



**Canadian Pensioners Concerned Incorporated
La Corporation des Retraités Canadiens Intéressés
National**

SUBMISSION

TO

HOUSE OF COMMONS

STANDING COMMITTEE ON HEALTH

Study on Prescription Drugs

October, 2003

Presented By:

Gerda Kaegi, President

Barbara Black, Past President

10 Trinity Square, Toronto, Ontario, M5G 1B1

Phone: 416-368-5222 ~ Fax: 416-368-0443

Toll Free: 1-888-822-6250

Email: canpension@lefca.com

www.canpension.ca

On behalf of Canadian Pensioners Concerned, Inc. National, we wish to thank the Commons Committee for making it possible for us to participate in their cross-country hearings on Prescription Drugs. We believe that your study is of vital importance to all Canadians, but most especially to those on low incomes.

Who we are

Canadian Pensioners Concerned, founded in 1969 in Ontario, is a provincial and national membership based nonpartisan voluntary advocacy organization of mature Canadians committed to preserving and enhancing a human-centred vision of life. In our education and advocacy role, we act on issues such as pensions, health care, housing and transportation. We are concerned not only about those matters which involve older citizens but also about all of the factors that make a just, caring, compassionate, civil society for all age groups.

An Overview of the Issues

The practice of Medicine has changed dramatically since the introduction of a national Medicare program through the Canada Health Act, now many years ago. The introduction of new technologies - one of the most important of which is the use of prescription drugs - has brought amazing changes to the “Health Cure” system. People are living longer with chronic diseases because of the use of prescription drugs and other technologies. However, the concepts of health care known in the late 60s and early 70s could not have predicted the remarkable changes that have taken place, changes that have not been reflected in the Health Services covered under the Canada Health Act. Furthermore, the use of new technologies and the resulting changes to practice and treatment have resulted in the limitation of hospitalization, the closing of hospital beds and the shifting of the burden of drugs costs from the institutions to the community and individuals. It is this burden of drug costs that we wish to address in our brief.

We will focus on three main issues: first, the impact of prescription drug costs on individuals and the healthcare system, and second, the role of the special treatment given to the largely international pharmaceutical industry by the Government of Canada. This special treatment has resulted in unnecessary delays to the introduction of lower cost generic equivalents. Lastly, we will touch on the matter of advertising prescription drugs to the public.

1. Drug Costs and the Issue of Affordability

We addressed this issue in our earlier briefs to the House of Commons Industry Committee and to the Senate Standing Committee on Industry, Science and Technology in 2001 when Bill S-17, An Act to Amend the Patent Act, was passing through the parliamentary process before it became law. We hope you will forgive us for repeating many of the points we made then. They are still as true today as they were then.

We will touch briefly on the critical issue of health needs and the capacity to pay. We all know the significant determinants of health which include food, clothing, housing, clean air and water, adequate income. The paper released by Statistics Canada titled *The Assets and Debts of Canadians: An Overview of the results of the Survey of Financial Security* identified a very dramatic problem for many Canadians.

The median after-tax income of Unattached Individuals was \$16,700

20% of Unattached Elderly Women and 32% of Unattached Non-Elderly women had a median after-tax income of \$15,600 or less.

Lone-parent families of two or more had a median net worth (after debts) of \$14,600 and a median after-tax income of \$21,800¹

These are national figures and we know, through the work of the National Council on Welfare, that 'low income rates' vary greatly from one province to another. A

¹ *The Assets and Debts of Canadians: An Overview of the results of the Survey of Financial Security*, Statistics Canada, Income Statistics Division, Cat. No. 13-595-XIE, Minister of Industry, Ottawa, 2001,

their report Poverty Profile 1999, Volume 117

summer of 2002 s very clearly.

The National Health Survey 1996/97 carried out by Health Canada identified some disturbing information :

40% of seniors over the age of 65 lacked Health Insurance covering prescription drugs

the ages -69 had used prescription medications

Council on Aging Interim Report Card on *Seniors in*

Canada 2003 reiterates issues that we and others have been pointing out before.

Here are some of the issues they raise:

Seniors spend more for drugs than other age groups, despite coverage by drug benefit plans; for instance, Manitoba drug use data shows that seniors in that province spent four times more per person for prescription drugs in 1999-2000 than younger residents: \$708 vs. \$177.

In 2000 the average after tax income of unattached senior women was \$19,299, that of unattached senior men \$22,025.

Seniors who receive GIS are the poorest seniors in Canada. 36% of seniors who get OAS also depend on the GIS and this percentage changes from a high of 66% in Newfoundland and Labrador to 28% in Ontario. [If you were living on OAS and GIS as a single unattached person your maximum yearly income would be \$1009.55 a month]

Now, think about having to pay for housing, clothing, or cut back on adequate food intake in order to pay for drugs. People have to forgo needed prescription medication in order to pay for their basic necessities. Public Health Nurses have testified to instances where low income clients, including seniors, will alternate days on which they will take their medication, or take one a day instead of the required three.

The Canadian Institute for Health Information now releases an annual statistical report on healthcare expenditures in Canada. They have documented the incredible rise in yearly expenditures on drugs – an increase in 2001 of 11.9%. The rate of increase in public spending has slowed while that of private spending is now approximately 55% of all spending on prescription drugs. The Health Cure System is increasingly turning to the use of prescription drugs and, if they are used outside a hospital, they then become the responsibility of the individual to cover the cost. Drug therapy is one of the fastest changing components of modern medical care (e.g. drug therapy as an alternative to surgery).²

Provincial Governments are trying to control their escalating health costs. One strategy is the exclusion of new prescription medications from Provincial Formularies; another is to delay the inclusion thus leaving the cost to the individual. Many new generic treatments are not finding ready or quick acceptance on these critical lists. British Columbia takes an average of 84 days to list a new drug while Ontario takes 314 days. All Provinces now require co-payments from those on their drug benefit plans. In Ontario, those on social assistance as well as beneficiaries of the Ontario Drug Benefit program (ODB) are required to pay. For those on the ODB, the first co-payment of \$100 may occur on the very first prescription drug purchase of the year. In addition, there are dispensing fees for all remaining prescriptions. Co-payments are a standard feature of Provincial Drug Benefit Programs across the country and they tend to rise every year without taking into account the individual's capacity to pay.

2. The Special Treatment given to the Pharmaceutical Industry under the Patented Medicines (Notice of Compliance) Regulations of the Patent Act

When the Regulations came into force in March 1993, the decision to grant an NOC for a generic drug moved beyond the health and safety issue to include the patent status of the brand name drug. The brand name company can now automatically stop the generic drug from getting a NOC from Health Canada

² Canadian Institute for Health Information, Drug Expenditures in Canada 1985-2000, p.21

simply by claiming that it has patent rights that would be infringed by the generic drug entering the market. The brand name company has a short period of time to start legal proceedings that will ultimately stop the generic manufacturer from being issued an NOC by Health Canada.

Let us begin by saying we recognize the need to protect intellectual property rights in the interest of the developer of those ideas as well as in the broader public interest. However, we see limits to those rights when they are balanced against the public interest. In a civil society such as Canada, no one has absolute rights to private property.

The issue of the cost of prescription medications is not a new one for us. We have argued that the changes in patent protection and the regulations governing the drug industry have been a recipe for disaster. What has been

introduction of a generic drug to the market, an injunction that holds until the matter is settled in court. This special treatment is not justifiable.

The Patent Register available on the Health Canada website is a very useful research resource on drug patents. The widely used drug Losec has been the subject of a number of news articles on abuse of the Regulations and the findings were very disturbing. It was astonishing to find that AstraZeneca has listed 10 patents on this one drug. Please note that the latest of these patents does not expire until 2018, even though the original patent expired in 1999.

Patent Number	Expiry Date
1292693	December 3, 2008
1302891	June 9, 2009
2025668	February 2, 2010
2133762	April 20, 2013
1338377	June 11, 2013
2284470	November 10, 2018
1264751	January 23, 2007
2166483	July 8, 2014
2166794	July 8, 2014
2170647	June 7, 2015

In Canada, there are still no generic versions of this drug on the market as the generic companies have been tied up in court by AstraZeneca under the Regulations. Our concern is with the unnecessary cost to individuals and to the Health Care system through the perfectly legal but morally questionable practice through market monopoly extensions.

The tactic of filing a number of patents on the same drug is the way brand companies abuse the system. For each of the patents listed above, AstraZeneca can claim patent infringement and trigger the automatic stay. This is undoubtedly

The United States and Canada are the only two countries in the world with automatic stays that allow brand companies to block generics. In the United States, I understand the stay is 30 months, while in Canada the stay is 24 months. No matter the length of each stay, the tactics, as stated by U.S. politicians in the media at least, is the same in both countries. The brand companies list additional patents on a single drug in order to have more opportunities to claim patent infringement and trigger the automatic stay, thus lengthening market monopolies to make more money. President Bush in the United States has recognized the abuse of the system and has acted to stop it – yet we have done nothing in Canada except talk.

One final note on patents and the cost of prescription drugs for individuals and provinces. To quote from the Canadian Institute for Health Information Report *Health Care in Canada 2002*:

New drugs are introduced each year. In some cases, they are better than older drugs....But newer drugs may also be more expensive than older ones and are not always the best choice for particular patients. For example, a study showed that in Manitoba between 1995 and 1998, the number of prescriptions for newer broad-spectrum antibiotics grew relative to prescriptions for older antibiotics. The increase occurred even though broad-spectrum antibiotics are more expensive and their widespread use may increase the risks of antibiotic resistant organisms. (Pp81-82).

The evidence also shows that the other stated goal, of encouraging research and development of new drugs through the special treatment afforded these brand name pharmaceutical companies, has not been met. The Patent Medicine Prices Review Board (PMRB) January 2003 Report states A...Canada still ranked behind the other industrialized countries by several measures. Most importantly, the ratio of R & D to domestic sales in Canada remained well below values observed in Europe and the US. ...only Italy had a lower ratio than Canada in 2000.”(Page 6)

The multinational pharmaceutical companies are developing their new drugs in their home countries, not here in Canada. The National Research Council recently published data showing that Canada's trade deficit in pharmaceuticals has grown from \$1.8 billion in 1997 to \$4.8 billion in 2001. It also reports that this figure is on track to reach \$7.7 billion by 2005 and \$11.4 billion in 2010. It is my understanding, supported by the PMRB Report, that the spending they do in Canada for R & D is for things like clinical trials in order to get government approval to sell their drugs. It is not, primarily, basic research.

Surely it is now time to admit that Canada's current drug patent regime is failing. The facts show that it is only ensuring that Canadians get the worst of both worlds, higher drug costs than necessary and minimal spending on the development of new drugs

3. Public Advertising of Prescription Drugs

The brand name pharmaceutical companies and the media are pressuring the government to allow direct advertising of prescription drugs to the public. This is widespread in the United States. How many times do we see men leaping for joy because they have been prescribed "Viagra" after they asked their Doctor about "erectile dysfunction"? Such advertising will only increase the pressure on physicians to prescribe more medications for new "syndromes" or so called "illnesses". It will encourage people to take drugs for one health problem without consideration of the possible negative effect on other conditions. The danger will increase of people disregarding possible negative effects of taking combinations of drugs that are incompatible.

Direct advertising will increase the market for drugs that are often of little value, if any, to the health and well-being of the public. It is diverting money away from the development of drugs that are really needed in the world, drugs that will tackle the diseases that are killing people living in poverty around the world. It encourages people to look to drugs to solve their problems. Finally, it is wasting

money that could be spent in keeping people healthy through public health expenditures and disease prevention.

RECOMMENDATIONS

1. Canada must have a National Pharmacare Program that will be included under the Canada Health Act, or with the same set of principles applied to a new Pharmacare Act. All Canadians would be covered for required prescription drugs.

2. We need a National Pharmaceutical Agency, created through Federal, Provincial and Territorial Agreement that will:

a) Purchase drugs – thus reducing their cost at the initial stages through bulk buying

b) Agree on the testing and approval of drugs in an effective and expedient manner.

c) Agree that drugs that have passed the approval process will be made available to all Canadians on an equitable basis regardless of province or territory.

Provincial governments vary widely in respect to the listing of drugs on their formularies which in turn leads to great inequities of access especially for seniors.

d) Ensure that generic equivalents are recommended for substitution once they have been approved. The cost of generic drugs is well below that of the original patented drugs.

3. Until a new National Pharmacare Program is introduced, we believe that all drugs needed for “catastrophic illnesses” must be covered for all Canadians under an interim Federal/Provincial/Territorial Agreement.

4. Impose an absolute limit of 20 years on new drug patents not slightly modified drugs

5. The 20-year time limit should begin the moment a filing is submitted to Health Canada and no additional patents should be allowed unless it is a significantly different modification and then it should be limited to one.

6. Repeal the special Regulations targeted at the pharmaceutical industry and treat the industry like any other patent holder so that lower cost generic versions can become available after the original patents on the medicine have expired.

7. Limit the number of patents per drug to a maximum of two.

8. Continue to prohibit direct-to-customer advertising for prescription drugs to the public and enforce the current rules.