian Press (2005, April 8). Canada Joins Call for Pfizer to Halt Sale of Bextra.
[27] Rinehart, D. (2005, March 19). A wonder drug and a dilemma. *Globe and Mail*, p. F9.
[28] Lasser, K.E., Allen, P.D., Woolhandler, S.J., Himmelstein, D.U., Wolfe, S.M., Bor, D.H. (2002). Timing of new black box warnings and withdrawals for prescription medications, *Journal of the American Medical Association*, 287:2215-20.

sponsors, researchers, number and characteristics of patients, research objectives and methods, as well as proposed research sites. This registration system must be publicly available.

The government should also mandate information about proper usage of the drugs, proper safety warnings in plain language, and listing possible alternatives to the drug where appropriate. Warnings must be given out with all prescriptions and must be approved by the regulatory agency.

Drug safety board to investigate safety issues post-marketing

An independent agency should monitor adverse drug reactions once a drug hits the market. It would make all information on investigations public - while exempting information that would identify individuals - allowing easy access through a vehicle such as a searchable web-based database.

Accountable and transparent decision-making

Both health care practitioners and the general public should have access to all information used to make decisions on drug approvals, including unedited pre-clinical and clinical trial data and summaries of the trial data. The government should establish expert advisory panels to hear evidence on new medications. Panel members would be subject to strict conflict-of-interest rules. It should also provide opportunities for public input in the drug approval and review process.

4. National Pharmacare is Affordable

Who Pays for Drugs Now?

In 2002, prescription drug costs in Canada totaled $15 billion. As presented in the table below, funding comes from both public and private sources. Public funding covered 46 percent of this cost, while private payments were made for the other 54 percent. Provinces accounted for 40 percent, while the federal government contributes only three percent.

Private funding is divided into two categories: insurers and individuals.

a. Insurers pay for 34 percent of all drug costs. This is the segment of drug costs paid for by employers through premiums to insurance companies to cover their workers in group health plans.

b. Payments by individuals, called out of pocket expenditures, make up 20 percent of total drug costs.

Prescription Drug Costs in Canada, 2002

	$ millions	**%**
Public expenditures		
Provincial/territorial	5911.2	39.9
Federal	427.0	2.9
Social services*	563.9	3.6
Subtotal	**6875.1**	**46.4**
Private expenditures		
Insurers (employers)	5004.1	33.8
Out of pocket (individuals)	2934.1	19.8
Subtotal	**7938.2**	**53.6**
Total Drug Costs	**14813.3**	**100.0**

* *Workers Compensation Board and the Quebec Drug Insurance Plan for those otherwise not covered. Source: Canadian Institute for Health Information, "Drug Expenditure in Canada, 1985-2003", Ottawa, 2005.*

What We Need

Paying for drugs: government

Prescription drug coverage should be funded on the same basis as federal-provincial cost sharing for other health care services. This means that the federal government would contribute 25 percent of the public share of drug costs, providing financial relief to the provinces. Using 2002 figures, at 25 percent of public costs, the federal government share would have been $1.7 billion for that year. This is an entirely feasible contribution.

The combined federal and provincial contribution to drug expenditures is low in Canada compared to the public contribution in other countries.[29] An increase in the overall proportion paid by government would reduce the share paid through the private sector, by employers and individuals.

Paying for drugs: employers and insurers

For employers, public health care is a major competitive advantage. It relieves them of responsibility for workers' health care costs, and it averts the serious expenses and disputes experienced in the U.S.[30] Drugs are not part of that universal health care system in Canada, and employers find that private drug plans are expensive, complex to negotiate, and a source of increasing disputes and strikes. A public and universal drug program, as with other public health services, would be advantageous to employers.

Canada's publicly funded universal health care system provides our businesses with a competitive advantage over businesses in the United States. A national public drug plan would strengthen that advantage. Our public system operates much more efficiently than the largely private system in the U.S. Health care spending in the U.S. is well over $5,000 per person – almost two and a half times Canada's per capita spending.[31] Taking just one example of how this translates into a competitive business advantage, General Motors in the U.S. reports that private health care plans cost them more than they spend on steel - about $1,500 per vehicle. GM Canada pays only $500 per vehicle.[32]

With public health insurance, Canadian employers also enjoy more workplace stability. In the United States, every significant strike or bargaining conflict involves health insurance costs.[33] If we fail to address rising drug costs, labour-management conflicts over work-place benefit plans will also intensify in Canada.

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[29] Lexchin, J. (2001). *A National Pharmacare Plan: Combining Efficiency and Equity*. Ottawa: Canadian Centre for Policy Alternatives.

[30] Green, J.P., MacBride-King, J. (1999, March). *Corporate Health Care Costs in Canada and the U.S. Ottawa*: Conference Board of Canada.

[31] World Health Organization (2005). *World Health Report*, pp. 200-203. Retrieved Aug. 15, 2005, from http://www.who.int/whr/2005/en/index.html

[32] Canadian corporations need to stick up for our health-care system: Praise from head of GM of Canada underscores value of public health (2005, July 17). *The Edmonton Journal*; and U.S. Healthcare problem too big for employers and workers (2005, June 20), *The L.A. Times*.

[33] AFL-CIO (2005). *Quality, Accessible Healthcare*. \ Retrieved Nov. 17, 2005, from http://www.aflcio.org/issues/legislativealert/stateissues/healthcare/

The Conference Board of Canada found that large employers expect to continue contributing to health costs, but are concerned about cost containment and reduction.[34] The following proposals address these concerns.

Pharmacare would equalize contributions for drug coverage among employers. Currently, only 58 percent of workers (7.6 million) are covered by work-based plans.[35] Often part-time workers and those who work in small businesses (25 or fewer workers) have no insurance for drug costs. One serious problem in the current private insurance system is that it is often too expensive for small workplaces to obtain drug benefit coverage. While the average administration fee for privately insured drug plans is eight per cent, insurance companies charge small groups up to 25 percent for administration.[36]

Of the 42 percent of workers not covered by work-based drug plans, some are paying for drugs themselves as individuals, a few may be covered by provincial government plans, and many are covered by the work-based plans of their family members. While 7.6 million workers have drug coverage, their plans also cover another four million adult family members under the age of 65 years and 4.4 million children.[37]

It is clear that some employers pay the $5 billion price tag for drugs purchased through insurance companies, while others pay nothing. A more equitable system would be a Pharmacare tax applied fairly to all employers, which would both reduce the amount paid by employers who currently contribute and reduce the share paid by individuals.

Also important is that employers pay substantially more in premiums to insurance companies than the amount paid by insurers for drugs. "Typically, the actual cost of prescriptions (i.e. the medication and the professional fee) makes up 75 percent of prescription drug plan costs for an employer. The remaining 25 percent of costs are generated by the insurer's administration costs (including adjudication transaction costs), plan reserves, taxes and commissions or fees for the benefits consultant or broker."[38] By this estimate, in 2002 employers paid $6.7 billion in insurance premiums for $5 billion worth of drugs.

The administration of private drug plans is an enormous expense. Millions of workers are making claims for themselves and their families, and the plan at every work place differs with regard to eligibility, deductibles, co-payments and prescription coverage. Each claim must be assessed under the plan for that workplace and reimbursed or rejected individually. In a universal public plan, administrative costs would be drastically reduced. Average administration costs in private plans are eight percent compared to two percent in large

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[34] MacBride-King, J. (1998). *From Payer to Player: The Employer's Role in the Canadian Health Care System*. Ottawa: Conference Board of Canada, p.12.

[35] Applied Management with Fraser Group Tristat Resources (2000, March). *Canadians' Access to Insurance for Prescription Medicines, Volume 2*, submitted to Health Canada, p. 28.

[36] Palmer D'Angelo Consulting Inc. (1997, September). National Pharmacare Cost Impact Study, Ottawa, p.24; Discussions with Services Actuariels Inc. of Montreal, Quebec (2005, September).

[37] Applied Management with Fraser Group Tristat Resources (2000, March). Canadians' Access to Insurance for Prescription Medicines, Volume 2, submitted to Health Canada, pp. 28-29.

[38] Hutty, S. (2002, June). *Third party issues: Understanding drug benefits for better patient care*. Regina: Canadian Council on Continuing Education in Pharmacy, p. 2.

public plans.[39] Another four to six percent of employers' premium costs cover insurers' profits, brokers' fees, and commissions - costs that would not apply in a public system.

Moving to national, public Pharmacare plan would save a significant amount of money. For 2002, the additional administrative and other costs of the private insurance drug system amounted to between $670 and $800 million (10 –12 percent of total costs).
In a universal, public Pharmacare system, the role of insurance companies would be greatly reduced. The loss of jobs that would result should be recognized and a transition program designed to help those affected. However, concern over job loss in the insurance industry should not prevent the introduction of a more cost effective, public Pharmacare program that would benefit all Canadians.

Paying for drugs: individuals

Individuals currently pay 20 percent of all drug costs themselves. This places a significant burden on many Canadians. In this Pharmacare proposal, additional funding would be available from controls on the cost of drugs, increased government funding, contributions from additional employers, and savings of money now going to insurance companies for administration, profits and marketing.

These funds could be applied to substantially reduce out-of-pocket expenses for individuals. This would provide, if not for immediate first dollar coverage for everyone, at least for much broader first dollar coverage for drugs than now exists.

[39] Palmer D'Angelo Consulting Inc. (1997, September). *National Pharmacare Cost Impact Study*. Ottawa, p. 24.

Universal Public Pharmacare is Affordable

In a universal system, there would be increased costs because more Canadians would have access to prescribed drugs. For those who are now uninsured or under-insured and who therefore fail to obtain drugs prescribed for them, drug consumption would increase.[40] However, higher consumption costs would be far outweighed by savings from this Pharmacare strategy.

Our analysis suggests four additional sources of funding for a universal public Pharmacare system:

1. Reductions in the costs of drugs, with new drugs under stricter scrutiny, a national drug formulary, advertising and promotion controlled, direct cost control mechanisms introduced, patents restricted, and savings realized from a single payer system;

2. Savings from the current administration, profits and marketing costs of insurance companies;

3. Contributions from employers for the 42 percent of workers not currently covered in work based plans; and

4. Additional public funding if federal government contributions were used at least in part as additional funding, as opposed to just replacing provincial funding.

We estimate that a public system as outlined above could finance the additional costs of increased usage by those now without adequate insurance, reduce the amount currently paid by contributing employers and substantially decrease payments by individuals.

A universal public Pharmacare plan would also remove a major barrier to paid employment for people on social assistance resulting in cost savings for welfare.

We propose that government fund a thorough and reliable research project to analyze these possibilities in more detail.

[40] Lexchin, J. (2001, March). *A National Pharmacare Plan: Combining Efficiency and Equity*. Ottawa: Canadian Centre for Policy Alternatives.

Conclusion

We call on governments to take responsibility for the provision of prescription drugs, an element of health care no less critical than hospitals and physicians.

We need a national Pharmacare plan that will provide drugs in a manner that is cost effective, accessible to all Canadians, and safe.

Glossary

Catastrophic coverage:	See: Last-dollar coverage
Common Drug Review:	A single common process for reviewing new drugs to assess potential coverage under Canadian public drug benefit plans, established in September 2001 by federal, provincial and territorial Health Ministers (except Quebec).
Co-payments	Some benefit plans require that you pay part of the cost of each benefit or service. This is called a co-payment. It can be the same amount each time, like $5, or it can be a percentage of the total cost, such as 20%.
Deductible:	A patient or user pays 100% of prescription drug costs until an annual maximum is reached. Once you reach the deductible amount, further eligible costs may be covered for the remainder of the calendar year. In some plans co-pays are added up until they reach the deductible, e.g, if the co-pay is $5 per prescription and the deductible is $100 then after you've filled 25 prescriptions you don't pay the co-pay any more.
Evergreening	Tactics used by brand name pharmaceutical manufacturers to extend the duration of a drug's patent. It includes, for example, a company bringing out a new once-a-day version with its own patent when the patent on the three-times-a-day version is due to expire.
Formulary	A list of prescription drugs established by a regulatory body. Governments can define formulary drugs covered by public insurance. Private insurance plans also have a formulary.
First dollar coverage	A drug insurance plan that pays for all of the drug costs covered starting with the first prescription and with no co-payment, deductible, or out of pocket payment.
Last dollar coverage (Catastrophic)	A drug insurance plan that only covers a person's drug costs beyond a large annual deductible (e.g. $1,500). Also called a catastrophic drug insurance plan.
First-line treatment	The drug therapy that should be tried initially in the treatment of a disease. If this fails to work, you move to a second-line treatment.

OECD	The Organization for Economic Co-Operation and Development, a Paris-based organization that acts as a meeting ground for 30 countries which believes strongly in the "free" market system but supports monopoly patents on medicines to prevent competition.
Pharmacare	A government operated prescription drug insurance program.
Reference based pricing	Setting a maximum reimbursement price for a group of drugs considered to be equally as effective and the most cost effective in a therapeutic category

APPENDIX A

2004 Health Accord (Federal/Provincial/Territorial)

National Pharmaceuticals Strategy

The founders of Medicare a half-century ago established the principle of equity of access to hospitals and doctors' services for all Canadians. First Ministers agree that no Canadians should suffer undue financial hardship in accessing needed drug therapies. Affordable access to drugs is fundamental to equitable health outcomes for all our citizens.

First Ministers direct Health Ministers to establish a Ministerial Task Force to develop and implement the national pharmaceuticals strategy and report on progress by June 30, 2006. The strategy will include the following actions:

- develop, assess and cost options for catastrophic pharmaceutical coverage;
- establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness;
- accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
- strengthen evaluation of real-world drug safety and effectiveness;
- pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
- enhance action to influence the prescribing behavior of health care professionals so that drugs are used only when needed and the right drug is used for the right problem;
- broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record;
- accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and
- enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

[It is understood that Quebec will maintain its own Pharmacare program.]

APPENDIX B

The Canadian Health Coalition's 10 Elements of a National Strategy for Pharmacare

1. Universal public drug insurance

- Expand first-dollar coverage according to the principles of the Canada Health Act: no user fees, co-payments or premiums for insured first-line therapeutic treatments.
- Fully fund the insurance plan through the public sector. Governments self-insure to control costs. No partnerships with the private sector.
- Options for "catastrophic" drug coverage (covering costs that exceed high thresholds) must not become a means of limiting the current first-dollar programs.

2. National formulary for essential drugs

- Insure first line therapies on a national formulary based on evidence of efficacy, safety, and comparative cost-effectiveness.
- Decisions would be made by a national formulary committee governed by strict conflict of financial interest rules.
- The public plan pays only for what works and is cost-effective.
- The committee would make allowance for special needs, and there would be an appeal mechanism.
- Use nationally integrated cost-management methods, including: bulk purchasing, cost-volume price negotiations, and reference based pricing.

3. Drug regulation that puts safety and efficacy first

- Replace Health Canada's Therapeutic Products Directorate with an accountable and transparent regulatory agency that reports to the federal Minister of Health and that receives no funding from the industry it regulates.
- Mandate information on proper use of drug as well as safety warnings in plain language, listing possible alternatives to the drug where appropriate. Warnings must be given out with all prescriptions and must be approved by the regulatory agency.
- Create an independent agency to monitor and investigate the safety of drugs after they reach the market, modeled on the Transportation Safety Board..
- Make all information on investigations publicly available and easy to access, using a searchable web-based database with personal identifiers removed.

4. Reform of the Patent Medicine Prices Review Board

- Change the Patent Medicine Prices Review Board regulations in order to prohibit new drugs with moderate, little or no therapeutic improvement to be priced as high as existing therapies in the same class of drugs.
- Change the regulations governing the PMPRB's methodology so that the introductory price of new drugs reflects the OECD countries that have a similar level of industry activity as Canada.

5. Accountable and transparent decision-making

- Guarantee public access to all information used to make decisions on drug approvals and formularies, including unedited pre-clinical and clinical trial data, summaries of the trial data, and financial assumptions used to decide what drugs get listed on the formulary.
- Establish expert advisory panels to hear evidence on new medications. Panel members would be subject to strict conflict-of-interest rules.
- Provide opportunities for public input in the drug approval and review process.

6. Patent reform

- End the "evergreening" of patents by repealing the Patented Medicines (Notice of Compliance) Regulations. By evergreening, companies keep a monopoly position on drugs past the time when the patent should have expired.
- Abandon proposed amendments to Food and Drugs Regulations that offer increased data protection and extend monopolies.

7. Regulation of drug promotion and marketing

- Improve and enforce sanctions that prevent prescription drug advertising aimed at the public.
- Establish strict rules and sanctions governing industry promotion and marketing to health professionals.
- Establish an independent body to oversee regulation of drug promotion and marketing - based in legislation, with representatives nominated from health professional groups and consumer/patient groups, independent of the drug or advertising industries.

8. National prescribing service

- Make better use of pharmacists, nurse practitioners and other health professionals working in teams.
- Work through the Royal College of Physicians and Surgeons, College of Family Physicians, and national and provincial pharmacists' organizations to promote better prescribing practices.
- Consider establishing an independent body along the lines of the Australian National Prescribing Service. This service would work through national and provincial health professional associations to develop and fund prescribing strategies.

9. Establish a public drug information system

- Develop a national, unbiased, evidence-based drug information system for physicians, pharmacists and patients.
- This information system would include independent comparative information on drug and non-drug treatments.

10. Regulation for ethical conduct in clinical trials and research

- Monitor the quality and effectiveness of pharmaceutical industry research.
- Establish and enforce national rules for ethical conduct in clinical trials and health research.
- Institute mandatory registration prior to clinical trials as a precondition for drug approval consideration. Registration of clinical trials would identify: funders, sponsors, researchers, number and characteristics of patients, research objectives and methods, and research sites.