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Review of the *Patent Act Amendment Act, 1992* (Bill C-91)

February 1997

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Contents

Introduction

This information package has been prepared jointly by Industry Canada and Health Canada to provide factual background material for the review of the *Patent Act Amendment Act, 1992* (Bill C-91). The House of Commons Standing Committee on Industry has been tasked with undertaking this review, as required by the review clause set out below.

Canada's drug patent policy has three key objectives:

- to support the development of the pharmaceutical industry in Canada;
- to ensure patented drugs are available at non-excessive prices; and
- to ensure conformity with Canada's international obligations.

Bill C-91 Review Clause

14(1) On the expiration of four years after this Act is assented to, the provisions of the *Patent Act* enacted by this Act shall be referred to such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established for the purpose of the review referred to in subsection (2).

(2) The committee shall undertake a comprehensive review of the provisions of the *Patent Act* enacted by this Act and shall, within one year after the review is undertaken or within such further time as the House or Houses that designated or established the committee may authorize, submit a report thereon, including such recommendations as the committee may wish to make pertaining to those provisions.

Legislative Background

Objectives of the Patent Act

Patents are an important instrument of industrial policy and are designed to protect inventors from the unauthorized use of their inventions. A patent grants the holder the right to exclude others from making, selling or using the invention for a certain period. Patent holders who feel their rights have been infringed may seek redress through the courts.

Such protection enables inventors to benefit from their creations, providing an incentive to perform research and development and stimulating the advancement and diffusion of technology. Under Canada's *Patent Act*, the information in patent documents must be made public within a specific period of time. Thus, patents also promote the sharing of technical knowledge.

The international community has long recognized the importance of ensuring minimum standards of patent protection worldwide. Accordingly, the development of international rules and guidelines for recognizing patent rights was among the earliest activities of international bodies such as the World Intellectual Property Organization. Canada, along with most of its trading partners, belongs to such organizations. As a condition of membership in these organizations, countries must adhere to common rules regarding patent protection. More recently, intellectual property has been a focus for trade agreements, including the North American Free Trade Agreement (NAFTA) and an international agreement negotiated under the auspices of the World Trade Organization on trade-related aspects of intellectual property rights (WTO TRIPs).

Patent Act Provisions Relating to Drugs

In 1923, Canada introduced a modification to patent protection for drugs – a regime called compulsory licensing. A compulsory licence permitted someone to make, use or sell a patented drug before the patent expired. In exchange, the licensee had to pay a royalty to the patent holder. Licences could be granted without the authorization of the patent holder and at any time during the period of patent protection. Obtaining a licence was complicated, however, by a requirement under the *Patent Act* that active ingredients used in generic drugs (copies of brand-name drugs) be produced in Canada. Since it was difficult to obtain Canadian-made active ingredients, few compulsory licences were granted at that time.

The requirement regarding active ingredients was removed in 1969. As a result, numerous compulsory licences were granted, triggering the growth of the generic drug industry. The royalty rate was generally set at 4% of the sales of the generic product.

In 1987, the *Patent Act* was amended further. Until then, the Act provided for a period of patent protection of 17 years from the date the patent was granted. The new legislation made this 20 years from the date of filing a patent application. The provision became effective in 1989.

Producers of generic drugs were still able to obtain compulsory licences during the term of the patent. However, now these licences could only be used after the patented drug had been on the market for 7 years (or 10 years if the active ingredients for the generic drug were imported). The practical effect of these amendments was to provide holders of drug patents 7 or 10 years of market exclusivity.

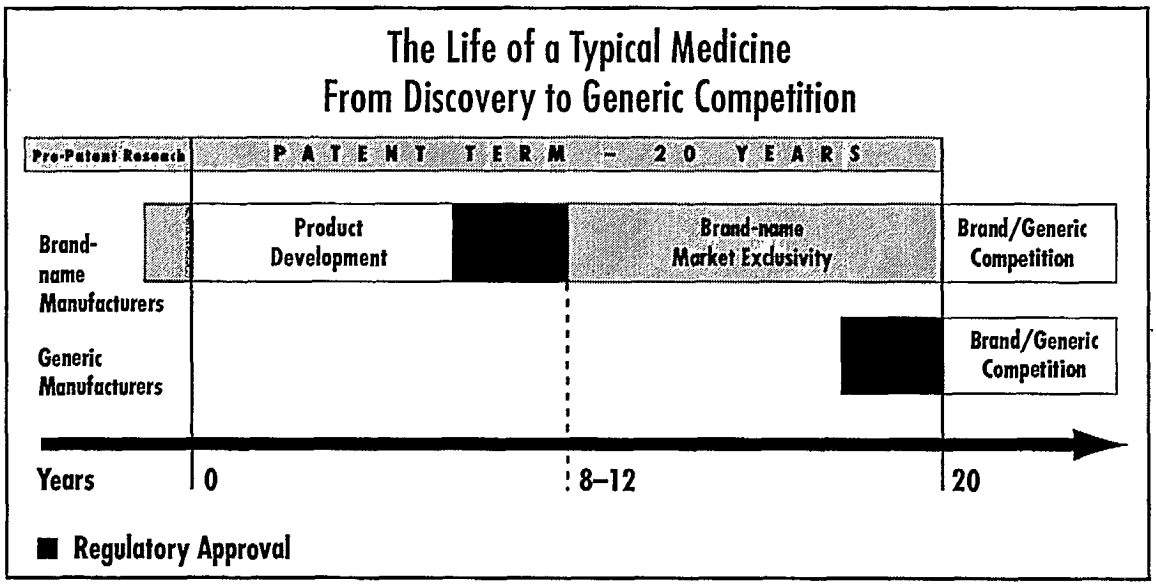
In addition, the amendments created the Patented Medicine Prices Review Board (PMPRB). Among other things, the PMPRB regulates the prices of existing and new patented medicines to ensure they are not excessive. It also monitors and reports on research and development (R&D) investments by patentees. (See PMPRB fact sheet.)

Bill C-91

Bill C-91 came into force in February of 1993. Its provisions include:

Elimination of compulsory licensing. The end of Canada's compulsory licensing regime meant that competition from producers of generic drugs was delayed until patent expiry. However, it takes approximately 8 to 12 years to develop a drug and receive regulatory approval, which takes place during the 20-year patent term. The resulting period of market exclusivity under Bill C-91 varies from drug to drug. Estimated averages range from 8 to 10 years, according to the Pharmaceutical Manufacturers Association of Canada (PMAC), or 12 to 14 years, according to the Canadian Drug Manufacturers Association (CDMA).

A regime of compulsory licensing, similar to what existed prior to Bill C-91, would be contrary to Canada's international treaty obligations under the WTO and the NAFTA.



Strengthened powers of the Patented Medicine Prices Review Board (PMPRB). Bill C-91 enabled the PMPRB to enforce its price reduction orders and to impose a monetary penalty on a company when the price of its patented drug exceeded Board guidelines. (These penalties include price rollbacks, reimbursement of excess revenues, and fines up to twice the excess revenues.)

Introduction of exceptions to patent infringement for regulatory approval and stockpiling. Bill C-91 included two exceptions to the rule that anyone who makes, uses or sells a product on which a patent is in force is infringing the patent. The exceptions give generic manufacturers: 1) the right to use a copy of the patented drug to begin the process of seeking regulatory approval for it, and 2) the right to develop and stockpile their copy prior to patent expiry. This enables generic manufacturers to begin marketing their products as soon as the relevant patents expire.

Introduction of the Patented Medicines (Notice of Compliance) Regulations. The Regulatory Impact Analysis Statement accompanying these regulations indicated their purpose as being... "to ensure this [regulatory approval] exception is not being abused by generic drug applicants seeking to sell their product in Canada during the term of their competitor's patent." Accordingly, the regulations govern the issuance of what is called the Notice of Compliance (NOC). This is issued by Health Canada upon successful completion of the drug approval process. Before it may sold in Canada, the drug must be found safe to use and effective in treating what it claims to treat. Although generic companies may go through or undertake the *process* of seeking regulatory approval before patent expiry, they cannot receive an NOC unless the relevant patents on the brand-name drug have expired. Thus, approval of generic drugs is linked to the patent status of the brand-name equivalents.

To be protected by the NOC link, a patent holder must submit to Health Canada a patent list setting out all of the relevant patents to the product and their expiry dates. When a generic manufacturer seeks an NOC, it must indicate whether or not it accepts this patent list.

If the generic manufacturer agrees with the list, the NOC will not be issued until the expiry of the last patent relevant to the product, as set out in the patent list. The generic company's application will remain confidential. If, however, the generic manufacturer disagrees with the patent list, it serves the patentee with a notice of allegation, which makes the existence of the generic application known to the patentee. The patentee then has 45 days to decide whether it will initiate court proceedings, which would seek to prevent the Minister of Health from issuing the NOC until the expiry of the listed patents.

Once the court proceedings are initiated, the Minister of Health cannot issue to the generic manufacturer its NOC until the parties reach agreement, the listed patents subsequently expire, the court renders a decision, or a period of 30 months elapses, whichever comes first. The court proceedings run in parallel with Health Canada's approval process.

If a generic company wins, it may enter the market once the Health Canada NOC has been issued. If the patentee wins, the generic manufacturer must wait until patent expiry before receiving its NOC and entering the market, as intended by the Regulations.

PMAC Commitments

Following the passage of Bill C-91, the Pharmaceutical Manufacturers Association of Canada (PMAC), which represents most brand-name pharmaceutical companies, made a number of commitments with respect to its members' R&D and investment performance. (See PMAC Commitments fact sheet.)

The Patented Medicine Prices Review Board (PMPRB)

The PMPRB is an independent, federal, quasi-judicial board that regulates the prices of patented drugs. It was established in 1987 by amendments to the *Patent Act*. Since the passage of Bill C-91, the PMPRB reports to the Minister of Health.

Mandate and Jurisdiction

The PMPRB ensures that prices charged by manufacturers of patented drugs are not excessive. The Board carries out its mandate through a policy of voluntary compliance backed up by the power to impose penalties on companies that do not comply with its guidelines. Decisions of the PMPRB are subject to judicial review by the Federal Court of Canada on jurisdictional or procedural grounds – i.e., challenges to the Board's jurisdiction or procedures.

In addition, the PMPRB reports annually to Parliament on the price trends of all medicines in Canada and on the ratio of research and development (R&D) expenditures to sales by pharmaceutical patent holders.

The PMPRB regulates manufacturers' prices for all drugs sold in Canada that are protected by a Canadian patent. It has no jurisdiction over drugs which have never been patented, or over those for which the patent has expired or is pending. The Board also has no authority over the prices charged by wholesalers and retailers or over pharmacists' dispensing fees, nor can it govern how a drug is utilized or how it is paid for by provincial or private health plans.

Patented Medicine Price Regulation

The PMPRB ensures compliance with the *Patent Act* through a compliance and enforcement policy and guidelines for pricing new and existing medicines. Among other things, these guidelines:

- limit prices for most new patented drugs to the range of prices for existing drugs used to treat the same disease;
- limit prices of breakthrough patented drugs to the median of the prices charged for the drug in the seven industrialized countries listed in the Patented Medicines Regulations (France, Germany, Italy, Sweden, Switzerland, U.K., U.S.); and
- limit price increases for patented medicines already on the market to the consumer price index (CPI).

The guidelines are developed in consultation with provincial ministries of health, consumers, and the pharmaceutical industry.

Canada is the only country in the world to regulate or control drug prices through a patent act.

Powers of the PMPRB

Since the passage of Bill C-91, the PMPRB has had significant power to take action against companies that do not comply with its guidelines. When the Board finds the price of a patented drug to be excessive, it can order the manufacturer:

- to reduce the price to what the Board considers to be a non-excessive level;
- to relinquish any excess revenues received from charging an excessive price; and
- to relinquish double its excess revenues if the company has engaged in a policy of selling at an excessive price.

Excess revenues can be relinquished through monetary penalties or price reductions below the non-excessive level.

The PMPRB's enforcement activities have had a direct impact on drug costs in Canada. Over the years there have been more than 100 cases of patent holders adjusting their prices to comply with Board guidelines. It is estimated that these adjustments saved consumers almost $33 million in 1995, for total savings of more than $100 million since 1990 (PMPRB).

Drug Prices/Expenditures

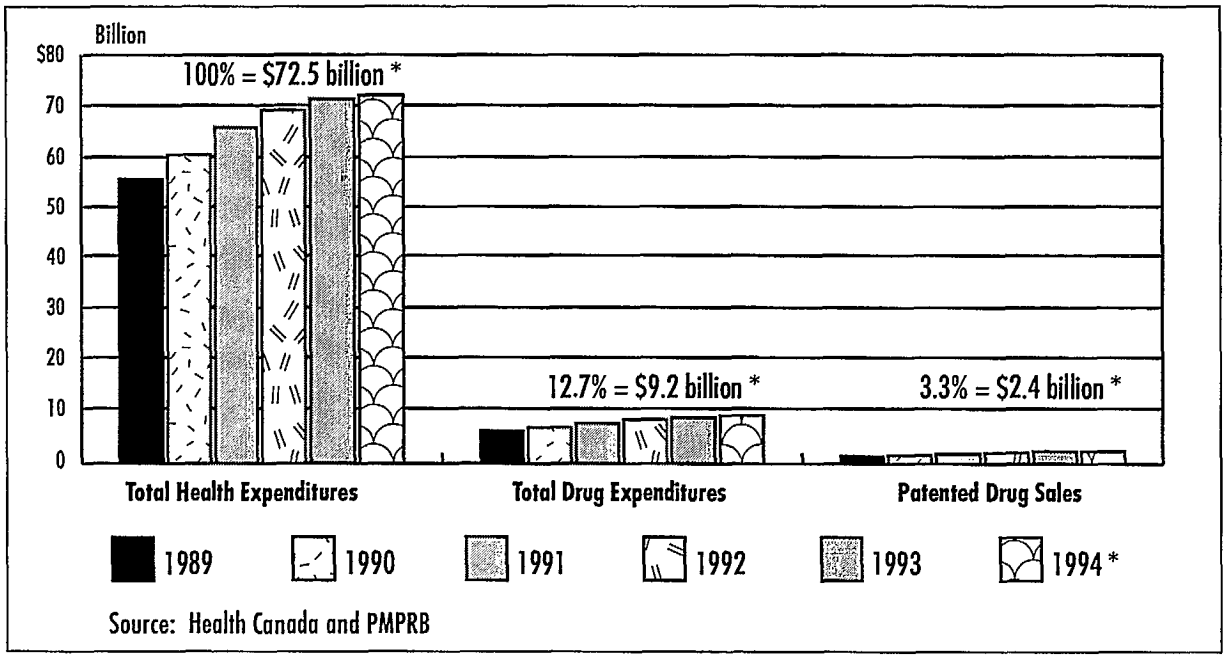
Drug Expenditures in Canada

In 1994, Canadians spent $9.2 billion on drugs, or an average of $314 per person. This represents 12.7% of national health expenditures. Drug expenditures include prescribed drugs, non-prescribed drugs, and personal health supplies (e.g. toothpaste), at retail level prices. The figure of $9.2 billion therefore includes ingredient costs, distribution mark-ups, and dispensing fees. However, these numbers exclude drugs used in hospitals (Health Canada). Also included in the $9.2 billion spent on drugs are actual manufacturers' sales of drugs to drugstores and hospitals, before retail mark-ups and dispensing fees, which were estimated at $5.8 billion in 1994 (IMS), or 8% of national health expenditures. In the same year, manufacturers' sales of patented drugs were 41% of all drug sales or $2.4 billion (PMPRB). This is equivalent to 3.3% of national health expenditures.

Trends in Drug Expenditures

Drug expenditures increased by 3.8% in 1994 and by 4.6% in 1993, compared to average annual increases of 13% between 1976 and 1992 (Health Canada).

Total Health Expenditures, Total Drug Expenditures, and Patented Drug Sales



Overall drug expenditures are influenced by a range of factors, including:

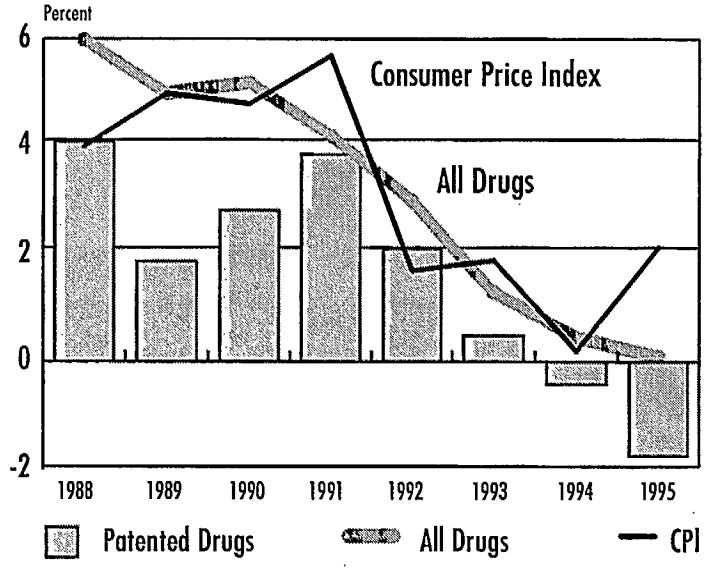
- utilization factors, such as demand from an aging and growing population, and physicians' prescribing practices;

- price factors, such as manufacturers' prices, wholesale and retail mark-ups, and pharmacists' dispensing fees;
- support for drug expenditures through provincial or private health care plans; and
- treatment changes, such as the substitution of new drugs for old, drug therapy instead of other treatment such as surgery, and a shift in health care from hospitals to the home.

Patented Drug Prices

Prior to 1987, the prices of all drugs in Canada, patented and non-patented, went up at a rate much higher than the rate of inflation. Since 1987, the year the Patented Medicine Prices Review Board (PMPRB) was created, the prices of patented drugs have increased on average 1.6%, well below the increase in the consumer price index of 3.1%. In 1994, prices of patented drugs actually fell by 0.42% and by another 1.75% in 1995 (PMPRB).

Year-over-Year Price Changes: Patented Drugs, All Drugs, and CPI, 1988–95



Source: Statistics Canada and PMPRB

Price Trends in Canada Versus Other Countries

The prices for patented drugs in Canada are dropping compared to prices in other countries. Limits on the introductory prices of new patented drugs have meant that, from 1992 to 1994, Canadian prices declined, on average, from about 3% above the median of foreign prices to just below the median of foreign prices. This puts Canadian prices below those of the U.S., Germany, and Switzerland (PMPRB, *The Top 200 Selling Patented Drug Products in Canada 1994*).

Drug prices in Canada are much lower than those in the U.S. and the gap is widening. From 1983 to 1987, Canadian prices rose faster than U.S. prices, but that trend reversed in 1987. In 1992, the U.S. General Accounting Office reported that drug prices in Canada were 32% below those in the U.S. PMPRB data suggests that the Canada/U.S. gap for patented drugs had widened to 47% by 1994.

Pharmaceutical Manufacturers Association of Canada Commitments

In June 1993, after Bill C-91 came into force, the Pharmaceutical Manufacturers Association of Canada (PMAC) made a number of commitments with respect to its members' research and development (R&D) performance. (See PMAC Letter, Annex A.) These commitments were to be met collectively by the members of the PMAC. An independent assessment of the status of these commitments was recently undertaken by the auditing firm Ernst & Young. The results of this assessment are presented below:

PMAC Commitments

COMMITMENT	STATUS
To reach an annual R&D-to-sales ratio of 10% by 1996 (i.e. 10% of sales revenues to be spent on R&D). Subject to a stable federal and provincial regulatory environment, to maintain this ratio in future years.	In 1995, PMAC member companies had reached an R&D-to-sales ratio of 12.5%. – i.e. 12.5% of sales revenues was spent on R&D.
To make a minimum of $400 million in new investments by the end of 1996. These new investments were to be in addition to expenditures member companies expected to make during this period, prior to the passage of Bill C-91.	By the end of 1996, total additional capital expenditures were $506 million; total additional R&D expenditures were $556 million.
By 1996, to distribute extramural clinical research regionally, by population, where feasible. Extramural R&D is clinical R&D funded by, but performed outside, a company.	Distribution during 1995: R&D Pop. West 18.9% 29.3% Ontario 46.3% 37.6% Quebec 31.1% 24.9% Atlantic 3.7% 8.2%
Through the $200-million Medical Research Council/PMAC Health Program, to enhance support for biomedical research and training in universities and related research institutions across Canada over five years (1993-1998).	Amount contributed up to July 31, 1996, was $78.8 million (Ernst & Young). Amount contributed as of December 31, 1996, was $120.2 million (more recent figures provided by the Medical Research Council [MRC]).
To increase procurement from Canadian fine chemical companies over 1993-1995 to a target of $15–20 million over three years, with the expectation that these relationships will continue after 1995.	Total procurement up to December 31, 1995, was $20.1 million.
To identify opportunities for expanded investments in basic research, procurement and industrial projects in all regions.	PMAC members have participated in a number of pharmaceutical fairs and clinical trial networks. Other events to improve awareness of Canadian capabilities have also taken place since 1993.

International Obligations and Comparisons

International Obligations

Canada's obligations under international treaties require, among other things:

- a minimum term of patent protection of 20 years from the date of filing a patent application (Article 33 WTO TRIPs*), with no discrimination between different fields of technology (Articles 1709.7 NAFTA and 27 WTO TRIPs);
- no compulsory licensing except in very limited circumstances (Articles 1709.10 NAFTA and 33 WTO TRIPs);
- in intellectual property issues, Canada must treat nationals from WTO and NAFTA member states as favourably as it treats its own citizens (i.e. national treatment) (Articles 1703.1 NAFTA and 1.3 WTO TRIPs); and
- Canadian patents must be independent of patents obtained for the same invention in other countries (Article 4bis(1) of the Paris Convention for the Protection of Industrial Property).

International Comparisons

Drug Patent Policy in Canada, the United States and the European Union

	Canada	USA	EU Countries
Patent Term • Basic Patent Term • Patent Term Extension/Restoration	 20 Years No	 20 Years max 5 Years	 20 Years max 5 Years
Exceptions to Infringement • Regulatory Approval • Stockpiling	 Yes Yes	 Yes No	 No No
Enforcement of Patent Rights • NOC-Patent Linkage • Enhanced Damages (Willful Infringement)	 Yes No	 Yes Yes	 No No
State Price Control • Patented Drugs • Non-Patented Prescription Drugs (Including Generics)	 Yes No	 No No	 (Yes) All (Yes) Most

* Note: World Trade Organization trade-related aspects of intellectual property rights. (See Glossary.)

Current patent protection in Canada meets the minimum World Trade Organization requirement of 20 years. The United States and the European Union provide for an additional period of market exclusivity of up to 5 years for drugs in order to compensate for delays in getting a drug to market. This is done through patent term restoration policies.

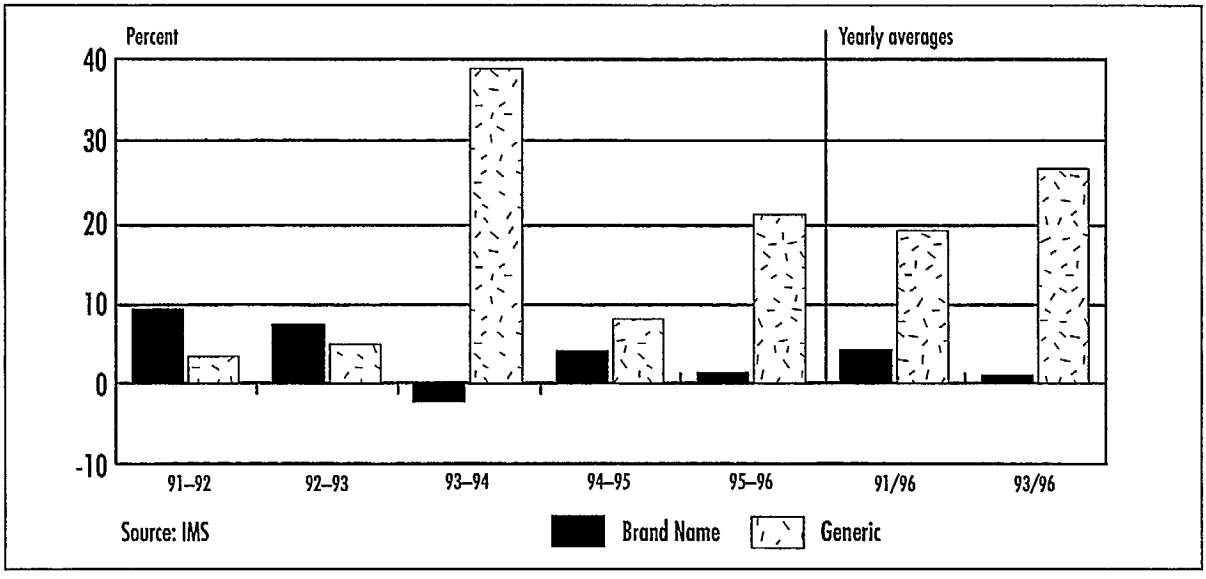
Canada and the United States are the only countries that have a legislated exception to patent infringement allowing generic manufacturers to initiate the process of obtaining regulatory approval for generic drugs prior to patent expiry. In addition, Canada is the only country to allow these manufacturers to develop and stockpile a generic copy of a patented drug prior to patent expiry. This enables generic manufacturers to market a generic drug immediately upon expiry of the relevant patents.

In addition to traditional patent enforcement (such as action for patent infringement), Canada provides enforcement through the Patented Medicines (Notice of Compliance) Regulations. These Regulations link regulatory approval of a generic drug to the patent status of the drug being copied. The United States has a somewhat similar system of patent linkage and, in addition, awards triple damages for willful patent infringement.

Pharmaceutical Industry: Profile

- The world pharmaceutical market was estimated to be US$287 billion (at manufacturers' prices) in 1995. Canada has the 11th largest market for pharmaceuticals and represents 2% of the global market (IMS). In 1995, total Canadian sales of medicines at the manufacturer's level were valued at $6 billion Canadian (PMPRB).
- In 1995, according to Statistics Canada, there were 117 pharmaceutical establishments in Canada, employing approximately 21 000 people. Of these employees, 45% were in Ontario, 32% in Quebec, 20% in the Western provinces, and 4% in Atlantic Canada. (Note: Statistics Canada's figures include only establishments that are primarily involved in pharmaceutical manufacturing activities. Establishments that are primarily involved in research activities [most biopharmaceutical firms] or wholesale activities [firms which mainly sell imported drugs or those manufactured in other establishments] are excluded.)
- From 1991 to 1996, generic companies saw an average yearly growth of 18.9%, while the rate for brand-name companies was 4.1%. Over the 1993–1996 period, annual sales growth of generics (26.4%) significantly outpaced growth of brand names (1.0%) (IMS).

Average Growth in Sales by Type of Pharmaceutical Company



- Domestic sales growth is forecast to be less significant over the next 10 years for both generics (estimated annual growth of 4.5%) and brand names (estimated annual growth of 3.5%) (W.N. Palmer & Associates).

PERFORMANCE BY SECTOR

The Brand-name Sector

- **Definition and Employment**. Brand-name companies specialize in the development and marketing of innovative drugs. Most brand-name firms in Canada are represented by the Pharmaceutical Manufacturers Association of Canada (PMAC) and are multinationals. The brand-name sector comprises the largest segment of the pharmaceutical industry in Canada. In 1995, PMAC companies employed an estimated 17 900 people, including over 3000 research staff (PMAC).
- **Market Share**. In 1996, brand-name companies accounted for 84.5% ($5.3 billion) of the dollar value of the drug market (both prescription and over-the-counter), and 60.3% of the number of prescriptions filled (IMS). The prescription market includes both patented and non-patented drugs. On average, patented drugs account for 40–45% of all drug sales (PMPRB).
- **Research and Development**. R&D investments by the brand-name sector have grown from $165.7 million in 1988 to $624 million in 1995, representing 11.8% of their sales revenue. (The R&D-to-sales ratio is even higher – 12.5% for PMAC member companies.) This is nearly double the ratio of 6.1% achieved in 1988 (PMPRB).

The Generic Sector

- **Definition and Employment**. Most generic firms are represented by the Canadian Drug Manufacturers Association (CDMA) and are Canadian-owned. Generic firms specialize in the manufacture of off-patent drugs and drugs licensed under the previous compulsory licensing regime. CDMA companies employ an estimated 3630 people (CDMA).
- **Market Share**. In 1996, generic companies accounted for 15.5% ($973 million) of the dollar value of the drug market (prescription and over-the-counter), and 39.7% of the number of prescriptions filled (IMS).
- **Research and Development**. R&D investments by CDMA members were estimated at $127 million in 1995 (CDMA).

In 1995, generic companies held 14.3% of the dollar value of the prescription market in Canada (IMS). This was higher than the generic share in the U.S. (10%) and in Europe (on average 9%) (SCRIP Yearbook).

The Biopharmaceutical Sector

- **Definition and Employment**. Biopharmaceutical companies use biotechnology to develop innovative drugs. Data on this emerging sector is often incomplete. There are at least 64 biopharmaceutical companies in Canada, which employed close to 4000 people in 1996, including almost 1600 research staff (Contact Canada). Most of these firms are Canadian-owned small or medium-sized businesses. Many of these companies are members of the Industrial Biotechnology Association of Canada (IBAC). Ten are also PMAC members and 3 are CDMA members.
- **Research and Development**. R&D investment by these 64 companies in 1995 was estimated at $251 million (Contact Canada).

A 1997 study by Ernst & Young provides additional data on the entire biotechnology industry. The study indicates that there are 224 core biotechnology companies in Canada, 59% of which are active in the health care field (including biopharmaceuticals). Other firms are invloved in the agricultural-biotechnology field (26%), the environmental field (12%) or are industry suppliers (3%). In 1995, the companies had increased their revenues by 45% and increased their R&D expenditures by 24%.

Contract Research

Research activities of pharmaceutical companies are often carried out by contract research organizations (companies, institutes, universities and hospitals). In 1995, some 156 contract research organizations employed an estimated 25 500 people in Canada, including 5400 R&D staff (Contact Canada).

Research and Development (R&D)

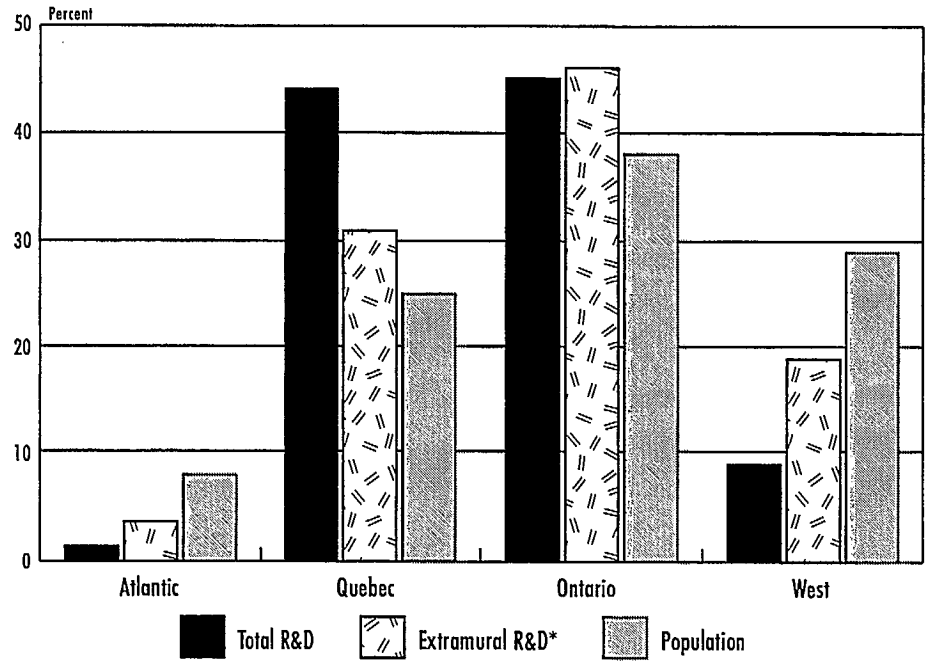
- Pharmaceutical companies are among Canada's leading investors in R&D. In 1995, pharmaceutical firms accounted for 26 of the top 100 R&D spenders in Canada (Research Money).

RANK	COMPANY	TYPE OF FIRM*	R&D IN MILLIONS OF $
5	Merck Frosst Canada Inc.	BN	154.6
12	Connaught Laboratories Ltd.	BN	86.0
21	Apotex Inc.	G	55.9
25	Hoechst Marion Roussel Canada Inc.	BN	43.6
28	Glaxo Wellcome Canada	BN	40.3
35	Wyeth-Ayerst Canada Inc.	BN	35.3
36	Novopharm Ltd.	G	35.0
37	Boehringer Ingelhelm (Canada) Ltd.	BN	32.1
39	Eli Lilly Canada Inc.	BN	29.0
42	Hoffmann-LaRoche Ltd.	BN	27.2
44	Janssen Ortho Inc.	BN	26.8
45	Astra Pharma Inc.	BN	26.7
49	BioChem Pharma Inc.	B	23.4
52	Bayer Inc.	BN	22.5
59	Pfizer Canada Inc.	BN	17.3
61	Sandoz Canada Inc.	BN	16.9
62	Allelix Biopharmaceuticals Inc.	B	16.7
65	Ciba-Geigy Canada Inc.	BN	16.0
68	Biomira Inc.	B	15.8
74	Rhone Poulenc Rorer Canada Inc.	BN	12.5
75	QLT Photo Therapeutics Inc.	B	12.5
80	Pharmacia & Upjohn Canada	BN	11.3
81	Hemosol Inc.	B	11.1
90	Hyal Pharmaceutical Corporation	B	9.6
96	Schering Canada Inc.	BN	8.0
100	Ibex Technologies Inc.	B	7.6

Source: Research Money
* by main line of business BN – Brand-name G–Generic B–Biopharmaceutical

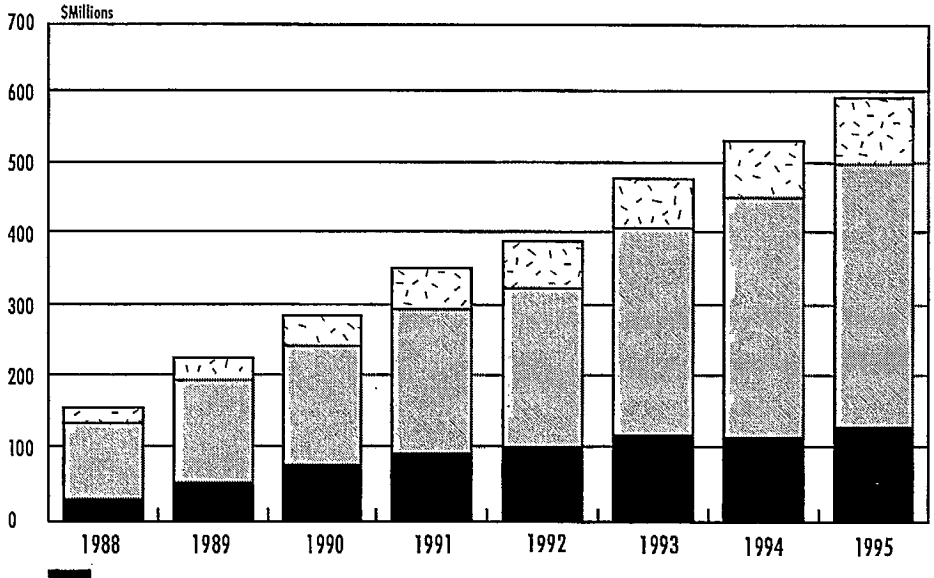
- Pharmaceutical companies are now the largest funders of Canadian health research. In 1995, 30% of all health research undertaken in Canada was funded or directly performed by industry, largely by pharmaceutical and biotechnology companies. The balance was funded by the federal government (24%), universities (18%), charities (13%), provinces (9%), and foreign investors (6%) (MRC).
- According to the Patented Medicine Prices Review Board, all pharmaceutical patentees invested $624 million in R&D in 1995, which is equivalent to 11.8% of company sales. This ratio was 12.5% for PMAC member companies.
- According to the CDMA, generic manufacturers spent $127 million on R&D in 1995 (CDMA).
- In 1995, 64 biopharmaceutical companies spent $251 million on R&D (Contact Canada).

Regional Distribution of Canadian R&D by Pharmaceutical Patentees–1995



* Clinical R&D, funded by a PMAC Member, but performed outside a company. Source: PMPRB – 1995 Annual Report, Ernst & Young, and Statistics Canada.

Current R&D Expenditures* by Type of Research by Pharmaceutical Patentees



* Current expenditures exclude capital equipment and depreciation expenditures.
Source: PMPRB – 1995 Annual Report.

Canada's Health Care System and Drug Utilization

Financing of Drugs in Canada

Canada's system of national health insurance covers medications received in hospital, but does not include drugs that are prescribed in the community.

Roughly one third of drug expenditures outside hospitals are paid for by provincial health care plans (30%) or the federal government (2%). The remaining two thirds are paid for by the private sector. In 1994, this meant that the public sector paid $2.9 billion, or 32% of total drug expenditures. Provincial drug plans accounted for 5.7% of provincial health expenditures in 1994. This figure has been increasing steadily since 1980, when drug plans accounted for 2.7% of provincial health expenditures (Health Canada).

The private sector spent $6.3 billion through: employers who provided drug coverage as an employee benefit; insurance companies; and individuals who paid out of their own pockets (Health Canada).

Drug Plan Coverage

Most provinces and territories provide some supplementary coverage for at least seniors and those on social assistance, although coverage varies widely from province to province. British Columbia, Saskatchewan, Manitoba, and Quebec all have some form of universal drug program.

Most Canadians receive some help in paying for prescription drugs. In 1995, 62% of Canadians were covered under private plans, 19% under provincial plans, and 7% under both – for a total of 88% of Canadians with some form of coverage (W.M. Mercer Ltd.).

Of the 12% of the population without any drug insurance, more than half (just under 7%) were employees and their dependents who were not covered by a supplementary plan paid for by an employer. Less than 4% were self-employed entrepreneurs and their dependents, and 2% were unemployed people who did not qualify for government or private plans (W.M. Mercer Ltd.).

The federal government pays prescription drug costs for veterans, the Royal Canadian Mounted Police, the military, and First Nations when these costs are not covered by provincial and territorial health plans or other third-party plans.

Use of Drugs by Canadians

In 1995, 228 million prescriptions were written in Canada, an average of eight prescriptions for every Canadian. Physicians prescribe drugs in 60% of all office visits by patients (IMS).

Prescription Categories

About half of all prescriptions fall into five therapeutic categories: treatments for cardiovascular diseases; anti-infectives, such as antibiotics; psychotherapeutics, such as anti-depressants; analgesics, such as pain-killers; and hormones, such as birth control pills (IMS).

Frequent Users

Seniors are by far the largest consumers of prescription drugs in Canada. In 1994, they made up about 12% of the population (Health Canada), but consumed between 20% and 40% of all prescription medicines (Quinn, Baker & Evans).

Inappropriate Use of Drugs

Between 19% to 28% of hospital admissions for patients over 50 years of age result from medication problems (Grymonpre et al.). Sixty per cent of these admissions are attributed to adverse reactions to medication and 40% to inappropriate use of the medication (Fanale & Kronholm). It is estimated that seniors use anywhere from 18% to 50% of their medications inappropriately (Tamblyn et al.).

A 1995 study estimated that inappropriate use of pharmaceuticals costs the Canadian economy $3.5 billion to $4.5 billion each year in direct health costs (e.g. hospitalization, physician visits and laboratory tests). Adding indirect costs (e.g. lost productivity due to absenteeism and premature death) brings the total to $7–$9 billion (Coambs et al.).

Using drugs inappropriately includes taking drugs in the wrong dosage, at the wrong time, not long enough or not at all, or in inappropriate combination with other drugs or other substances (e.g. alcohol) that alter their effectiveness.

Drug Approval Process

Health Canada is responsible for the approval of all drugs that enter the Canadian market. The approval of a drug means that it is safe for Canadians to use and it is effective in treating what the drug claims to treat.

Approval Process for New Drugs

Before marketing a new drug, a manufacturer must file a new drug submission with Health Canada's Drugs Directorate. This submission contains virtually all information known about the drug, including: its proper name; its chemical name(s); details of how it is manufactured and purified; its pharmacological and chemical properties; a quantitative listing of all ingredients used in making the drug; packaging and labelling information; results of stability tests; therapeutic claims; and side effects.

Details of clinical studies to support the safety and efficacy of the drug must be available, as must any results of preclinical and clinical studies at several dose strengths and a variety of dosage forms. The submission may also include a sample of the market-ready product for testing, if needed.

Review and Evaluation of New Drug Submissions

Multidisciplinary teams made up of staff within Health Canada's Drugs Directorate, together with outside experts as needed, review all submissions. The final review deals with the wording of the product "monograph." The monograph is a document that provides all information on the drug and complete prescription instructions for physicians. When the new drug submission is satisfactory, Health Canada examines the labels and issues a Notice of Compliance. This allows the manufacturer to sell the product.

Post-approval Controls on the Marketing of Drugs

Once a new drug is on the market, safety and efficacy controls continue. The manufacturer must report any new information received from medical practitioners, consumers and pharmacists concerning serious side effects, including failure of the drug to produce the desired effect. On request, the manufacturer must inform Health Canada of any animal tests that have provided new safety information. If it can be shown to be in the interests of public health, Health Canada can remove a drug from the market.

Changes Brought by the Patented Medicines NOC Regulations

The Regulations link the issuance of a Notice of Compliance for a generic substitute to the patent status of the brand-name equivalent. The process up until the NOC issuance remains unchanged.

Glossary of Terms

Biopharmaceutical	a pharmaceutical product developed through the application of biotechnology. In the context of pharmaceuticals, this involves using living organisms, or parts or products of living organisms, in their natural or modified forms, to create therapeutic drugs, as opposed to traditional chemistry.
Brand-name drug	a patented or previously patented drug developed and manufactured by a brand-name manufacturer.
Brand-name manufacturer (patentee)	a company specialized in the development, manufacturing and selling of innovative drugs (often used interchangeably with the term *patentee*).
Breakthrough drug	the first drug product to effectively treat a particular illness, or a new drug product which provides a substantial improvement over an existing drug product.
CDMA	Canadian Drug Manufacturers Association, which represents most Canadian generic drug manufacturers.
Compulsory licence	licence granted by the Commissioner of Patents that permits the licensee to import, make, use or sell a patented invention in exchange for a royalty.
Drug expenditures	in this document, sales of drugs (usually includes personal health supplies) at retail prices.
Drug sales	in this document, sales of drugs (usually excludes personal health supplies) at manufacturers' prices.
Exceptions to patent infringement	provisions that permit activities which would otherwise infringe a patent. In Canada, these include making or using a patented drug for the purposes of obtaining regulatory approval and for stockpiling a drug prior to patent expiry.
Generic drug	a pharmaceutical product that is a copy (i.e. the same active ingredient, strength and dosage form) of a brand-name drug.
Generic manufacturer	a company specialized in the manufacturing and selling of copies of brand-name drugs.
IBAC	Industrial Biotechnology Association of Canada, which represents most biotechnology firms.

IMS	IMS of Canada Limited gathers and publishes statistics on the Canadian pharmaceutical industry, including drug sales to hospitals and drugstores.
Intellectual property	a form of creative endeavour that can be protected through a patent, copyright, industrial design, trade-mark, or integrated circuit topography.
NAFTA	the North American Free Trade Agreement.
Notice of Compliance (NOC)	Health Canada's safety and efficacy approval. This regulatory approval is required to sell any drug, patented or generic, in Canada.
Patent	a government-granted and limited right to exclude others from making, using or selling one's invention.
Patented Medicines (Notice of Compliance) Regulations	regulations made under the *Patent Act*, linking the issuance of Health Canada's safety and efficacy approval to the patent status of a drug.
PMAC	Pharmaceutical Manufacturers Association of Canada, which represents most Canadian-based brand-name drug manufacturers.
PMPRB	Patented Medicine Prices Review Board, an independent federal board created under the 1987 amendments to the *Patent Act*.
Research and Development (R&D)	basic or applied research and development for the purpose of creating new, or improving existing, materials, products or processes.
TRIPs	an international agreement negotiated under the auspices of the World Trade Organization on trade-related aspects of intellectual property rights.
World Trade Organization	a multilateral agency devoted to the promotion of trade liberalization between member countries (formerly the GATT).

Annex A

PMAC Letter

Bringing Research to Life
La recherche : source de vie

PHARMACEUTICAL MANUFACTURERS ASSOCIATION OF CANADA
ASSOCIATION CANADIENNE DE L'INDUSTRIE DU MÉDICAMENT
Researchers and developers of original brand name medicines
Les concepteurs et fabricants de médicaments d'origine

June 10, 1993

BY FACSIMILE AND COURIER

Honourable Michael Wilson
Minster, Industry, Science & Technology
House of Commons
Centre Block
Room 515-S
Ottawa, Ontario
K1A 0A6

Dear Minister:

Now that Bill C-91 has passed I would like to take this opportunity to discuss the investments our members expect to achieve. The achievement of these investments assumes that the international and national business and regulatory environments (including but not limited to such elements as patent protection, federal and provincial pricing regulations, approval of products for safety and efficacy and access to provincial formularies) for the pharmaceutical industry will not undergo substantial change.

The Association's original forecast, at the time of tabling of Bill C-91, June 23, 1993, that over $400 million in new investments would be made in the next 5 years across Canada has been surpassed. To date $684 million in investments have been announced (list attached as EXHIBIT A). The research and development (R&D) component of these investments will be reported in the Patented Medicine Prices Review Board (PMPRB) annual report. The Association, through its Annual Statistical Survey, will compile the non-R&D component of these investments.

The Association and the Medical Research Council of Canada (MRC) announced on May 17, 1993, the creation of a major new Health Partnership which will significantly enhance support for biomedical research and training across Canada over the next five years. The Partnership is expected to inject more than $200 million, some of which is in addition to the Bill C-22 commitments made by our member companies, into medical research, including training at Health Science facilities. It will provide a mechanism to facilitate the implementation of several initiatives, such as studentships, fellowships and scholarships in research and training, the establishment of clinical networks, peer review of clinical trials, chairs in specialized disciplines at universities, and research development grants. The Partnership will produce an annual report summarizing its collective activities (see press release attached as EXHIBIT B).

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The Association expects that members, where feasible, will distribute extramural clinical research in Canada regionally, in relation to population by the year 1996. Extramural clinical research is expected to reach $540 million for the period 1992 to 1996 and $800 million for the period 1997 to 2002. The Association through its annual statistical survey tracks regional distribution of members extramural clinical research.

Association members will increase procurement from Canadian fine chemical companies, with a cumulative target of $15-20 million over a three year period from 1993 to 1995, with an expectation that these relationships will continue. The Association's annual statistical survey also tracks members purchases from Canadian fine chemical companies.

Association members stand by the Bill C-22 commitment to invest 10% of sales revenues in R&D by the year 1996 and to extend that commitment for as long as Bill C-91 stays in effect. It is forecast that the industry will invest $2 billion into R&D between 1992 and 1996 and an additional $3 billion between 1997 and 2002. The PMPRB reports on the members R&D to sales ratio.

Association members will work to establish strong working relationships with Industry, Science and Technology (ISTC) Canada, other industrial economic development agencies, and provincial governments in all regions across Canada, to identify internationally competitive opportunities for investment in basic research, procurement, and industrial projects, with a goal of expanding, as rapidly as is practical, the contribution of the pharmaceutical industry to the economies of all regions.

Given ISTC's experience and expertise in working with our industry, it is recommended that they be involved in all national initiatives relating to the industry. A major initiative currently underway is National Health and Welfare's development of a National Pharmaceutical Strategy.

In order to achieve maximum benefit in terms of economic development, that strategy must involve the active participation and coordination of health and trade ministers at both the federal and provincial levels. Duplication of regulation and lack of coordinated policy, are a detriment to the industry's ability to attract investment. National standards (ie. a national pharmaceutical information assessment service to provide comparative information on new and existing drugs to decision makers to avoid the existing duplication by provincial health personnel) involving federal and provincial cooperation should be supported.

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In closing, I would like to say that I am confident that the members will achieve these investments and that Bill C-91 is in the best interest of both the public and the pharmaceutical industry.

Yours sincerely,

Judith A. Erola, P.C.
President

c.c. Honourable Harvie Andre, Government House Leader
Honourable Benoît Bouchard, Minister of National Health and Welfare
Honourable Pierre Vincent, Minster, Consumer and Corporate Affairs
Honourable John Crosbie, Minister, Atlantic Canada Opportunities Agency
Honourable Mary Collins, Minister, Western Economic Diversification
Mr. Glen S. Shortliffe, Clerk of the Privy Council and Secretary of the Cabinet
Bob Little, A/Sr ADM Industry, Science & Technology
Dann Michols, Assistant Deputy Minster, National Pharmaceutical Strategy