

Generic Drug Makers at a Crossroads:

**The Path to Health-Care Savings and the Sustainability
of Canada's Generic Pharmaceutical Industry**

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Executive Summary

Canada's Generic Pharmaceutical Industry at a Crossroads

From its beginning 50 years ago as the dream of a few determined entrepreneurs, Canada's generic pharmaceutical industry has become a world-class enterprise that plays a key role in the country's health-care system and its economy.

By providing safe, proven, high quality medicines at substantial cost savings, Canada's generic drug makers spurred the development and proliferation of the public and private drug-benefit plans that more than two-thirds of Canadians now enjoy.

Canada's generic pharmaceutical industry has become a much larger and more important player in the country's cherished health-care system. Since 1997, Canadians have spent more on drugs each year than they have on doctors. Between 1997 and 2003, that spending rose from \$6.8 billion to approximately \$14 billion. It is a trend that will continue to grow as the population ages, as expensive, new medicines replace existing ones, and as drug treatments form a larger part of patient care.

Today, Canadians and their elected representatives face fundamental questions about the affordability and sustainability of publicly funded health care. Even as the questions become more urgent, Canada's generic drug makers are fighting for survival in a legal and regulatory environment that limits their ability to provide cost-saving medicines to Canadians and mutes the industry's growth, investment and job creation in Canada.

Changing competitive environment

The competitive environment for generic drug makers in Canada has changed dramatically over the past 20 years. The market was once dominated by two major players but now there are several generic firms in Canada aggressively fighting for market share.

Another significant development is the acquisition of several of the major Canadian firms by German and Israeli pharmaceutical companies. Unlike the entrepreneurial companies that dominated the industry in the past, these publicly traded companies are responsible for providing shareholder value and contributing to the overall value of the parent company.

This fierce competition for market share, along with rising costs of bringing products to market and relatively flat prices, has squeezed the industry to the breaking point. One response has been to drop product lines that are no longer viable due to government price freezes imposed in the mid 1990s.

Tougher decisions are ahead as Canada's generic drug makers struggle to recoup the increased cost of doing business.

On average it takes three to five years to develop a generic drug and costs millions of dollars. These costs include research and development, production, bioequivalence studies, raw materials, well-trained staff, expensive equipment, high-tech facilities and, increasingly due to the *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act*, litigation.

Canadian generics: the gold standard for quality

The generic industry in Canada is one of the oldest, most well established in the world. Generic products produced in Canada are renowned for their excellent quality. In fact, other countries seek the advice and expertise of Canadian generic drug makers to help build and enhance their domestic industries.

As well, Health Canada's system for establishing the bioequivalence of generic drugs is second-to-none, and has been studied and emulated by countries around the world.

Canadians are fortunate that their generic industry is the gold standard for quality, but producing pharmaceutical products at the highest standards in the world costs a significant amount of money.

Generic prices not keeping pace with cost of production

On the pricing front, the small increases in generic prices over the past ten years have not kept pace with the increasing costs of production. To help illustrate this fact, IMS HEALTH Canada reports that from 1992 to 2002, the average price of a brand-name prescription increased by 76% from \$31.52 to \$55.56. Over the same period of time, the average price of a generic drug increased from \$16.35 to \$21.57, or 32%.

This in an environment where the price of patented drugs is monitored by the Patented Medicine Prices Review Board (PMPRB).

At the half-century mark of the industry's presence in Canada, the Canadian Generic Pharmaceutical Association (CGPA) believes the time has come to reach a new deal with Canadians and their governments that will save Canada's health-care system billions of dollars while securing the future of the country's generic drug makers.

The CGPA's five-point plan

To achieve that goal, the Canadian Generic Pharmaceutical Association (CGPA) proposes the following five-point plan.

The first two initiatives fall directly under the responsibility of the federal government, while the remaining three require action by provincial governments to achieve health-care savings.

Federal Government

1. The federal government eliminate the automatic injunction under the *Patented Medicines (Notice of Compliance) Regulations* of the *Patent Act* so that the pharmaceutical industry is brought in-line with every other industry under the *Act*
2. The federal government direct more funding to Health Canada to reduce the time needed to properly review generic pharmaceutical products

Provincial Governments

3. Provincial governments make interchangeable and list cost-saving generic pharmaceutical products on their drug plan formularies immediately following Health Canada approval and without additional, redundant review
4. The Ontario government institute "Off-Formulary Interchangeability," which would allow generic pharmaceuticals not covered by the government's drug plan to be interchangeable with branded drugs so that Ontario employers and consumers can save on the cost of their drug plans
5. The Quebec government repeal the "15-year rule," which extends brand-name drug companies' market monopolies beyond patent terms and adds \$32 million per year to the province's prescription drug expenditures

The proposals outlined above will achieve two important results. They will substantially reduce Canada's prescription drug expenditures and they will create a climate where generic pharmaceutical makers can increase their investment in the Canadian economy. If governments take action on these five proposals, Canada's generic pharmaceutical industry will be able to:

- Provide greater savings to the health-care system
- Employ more Canadians in well-paid, highly skilled jobs
- Increase spending on research and development
- Increase investment in infrastructure

Canada's Generic Pharmaceutical Industry at a Glance

The Canadian Generic Pharmaceutical Association (CGPA) represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.

The CGPA's 21 members represents more than 90% of Canada's generic pharmaceutical industry, an industry that in 2002 filled more than 139 million, or 40.4% of all written and filled prescriptions in Canada.

A list of CGPA member companies is included in Appendix B.

Employment

Canada's generic industry employs approximately 10,000 people in well-paid, highly skilled jobs in laboratories, production facilities and other operations.

Innovation

The generic industry fuels the Canadian economy through direct capital expenditures and spending on research and development. CGPA member companies spend approximately \$250 million annually on R&D in Canada. CGPA member companies invest about 15% of sales in research and development and have more than 100 products currently in development. R&D expenditures have increased more than seven-fold since 1990 and CGPA member companies have targeted more than \$1.25 billion for R&D over the next 4 years.

Highly successful exporting industry

Canada's generic drug industry has built a successful international business, generating 20% of its sales volume from exporting high quality, made-in-Canada pharmaceuticals to 120 countries. The majority of the industry's revenue stays in Canada, helping to preserve and create jobs for Canadians.

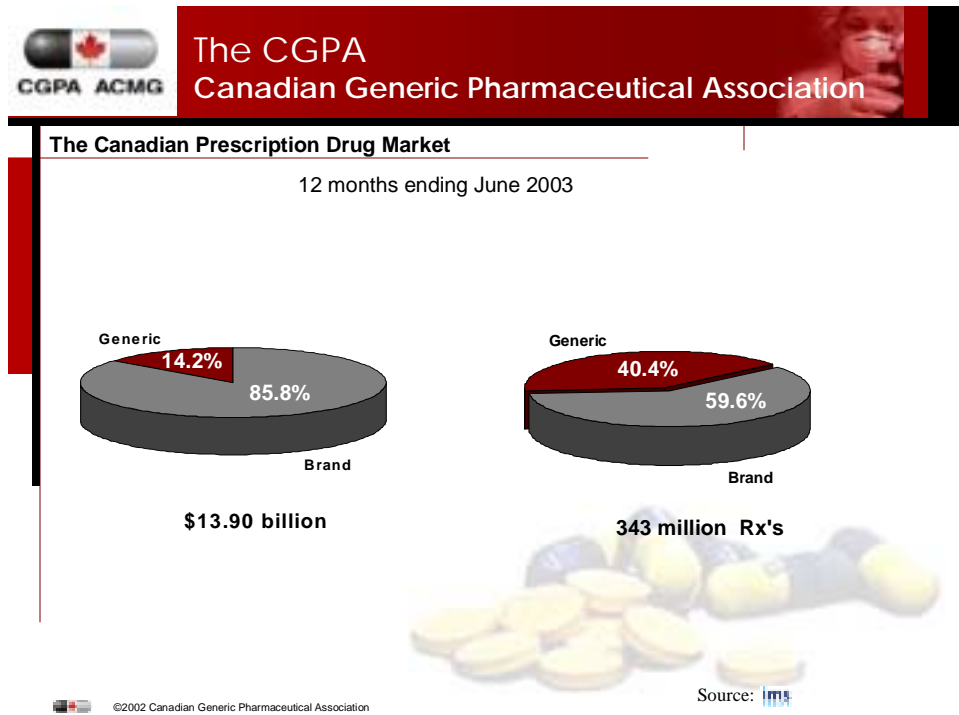
The international community also looks to Canada's generic drug makers for high-quality, low-cost prescriptions to assist in times of health crises, such as the HIV/AIDS pandemic in sub-Saharan Africa.

Savings to Canada's health-care system

No other industry has made, or continues to make, a greater contribution to affordable health care in Canada than the generic pharmaceutical industry. Last year alone, the use of generic pharmaceuticals saved Canada's health-care system more than \$1.5 billion.

Canada's Prescription Drug Expenditures

While generic drugs fill 40.4% of all prescriptions in Canada, generics account for only 14.2% of Canada's \$13.9 billion annual prescription drug expenditure.



Based on these data, it is impossible to dispute that generic pharmaceuticals provide substantial savings to the health-care system. It is equally impossible to dispute that the use of generics, and the introduction of generic medicines more quickly, will result in even greater savings to governments, employers and consumers.

As the chart above illustrates, despite the indisputable savings to be achieved from the use of generics, brand-name medicines continue their stranglehold on the market. As a result, Canada's prescription drug bill continues to show double-digit annual increases.

Provincial/Territorial prescription drug expenditures

Drug costs are the fastest rising cost in Canadian health care. According to the Canadian Institute on Health Information (CIHI), from 1982/83 to 2002/03, drug expenditures have experienced the most significant gain in share of total provincial/territorial health-care expenditure, reaching 7.8%, 4.9 percentage points above the 2.9 percent of total expenditure that it was in 1982/83.

Provincial/Territorial Drug Expenditures

Year	\$ (billions)	Annual Percentage Increase
2000/01	4.7	17.3
2001/02 (forecast)	5.4	14.6

Source: CIHI

Per capita spending on prescription drugs

Per capita provincial/territorial spending on prescription drugs has increased from \$26.19 in 1982/83 to \$173.71 in 2001/02. (*current dollars*)

Prov./Terr. Per Capita Spending on Prescription Drugs

Year	\$ (per capita)	Annual Percentage Increase
2000/01	153.12	16.2
2001/02 (forecast)	173.71	13.4

Source: CIHI

Drug costs rising faster in Canada than rest of World

IMS HEALTH data for the 12 months ending September 2002 shows that Canada's drug costs are increasing faster than any country in the world. Canada's expenditures were up 16%, while costs were up 13% in the U.S., 12% in the U.K., 10% in Spain, 9% in Germany, 5% in Italy and 3% in France.

The price of pharmaceuticals: Brand vs. Generic

A price comparison based on data from IMS Health comparing brand name and generic prices of virtually every multi-source product on the Canadian market shows that the average price differential between generic and brand products is 45%.

According to data from IMS Health, the average cost of a brand-name prescription has increased by 76% from \$31.52 in 1992 to \$55.56 in 2002. During the same period of time, the average cost of a generic prescription increased from about \$16.35 to \$21.57, or 32%.

Price per prescription	1992	2002	% Increase
Brand	\$31.52	\$55.56	76%
Generic	\$16.35	\$21.57	32%

Source: IMS HEALTH

To further highlight this point, the report *Health Care in Canada: 2002* released May 29, 2002 by the Canadian Institute for Health Information (CIHI) notes that “[b]y 1998/1999, provincial drug plans in Ontario, Saskatchewan, Alberta, and British Columbia were paying more, in total, for drugs introduced after 1991/1992 (“newer” drugs) than for older (“existing”) drugs. Between 1993/1994 and 1998/1999, total drug expenditures climbed, while spending on existing drugs decreased.”

The CIHI Report goes on to say that: “The average cost of new drugs, however, has increased steadily over time, in excess of what would be expected on the basis of inflation alone. New drugs introduced between 1998 and 2000, for example, cost, on average, \$114.41 per prescription in 2000.”

The price of generic pharmaceuticals: Canada vs. United States

Over the past several months, data from a number of sources has been used to make a variety of claims about the price of generic pharmaceuticals in Canada versus the United States.

In order to obtain an independent, accurate picture of the price of generics in Canada and the United States, the CGPA examined sales data from IMS HEALTH Global Services for the 28 top-selling generic drugs common to both countries for the 12 months ending September 2002.

To ensure a valid comparison, the data from IMS HEALTH Global Services are prices into drug stores based on wholesaler and manufacturer invoices in both the United States and Canada. The prices represent the average price per unit (i.e. capsule, tablet). Dispensing fees and any wholesaler markup are not included.

All prices provided from IMS HEALTH Global services were in U.S. funds. The CGPA converted the prices to Canadian funds using IMS’s conversion factor of 1.561147, which was the average exchange rate for the 12-month period of they study.

Generic prices lower in Canada than in US

The data shows that the 28 top-selling generic drugs common to both countries are priced, on average, 28% less in Canada.

Please see chart on following page

Canadian vs. US Generic Prices							
Generic Name	Canadian Brand Name(s)	Strength	Main Indication	Price per tablet (CDN\$)		Bottle of 100	
				Canada	US	Canada	US
acebutolol	Monitan/Sectral	200mg	Heart	0.20	0.54	20.14	54.17
amiodarone	Cordarone	200mg	Heart	1.11	0.94	111.31	93.82
amoxicillin	Amoxil	500mg	Anti-infective	0.16	0.15	16.39	15.14
atenolol	Tenormin	50mg	Blood Pressure	0.32	0.03	31.54	3.12
cephalexin	Keflex	500mg	Anti-infective	0.26	0.33	26.23	33.25
clindamycin	Dalacin C	300mg	Anti-infective	0.93	3.51	92.89	351.26
clonazepam	Rivotril	0.5mg	Seizure Treatment	0.10	0.10	10.30	9.52
cyclobenzaprine	Flexeril	10mg	Muscle Relaxant	0.30	0.24	30.13	23.57
diclofenac	Voltaren	50mg	Arthritis/Pain Reliever	0.32	0.38	31.85	37.78
diltiazem hcl	Cardizem CD	240mg	Heart	1.27	1.45	127.08	145.50
famotidine	Pepcid	40mg	Ulcer	0.86	0.74	85.55	73.53
fenofibrate	Lipidil Micro	200mg	Anti-Cholesterol	0.98	2.80	97.73	279.76
fluoxetine	Prozac	20mg	Anti-depressant	0.79	1.38	79.46	138.32
fluvoxamine	Luvox	100mg	Anti-depressant	0.74	1.20	74.15	120.05
glyburide	Diabeta	5mg	Diabetes	0.06	0.14	5.78	13.74
lisinopril	Prinivil/Zestril	20mg	Blood Pressure	0.79	0.54	78.84	53.86
lorazepam	Ativan	1mg	Anti-anxiety	0.04	0.13	3.90	13.11
lovastatin	Mevacor	20mg	Anti-Cholesterol	0.97	0.92	97.26	91.80
metformin	Glucophage	500mg	Diabetes	0.10	0.29	10.46	29.35
metoprolol	Lopresor/Betaloc	50mg	Blood Pressure	0.10	0.12	9.99	11.86
minocycline	Minocin	100mg	Anti-infective	0.86	0.74	86.49	73.53
naproxen	Naprosyn	500mg	Arthritis/Pain Reliever	0.17	0.14	17.02	13.58
ranitidine	Zantac	150mg	Ulcer	0.32	0.14	31.54	14.05
sotalol	Sotacor	80mg	Blood Pressure	0.49	0.38	49.18	37.62
terazosin	Hytrin	5mg	Prostate	0.51	0.71	50.58	70.72
trazodone	Desyrel	50mg	Anti-depressant	0.18	0.53	18.42	53.08
verapamil	Isoptin	120mg	Heart	0.76	0.38	75.56	38.33
warfarin	Coumadin	1mg	Blood Thinner	0.18	0.33	17.64	33.25
Total of 28 products				\$ 13.87	\$ 19.27	\$ 1,387.39	\$ 1,926.69
Price Difference Canada vs. US (Based on bottles of 100, 28 products)							\$ 539.30
Percentage Difference Canada vs. US							-28.0%

Source: Prices into drugstores based on wholesaler and manufacturer invoices-IMS HEALTH Global Services, 12 months ending September 2002

Prices=average price per unit, derived by dividing sales by units sold

Note: Dispensing fees not included in prices

Exchange rate IMS HEALTH Global as of Qtr3/2002=1.561147

Products in study =leading strength of top generic oral solids(IMS Canada prescription sales) with equivalent product in the US

The Generic Pharmaceutical Business in Canada: Uncertainty Rules

In any business, the most important decisions that impact success or failure are those concerning resource allocation. For generic drug makers this process begins years before production with the selection of patented pharmaceutical products for which to produce generic equivalents.

Obviously, the sales of the patented product play a key role in determining which products to pursue. While the sales of a patented product go to a single manufacturer, once the product comes off patent, there will be several manufacturers competing for those sales at significantly reduced prices. So the sales of the patented drug must be at a level that can sustain several manufacturers at a price much lower than the brand price.

Once patents expire, the unit sales of those products will decline immediately as brand companies stop marketing those products and attempt to switch the market to newer, patented products by aggressively marketing them to doctors and lobbying provincial governments to add the new drugs to their formularies.

Provincial governments' savings from a generic alternative of a top-selling patented drug are often lower than anticipated because, by the time the generic drug finally makes it onto provincial formularies, the market for the drug is significantly reduced as physicians are prescribing a newer, and inevitably more expensive, patented drug.

All of these factors are taken into account in the business planning of generic pharmaceutical companies, as is the other key piece of information: the patents listed on the branded drug.

For this, generic drug makers carefully monitor the Patent Register to see when patents are set to expire. Generic drug makers do not want to waste resources researching and developing a drug long before patent expiries. In the best-case scenario for a generic drug maker, and for Canada's health-care system, the generic version should have its Notice of Compliance from Health Canada just as the patent on the branded product is set to expire. That way, it can begin producing and marketing its version of the product almost immediately after patent expiry. The generic firm can begin recouping its investment, and Canadians can begin saving money.

However, these decisions are becoming increasingly difficult for generic drug makers in Canada as a number of hurdles make the process of bringing a generic product to market much longer and more expensive. For Canada's generic drug makers, uncertainty rules.

Proposal 1: The *Patented Medicines (Notice of Compliance) Regulations*

One of the most significant barriers to the ability of generic drug makers to provide Canadians with low-cost prescription drugs is the *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act*.

Due to changes to drug patent law in the United States that came into force on August 18, 2003, Canadian generic pharmaceutical companies are now less competitive with their counterparts in the U.S.

What are the *Patented Medicines (Notice of Compliance) Regulations*?

The *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act* allow brand-name drug companies to stop Health Canada approval of generic drugs simply by *alleging* patent infringement.

The automatic 24-month injunction under the *Regulations* prevents Health Canada from granting approval to a generic drug until any alleged patent infringement claims are decided in court. The *Regulations* withhold Health Canada approval not when a patent is actually infringed, but when a brand-name company says it might be. Unlike patent disputes in every other industry, a brand company does not have to obtain a preliminary injunction from the courts to stop generic drug approval.

This provides an enormous financial incentive to brand-name drug companies to allege patent infringement regardless of the possible outcome of the litigation. They strategically list a number of additional patents on a single drug in order to prolong the litigation under the *Regulations* and keep competition off the market. This practice is called "evergreening" or "layering".

Even when the generic manufacturer wins (which has happened in 77 per cent of the cases since the last amendments to the *Regulations* in 1998), the generic drug is still kept off the market through lengthy and costly litigation – often for years past the expiry of the original patent. The Supreme Court of Canada has described the *Regulations* as "draconian" in their effect on the generic industry.

No Certainty for Generic Market Entry

Under the *Regulations*, for a generic drug maker to get a product on the market, it has to spend millions of dollars developing the drug to meet Health Canada's requirements, knowing that as soon as the brand company receives the Notice of Allegation as required by the *Regulations* its development work is virtually guaranteed to be stopped, sometimes for years.

The generic then has to spend millions more dollars in litigation with the real possibility that, at the end of it all, even if it wins in court, by the time it gets its product on the market, much of the market may be shifted to a “new and improved” patented product through the marketing practices of the brand company.

Generic drug makers in Canada now frequently find themselves fighting in court to get their products to market against patents that were not even listed on the Patent Register when important business decisions about resource allocation were being made, or even at the time they submitted their products to Health Canada for safety and efficacy reviews.

What is worse, generic drug makers commonly find new patents listed on the Patent Register for a drug while litigation under the *Regulations* is proceeding on that same medicine.

Patents are stacked one upon the other, timed purposely to create a minefield of patent uncertainty.

Not only is this abuse of Canada’s patent regime extremely harmful to Canada’s generic pharmaceutical industry, Canadian taxpayers lose out on millions of dollars in savings by having to pay for higher-priced brand-name drugs for extended periods of time. The CGPA estimates that abuse of the *Regulations* has cost the health-care system at least \$1 billion since 1993.

Regulations are failing Canadians

The federal government’s stated goal for enacting the *Patented Medicines (Notice of Compliance) Regulations* was to encourage innovation and research and development in Canada. After 10 years under this draconian regime, it is now evident that the *Regulations* have been an unqualified failure.

Canadians have the fastest rising drug costs in the world. Many of the new, expensive pharmaceutical products provide little therapeutic improvement over existing medicines. Little basic research is being conducted in Canada. Our trade deficit in pharmaceuticals increased from \$2 billion in 1997 to \$5.5 billion in 2002.

An incentive to litigate, not innovate

Brand companies argue that the *Regulations* are needed to effectively protect patents and encourage innovation in the pharmaceutical sector. But instead of encouraging brand-name drug companies to develop new, innovative products that make a significant improvement to the health of Canadians, the *Regulations* have encouraged brand companies to devise complicated legal strategies to delay competition from generic products.

Many new pharmaceutical products not innovative

In order to take full advantage of the extraordinary legal tools provided under the *Regulations*, the brand companies have also been encouraged to make minor changes to existing medicines in order to file for new patents and further delay competition.

In its 2000 Annual Report, the PMPRB reported that of the 81 new drug products introduced in Canada in 2000 only three could be categorized as “*breakthroughs*” while more than half, 42, provided “*little, moderate, or no improvement over existing medicines.*”

This data is supported in a study by the U.S. National Institute for Health Care Management (NICHM), which found that two-thirds of prescription drugs approved by the U.S. Food and Drug Administration (FDA) during the 1990s were modified versions of existing medicines, or identical to products already on the market. Only a third were new molecular entities. The report also stated that the recent increase in U.S. spending on pharmaceuticals was for products that the FDA had determined did not provide significant benefits over those already on the market.

Appropriate levels of profit

Canada’s generic pharmaceutical industry supports patent rights, intellectual property protection, and the right of any pharmaceutical company, brand or generic, to recoup its investment and make a reasonable profit.

However, the key word is “reasonable.” Canadians and their governments should not be drawn into the false argument that it is necessary for the pharmaceutical industry to consistently and significantly top every other industry in every measure of profit in order to be able to afford necessary and desirable investment to discover and develop new medicines.

Most Profitable Industries

Fortune April 14, 2003

Rank	Industry	2002 Profits as % of Revenues	Rank	Industry	2002 Profits as % of Assets	Rank	Industry	2002 Profits as % of Equity
1	Pharmaceuticals	17.0	1	Pharmaceuticals	14.1	1	Household and personal products	30.7
2	Commercial Banks	16.9	2	Household and personal products	10.7	2	Pharmaceuticals	27.6
3	Medical Products and Equipment	11.9	3	Medical Products and Equipment	9.5	3	Food Consumer Products	23.2
4	Household and personal products	10.8	4	Food Services	9.4	4	Medical Products and Equipment	23.1
5	Diversified Financials	10.6	5	Publishing, Printing	8.2	5	Homebuilders	21.3
	The 500 Median	3.1		The 500 Median	2.3		The 500 Median	10.2

In fact, unreasonable market exclusivity stifles competition, thereby removing the incentive for true innovation. The dangers of monopolies are recognized in virtually every other area of our economy and it is time for the federal government to recognize the damage that abuse of our drug patent laws is inflicting on our nation's health-care system.

Periods of market exclusivity for patented pharmaceutical products

In defence of the *Regulations*, representatives of brand-name drug manufacturers in Canada claim that generic pharmaceuticals in Canada come to market more quickly than is the case in the United States. This is false.

In his October 21, 2002 remarks regarding his initiatives to end abuse of U.S. drug patent law U.S. President George W. Bush said, "*New drugs, on average, are sold for 11 years under patent protection, then generic versions become available.*"

The CGPA examined Canadian sales figures from IMS HEALTH Canada between January 1997 and October 2002 listing when a brand product launched and the length of time before a generic version was introduced. To determine the length of market exclusivity for brand-name products, the CGPA took the date of the first sales of the brand product, and the first sales of the first generic equivalent, then simply subtracted.

This data shows the average period of market exclusivity for the brand companies was 13.7 years in Canada. This figure compares closely to a 1997 study conducted by Professor Malcolm Anderson of Queen's University's Faculty of Medicine, which found the average period of market exclusivity in Canada was 12 to 14 years.

Questionable figures on R&D expenditures

The mantra of the brand-name pharmaceutical industry is that without high-priced drugs and extraordinary rules like the *Patented Medicines (Notice of Compliance) Regulations* there will not be enough profit to recoup investments in research and development.

In fact, the lobby group for the brand-name industry in Canada claims that the average cost to develop a new medicine is \$1.3 billion. This figure is a conversion to Canadian dollars from the US\$800 million figure used by the brand industry in the United States.

One of the most commonly cited sources for this figure is a November 2001 report from the Tufts Center for the Study of Drug Development, which receives 65% of its funding from drug companies.

In a February 18, 2003 article in *The Guardian* newspaper, Graham Dukes, professor of pharmacotherapy at the University of Oslo in Norway, says these figures are grossly exaggerated. Dukes said, “*The figures vary so widely that most of them must be wrong.*”

He said many of them include the costs of advertising, marketing and sales, and half the Tufts figure is “opportunity costs of capital” or what the money would have earned if it had been invested in something else instead. Dukes says a reasonable figure would be somewhere between US\$100 million and US\$200 million per new drug.

These figures correspond with a 2002 report from Public Citizen, a US-based non-profit research group, which found brand companies spend an average of US\$240 million on each new drug.

One thing is clear: even though the \$1.3 billion figure is used by the brand companies in Canada to argue for the maintenance of the *Regulations*, they spend only one-tenth of that amount per drug in Canada.

According to the 2002 Annual Report of the Patented Medicine Prices Review Board (PMPRB), R&D expenditures for all patentees in 2002 was \$1.18 billion. In that same year, there were 94 new, patented drug products for human use. This translates to an expenditure of approximately \$13 million per new drug in Canada.

Falling investment in research and development

The latest Annual Report of the Patented Medicine Prices Review Board reveals, “*The R&D-to-sales ratios for the past three years have been lower than any year since 1992.*” (Page 31 of PMPRB 2002 Annual Report)

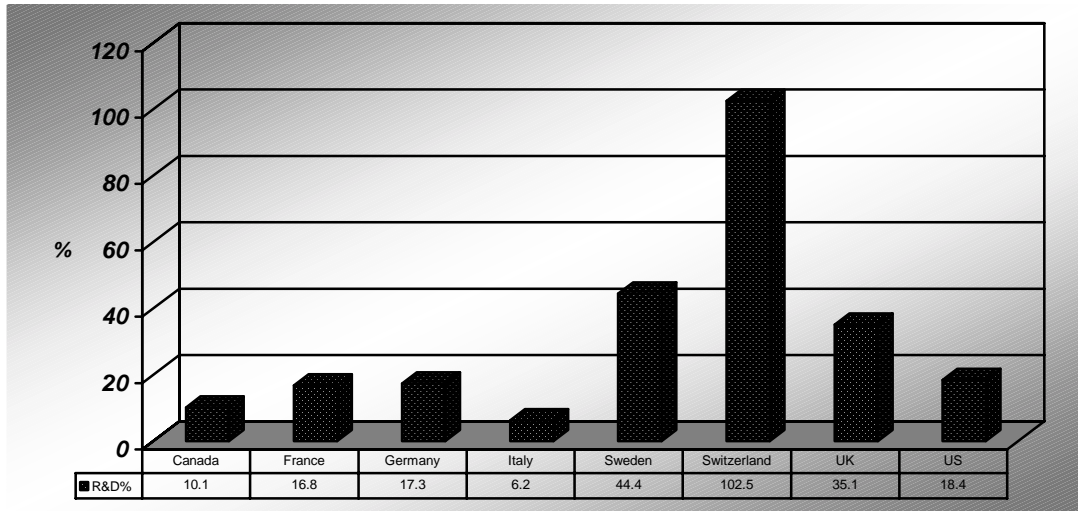
Canada’s pharmaceutical R&D spending well behind other countries

The PMPRB’s December 2002 report *A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries*, reported the following:

- Despite growth in R&D spending, Canada ranked behind other major industrialized countries in R&D spending by several measures.
- The ratio of R&D to domestic sales in Canada remains well below values in the United States and Europe. In 2000, the Canadian ratio was 10.1% while the aggregate ratio for the seven countries used for the PMPRB’s comparison was nearly double that at 19%. Only Italy had a lower ratio than Canada.
- Among major industrialized countries, Canada accounts for a share total R&D that is roughly one-half of its share of total pharmaceutical sales.

R&D-to-domestic-sales ratio, Canada and selected countries, 2002

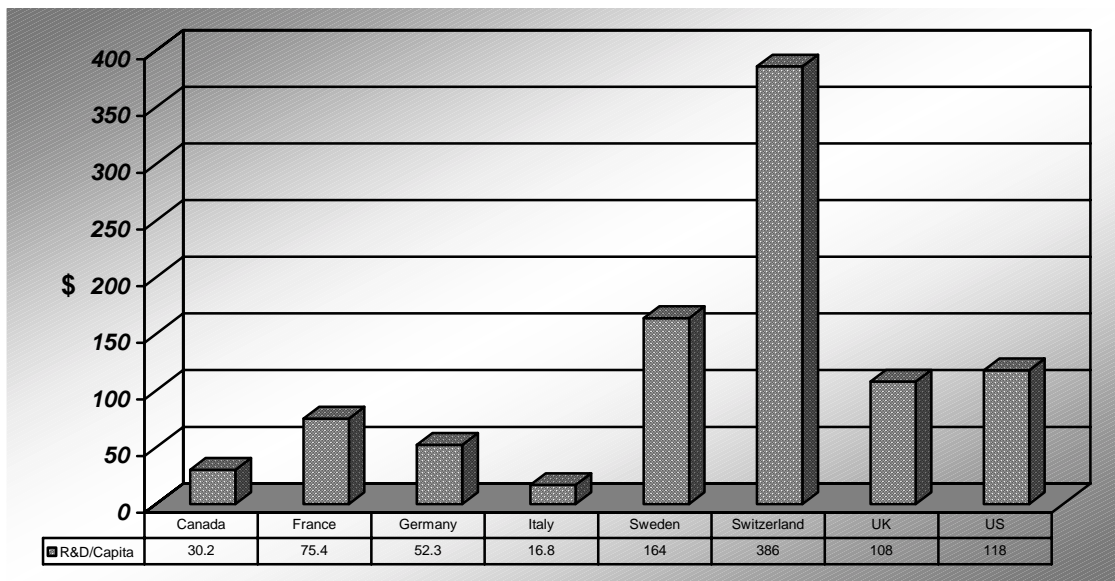
Source: *A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries*



The PMPRB report also shows that, in 2000, R&D spending in Canada was \$30.2 per person, well below the aggregate value of \$90 for the other countries. Once again, Canada surpassed only Italy in R&D spending per capita.

Pharmaceutical R&D spending per capita, 2002

Source: *A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries*



Shares of world pharmaceutical sales and R&D spending

As an alternative way of assessing Canada's R&D performance, the PMPRB report also compared world shares of R&D spending and sales.

The report stated: "To the extent sales revenue earned in a particular country governs the pharmaceutical industry's ability to conduct research in that country, one might expect a rough equality between the world shares of research investment and sales."

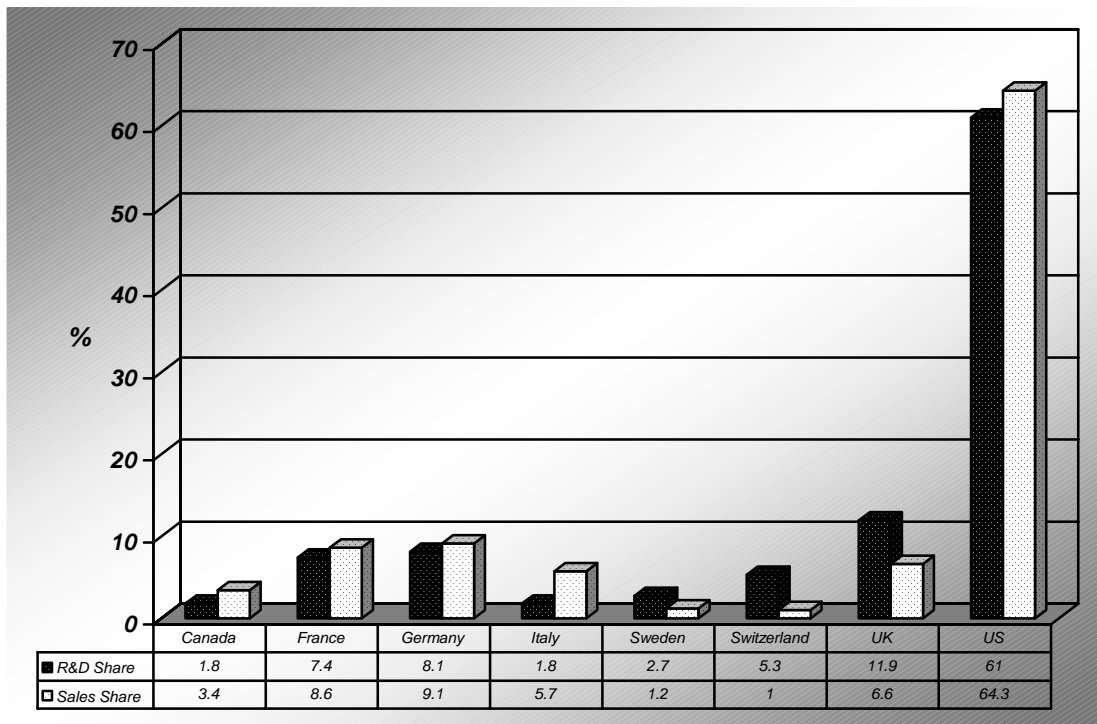
This is not what the PMPRB found in Canada.

In 2002, sales in Canada accounted for 3.4% of the total sales (\$275 billion) of the eight countries, while research and development spending accounted for only 1.8% of total R&D.

Sweden, Switzerland and the UK all had R&D shares substantially higher than their sales shares. In France, Germany and the US, R&D and sales shares were about equal.

Distribution of pharmaceutical R&D spending and sales, 2002

Source: *A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries*

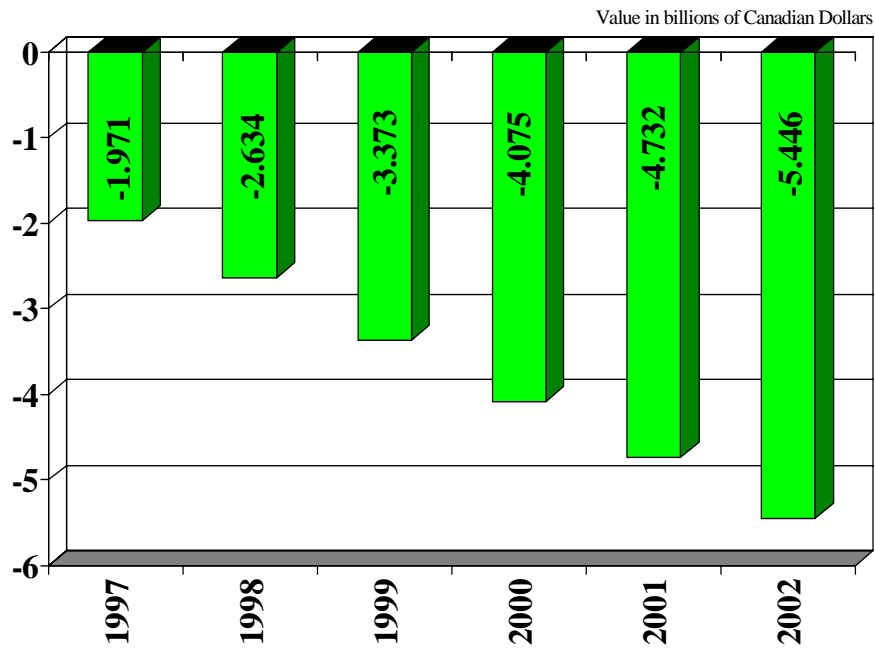


This demonstrates that the multinational pharmaceutical companies are developing their new drugs in their home countries, not here in Canada. The vast majority of spending on R&D they do in Canada is for things like clinical trials in order to get government approval to sell their drugs.

Canada's trade deficit in pharmaceuticals

To support this point, data from Statistics Canada shows that Canada's trade deficit in pharmaceuticals has grown from \$2 billion in 1997 to \$5.5 billion in 2002.

Canadian Trade Balances Pharmaceutical and Medicine Manufacturing



Source: Statistics Canada

Regulations contributing to skyrocketing prescription drug costs

Other than the brand-name drug companies and their armies of lawyers, the *Regulations* are not serving Canadians. Innovation is being replaced by litigation, and this litigation is unfairly delaying generic competition and adding hundreds of millions of dollars in unwarranted costs to Canada's already cash-starved health-care system. The CGPA estimates that, since 1993, the *Regulations* have cost Canada's health-care system more than \$1 billion.

Impact of Regulations on the private sector

In its submission to the Commission on the Future of Health Care in Canada, Green Shield Canada, the company that runs the Ontario government's \$2.4 billion drug-benefits plan, and plans for private sector industrial employees including the Big Three automobile manufacturers, urged the federal government to repeal these regulations. To make its point, Green Shield cited the ulcer medication omeprazole, sold under the brand name Losec.

Losec, has annual sales in Canada of \$430 million. A patient taking a tablet every day to control heartburn will pay more than \$800 a year once dispensing fees are factored in.

Green Shield told the Commission that if a generic had been available in 2001, for just this one drug, the average employer's total drug benefit costs would have dropped by 1.6 per cent.

Despite the fact that the original patent on Losec expired in 1999, to this day there are still no generic versions on the market in Canada, even though generics are available in the United States and Europe.

Generic versions have been blocked by the automatic 24-month stay under the *Regulations*.

First, AstraZeneca switched the Losec pill from a capsule to a tablet and acquired new 20-year patents on the tablet form. This triggered the automatic stay, stopping the first generic company that applied to Health Canada to make a lower-cost version dead in its tracks.

As that court case was going on, AstraZeneca filed several other patents on minor modifications of the drug, including patents on:

- A new coating
- Different dosages
- The inactive chemicals used in the pills, basically the fillers

The Patent Register on Health Canada's website shows that AstraZeneca has listed at least 10 additional patents on this one drug, the latest of which does not expire until 2018, even though the original patent expired in 1999.

Losec (omeprazole)

Patent number	Expiry Date
1292693	December 3, 2008
1302891	June 9, 2008
2025668	February 2, 2010
2133762	April 20, 2013
1338377	June 11, 2013
2284470	November 10, 2018

Losec (omeprazole magnesium)

Patent Number	Expiry Date
1264751	January 23, 2007
2166483	July 8, 2014
2166794	July 8, 2014

Losec MUPS (omeprazole magnesium)

Patent Number	Expiry Date
2170647	June 7, 2015

Each new patent provides AstraZeneca another way to allege patent infringement and start additional two-year stays against any generic drug maker trying to produce and sell omeprazole.

By carefully timing the filing of patents and injunctions, AstraZeneca has successfully blocked generic competitors for years.

In the case of omeprazole, AstraZeneca earns well over \$1 million in sales for each day generic versions are kept off pharmacy shelves.

It is hard to imagine that the people who drafted and approved the *Regulations* would have fully anticipated the creative ways in which the patent challenge process could be manipulated to prevent competition.

Canada's international trade obligations

Repealing the *Regulations* would leave Canada in full compliance with our international trade obligations, and the brand-name industry would still have full legal recourse to protect their patents.

In fact, when former Industry Minister John Manley appeared before the Industry Committee on February 17, 1997, he said: "*Since the inception of Bill C-91, Canada already has a stronger system than that required by the GATT treaty.*"

Minister Manley went on to say: "*Therefore, it is possible to abolish regulations. It is not an international commitment.*"

The brand industry lobbyists argue that the *Regulations* represent the only effective enforcement mechanism by which Canada meets its international obligations. This is false.

If the *Regulations* were repealed, patent holders would still be entitled to sue generic companies but, like all other industries, they would have to obtain a preliminary injunction from the court to stop generic drug approvals. In fact, eliminating the 24-month injunction would infuse legal discipline and accountability into the system.

U.S. moves to end abuse of drug patent laws

Canada's *Patented Medicines (Notice of Compliance) Regulations* are modeled after similar provisions of U.S. drug patent law (*Hatch-Waxman*, 1984).

As in Canada, the brand companies have discovered ways of gaming the system to prolong market monopolies. But unlike Canada, the federal government and state governments have taken action to stop it.

Given the fact that the U.S. has identified problems with the automatic injunction under *Hatch-Waxman* and taken steps to close these loopholes, Canada should now follow the U.S. lead and stop abuse of the 24-month injunction.

"There have been some legalistic ways of extending patent life, which I don't think are legitimate. One has to accept that patents have an end."
Daniel Vasella, chairman and CEO of Novartis, USA Today June 6, 2002

Federal Trade Commission (FTC) investigation

In July 2002, the United States Federal Trade Commission published findings of its investigation of brand-name drug companies' abuse of the automatic injunction under U.S. patent law. The FTC's first recommendation was to permit only one automatic injunction per drug.

Recommendation 1: Permit only one automatic 30-month stay per drug product per ANDA to resolve infringement disputes over patents listed in the Orange Book prior to the filing date of the generic applicant's ANDA.
Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002

Bristol-Myers Squibb settles lawsuits over BuSpar and Taxol

The abuse of the automatic injunction has also been the subject of anti-trust lawsuits filed by 29 state governments against Bristol-Myers Squibb over the cancer drug Taxol and the anxiety medication BuSpar. In January 2003, Bristol-Myers Squibb announced it would pay \$670 million to settle the litigation.

The states' BuSpar lawsuit, filed in December 2001, was sparked by the company's 11th-hour attempt to extend the patent that was due to expire in November 2000 by seeking a further patent on the drug's metabolite, or the way the body breaks down the drug.

On Friday, March 7, 2003, The U.S. Federal Trade Commission (FTC) announced Bristol-Myers Squibb agreed to settle antitrust charges that it illegally kept cheaper generic versions of three drugs off the market.

"This case, and others we have brought and will bring, stands for an important proposition: competition must be on the merits, not through misusing the government to stifle your competition."

**Timothy J. Muris, Chairman of the Federal Trade Commission,
FTC news release, March 7, 2003**

The FTC had accused Bristol-Myers of a series of anti-competitive acts over the past decade to obstruct generic competition to its anti-anxiety drug BuSpar, and cancer drugs Taxol and Platinol.

"Bristol's illegal conduct protected nearly \$2 billion in yearly sales from the three monopolies, forcing cancer patients and others to overpay by hundreds of millions of dollars for important and often life-saving medications." FTC Chairman Timothy J. Muris, Friday, March 7, 2003

The settlement, lasting 10 years, eliminates Bristol-Myer Squibb's ability to fend off generic competitors for 30 months at a time by filing additional patents for a particular drug.

"The restrictions should not significantly impact the protection of the company's patent and other intellectual property rights, nor adversely impact its financial position." BMS news release, March 7, 2003

The above statement from Bristol-Myers Squibb directed at investors begs an obvious question: If this is true, then why does the brand industry continue to argue that it needs automatic injunctions?

Business for Affordable Medicines

Major U.S. corporations such as General Motors, Wal-Mart, Motorola, Kellogg and Weyerhaeuser have joined forces with state governors and the AFL-CIO to form BAM, Business for Affordable Medicines, to lobby for changes to drug patent rules that are costing them billions of dollars by needlessly delaying generic competition.

McCain-Schumer Bill

On January 7, 2003, US Senators Charles E. Schumer and John McCain re-introduced legislation along with US Senators John Edwards, Susan Collins and 15 others to ban the automatic 30-month injunction under U.S. patent law.

Waxman says automatic injunction not needed

The architect of the 1984 U.S. federal drug patent legislation known as the Hatch-Waxman Act, Representative Henry Waxman, says he will introduce a generic drug reform bill this session that would eliminate brand companies' ability to obtain even one 30-month delay while patent lawsuits are in play.

"There no longer is good justification" for the 30-month stay. In the mid-1980's, "we were told the generic industry was a fly-by-night industry, and if the brand name companies got a judgment, they would never be able to collect. No one can make the argument today."

Representative Henry Waxman, January 28, 2003

U.S. President George Bush takes aim at drug patent law abuse

On October 21, 2002, U.S. President George W. Bush announced he is taking action to close loopholes in U.S. drug patent laws that brand-name drug manufacturers have manipulated to unfairly delay the approval of competing generic drugs. President Bush's proposal calls for a limit of one automatic injunction per drug.

"When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand name company buys time through repeated delays, called automatic stays, that freeze the status quo as the legal complexities are sorted out. In the meantime, the lower-cost generic drug is shut out of the market."

U.S. President George W. Bush, October 21, 2002

President Bush's reforms came into force on August 18, 2003, leaving Canada as the only country in the world that allows brand-name drug companies repeated automatic injunctions against generic competition.

Bush Proposals to Curb Abuse of Drug Patent Laws

USA Proposals	What Big Pharma Says About Canada	The Truth
Limiting the types of patents that can be listed. Patents that claim packaging or intermediaries of a drug cannot be listed	Canada already has these rules	Multiple patents are listed for many drugs, leading to multiple automatic injunctions
Permitting the listing of patents that claim the active ingredient, a composition or formulation, methods of using the drug. Product by process claims can also be listed	These rules already apply in Canada	Multiple patents are listed for many drugs, leading to multiple automatic injunctions
Requiring the innovator to submit more detailed information for the patents submitted, including identifying the claims that relate to the drug substance, drug product or method of use	Health Canada currently reviews each patent submitted to determine whether the claims relate to the medicine itself or the use of the medicine	When Health Canada attempts to remove brand patents, the brand companies sue them. As a result many improperly listed patents are still listed
Allowing only one 30-month injunction per generic application (ANDA) per drug to address the FDA's inability to audit the patent list	This is not necessary in Canada. The Minister of Health monitors, and audits, the list in order to ensure that only eligible patents are on the Patent Register	In Canada, while court cases are ongoing and generics are subject to 24-month injunction, brand companies continue to list additional patents in order to trigger additional injunctions and restart the process over and over again. The <i>Regulations</i> must be eliminated.

Overall Differences Between Patent System in the USA and Canada

<u>Provision</u>	<u>What Big Pharma Says</u>	<u>The Truth</u>	
	Canada	USA	
20 Year Patent Term	Yes	Yes	CORRECT
Practical Availability of Interlocutory Injunctions <i>(Legal mechanism to prevent market entry due to suspected infringement)</i>	No	Yes	FALSE. As is the case in patent disputes in every other industry in Canada, if the innovator makes a sound legal argument, the courts may order an interlocutory injunction
Linkage Regulations <i>(a system to ensure that a generic drug does not infringe the patent of the drug it seeks to copy before market entry)</i>	Yes	Yes	CORRECT. Canada and the U.S. are the only two countries in the world that provide an automatic block against generic drug approvals without requiring brand companies to provide any proof of patent infringement
Effective data protection <i>(the ability to protect a patentee's clinical data for a drug from being copied)</i>	No	Yes	FALSE. The Federal Court of Appeal has ruled that Canada's data protection is consistent with NAFTA provisions, which were negotiated with the U.S.
Patent Term Restoration <i>(the ability to add time to the end of a patent if the development time and government's approval time is excessive)</i>	No	Yes	MOOT. In his October 21 announcement, President Bush said brand drugs are on the market in the U.S. for an average of 11 years before generic versions are available. In Canada, review of data from IMS HEALTH shows that brand drugs are on the market for an average of 13.7 years before generic versions are available
Government's Ability to monitor and audit Patent Register	Yes	No	FALSE. When Health Canada attempts to remove patents from the list, brand companies sue them. Health Canada often leaves improperly listed patents on the register
Damages available to generics if they are delayed by patentee	Yes	No	MISLEADING. There has never been a damage award to a generic in Canada even after a brand patent(s) has been found invalid or the generic not to infringe. Furthermore, brand companies have attacked Canada's damage provisions as unconstitutional
Tendency for generics to initiate multiple court cases to attempt to bypass patents	Yes	No	HIGHLY MISLEADING. Brand companies list multiple patents on drugs to initiate multiple injunctions. Generics have no choice but to challenge each patent in order to come to market.

Final Report of the Commission on the Future of Health Care in Canada

The Final Report of the Commission on the Future of Health Care in Canada released on November 28, 2002 recommended an immediate review of Canada's drug patent laws to improve access to generic drugs.

Of the recommendations on pharmaceuticals, the Commission calls for the review to be implemented first.

“The federal government should immediately review the pharmaceutical industry practises related to patent protection, specifically, the practises of evergreening and the notice of compliance regulations. This review should ensure that there is an appropriate balance between the protection of intellectual property and the need to contain costs and provide Canadians with improved access to non-patented prescription drugs.”

Recommendation 41: (Page 208)

Final Report, Commission on the Future of Health Care in Canada

The Report said, *“certain aspects of Canada's patent laws should be reviewed to improve access to generic alternatives and to contain costs.”* (page 19 of Executive Summary).

“A particular concern with the current pharmaceutical industry practice is the process of ‘evergreening,’ where manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage. This delays the ability of generic manufacturers to develop cheaper products for the marketplace and it is a questionable outcome of Canada's patent law.

Furthermore, regulations under the patent law require generic drug manufacturers to demonstrate that their product is not infringing on a patent held by another drug manufacturer rather than putting the onus on the patent drug manufacturer to show that their patent has been infringed – what is referred to as the notice of compliance regulations. Suggestions have been made that this leads to “pre-emptory” lawsuits from patented drug manufacturers as a way of delaying the approval of generic drugs. Clearly, if this is the case, the practice is not in the public interest. The federal government should review this issue, determine what constitutes a legitimate extension of patent protection, and also consider ways of streamlining the approval of generic drugs.”

Final Report, Commission on the Future of Health Care in Canada, pg. 209

Patent disputes in the pharmaceutical industry should be resolved through the normal litigation process used by every other industry in Canada. The world's richest companies do not need their own special set of rules for patent disputes, particularly when these rules are being systematically abused to extend monopolies beyond the expiry of the basic patents, and force Canadians to pay higher drug prices for longer.

The automatic injunction under the *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act* should be eliminated. The normal patent litigation process should be used to resolve patent disputes in the pharmaceutical industry, as in all other industries.

The courts can then determine what interlocutory relief or other procedural measures are appropriate in any given case, and determine the patent issue at trial.

By eliminating the automatic injunction, the federal government would accomplish three important goals:

- 1) Encourage the brand-name pharmaceutical industry to direct its considerable resources to developing new, innovative products instead of squeezing more profit at monopoly prices out of existing products, even after 20-year patents have expired.
- 2) Provide generics firms with date-certain market entry for recouping their investment. This will encourage more investment, job creation and R&D spending by generic drug makers.
- 3) Help provincial governments and Canadian employers control rapidly escalating prescription drug expenditures.

If the *Regulations* are eliminated:

- Brand companies will still have 20-year patent terms
- They will still be able to seek multiple patents on the same medicine if they make improvements to it
- They will still have full legal recourse to defend their patents under the provisions of the *Patent Act* used by every other industry in Canada
- And Canada will be in full compliance with its international trade agreements

The only thing the brand companies will no longer have is the automatic injunction.

Proposal 2: Speeding Health Canada's Approval Generic Drugs

Another problem that adds tens of millions of dollars annually to Canada's prescription drug costs is the lengthy delays in Health Canada's approval of generic pharmaceutical products.

This problem is exacerbated by abuse of the *Patented Medicines (Notice of Compliance) Regulations*.

Before generic drugs are sold in Canada, they are approved by Health Canada.

Due to a lack of resources at the drug review directorate at Health Canada, generic drug approval submissions often wait months before they are reviewed.

These delays hold up the introduction of generic drugs and result in millions of dollars in lost savings every year for provincial governments, private insurers and those Canadians who pay out-of-pocket for their prescriptions.

While the federal government has taken some steps to increase these resources, the average approval time for generic drugs is still almost double Health Canada's own performance target of 225 days.

The federal budget included a commitment of \$190 million over five years to speed up Health Canada's drug approvals. However, it remains unclear how much, if any, of this money will be directed to generic approvals and how the money will be spent.

The lack of specifics in the February 2003 budget is in contrast to the budget initiative implemented in the United States, which added funds directly to the U.S. Food and Drug Administration's generics program, allowing the agency to hire about 40 more people to evaluate applications.

In August 2001, researchers from Queen's University's Faculty of Medicine published a study that examined the approval of 34 generic drugs between 1995 and 1999. The results showed that delays in approving and listing just these 34 drugs cost our health-care system \$186,000 each day, \$1.3 million per week, \$6 million per month and \$36 million over six months.

While the provinces are partly responsible for these delays, one of the study's five recommendations is to increase resources at Health Canada to reduce delays in reviewing and approving generic products.

It is extremely important to note that the *Patented Medicines (Notice of Compliance) Regulations* prevent Health Canada's final approval of generic drugs until all allegations of patent infringement are decided by the courts. This means that Health Canada often completes its safety, efficacy and bioequivalence review of generic drugs yet still cannot give final approval because of delays caused by the *Regulations*.

Staff at Health Canada's Therapeutic Products Directorate (TPD) who are responsible for reviewing generic drug submissions are fully aware that, under the *Regulations*, a Notice of Compliance cannot be granted for a generic product until all allegations of patent infringement are litigated. Unfortunately, litigation is now so commonplace that staff may be placing less priority on the speedy review of generic submissions.

CGPA Proposal

The federal government must direct more funding to Health Canada to reduce the time needed to properly review generic pharmaceuticals.

A good first step would be increasing resources to the level where Health Canada's Therapeutic Products Directorate could meet its own performance target of 225 days.

Proposal 3: Streamlining Provincial Approval of Generic Pharmaceuticals

After a generic drug is finally clear of litigation under the *Patented Medicines (Notice of Compliance) Regulations* and has received its Notice of Compliance from Health Canada, the next step in the long journey to full market access is getting listed on provincial government formularies.

When generic drugs are submitted for inclusion on provincial formularies (the list of drugs for which each province will pay), they have already been approved by an exhaustive evaluation process at Health Canada.

Yet while Health Canada's standards of review are internationally recognized, some provinces continue to operate their own redundant review systems. This needless duplication of the federal approval delays the entry of generic drugs and costs taxpayers millions of dollars every year as provinces continue to pay for higher-priced brand versions for longer than necessary.

The approval of generic pharmaceuticals at the provincial level should be a quick and easy process. Once a provincial government has weighed the therapeutic value of a new drug against its cost and decided to pay for it, the decision to add the generic version to its formulary when it becomes available should be clear. After paying for a brand-name drug for years while it is under patent protection, governments should start saving money at the earliest opportunity by listing cheaper generic versions as soon as they are approved by Health Canada.

A faster process would also provide Canadian employers with significant savings because private sector drug plans often base their benefits on what drugs are covered by government plans.

CGPA Proposal

Provincial governments should maximize savings by ending duplication of Health Canada's review of generic pharmaceuticals. Generic equivalents should be designated as interchangeable with the innovator product and added to provincial formularies as soon as they receive their Notice of Compliance from Health Canada.

Proposal 4: Off-Formulary Interchangeability in Ontario

Ontario represents approximately 40% of the pharmaceutical market in Canada. Special rules in Ontario limit generic drug makers' access to the huge private sector market in the province, which costs employer sponsored drug plans and generic drug makers tens of millions of dollars annually.

Unlike virtually every other jurisdiction in North America, Ontario does not designate a generic drug as "interchangeable" with its higher-priced brand-name equivalent unless it is covered by the government's drug plan.

Off-Formulary Interchangeability (OFI) means designating generic drugs as interchangeable with brand-name drugs that are not listed on the Ontario government's drug formulary. This would provide Ontarians with easier access to lower-cost generic drugs.

After Health Canada approves a generic version of a brand-name drug for which the patent has expired, the generic version is considered for inclusion on the Ontario Drug Benefit (ODB) Formulary. Health Canada approval means the generic drug is "bioequivalent" or as safe and effective as its brand-name equivalent.

Once the generic drug is listed on the formulary it is considered "interchangeable" with the brand-name drug already listed on the formulary. Then, when patients covered under the ODB, including Ontario seniors and social assistance recipients, go to their pharmacist to fill a prescription, pharmacists dispense the less-costly generic equivalent.

There are many brand-name drugs not listed on the formulary that can be prescribed by physicians. This means consumers pay for the drugs directly or they are paid for by employer-sponsored drug plans. The generic equivalents of these non-listed brand drugs have been approved by Health Canada but pharmacists cannot dispense them without approval from the prescribing doctor. This is because they have not been listed on the formulary and, therefore, are not officially designated "interchangeable" with the brand drug.

The insurance industry, employers who sponsor drug plans for their employees, and pharmacists have expressed the need for OFI because making lower-priced pharmaceuticals more widely available will result in more cost-efficient benefits programs – particularly for small- and medium-sized businesses.

CGPA Proposal

Ontario should follow the lead of other provinces and the U.S. and list as interchangeable all generic drugs that are not covered by the Ontario Drug Benefit Plan but have been approved by Health Canada.

Proposal 5: Quebec's 15-Year Rule

Quebec has lowest generic usage in Canada

Quebec has the lowest generic usage of any province in Canada. In Quebec, generic pharmaceutical products account for less than 11% of the money spent annually on prescription drugs in Quebec but fill 36.2% of prescriptions.

\$140 million in additional annual savings available

If generic usage in Quebec increased to the level of usage in the rest of Canada, Quebecers could save at least an additional \$140 million per year.

The average use in Canada is 15%. If Quebec was at 15%, that would bring savings to \$140 million

Prescription drug spending in Canada	
<small>Source: IMS Health (12 months ending June 2003)</small>	
Total annual spending on prescription drugs:	\$13.9 billion
Brand name:	\$11.9 billion (85.8%)
Generic:	\$2 billion (14.2%)
Total number of prescriptions filled:	343 million
Brand name:	204 million (59.6%)
Generic:	139 million (40.4%)
Quebec	
Total annual spending on prescription drugs:	\$3.6 billion
Brand name:	\$3.18 billion (89.1%)
Generic:	\$389 million (10.9%)
Total number of prescriptions filled:	127 million
Brand name:	81 million (63.8%)
Generic:	46 million (36.2%)

The 15-year rule: an industrial subsidy to brand companies

The Quebec government continues to support the "15-year rule" that delays the listing of cost-saving generic drugs onto the province's drug-plan formulary. This effectively grants additional periods of monopoly to multinational brand-name drug companies beyond the patent period prescribed by the Canadian *Patent Act*.

Quebec is currently the sole province that does not automatically reimburse only the lowest-priced drug available. Brand-name drugs are purchased for 15 years on the provincial formulary, regardless of whether a lower-cost generic alternative is available.

The 15-year rule, which amounts to an industrial subsidy to brand-name drug companies, costs Quebec taxpayers \$32 million annually. This added protection is maintained while senior citizens and those on social assistance are struggling with drug plan fees that were increased by 9% in July 2003.

In many cases, by the time the 15 years has expired and generic-only reimbursement is put in place, the drug has been replaced by a newer, more expensive medication. As a result, taxpayers are often never able to benefit from the substantial savings offered by generic drugs.

Many consumer and health groups in the province, including the Conseil de la santé et des services sociaux and the Coalition on Medication Insurance in Quebec, have called on the government to re-examine its drug program and the 15-year-rule, particularly in light of Quebec's continuing efforts to control the skyrocketing costs of health care.

CGPA Proposal

The Quebec government should repeal the 15-year rule, which extends brand-name drug companies' market monopolies beyond patent terms and adds \$32 million per year to the province's prescription drug expenditures. Quebec should take full advantage of the cost savings from generic drugs as soon as they are allowed onto the market.

Conclusion

After a half-century of operating in Canada the generic pharmaceutical industry has reached a crossroads. Generic drug manufacturers need the federal government and provincial governments to work with them to put the industry on a sound and sustainable footing.

The CGPA proposals in the five-point plan have two things in common: they save money for our health-care system and they improve the environment for generic pharmaceutical manufacturers in Canada.

As prescription drug expenditures continue to consume an ever-increasing share of health-care dollars, the demand for high quality, low-cost prescription drugs will increase. The question is: Will Canada's generic drug makers be allowed to meet that demand, deliver billions of dollars in savings, and make their full contribution to the country's health-care system and its economy?



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Appendix A: PMPRB Study on Top-Selling Multiple Source Medicines

Summary of CGPA Analysis of Study

The Patented Medicine Prices Review Board (PMPRB) prepared a report on multiple source medicines comparing Canadian prices with prices in other countries at the request of the Federal/Provincial/Territorial Working Group on Drug Prices (WGDP).

The study, *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*, was completed in November 2002 and released to the public on Wednesday, June 18, 2003.

The Canadian Generic Pharmaceutical Association (CGPA) has identified several problems with data in the report. Some data is simply not accurate and some is presented in improper context, which has led to false conclusions about the price of generic medicines in Canada compared with other countries.

1) Different countries used than for PMPRB price comparisons of patented medicines

The CGPA's first concern is that in its report on multiple source medicines, the PMPRB compares multiple source prices to different countries than it uses in its comparison of patented drugs prices.

The PMPRB should have known that the news media, politicians and government officials would, and are, incorrectly comparing the PMPRB's work on patented drugs (1% above international average) with its study on multiple source pharmaceutical products.

The PMPRB compares the price of patented drugs in Canada with prices in the United Kingdom, United States, France, Germany, Switzerland, Sweden and Italy.

The PMPRB's examination of multiple source prices includes the seven countries listed above but also adds Australia and New Zealand. The inclusion of these two countries significantly lowers the overall average foreign prices for multiple source medicines, particularly in the case of New Zealand.

Conversely, if Australia and New Zealand were included in the PMPRB's study of the price of patented (brand-name) drugs, it would have a huge impact on its results by lowering the overall average foreign prices for patented drugs.

2) Brand vs. generics: Fair comparison shows generics better value

Brand-name drug prices typically remain unchanged when they come off patent. Evidence of this can be found in provincial drug formularies across the country.

As brand drug prices remain static, the PMPRB's multiple source study can be used to compare the price of generic drugs and brand-name drugs in Canada with the same group of countries.

The multiple source study found that prices for the top selling generic drugs in Canada in 2000 were over 35% lower than prices for the equivalent brand-name drugs in the other nine countries studied. Brand-name multiple source drugs were found to be between 39% and 54% higher in Canada than the median prices in the other nine countries studied.

This provides strong evidence that generic prices in Canada are actually a better value than brand-name prices when both are compared with the same group of countries.

3) Different sources used for U.S. prices

Another problem with the multiple source report is that the PMPRB used different sources for determining generic prices in the United States than it does when determining the price of patented medicines in the United States.

Drug prices vary greatly in the United States, depending on the source of information used.

The PMPRB comparison of patented drug prices in Canada and the U.S uses prices from the Federal Supply Schedule, published wholesale prices, hospital prices and pharmacy prices. In its multiple source study, the PMPRB used only the listed wholesale prices and prices from the U.S. Federal Supply Schedule (FSS) in determining U.S. prices. Obviously, the use of different data sources skews results and makes an accurate comparison impossible.

In order to obtain an independent, accurate picture of the price of generics in Canada and the United States, the CGPA obtained sales data from IMS HEALTH Global Services for the 28 top-selling generic drugs common to both countries for the 12 months ending September 2002.

The data shows that the 28 top-selling generic drugs common to both countries are priced, on average, 28% less in Canada.

4) Share of prescriptions in the US and UK filled by generics

Another concern the CGPA has with the PMPRB's report is wildly inaccurate data provided for generic market share in the United States and the United Kingdom.

The study claims generics fill 20% of prescriptions in the US and 70% in the UK. The correct figure for both countries is approximately 50% (In Canada, generics fill only 40% of all prescriptions).

While the PMPRB has acknowledged that these data are inaccurate, their publication in the report is disconcerting to the CGPA because these statistical anomalies should have been obvious to the PMPRB, and accurate information on these two large prescription drug markets is easily obtained.

CGPA Analysis of PMPRB Study on Top-Selling Multiple Source Medicines

The Patented Medicine Prices Review Board (PMPRB) prepared a report on multiple source medicines comparing Canadian prices with prices in other countries at the request of the Federal/Provincial/Territorial Working Group on Drug Prices (WGDP).

The study, *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*, was completed in November 2002 and released to the public on Wednesday, June 18, 2003.

The 110-page document contains a variety of information comparing the price of generic drugs to the price of brand-name drugs in Canada, and information comparing multiple source drug prices in Canada with those in selected other countries.

Before its public release, the PMPRB Report was leaked to the *National Post* newspaper, which ran a front-page story on June 2, 2003 under the headline “*Canadians pay up to 51% more for generic drugs: Compared to Europe, U.S.*”

June 2, 2003 was also the first day of hearings by the House of Commons Standing Committee on Industry, Science and Technology into the *Patented Medicines (Notice of Compliance) Regulations of Canada's Patent Act*.

At the Industry Committee hearings, and in the months following the publication of the *National Post* story, the news media, representatives of the brand-name pharmaceutical industry and some federal and provincial politicians have used the PMPRB's multi-source study to claim that the price of generic pharmaceuticals in Canada are too high.

They have juxtaposed the PMPRB's comparison of generic prices in Canada with selected other countries with the PMPRB's comparison of patented medicines in Canada with other countries.

On Wednesday, June 18, 2003, representatives of the Canadian Generic Pharmaceutical Association (CGPA) obtained a copy of the PMPRB's multiple source medicines report. The following is the CGPA's analysis of the PMPRB study.

Generic Prices in Canada vs. Other Countries

A) Choice of Countries Used for PMPRB Price Comparisons

After examining the report, the CGPA noted that when the PMPRB compares the price of patented drugs in Canada with prices in other countries, it compares these prices with prices in a basket of seven countries: the UK, US, France, Germany, Switzerland, Sweden, and Italy. It does not include Australia or New Zealand in that comparison as it has done in its study on multiple source drugs.

The inclusion of these countries significantly lowers the overall average foreign prices for multiple source products, particularly in the case of New Zealand.

Conversely, if Australia and New Zealand were included in the PMPRB's study of the price of patented drugs (brand name), it would have a huge impact on its results.

For example, Australia was listed in the PMPRB's report having generic prices among the lowest in the world, but the report also says generic prices in Australia are 89% of the brand, which is the highest ratio of all the countries measured. This also means that the price of the brand in Australia is very low.

CGPA Question to PMPRB:

The CGPA posed the following question to Dr. Ronald Corvari, the PMPRB's Director of Policy and Economic Analysis: "Given that politicians, government officials, the news media and brand companies will use the PMPRB numbers to compare the price of generic and brand-name products in Canada vs. other countries, why did it add New Zealand and Australia to the generic study?"

PMPRB Response:

Dr. Corvari responded that the study was undertaken in response to a recommendation of the Federal/Provincial/Territorial Working Group on Drug Prices (WGDP). Australia and New Zealand were included in the report at the WGDP's request.

CGPA Rebuttal:

In terms of the additional countries, the CGPA accepts that the WGDP requested this information.

However, the CGPA also believes that the PMPRB should have known that the news media, politicians, government officials and Rx&D would, and are, comparing the PMPRB's work on patented drugs (1% above international average) with its study on multi-source pharmaceutical products.

The report should have stated clearly and prominently that the numbers are not comparable.

B) Ratio of Generic-to-Brand Prices

If generic prices in Canada were “21% to 51%” higher than the median of foreign prices as the PMPRB states and brand prices are 1% higher than the median of foreign prices, one would logically expect to find the ratio of generic to brand prices in Canada to be much higher than in the other countries studied. However, this is not what the PMPRB reported.

The PMPRB found the price difference between generic and brand-name products was less in Australia, France, Italy, and Sweden, and higher in Germany, New Zealand Switzerland, the U.K. and the U.S. This puts the Canadian generic-to-brand ratio right in the middle of this group of countries.

The majority of countries showed generic prices at between 58% and 74% of brand prices. The Canadian figure was 65%. The widest spread between generic and brand prices was found in the United States, which has the highest prices for brand-name drugs in the world.

C) Comparison of Brand-Name Prices in PMPRB Study

The PMPRB study also reports (page 5 of the executive summary) that prices for brand-name multiple source drugs (brand drugs that are no longer under patent protection) were between 39% and 54% higher in Canada than the median prices in the other nine countries studied.

In each of its annual reports, the PMPRB provides a comparison of the price of patented products in Canada with seven other countries (US, UK, Germany, Sweden, Switzerland, France and Italy). For the past several years, the PMPRB has reported that the price of patented products in Canada is very close to the median of the prices in these other countries. For example, in its latest annual report (2002), the PMPRB reported that Canadian prices for patented medicines were 1% above the international median.

This has led Canadians and their governments to believe that the price of patented products in Canada is reasonable. However, brand companies do not change the price of their products in Canada once they come off patent, particularly if they are listed on provincial drug benefit plan formularies. Therefore, when the prices of generic and brand drugs in Canada are compared with the same countries, Canadian generic prices are proportionately lower than Canadian brand-name prices.

This also highlights the CGPA's contention that the PMPRB should have made clear that its study of generic prices is not comparable to its annual study of patented drugs because different countries are used in each study.

Comparison of Prices of Generics in Canada vs. the United States

Issue:

The generic price comparison of most interest to Canadians is between Canada and the United States. They care less about what the price of drugs is in New Zealand or Italy than they do about prices in Canada's closest neighbour and largest trading partner.

The PMPRB study states that the listed wholesale prices for generics in the U.S. in 2000 were 248% higher than prices on the Ontario Drug Benefit Formulary, but prices listed on the U.S. Federal Supply Schedule (FSS) in 2000 were 69% lower.

CGPA Analysis

The FSS numbers represent a very large tendered contract. The prices of both generic and brand-name drugs listed on this schedule are much lower than prices widely available on the U.S. market.

The "248% higher" figure is from the U.S. Redbook, which publishes wholesale prices for generic drugs in the United States. This figure is also not considered accurate by most industry observers, as the prices listed are often higher than prices widely available on the U.S. market.

When the PMPRB does its comparison of brand-name drug prices in Canada and the U.S., it uses the FSS price but only as part of its calculation of average U.S. prices for brand-name products, along with hospital, pharmacy and published wholesale prices.

CGPA Question to PMPRB:

Why did the PMPRB use different sources for comparing generic prices in the U.S. and Canada than it did for its comparison of brand prices in the U.S. and Canada?

The difference in the numbers on generic pricing in the U.S. provided in the multiple source study are so enormous that it is unlikely to provide much insight to anyone.

PMPRB Response:

For purposes of its regulatory activities under the Patent Act, the PMPRB relies on price information filed by manufacturers of patented medicines, as required under the Patented Medicines (Notice of Compliance) Regulations.

In the case of the United States, manufacturers are required to file information showing the publicly available ex-factory prices charged to pharmacies, wholesalers, hospitals and others, including the Federal Supply Schedule (FSS).

Manufacturers of non-patented medicines, including manufacturers of brand-name and generic multiple-source drugs, are not required to file price information and therefore it was necessary for purposes of this study to obtain the best information available from other sources.

Regarding the use of FSS prices, you (CGPA) assert “the prices listed on this schedule are much lower than prices widely available on the U.S. market”.

Some experts would disagree with this claim. For example, in his (unpublished) review of the study, Professor Iain Cockburn of Boston University, states: “...prices obtained by many government agencies and large private sector purchases are effectively well below the FSS”. (This observation was affirmed by Professor Panos Kanavos in his presentation “Approaches to Pharmaceutical Regulation in Europe and the USA”, given to the PMPRB Symposium last October.)

Professor Cockburn argues on this basis that Canadian-to-foreign price ratios based on FSS prices should not be viewed as upper-bound estimates. That is, Canadian generic prices may in fact be more than 51% higher on average than median international prices.”

CGPA Rebuttal:

The statement that “Canadian generic prices may in fact be more than 51% higher on average than median international prices” because of the FSS price comparison is not credible.

In order to obtain an independent, accurate picture of the price of generics in Canada and the United States, the CGPA examined sales data from IMS HEALTH Global Services for the 28 top-selling generic drugs common to both countries for the twelve months ending September 2002.

To ensure a valid comparison, the data from IMS HEALTH Global Services are prices into drug stores based on wholesaler and manufacturer invoices in both the United States and Canada. The prices represent the average price per unit (i.e. capsule, tablet). Dispensing fees and any wholesaler markup are not included.

All the prices provided from IMS HEALTH Global services were in U.S. funds. The CGPA converted the prices to Canadian funds using IMS’s conversion factor of 1.561147, which was the average exchange rate for the 12-month period of the study.

The data shows that the 28 top-selling generic drugs common to both countries are priced, on average, 28% less in Canada. *(Please see chart on page 5)*

CGPA Question to PMPRB:

The other question the CGPA had regarding how generic prices in Canada and the U.S. are portrayed. The fourth paragraph states “...*Canadian prices for generic drugs were between 21% and 51% higher depending on the source of U.S. price information. When the U.S. is excluded, this difference is 49%.*”
(Please see executive summary, page 5)

Why was this last sentence included? Why did the PMPRB feel that it was necessary to remove the one country most Canadians are interested in comparing prices to and publish that number? Why not remove Australia or New Zealand so that the countries compared were the same as the PMPRB's brand price comparison? What was the motive?

PMPRB Response:

“These results were included in the report at the WGDP’s request.”

Share of Prescriptions in the United States Filled by Generics

Issue:

The PMPRB multiple source report states that in the U.S., generics fill 20% of prescriptions compared with 40% in Canada, 70% in the U.K, 40% in Germany, etc. (see executive summary, page 5).

Data from IMS HEALTH shows generics fill 45% of prescriptions in the U.S. This is the number consistently quoted by most industry observers in the U.S.

CGPA Question to PMPRB:

Given the dramatic difference in the numbers for U.S. generic market share in the PMPRB report and the numbers from IMS HEALTH, is this simply a mistake in the report or is there another explanation?

PMPRB Response:

“The study does not state generics fill 20% of prescriptions in the U.S, it states (on page 5) “Generics represent about 20% of the U.S. market...”

This statement refers to market-share by value of sales not number of prescriptions. (Admittedly, the text might have been clearer on this point.)

IMS data (reproduced on the U.S. Generic Pharmaceutical Association website) imply that in 2000 generics accounted for 18.6% of sales in U.S. prescription drug market.”

CGPA Rebuttal:

The PMPRB’s explanation of the 20% figure for U.S. market share is not valid for two reasons:

i) The first paragraph of page 5 of the study (to which the PMPRB’s response refers) reads as follows:

“The UK, Canada and Germany are among the countries that have a significant utilization of generic medicines, at about 70%, by volume, in the UK and approximately 40% in Canada and Germany. Generics represent about 20% of the U.S. market and 10% in Australia and New Zealand. The generic sector is less significant in France, Italy, Sweden and Switzerland. Many of the countries used for comparison purposes in this study regulate the prices of generic medicines in some manner.”

If it were simply a matter of poor wording, why would the PMPRB not include the U.S. with the UK, Canada and Germany as “countries that have significant utilization of generic medicines”? At 45-50%, the U.S. would have been second only to the UK.

ii) Furthermore, in the chart on page 29 of the multi-source study, under the heading "*Estimated Generic Market Share (by Volume)*" the figure for the UK is 70%, the figure for Canada is 40%, the figure for Germany is 41%, the figure for Australia and New Zealand is 10% and the figure for the U.S. is 20%.

Clearly, it is not a matter of unclear text or poor wording. The numbers for generic market share in the U.S. in this study are simply incorrect.

During a September 30, 2003 conference call between the PMPRB and CGPA, Dr. Corvari stated that the figures were, indeed, incorrect and that they would be corrected in the electronic version of the study on the PMPRB's website.

Share of Prescriptions in the UK filled by Generics

Issue

The PMPRB multiple source report states that in the United Kingdom, generics fill 70% of prescriptions. (see executive summary, page 5 and chart on page 29 under the heading "*Estimated Generic Market Share (by Volume)*").

Britain's Department of Health reports that, for 2002, generic pharmaceuticals filled 53% of prescriptions.

CGPA Question to PMPRB:

Can the PMPRB explain the dramatic difference in the numbers for UK generic market share in the PMPRB report and the numbers from the Department of Health?

Did the PMPRB contact the Department of Health to get its number? If not, what is the source for the "70%" number?

PMPRB Response:

During a September 30, 2003 conference call between the PMPRB and CGPA, Dr. Corvari stated that the figures were incorrect and that they would be corrected in the electronic version of the study on the PMPRB's website.

Other Issues with Data in the PMPRB’s Multiple Source Medicines Report

Page 4 of the PMPRB multi-source study states: “According to the Canadian Generic Pharmaceutical Association (CGPA, formerly the Canadian Drug Manufacturers Association), generic market penetration increased to 13.8% of retail prescriptions in the twelve months ending June 2002.”

This is data from IMS HEALTH and the 13.8% figure is for hospital and pharmacy sales, not retail (pharmacy) sales.

Quick facts on prescription¹ drug spending in Canada, 2002			
Source: IMS HEALTH Canada (12 months ending December 2002)			
Estimated \$ value of hospital and drug store purchases:	\$13.2 billion		
Brand name:	\$11.3 billion (86.2%)		
Generic:	\$1.8 billion (13.8%)		
Estimated total number of prescriptions filled:	331 million		
Brand name:	198 million (59.7%)		
Generic:	133 million (40.3%)		
Average Price per prescription:	1992	2002	Increase
Brand name:	\$31.52	\$55.59	76%
Generic:	\$16.35	\$21.53	32%

¹ Includes both prescription and OTC products that must be dispensed by a hospital or retail pharmacy.

Obviously, this is not an issue of enormous importance. It does, however, highlight the fact that the PMPRB would have had more recent, more accurate and properly interpreted figures if it had contacted the CGPA while drafting the study, at the very least regarding information it was going to attribute to the CGPA.

PMPRB Response:

“We acknowledge the 13.8% generic share cited on CGPA's website refers to hospital and pharmacy sales not retail prescriptions. We appreciate your bringing this to our attention.”

**Myths About the Price of Generic Pharmaceuticals in Canada
Dispelled by the PMPRB Report on Multi-Source Medicines**

Myth #1: Generic prices are higher in Canada than in the United States.

Palmer D’Angelo Consulting (whose primary clients are brand-name drug makers) released a document in August 2002 that claimed generic prices in Canada are 155% higher than in the United States.

This document and its findings have been widely disseminated by the brand-name industry’s association, Rx&D, and has been a source used by numerous news media outlets in Canada for stories regarding the price of generic drugs in Canada and the United States.

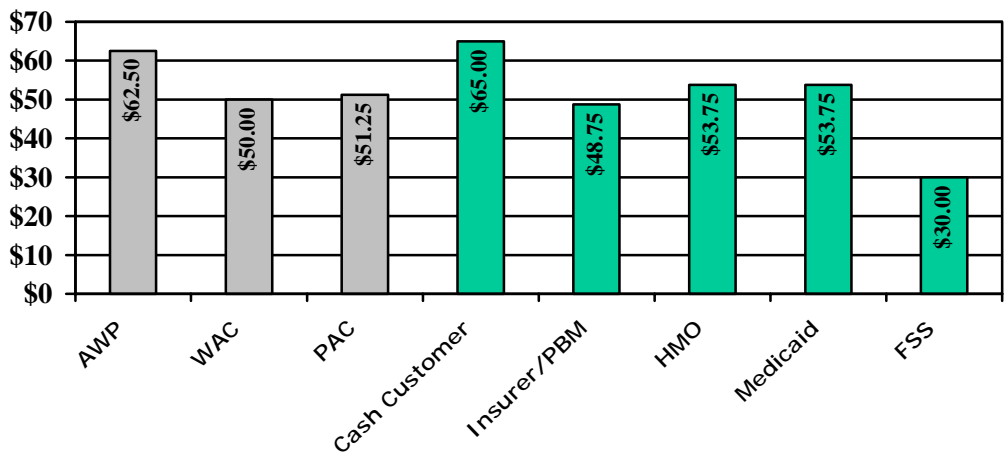
Reality:

While Palmer D’Angelo Consulting used only FSS prices as its source for U.S. prices in its August 2002 comparison of generic prices in the two countries, it certainly did not when defending prices of brand-name drugs in the presentation it made on Canada/US Cross Border Trade at IMS Briefing Session in Montreal and Toronto on September 3 and 4, 2003.

In its Power Point presentation for these briefings, Palmer D’Angelo said on page 25, “There is no single ‘US Price’. Prices vary depending on buying power.”

On page 26 of the presentation, the following graph appears.

Drug Prices in the United States
Example of a typical prescription



Source: US Dept. Health & Human Services

The PMPRB report released on June 18, 2003, shows that a comparison based on published list prices for generic drugs in the U.S. in 2000 showed those prices to be 248% higher than prices on the Ontario Drug Benefit Formulary, but prices listed on the U.S. Federal Supply Schedule (a large tendered contract) in 2000 were 69% lower.

While the PMPRB report totally discredits the Palmer D'Angelo Consulting figures, even its findings are not based on the best available comparable information on generic pricing in Canada and the United States.

The U.S. Federal Supply Schedule (FSS) numbers represent a very large tendered contract. The prices of both generic and brand-name drugs listed on this schedule are much lower than prices widely available on the U.S. market.

That is why when the PMPRB does its comparison of brand-name drug prices in Canada and the U.S., it only uses the FSS price as part of its calculation of average U.S. prices for brand-name products, along with hospital, pharmacy and published wholesale prices.

The "248% higher" figure is from the U.S. Redbook, which publishes wholesale prices for generic drugs in the United States. This figure is also not considered accurate by most industry observers, as the prices listed are often higher than prices widely available on the U.S. market.

To obtain the most recent, accurate, comparable information, the CGPA obtained sales data from IMS HEALTH, the leading source for prescription drug sales data, for the top-selling 28 generic drugs common to Canada and the United States.

Sales data from IMS HEALTH for the 12 months ending September 2002 shows that generic prices are, on average, 28% lower in Canada. (*Please see chart on page 5*)

Myth #2: Generic prices in Canada are too close to the brand-name price.

This myth has been spread by brand-name drug makers and even some journalists. For example, in a May 27, 2003 interview with Claude Thibodeau of CJMF radio, Andre Noel of *La Presse* said generic prices should be 10-20% of the price of the equivalent brand-name products.

Reality:

The PMPRB found the price difference between generic and brand-name products was less in Australia, France, Italy, and Sweden, and higher in Germany, New Zealand Switzerland, the U.K. and the U.S., which puts the Canadian generic to brand ratio right in the middle of the pack.

As well, in no country is the price of generic drugs 10-20% of the price of brand-name drugs. The majority of the countries showed generic prices at between 58% of the brand and 74% of the brand. The Canadian figure was 65%.

The widest spread between generic and brand prices was found in the United States, which has the highest prices for brand-name drugs in the world.

The message reinforced by the PMPRB report is that generic drugs are not “cheap knockoffs.”

In Canada, it takes an average of three to five years to develop a generic drug and millions of dollars. These costs include research and development, production, bioequivalence studies, raw materials, well-trained staff, expensive equipment and high-tech facilities, and due to the *Patented Medicines (Notice of Compliance) Regulations* of Canada's *Patent Act*, extensive and costly litigation.

According to data from IMS HEALTH, the average cost of a brand-name prescription in Canada has increased by 76% from \$31.52 in 1992 to \$55.56 in 2002. During the same period of time, the average cost of a generic prescription increased from \$16.35 to \$21.57, or only 32%.

Myth #3: Canada provides the best environment for generic drug manufacturers in the world.

At recent parliamentary committee hearings into the automatic injunction provisions of the *Patented Medicines (Notice of Compliance) Regulations*, representatives of the brand-name pharmaceutical industry and Industry Canada said repeatedly that Canada provides the best environment for producing generic drugs in the world.

Reality:

Nothing is a better indication of the environment for an industry in a particular jurisdiction than market share.

The PMPRB study states that generic drugs fill fully 70% of prescriptions in the United Kingdom, compared to 40% in Canada.

While the 70% figure for the UK contained in the PMPRB study is incorrect, the correct number, 53%, is still significantly larger than Canada's.

The study also states that generics fill only 20% of prescriptions in the United States. This number is also incorrect. Sales figures from IMS HEALTH show that 45% of prescriptions in the U.S. are filled with generic drugs, and this percentage is increasing rapidly.

In Canada, generic manufacturers have limited access to a limited market, as brand-name drugs retain a stranglehold on the overall industry.

While generics fill more than 40% of all prescriptions, they account for only 14% of Canada's \$14 billion annual prescription drug bill.

Brand companies are highly successful in marketing "new" more expensive drugs that may not be any more effective, or safer, than the proven, less-costly generics products they replace.

New, patented medicines are the cost driver for both public and private drug plans.

Once developed, average federal approval time for generic products in Canada is 15 months - double Health Canada's target of 225 days.

In addition, despite Health Canada's exhaustive and internationally recognized process, generic pharmaceuticals must go through another lengthy and redundant approval process to qualify for listing on provincial drug plan formularies.

Canadian generic manufacturers also bear high legal costs and delays in bringing their products to market, which generic drug manufacturers in other countries do not, as a result of an automatic injunction against generic drug approvals that can be triggered merely by an allegation of patent infringement by a brand company.

These patent rules exist only in the pharmaceutical industry, and only in the U.S. and Canada. On June 12, 2003, President George Bush announced changes to help fix these rules. These came into force on August 18, 2003.

The automatic injunctions under the *Patented Medicines (Notice of Compliance) Regulations* cause generics to spend millions of dollars developing a product knowing that getting it to market will be delayed, sometimes for years.

The generic company then has to spend millions more dollars in litigation with the real possibility that, even if it wins in court, much of the market may be shifted to a "new and improved" patented product through the marketing practices of the brand company by the time it gets its product to market.

Appendix B: Member Companies of the CGPA

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R3T 5Y3
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Cobalt Pharmaceuticals Inc.

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Fax: 905-814-8696



Genpharm Inc.

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Novex Pharma

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Nu-Pharm

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 **RhoxalPharma**

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**Torpharm**

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 **TorPharm**

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