Major Research Paper

An Analysis of the Canadian Pharmaceutical Industry: A Verification of the Self-Reported Deficiencies by Industry Stakeholders and Federal Government Policy Proposals to Rectify these Shortcomings

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Abstract:

The pharmaceutical industry in Canada is significant in terms of revenue, market capitalization, employment, and innovation, making it an important sector for economic growth. In a recent survey of industry stakeholders, three major industry deficiencies were listed: the ability to find sufficient capital financing, the need for strategic alliances between varying kinds of pharmaceutical companies, and weaknesses in the labour market. The follow analysis explores the background of each deficiency, analyses why it is a problem and what is the preferred outcome from a public policy perspective, and prescribes solutions from the federal-level of government to deal with the problems.

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Introduction

The Canadian economy is at a pivotal moment in its development. Its history is unique in its own right; long reliant on the export of commodities, from beaver pelts to lumber to agriculture, it continues to grow and outperform other developed countries by means of extensive energy and mineral resources. Canada has always been a demographically-small export-oriented country. In its early history, it relied on trade within the British Empire, and, as this empire faded, it developed closer economic ties to the United States (US) of America.

To this day, Canada remains dependent on its open economy to prosper and expand its gross domestic product (GDP). Commodities have continued to boost the Canadian economy and current account surplus, but these economic resources provide limited value-added and employment based on what the commodity market will bear. At the same time, traditional manufacturing has been hit hard by outsourcing and the current Western economic malaise.

Despite this adverse economic reality, one segment of the economy in particular plays a prominent role in boosting the Canadian economy and presents an important opportunity for expanding the value-added economy and employment - the bio-economy:

> The value of this bio-economy is estimated at $78 billion per year, or 6.4% of Canada's GDP, and includes the subsectors of health, cattle and truck farming, mining bio-processing, pharmaceutical manufacturing, chemical products and distilleries.[1]

Agriculture-based bio-technology will be significant in a country with vast tracts of arable land and limited opposition to genetically-modified products, but agriculture is

[1] Chong, "A Study of the Crisis Faced by Certain Industrial Sectors in Canada," p.43.

already highly efficient, hence the use of supply management to maintain output below market demand.

The life sciences industry, on the other hand, is tasked with the greater complexity associated with addressing human biology-related problems. The life sciences can further be divided into such sectors as human health, bioinformatics, and medical devices, of which human health dominates far and beyond, with 70% of all revenue and 90% of all research and development (R&D) in the entire biotechnology industry.[2] Human health is a broad designation for the whole pharmaceutical process, from finding out the cause of a human health problem (diagnostics) to providing a therapy (therapeutics) to finding the most efficient way of delivering said therapy (drug delivery systems).

The pharmaceutical industry is, therefore, the most important segment of the celebrated biotechnology industry and should be nurtured through federal government policy with the objective of improving the outcomes of three factors of importance that the industry holds for the Canadian national interest: increasing GDP, accelerating innovation, and the improving the efficiency of the healthcare system.

1) The Revenue Factor of Importance

The Canadian pharmaceutical industry generated $12 billion in revenue in 2009 with an average annual growth rate of 8.5% in the 2000's,[3] outpacing overall GDP growth. The Canadian industry does well relative to the global industry also:

> a 3 percent share of the global market making Canada the 9th largest world market. A 7 percent average annual growth over the period 2004–2008 makes Canada the 4th fastest growing market globally, after Brazil, China and Spain[4]

[2] Millson, *Canadian Life Sciences Industry in Montreal, Toronto & Vancouver*, p.4.
[3] Industry Canada, "Canadian Pharmaceutical Industry Profile," http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.html
[4] Ibid.

However, since much of this revenue is generated by foreign-owned companies, this indicator does not necessarily mean Canadian-owned companies are faring well or that value-producing R&D is being conducted in Canada.

Regardless, the government has a vested interest in seeing this industry thrive since there remains very little low-hanging fruit in terms of economic capacity building in existing industries given that Canada has an advanced economy. Pharmaceutical manufacturing contributes to the value-added economy by taking raw materials, which are plentiful in Canada, and transforming them into a value-added product through innovation.[5]

2) The Innovation Factor of Importance

The manufacturing of pills may not appear advanced compared to, say, the computer-influenced medical devices sector, because medicines of varying degrees of efficacy have been used for centuries. In fact, the pharmaceutical sector is revolutionizing the life science industry. Advances in the very same computer technology have allowed for the reverse engineering of biology to create biopharmaceuticals that open up the possibility of infinite solutions to modern medical problems.

Pharmaceutical research is the quintessential high tech and cutting edge industry that will drive economic growth through innovation. In an advanced economy like Canada's, innovation is the key to continued growth and therefore to the national interest. The federal, provincial, and municipal governments of Canada, during the Canadian economy's transition towards a knowledge-based economy, should develop the pharmaceutical industry as a viable path towards long-term growth and employment.

[5] Chong, "A Study of the Crisis Faced by Certain Industrial Sectors in Canada," p.30.

3) The Healthcare Factor of Importance:

Beyond pure economic reasons, pharmaceuticals ultimately contribute to the health of Canadians. The ability to improve and extend life provides considerable consumer utility. It is this fundamental utility that gives pharmaceuticals such a prominent place in the desire of consumers and thus what gives them their economic value.

Because healthcare is essential to the welfare of citizens, the federal and provincial governments have taken it upon themselves to provide universal healthcare coverage via a federally-mandated insurance system where physicians are compensated for their services by the provincial governments. However, unlike most developed countries outside of the US, Canada does not have a federal drug purchasing monopoly in place. Provincial governments are responsible for providing drug plans, and coverage varies from province to province. The federal government has instead decided that prices will be kept at reasonable levels through the Patented Medicines Prices Review Board (PMPRB).

Through price controls, discoveries in the pharmaceutical industry are able to alleviate some of the pressure between two competing policy objectives: greater healthcare coverage for citizens, and constraining government spending on healthcare. Due to the fact that pharmaceuticals may improve the efficiency of the healthcare system, they may therefore improve health outcomes while reducing costs, so long as the appropriate consumer safeguards are in place to prevent excessive price-level rises.

If a new pharmaceutical can prevent hospital trips, reduce the need to see a general practitioner as frequently or simply improve general health among a certain

section of the population (such as seniors or those with specific medical conditions) then it will have an enormous effect on healthcare spending per capita. This will subsequently relieve provincial budgetary pressures caused by universal healthcare coverage.

While this benefit may present the issue of free riding countries relying on the innovation of other countries, if Canada plays host to the most innovative firms, it will receive the benefits sooner through clinical trials and faster regulatory approval for Canadian citizens.

Research Question and Thesis

With the industry's significance to the Canadian national interest established in these ways, it is important to identify and analyse the primary deficiencies that are holding the Canadian pharmaceutical industry from being ever more productive. A 2011 survey of industry stakeholders[6] by PricewaterhouseCoopers, a consultancy firm, in conjunction with BIOTECanada, a biotechnology interest group, found the following three issues, in descending order, to be the primary concerns for the Canadian pharmaceutical industry in 2011: raising capital, forming strategic partnerships, and finding and maintaining adequate labour.[7] The present paper focuses on these three concerns.

The Three Primary Industry Concerns of 2011

To reiterate, the three primary concerns listed by industry stakeholders for 2011 are raising capital, forming strategic partnerships, and finding and maintaining adequate labour. These concerns are reported, as opposed to being deduced from market indicators,

[6] APPENDIX A
[7] Jans, "Inflection point: Canadian Life Sciences Industry Forecast," p.6.

so they must be verified by independent experts. They must also be checked against current government policies to assess whether gaps in policy are to blame for these deficiencies.

The following analysis of each reported industry deficiency will be structured in three parts. The first component will be descriptive; meaning the background of the reported deficiency will be described in detail to set the context. The second component will be analytical; meaning the state of affairs will be dissected and exposed to uncover how the deficiency is a problem for the Canadian industry and also the desired outcome of government policy. The third component will be prescriptive; meaning federal government policies will be proposed to fill in the gaps identified during the study of the deficiencies.

The proportions of the analysis dedicated to each deficiency will be reflective of the rank assigned by the stakeholders in the survey. Furthermore, there will be a minimal amount of overlap given that the three concerns are intertwined: with capital investments generally comes management expertise, with strategic partnerships comes management and scientific expertise along with further capital injections, with sufficient investment in academia comes labour expertise, and with experienced management comes networking, and so on. Any federal government policy that targets one of the deficiencies will inevitably impact the other areas. Each policy should therefore compound the success of the others, if it is properly implemented to prevent undesired consequences.

1) Raising Capital

In order to understand why it is important for the Canadian industry to raise large amounts of risk capital, each category of company, according to product line, must be

explored. As a second layer, the stage of development points to varying industry-wide funding profiles. Ultimately, the capital requirements are primarily for R&D expenditures because manufacturing in the pharmaceutical industry is fairly static. R&D is extremely capital intensive due to high tech costs and the considerably probable failure rate of 9 in 10 pharmaceutical products failing to make it to market.[8]

The manufacturing process, on the other hand, requires minimal inputs compared to other forms of manufacturing in the economy. While there are continual refinements in the mode of delivery of medicine, such as timed release mechanisms, the product design is simple and does not change radically over time. Accordingly, the average industry cost for manufacturing is four times less than for R&D.[9] In the instance of generics, where manufacturing may cost more than R&D, the financing issues are related to intellectual property (IP) rights, which is still R&D-centric in the sense that the policy debate is over the length of time that the government will recognize the proprietary rights to innovation.

If R&D is the lifeblood of the pharmaceutical industry, then its growth is of the utmost importance. Even generic pharmaceutical companies, which generally oppose 'Big Pharma' due to their competing interests over patent laws, rely on the innovations of pharmaceutical research to eventually make generic copies.

I) Description of the Financing Environment for Canadian Pharmaceutical Companies

Raising capital ranks first as a perennial concern in the small Canadian market, but recent events have exacerbated the issue. The financial and economic crises of the 21st century were the worst in post-Second World War history. Industries that require

[8] Giovannetti and Jaggi, "Beyond Borders: Global Biotechnology Report 2010" p.7.
[9] Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.35.

large sums of risky capital investments suffered an unfortunate interruption by the financial crisis**,** which decimated the fund raising of biotech firms, with Initial Public Offers (IPO) in Canada dropping from $1.7 billion in 2007 to a paltry $5.8 million and overall fund raising dropping 41% over the same period.[10]

Such a cataclysmic shift makes it difficult to assess the state of industry financing due to the economic aftermath, which continues to impact investment to the tune of a reported CA$1 billion shortfall in the industry in 2011.[11] Therefore, it is best to return to just prior to the recession to observe the state of financing during times of economic growth when the global and national economies were working near or at full capacity, under the assumption that slow but steady growth will return to much of the developed world, especially Canada, which is well positioned relative to the deficit and debt positions of other developed nations.

Prior to the recession, Canadian venture capital fund raising was significantly less than in the US and other comparable developed countries and the deals were also smaller than the Organisation for Economic Co-operation and Development (OECD) average.[12] Canada is missing a vibrant venture capital (VC) component to its R&D efforts. The risk aversion of Canadian investors was displayed during the financial crisis of 2007-2009, which pointed to a far more conservative investment climate in Canada than in Europe and the US. This attitude to risk may have benefited the general economy by avoiding toxic investments but, alas, in the case of the pharmaceutical industry, a certain degree of risk is essential to assure innovation.

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[10] Chong, "A Study of the Crisis Faced by Certain Industrial Sectors in Canada," p.43-44.
[11] Jans, "Inflection point: Canadian Life Sciences Industry Forecast," p.5.
[12] Myers, "Invest to Grow: Technology, Innovation and Canada's Productivity Challenge," p.21.

If the Canadian federal government wishes to increase investment in this vital sector, it will require innovative financial solutions to the dearth of capital now available in the Canadian financial system. Canada invests less as a proportion of GDP in R&D than other OECD countries and relies disproportionately on academia:

Table 13: Comparison of GERD 2003 for Canada, US, the EU and the OECD

	Canada	US	EU-15	Japan	OECD
R&D/GDP (%)	1.9	2.6	2.0	3.2	2.2
R&D by Performing Sector*					
• Industry	53	69	64	75	67
• Government	11	9	13	9	11
• Higher education	36	17	22	14	19
• Private/non-profit	-	5	1	2	3

Source: OECD Science, Technology, and Industry Scoreboard 2005. http://miranda.sourceoecd.org/vl=3277118/cl=29/nw=1/rpsv/scoreboard/. The latest year available for comparative data is 2003.
**Note that the sector data are percentages of GERD.*
[13]

i) According to Product Line:

Pharmaceutical companies in Canada break down into three broad categories according to product line: biotechnology start-ups (generally one or two newly developed products), foreign subsidiaries (a host of patented products) and generics (a host of non-patented products). Each category possesses unique characteristics in the industry that require specific government policies to help them grow.

Biotechnology start-ups are the base of innovation in the industry. They assemble high risk capital with high quality R&D teams to develop new market products from basic science. Often times they will acquire their primary pharmaceutical assets from academic institutions or on contract from larger firms that are unwilling to take on the risk and expense of developing niche products. The management team tends to be small

[13] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.53.

or consist solely of researchers until the product is ready for market, at which point specialized management may enter the process through investments of growth capital and/or the external hiring of additional professional management by the researchers involved in the project.

In contrast, foreign subsidiaries make up many of the larger sized companies. They are set-up on behalf of major multinational pharmaceutical corporations to take advantage of Canadian tax and regulatory policy. For the most part, their product line is patented medicines. Often times, they will contract out work or purchase assets developed by biotechnology start-ups. The industry is top heavy in terms of revenue generated by the largest firms; "In 2009, the top ten companies accounted for almost 66 percent of total pharmaceutical sales and the top 5 companies accounted for nearly 45 percent of total sales in Canada."[14]

The principal revenue generating companies in Canada are foreign-controlled subsidiaries; only one of the top ten companies operating in Canada, Apotex, is Canada-based. Apotex is a generic producing company that manages to rank second in prescription sales by volume and value:

Leading Pharmaceutical Companies in Canada in 2009

Source: *IMS Health*

Rank	Leading Companies	R&D Location in Canada	Total Purchases ($ Billions)	Market Share (%)
1	Pfizer	Montreal	2.94	13.4
2	Apotex	Toronto	1.55	7.0
3	AstraZeneca	Montreal	1.44	6.6
9	Schering-Plough	Montreal	1.33	6.0
4	Johnson & Johnson	Toronto	1.16	5.3
6	Novopharm	Toronto	0.92	4.2

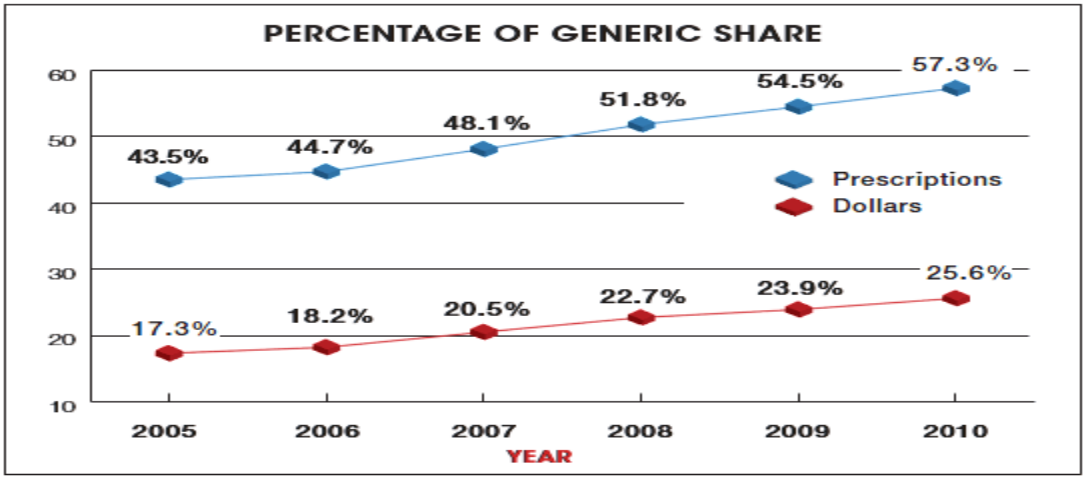
[14] Industry Canada, "Canadian Pharmaceutical Industry Profile," http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.html

7	Novartis	Toronto	0.89	4.0
5	GlaxoSmithKline	Toronto	0.88	4.0
8	Abbott	Montreal	0.85	3.9
10	Roche	Montreal	0.68	3.1

[15]

Globally, Canada has only one leading company among the four categories of medical technology manufacturers, pharmaceuticals, biotherapeutics and contracting: MDS Inc in the contracting category.[16] Contracting involves working on the patents of others, which is not as lucrative as developing assets through R&D because ownership is essential to value.

Nor is it as lucrative as being a large generics manufacturer, like Apotex. Generic pharmaceutical companies manufacture, market and sell medicines that lapse into the public domain. In terms of sales, generics have come to represent more market share in volume but remained lower in terms of revenue, given that generics are more ubiquitous, thanks to their lower costs, but name brands, which are often patented, have a higher price per unit:

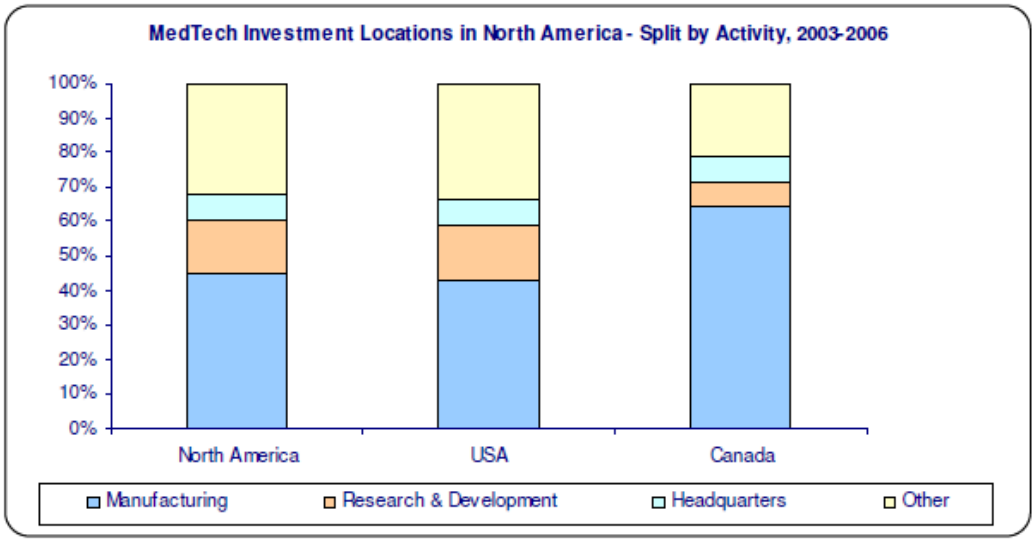


[17]

[15] Ibid.
[16] Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.69-70.
[17] Canadian Generic Pharmaceutical Association, Market Trends, http://www.canadiangenerics.ca/en/resources/market_trends.asp

Proportionally, investments in the Canadian industry go primarily into manufacturing, due to the Canadian industry's emphasis on generics and the US industry's emphasis on R&D:

Figure 47: MedTech FDI Projects in North America by Country and by Type of Business Operation 2003-2007



Source: IBM-PLI GILD

[18]

ii) According to Stage of Development:

Individual companies also vary within each category by revenue, the number and type of employees, R&D, product line and market capitalization according to their stage of development. Capital requirements adjust accordingly:

[18] Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.53-54.

Table 20: Capital Needs and Source and Use of Funds by Company Stage

Stage	Research Stage		Early Stage		Mid Stage	Late Stage
	Basic	Pre-seed or Commercial Idea	Seed	Start-Up	Scale-Up	Scale-up
Investment Needed	Variable	$0.1–0.5 M	$0.5-$1.5M	$3-8M	$5-40M	$75-150M
Source of Funds	Govt and other research grants	Research grants, Individuals	Research grants, Private funds from venture capital and angels	Venture capital, University funds, grants	Venture capital, Public equity, Strategic alliances	Strategic alliances, public equity
Use of Funds	Basic & discovery research	Applied research to test commercial idea	Confirm commercializ-able proto-types and IP	Initial preclinical product testing	Scale up to meet regulatory requirements to test product effectiveness and safety. Preclinical to early Phase II stage.	Late Phase II to Phase III clinical testing; some manufacturing infrastructure

Source: TRM Steering Committee.

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In terms of R&D distribution throughout the industry, the pharmaceutical industry is similar to other industries in that smaller operations generally innovate while larger operations consolidate corporate activity for economies of scale. Large pharmaceutical companies will spend less as a proportion on R&D "because they have the economic clout to participate more in downstream economic activities such as manufacturing and marketing."[20] Still, the industry-wide proportions of R&D expenditure are also inversed when compared to revenue:

> Large companies, representing only 13% of the firms in 2003, account for 64% of biotechnology revenues, but only 20% of R&D expenses. Medium-sized firms accounted for 24% of revenues and 47% of spending on R&D. Small firms accounted for 12% of revenues and 33% of R&D expenses.[21]

[19] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.82.
[20] Cumming and MacIntosh, "The Determinants of R&D Expenditures," p.362.
[21] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.72.

II) Analysis of the State of Fund Raising and Where the Federal Government Should Act to Improve Outcomes

Based on the previous descriptive section, several conclusions can be made about the industry. Notably, smaller companies fuel innovation while larger companies deal with efficient production and sales. At the same time, generic companies put pricing pressure on patent-holding companies to assure competition and lower prices for Canadian consumers. The different categories are at odds with one another as they battle for market share and investors. It is the responsibility of the federal government to design an environment that best promotes the national interest above the individual corporate interests. Given this mandate, the federal government should promote two outcomes:

i) Reduce the imbalance in bargaining and market power between Canadian-based companies and foreign subsidiaries of Big Pharma:

Canadian-controlled pharmaceutical companies are mainly small-to-medium sized biotechnology companies or medium-to-large sized generics companies. The federal government should address the concerns of both categories of companies in order to assure that Canadian-owned and controlled companies play an important role in the global pharmaceutical industry rather than being subsumed as second tier actors into foreign-controlled Big Pharma.

The Biotech Situation:

Previously, it has been demonstrated that the Canadian-controlled private corporations (CCPC) are the principal R&D spenders, but they are also the ones most sensitive to changes in capital availability because they lack revenue, industry alliances and assets. Biopharmaceutical CCPC rely on angel and VC investors, who

disproportionately invest in this sector of the life sciences[22] and are unpredictable compared to established institutional investors, who concentrate on safer, predictable investment patterns.

Market fluctuations in capital availability will directly impact how much R&D they can conduct and affect contractual negotiations by limiting the options available. Therefore, the state of the economy will determine whether Big Pharma or CCPC hold a stronger bargaining position during the licensing of assets or partnering on asset development.[23] An economic boom will boost up the valuations of small biotechnology companies and the assets they hold, as well as the capital at their disposal. This allows smaller companies to obtain a greater percentage of equity in mergers and acquisitions (M&A) and royalty on the products that make it to market. The opposite occurs during a bust; the shortage of money bids prices down and allows larger companies to include options to purchase a greater share of the assets should they pass certain milestones in clinical, regulatory and market barriers, while taking less of a risk on R&D themselves.

The CCPC also face the constant threat of running out of cash to pay for operating costs. This is an unacceptable imbalance since Canadian researchers and investors provide the talent and risk capital and foreign investors receive a disproportionate amount of the benefit. The government must promote an environment where Canadian biotech can bargain at the same level as the deep pockets of Big Pharma.

The Generics Situation:

Canadian generics are equally at a disadvantage despite producing the opposite kind of product. Generic pharmaceutical companies manufacture ‘bioequivalents’ of

[22] APPENDIX B
[23] Giovannetti and Jaggi. “Beyond Borders: Global Biotechnology Report 2010,” p.8.

exiting pharmaceutical products once the patent lapses into public domain. This activity requires far less investment in R&D to develop assets since the scientific experimentation, including clinical trials, have already been conducted and approved by regulatory bodies. The investments must instead go into extensive real capital for mass production with an emphasis on volume. Canadian firms have taken advantage of this segment of the market to become leaders, while other developed countries' industries focus primarily on patented medicines.

The Greater Toronto Area (GTA) hosts 80% of all generic manufacturers in Canada,[24] making Ontario the Canadian leader in generics. Apotex is the premier generics company in terms of market capitalization, volume, and revenue, and represents a prime example of Canadian success on the generics front that needs to be encouraged industry-wide through federal government policy. Assistance by the federal government to the generics industry would likely cause ire among other provincial governments unless it is coupled with assistance for smaller biotech companies throughout the federation. Nevertheless, a company like Apotex is spread throughout the country, so assistance for generics companies can have benefits outside the GTA. The federal government must assure that generics, which are global leaders in the Canadian industry, continue to grow in this lucrative market.

ii) Promote R&D within Canada whether through CPCC and Canadian-based Public Companies or Foreign Subsidiaries:

In academia, grants and contributions (G&C) fund basic research into biopharmaceuticals, but this is generally done without the business necessity of having to develop a product for market within a set time frame to recover risk-adjusted returns.

[24] Millson, *Canadian Life Sciences Industry in Montreal, Toronto & Vancouver*, p.20.

However, once these assets are ready to evolve to the next stage of development, business considerations must come into play when conducting R&D.

The limited risk capital environment caused by the financial crisis of 2007-2009 is worsened by the reality of the pharmaceutical development process, which "can take eight to 15 years and cost approximately US$800M."[25] Pharmaceuticals have a longer planning horizon than the typical biotechnology product, which accentuates the market risk of a long-term drop in consumer demand or a rise in competition from other products. Usually this kind of risk would result in a reduction in R&D expenditures.

Unfortunately, because "pharmaceutical firms […] have long planning horizons but large capital expenditures are required to develop new drugs," [26] pharmaceutical financing is unavoidably high risk and highly capital intensive. The process also goes through an extensive lifecycle of different types of investors, capital sources and stakeholders,[27] further complicating matters. The federal government should reduce this market failure of insufficient capital expenditure for otherwise sound pharmaceutical asset development to assure value-creating R&D is conducted inside of Canada. Otherwise, Canadians consumers will be stuck paying the premium on pharmaceutical products without the benefits that emerge from a vibrant R&D sector, such as higher income and corporate taxes.

iii) Financing Prescriptions at the Federal-Level of Government

The Canadian federal and provincial governments have already taken steps to improve investment in business. The harmonization of tax policy will have a profound effect on investments in the pharmaceutical industry despite these initiatives being taken

[25] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.65.
[26] Cumming and MacIntosh, "The Determinants of R&D Expenditures," p.362.
[27] APPENDIX C

to improve business investment as a whole. For example, several provinces have recently undertaken the harmonization of sales taxes, which will reduce the burden on capital investments and investing in business inputs.

More importantly, the 2007 initiative to harmonize corporate taxes is also well underway and assured by the victory of the Conservative Party of Canada majority in the May 2011 federal election. In an era of high capital mobility, this characteristic is favourable to investment, especially since Canada is moving towards value-added manufacturing in general and will require significant investments to achieve this end.

However, these measures do not specifically target the pharmaceutical industry. For that to occur, the federal government will need to increase its funding arrangements with academic institutions, reform the current tax credit system for R&D, create a new mechanism for incentivising risky equity investments in pharmaceutical companies, and reform the patent regime.

i) Sufficient Capital Availability through the Tax Code for CCPC

As previously mentioned, significant upfront capital costs are associated with the high R&D cash burn rate of pharmaceutical companies in the nascent stages of development. To alleviate funding pressures on CCPC, the federal government must inject cash at two stages. The first, the research stage, will require increasing grants through existing federal funding institutions. The second, the early and medium development stages, will require modifications to existing tax credit policy.

Grants and Equity Investments for Research and Early Stage Companies:

The federal government is involved in directly funding the industry through G&C for R&D. Examples of direct federal funding into primary research include the Natural

Sciences and Engineering Research Council of Canada (NSERC) and the Canadian Institutes of Health Research (CIHR), with each fund providing hundreds of millions of dollars in grants each year to students, professors, research institutions and academia-industry partnerships.[28]

The IP formed through research done with NSERC and CIHR grants is able to be commercialized with no ownership rights returning to the government and is in fact mandated when the grants are given to universities, with the innovator and university maintaining royalty rights on the innovation.[29] While around a billion dollars in R&D funding may appear more than apt for addressing R&D need, taking into consideration that the federal government's annual budget hovers around a quarter trillion dollars a year, there is ample room for expansion of the criterion for which academic institutions can apply for grants.

Additionally, if the federal government were to receive a mandate to be active in financing start-up biopharmaceutical firms, then it should also directly invest in the industry through government-run investment vehicles. The federal government could use the economic development agencies already at its disposal, such as the Business Development Bank of Canada and Export Development Canada, or create special sovereign VC funds to purchase equity with the objective of infusing capital into the R&D process.[30]

There are several drawbacks to this approach; it would require a completely new bureaucracy to select and monitor projects, including administration as support, with no guarantees that the bureaucrats will be able to respond to market demand by selecting the

[28] Dellelce, "Developing Biotechnology and Life Sciences Companies in Canada," p.72-73.
[29] Ibid., p.73.
[30] Myers, "Invest to Grow: Technology, Innovation and Canada's Productivity Challenge," p.42.

appropriate assets and firms. If elected governments become involved in selecting projects then pork barrel politics and special interests may corrupt the process if audit safeguards fail to prevent crony capitalism. However, given that the companies are small at this stage of the development, the opportunities for corruption would be minimal. Despite the potential risks, the federal government may wish to explore this option once it has fully exhausted the viability of projects submitted for grants to NSERC and CIHR.

Tax Credits for Early and Medium Stage Companies:

The more efficient option, instead of direct equity investments, would be through the tax code, which would only require monitoring to assure credits are valid, as opposed to the research that must go into the former activity. The Canadian federal government already provides generous R&D tax credits. The most generous go to small CCPC. The Scientific Research and Experimental Development (SR&ED) program is a partnership between the federal government and the Canada Revenue Agency (CRA) and "the largest source of federal government support for industrial research and development in Canada."[31]

The program allows for tax credit on corporate income based on R&D expenditures that can be carried forward into future fiscal years. While small CCPC benefit the most from this program, all companies operating in Canada are eligible:

[31] Johnson, Ndubuzor and Pavel, "Using Flow-Through Shares to Stimulate Innovation Companies in Canada," p.20.

Category	SR&ED expenditures	ITC rate	Refundable portion of ITC earned on		Non-Refundable portion of ITC earned on	
			Current expenditures	Capital expenditures	Current expenditures	Capital expenditures
Canadian-controlled private corporations (CCPCs)	Up to your calculated Expenditure Limit*	35%	100%	40%	N/A	60%
	In excess of your calculated Expenditure Limit*	20%	40%	40%	60%	60%
Other corporations		20%	N/A	N/A	100%	100%
Proprietorships, partners of a partnership and trusts		20%	40%	40%	60%	60%

* The expenditure limit ($3 million maximum) is based on the previous year's taxable income and previous year's taxable capital. The limit is reduced when taxable income is greater than $400,000 or taxable capital is greater than $10 million. The maximum expenditure limit is $2 million for tax years ending prior to February 26, 2008.

[32]

The SR&ED policy benefits from the fact that it is unlimited due to it being conducted through the tax code. This program and other tax measures place Canada second behind only France in terms of pharmaceutical-friendly tax subsidies.[33] Taking into consideration the financial state of the Canadian federal government vis-à-vis most developed European countries and the US, Canada can afford a continuation of its generous R&D incentive and even an expansion.

It is understandable that the federal and provincial governments would not want to relieve much of the corporate income tax made by profit-generating foreign-owned

[32] Canada Revenue Agency, http://www.cra-arc.gc.ca/E/pub/tg/rc4472/README.html
[33] APPENDIX D

companies, even if those same firms generated some of their R&D in Canada, since most of the value in the pharmaceutical industry is stored in the IP. Rather than expand the value of existing tax credits across the board, the federal government should tweak the existing credits and criteria to further favour CCPC.

The Canadian Manufacturers & Exporters, for one, suggest the federal government "Allow financial institutions to lend against accumulated SR&ED tax credits"[34] as an additional measure to incentivising investment. This small measure would assist start-ups in a substantial way to raise the required capital for initial R&D investments. To compound the borrowing against SR&ED tax credits, the percentage should be raised beyond 35% to a reasonable figure that balances treasury concerns on tax exemptions with the desire to assist the Canadian-based industry.

Focusing tax credits on CCPC would oblige foreign investors to partner with Canadian investors. This would encourage Canadian investors to pursue riskier investments in the pharmaceutical industry despite the conservative investment climate in Canada. It would also nurture the Canadian management that joins through investment, without necessarily limiting qualified foreign management that could be hired as well.

The drawback to the SR&ED policy is that tax credits do not assist in raising cash for capital and operating expenditures:

> Current SR&ED policies and tax credits are internationally competitive for mature and profitable companies who are the ones that carry out research that is related to the business. However, the current SR&ED and combined provincial tax incentives do not recognize the realities of early stage health innovation.[35]

[34] Myers, "Invest to Grow: Technology, Innovation and Canada's Productivity Challenge," p.42
[35] Johnson, Ndubuzor and Pavel, "Using Flow-Through Shares to Stimulate Innovation Companies in Canada," p.25.

The SR&ED tax credit theoretically targets CCPC but in reality it only targets a subsection of companies that are able to convince investors of the validity of a product before it has had the chance to be developed and before any assets can counterbalance the liabilities of risky R&D activities:

> Currently, there is no practical way of spreading the risks to individual investors in recognition that the failure rate will be very high. Also, there is no practical way of allocating expenditure to third party investors for tax purposes[36]

The options of loaning against SR&ED tax credits would solve some of the problem but capital financing would still be at the discretion of conservative financial institutions.

Consequently, a new financial device is required. The reality is that there are immense upfront costs to pharmaceutical R&D and the smaller, less profitable companies are conducting the majority of R&D. It thus makes sense to orient policy towards these companies through a financial device known as Flow Through Shares (FTS).

ii) FTS for R&D

The federal government should go beyond direct cash injections of grants and refundable tax credits. FTS will incentivize investment in risky pharmaceutical start-ups based in Canada through investment deductions in the personal income tax system. In the context of the Canadian economy, FTS are used in the prospecting for mining locations. These ventures also require extensive upfront capital investments and have a high likelihood of failure thereby making them a risky investment. A problem arises because "Companies that are engaged in resource exploration or […] in early stage of health innovation often do not yet have income from which they could deduce tax incentives."[37]

[36] Ibid.
[37] Ibid.

The government has thus allowed the use of FTS as a financial tool to offset the riskiness of the investment in small-scale mining prospecting and therefore encouraged investors to invest capital into Canada's mining sector; "The exploration industry is the foundation of the mining industry just as research for new drugs is the foundation of the pharmaceutical industry."[38]

The Greater Saskatoon Chamber of Commerce undertook consultation on the issue of implementing FTS for the sake of developing its provincial economy through innovation. Given that Saskatoon is one of the clusters of importance in Canada,[39] should the proposal be implemented then there would be an excellent experiment for its usefulness at the provincial level. However, for the time being, the federal government may wish to look at the decades-long example of FTS use in the mining sector.

Fundamentally, Canada suffers from a lack of commitment to national strategies that would allow it to excel in innovation. Switzerland excels in pharmaceuticals because it has a national strategy in place for the industry[40] despite being smaller than Canada. The application of FTS would be a simple first step in a national direction towards promoting investment explicitly in biotechnological innovation. The move would be at once focused and yet, since it is done through the tax code, simple to manage.

On top of the theoretical benefits, as previously mentioned, there exists a track record of success with FTS use in the Canadian mining exploration case study. Mineral prospecting may not seem similar to biopharmaceutical innovation but they essentially are:

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[38] Lane and Mercer, "Innovation in Canada's Mineral Exploration and Development Sector," p.2.
[39] APPENDIX E
[40] Johnson, Ndubuzor and Pavel, "Using Flow-Through Shares to Stimulate Innovation Companies in Canada," p.16.

> Mineral exploration by its very nature is an innovative activity. The explorer must discover economic deposits of minerals that previous people were unable to locate. Explorers who are not innovating are unlikely to be successful.[41]

FTS could be limited to CCPC or be industry-wide. Even if large Big Pharma corporations would be able to benefit from this form of equity investment from the public, smaller CCPC conduct a disproportionate amount of R&D and suffer from a lack of capital, and will thus benefit more so.

iii) Patent Reform for Canadian Generics:

Finally, Canadian generics could use assistance from the federal government as well. As stakeholders in the industry, the different categories of companies each have a conflict of interest in supporting various policies. As previously explored, biotech companies would prefer more generous risk capital markets and refundable tax credits to assure there is ample competition in investment to allow for a better bargaining position vis-à-vis the deep pockets of foreign subsidiaries.

Generics, on the other hand, would prefer less stringent IP rights, while foreign subsidiaries would rather reinforce them to assure longer *de facto* monopolies. In regards to patented medicine price regulation, Canada is somewhere in the middle of the pack between the near free market pricing in the US and the drug purchasing monopolies of other developed countries. As such, Canadian consumers require continuous vigilance from the federal government to protect against the high premiums normally charged by Big Pharma for patented medicines. A reform of the patent law may alleviate some of this need by increasing competition from generics.

Astoundingly, patent protection for pharmaceutical products sold in Canada were practically non-existent before 1993 because only the process by which a product was

[41] Lane and Mercer, "Innovation in Canada's Mineral Exploration and Development Sector," p.2.

created could be patented and even this could be overcome through compulsory licences, whereby the patent holders would receive a total fixed royalty of 4%, that began immediately upon the creation of bioequivalents in view of the fact that injunctions against patent violations were impractical to implement.[42] Naturally, this was to the benefit of generic producers and to the detriment of patent holders.

The revision in patent law was prescient since the advances in biotechnology continue unabated. The government would not want to return to the prior state of affairs because Canadian biotech would be decimated. Rather, the federal government should seek to clarify the *Patent Act* to prevent Big Pharma from using the courts to inspire hesitation in competitors. Canada maintains competitive patent law, which presents advantages to the patent-holding companies versus the generics, but the law is far from clear on all issues surrounding patents for medicines given that the legal issues are multifaceted. The Government of Canada itself admits that:

> the interaction between the market entry of new generic drug products and the defence of innovator patent rights in Canada is very complicated under the current regime and the law is continually evolving in this area. While procedural and litigation tools are available to both sides, there is no substitute for sound legal advice when sorting through the various strategic considerations and implications in these complex matters.[43]

Even with legal advice, the current process relies on litigation after the fact rather than government reviews to question the legality of bioequivalents.[44] The courts should act as a final measure against patent violation rather than a first measure. This would increase business stability since generics would not have to assume they will be sued at every opportunity that they bring a new product to market. Clarity of the patent challenge

[42] Gervais, "The Canadian Patent System: Biotechnology and Pharmaceuticals," p.20.
[43] Ibid., p.30.
[44] Ibid., p.29.

process is a desirable policy outcome that could be attained through reform of the institutions in place under the Minister of Health, who coordinates with the Canadian Intellectual Property Office.[45]

Furthermore, minor changes could be made to the *Patent Act* to balance out the Big Pharma-generic relationship. In 2001, the right to stockpile medicine prior to the expiration of a patent was revoked from the *Patent Act*, which retards the entry of generics into the market.[46] In practice, this extends the monopoly held by Big Pharma and should thus be reversed.

Finally, it could be argued that for the sake of consumer protection, generics be given the option of mandatory licensing for essential pharmaceutical products that dramatically improve the overall health of Canadians or Canadians with certain severe conditions. A compromise would be to assign a royalty system that is reasonable to generics but not as low as the fixed royalty of pre-1993.

By returning to compulsory licensing for certain products, the nature of the price controls regime already in place would be altered:

> The Patented Medicine Prices Review Board (PMPRB) ("the Board") is an independent quasi−judicial body established in 1987 under the Patent Act. Its mandate is to protect consumer interests and to contribute to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive.[47]

Canada does not have a national drug plan strategy. Instead, pharmaceutical plans are provided by the provincial governments, in various configurations, or in the private sector. The PMPRB is a substitute for the purchasing power present in other national jurisdictions whereby the state uses its monopoly over purchases to lower prices for

[45] Gervais, "The Canadian Patent System: Myths and Realities," p.5.
[46] Gervais, "The Canadian Patent System: Biotechnology and Pharmaceuticals," p.21.
[47] Ibid., p.30.

consumers. As an alternative, the Board reviews the prices of patented medicines sold in Canada and can take steps to impose price controls should it find that the prices are excessive relative to the global market for such goods; "The Board's review is restricted to the "factory gate" price – that is, the price at which a manufacturer sells the product to wholesalers, hospitals, or pharmacies."[48] This assures that the judgements do not affect the competitive element of wholesalers and retailers.

The current regime has protected Canadian consumers well. Unlike in the US where drug prices have outpaced inflation, prices in Canada have been below the rate of inflation ever since the PMPRB was created.[49] With compulsory licences, the role of the PMPRB would either be significantly reduced or abolished. The regime would thus switch from one of consumer price controls to support for generics, which would have lower prices for consumers as a secondary effect.

This new paradigm would present two benefits. First, generic companies would compete against Big Pharma and each other over prices, which would respond quicker to consumer demand than the PMPRB. Second, a switch from price controls to compulsory licences may reduce prices further for consumers as time goes on since generics could generate larger volumes and improve the efficiency of their operations thanks to stronger demand for their products.

The inherent conflict between patent-holders and generic manufacturers assures that the law is constantly being questioned in civil court and the court of public opinion, and subsequently the political area. Despite this seemingly intractable divide, the conflict may disappear on its own as Big Pharma purchases generic companies in order to

[48] Ibid., p.31.
[49] Industry Canada, "Canadian Pharmaceutical Industry Profile," http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.htm.

compete in the market for generics,[50] but this outcome is far from certain and Canadian companies should not be penalized by stringent national IP laws that are not replicated throughout the world.

The policy would also have its drawbacks. Such a move would surely upset many of Canada's trading partners. The US will find it unfair that US consumers are subsidizing innovation for the benefit of Canadian consumers. However, under the Barack Obama administration, the federal government is progressively becoming more and more involved in the healthcare system, which will perhaps ease some of the imbalance borne by US consumers. The George W. Bush administration has already contributed to this process through Medicare part-D, a pharmaceutical subsidy for seniors.

The second conflict would likely play out during the Canada-Europe trade negotiations over the European Free Trade Agreement, since 57% of Canada's pharmaceutical imports come from Europe.[51] However, given that European countries are not as loath to price controls on medication or state involvement in healthcare as the US, the conflict is not likely to derail the free trade negotiations. In both instances, the federal government must be ready to respond to criticisms that threaten the trade relationship between two of Canada's biggest trading partners.

The trade issue is important because beyond assisting Canadian-based generics to lead in the global industry, the federal government would also contribute to narrowing the persistent trade deficit in pharmaceuticals:

Total Canadian Pharmaceutical Trade (2000–2009)

[50] Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.38.
[51] Industry Canada, "Canadian Pharmaceutical Industry Profile," http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.htm.

Source: Statistics Canada

Year	in $billions		
	Exports	Impots	Trade deficit
2000	1.6	5.3	3.7
2001	2.1	6.4	4.3
2002	2.3	7.3	5
2003	3	8.2	5.2
2004	3.6	8.6	5
2005	3.9	9.1	5.2
2006	5	10.4	5.4
2007	6.3	11.3	5
2008	6.2	11.6	5.4
2009	7	13.4	6.4

[52]

Adequate financial capital is essential for R&D, and R&D is essential for the pharmaceutical industry. G&C provide the initial seed money into academia and form the roots of early biotech companies. Tax credits help once these start-ups begin to make revenue and profit that can be reinvested into further R&D. FTS would be able to provide an equity investment opportunity to fund R&D exclusively. As for generics, IP reform can transfer some of the market power held by foreign Big Pharma towards Canadian generics companies and Canadian consumers.

2) Strategic Alliances

Pharmaceutical firms do not exist in bubbles. They are part of a wider ecosystem of companies; their interactions may include anything from early R&D financing to equity investments to loans to licensing to mergers and acquisitions (M&A).[53] Strategic alliances are the partnership of financial and human resources with the set goal of increasing aggregate corporate capabilities to achieve the end of a mutually beneficial

[52] Ibid.
[53] Banerjee, "Investment Banks and Credit Assignment," p.10.

outcome through such activities as licensing agreements, co-development of pharmaceutical assets and marketable products, and contracting with various repurchasing and royalty options. Deals can vary from "as little as $1M-$3M in strategic investments, up to $1B+ in licensing or royalty arrangements)."[54]

As such, strategic alliances fill a gap in the industry when individual companies are unable to grow sufficiently with their own resources. Consequently, "pharmaceutical company alliances at founding experienced higher rates of patenting and growth in revenue, R&D and non-R&D employment, and R&D spending"[55] The federal government has a role to play in fostering these strategic alliances in order to grow the Canadian-based industry.

Big Pharma and biotech companies naturally harmonize in their capacities. Big Pharma can take the long view towards product development because it has the capital available to support the notoriously high R&D cash burn rate of early development.[56] In other words, Big Pharma has the luxury of time whereas start-ups do not. Biotech start-up strategies differ from company to company, with some hanging on to ownership to gain a higher return and others spinning assets off through licensing or development partnerships to gain a lower return in a shorter time frame. The latter may be forced by market conditions.

Additionally, larger companies are "more likely to be involved in adapting a product for better market penetration, moving into foreign markets or taking part in a merger or acquisition."[57] Big Pharma is also able to accumulate institutional memory;

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[54] Ibid.
[55] Baum, Calabrese and Silverman, "Don't Go It Alone," p.280.
[56] Ibid., p.273.
[57] Kobelak and Vanderbyl, "Critical Success Factors for Biotechnology Industry in Canada," p.75.

those who work on the management side will have come across many scenarios to draw upon when investing in the development of pharmaceutical assets to bring them to market. This allows larger companies to be more strategic; "Corporate investors usually seek out a portfolio of investments with strategic coherence and that retains an option value on products and technology for future corporate activity."[58]

Smaller companies have "less diversity and the majority of their resources [are] focused on product maintenance, R & D and clinical trials."[59] But biotech provides the most advanced R&D techniques, while Big Pharma provides so-called downstream commercialization services such as "market access, marketing and distribution infrastructure, technology and production facilities, and/or expertise in managing clinical trials."[60]

I) Description of the State of Strategic Alliances in the Canadian Market

The Canadian market is too small to support any one product on its own. A Canadian-developed pharmaceutical product must therefore be brought to the global market. Canada, however, does not have sufficient management with the requisite "knowledge and experience in international regulatory requirements, commercialization practices and foreign business operations"[61] to accomplish this objective. The financial crisis of 2007-2009 exacerbated the problem by reducing investment deals and thereby reducing the expertise that come along with those deals.

Necessity is the mother of all invention; an increasing role for strategic partnerships is "reflective of current economic conditions, as access to capital is limited

[58] Banerjee, "Investment Banks and Credit Assignment," p.10.
[59] Kobelak and Vanderbyl, "Critical Success Factors for Biotechnology Industry in Canada," p.75.
[60] Baum, Calabrese and Silverman, "Don't Go It Alone," p.273.
[61] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.82.

and companies will likely seek to leverage existing resources in a variety of ways."[62] The Canadian industry has rebounded thanks in part to increased strategic partnerships:

> While financing for Canadian public companies fell to a 10-year low, there was a significant increase in partnering activities in 2009 — a positive development for the Canadian industry. For the first time, there were six licensing agreements signed by Canadian biotech companies with potential values in excess of US$100 million each[63]

Strategic partnerships allow Canadian firms to go global by filling in the gaps in labour and capital and are thus tied to the other two deficiencies. International expertise is crucial to global growth, and the majority of industry respondents in the latest PricewaterhouseCoopers survey overwhelmingly indicated strategic partnerships as their expected primary source of financing for 2011[64] for all stages of development.[65]

In summation, foreign partnerships offer a larger pool of management, connections to major technology hubs (networking), financial hubs (financing), and greater foreign market opportunities. A healthy partnership environment will compound any government incentives for R&D since investors can be reassured by the fact that assets will be easier to bring to market through greater liquidity thus improving the risk-adjusted returns of investment.

It becomes clear from the actions and intentions of pharmaceutical companies regarding strategic partnerships that in order for the Canadian pharmaceutical industry to remain competitive with the ever accelerating pace of change in the global industry, the government will need to assist the strategic alliance environment in Canada.

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[62] Jans, "Inflection point: Canadian Life Sciences Industry Forecast," p.21.
[63] Giovannetti and Jaggi, "Beyond Borders: Global Biotechnology Report 2010," p.84.
[64] APPENDIX F
[65] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.96.

II) Analysis of the Strategic Alliances Relative to Other Forms of Inter-firm Activity

However, strategic partnerships are not the sole outcome of inter-firm interaction. An alternative to strategic alliances is M&A, which are an equally powerful incentive for attracting capital into the Canadian market. If investors recognize that there are increasing opportunities for high returns based on rising valuations that can be spun off through M&A, then they are more likely to invest into the risky pharmaceutical industry.

i) Why M&A Occur in the Industry:

Big Pharma has taken a keen interest in replenishing its product pipeline to compensate for expiring patents, thereby spurring on demand for the M&A of biotech companies with innovative new pharmaceutical assets. Over the last decade, the large pharmaceutical firms "have established independent corporate investment or corporate venture groups"[66] to fulfill this strategic objective. Currently, however, due in part to the economic climate, weak valuations is a principal factor discouraging M&A from the seller's side.[67] The mismatch of valuation prices has been the major obstacle to M&A since 2006, but "Other significant barriers to M&A include conflicting management personalities, funding and lack of interest from large firms."[68] This does not however negate the risk posed by M&A to the Canadian-based industry.

ii) Why M&A Should Be Discouraged in Favour of Strategic Alliances:

M&A encourage investment in the Canadian pharmaceutical industry but the act is not altogether benign. The preferred outcome would be that Canadian firms enter into equal partnership arrangements. Along with the influence and economic benefit that

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[66] Banerjee, "Investment Banks and Credit Assignment," p.10.
[67] Jans, "Inflection point: Canadian Life Sciences Industry Forecast," p.21.
[68] Ibid.

comes with Canadian-ownership and control, there are other reasons that strategic partnerships may be a better course for the Canadian industry than simply selling off firms and assets the minute they become viable to foreign companies, including building networks of Canada-based VC investors and a globally-connected Canadian academia.

The federal government must assure that Canadian start-ups, which are at a size disadvantage, are able to compete on an equal or near equal footing in negotiations lest acquisitions allow foreign companies to pilfer IP developed at the cost of Canada's favourable tax and subsidy environment. At the very least, M&A should squeeze every last dollar out of foreign investors during an acquisition, so that the proceeds can be reinvested into the Canadian pharmaceutical industry, or allow the Canadian party to become an equal partner during a merger.

Fortunately, while Canada may seem overwhelmed by the economic might of its southern neighbour, in international terms, Canada has led the way in M&A relative to its size.[69] This indicator should not discourage an active engagement by the federal government to promote strategic alliances since the industry is constant evolving and Canada could fall behind within a matter of years.

III) Federal Government Incentives for Forming Strategic Alliances

To grow Canadian firms, and thus ameliorate the position they hold during the formation of strategic partnerships, the federal government should mimic three innovation-focused economic development agencies that exist at the provincial-level in Quebec. This would allow the federal government to distribute more targeted G&C, offer

[69] APPENDIX G

financial and management services, and promote strategic alliances through equity investments and negotiations.

i) Economic Development Agencies Focusing on Global Industry Leadership:

The federal government should establish economic development agencies with the express mandate of growing Canadian-based pharmaceutical companies to the point where they can enter into equal strategic partnerships. The government should then participate in the formation of these inter-firm relations. *Dirigiste*-style government investments in private enterprise do not always work as planned. Industry may simply take the government subsidies and redistribute the profits or outsource the R&D and manufacturing.

However, the Canadian-based pharmaceutical industry is the perfect target for government investment. Most of the companies will have little or no profits to distribute for several years so the subsidies will not simply be redistributed to shareholders. Also, as previously mentioned, R&D and manufacturing have yet to be outsourced from the Canadian industry. The investment will therefore have a larger multiplier effect throughout the Canadian economy, which may serve to offset political criticisms. Foreign subsidiaries, on the other hand, are predisposed to look at labour market pressures given their global reach, whereas Canadian-owned companies will rely on extensive networks in academia, finance and between clusters to keep operations in Canada.

Provincial governments have made a point of supporting the industry due to the fiscal power they hold within the federation and their jurisdiction over education and healthcare. The importance of clusters also places the responsibility with the provincial government given that the assistance and coordination provided to the industry will

invariably benefit the larger municipalities. All provinces have some degree of support for the life sciences, whether through academia or through partnerships with the federal government. However, only the government of Quebec has a comprehensive strategy to assure continued investment and development in the industry.

Given that the scope of this policy analysis is on federal policy, the following will be an overview of best practices at the provincial-level that may act as a framework for federal policies. The focus will therefore be on Quebec, which has a significant innovation-based strategy for economic development that has led to the following outcomes:

> The world's 10 largest pharmaceutical companies have operations in Quebec. Quebec ranks fourth amongst North American States and Provinces for the number of biotechnology firms. Furthermore, Quebec accounts for 68% of Canadian prescription medication patents and 42% of Canada's pharmaceutical R&D investment.[70]

This explains how Quebec is able to raise twice as much VC as Ontario for biotech ventures and Montreal is able to raise four times as much as Toronto,[71] despite both being smaller markets.

The principal agencies used to fund pharmaceutical companies are *Innovatech Québec*, which provides VC to biotech firms, *Investissement Québec*, which focuses more on financial services such as loans as well as economic development through public-private partnerships, and *Société générale de financement du Québec (SGF)*, which invests in more mature firms to take them global.[72] The latter two were recently merged[73] but best practices can be drawn from the previous structure.

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[70] Dellelce, "Developing Biotechnology and Life Sciences Companies in Canada," p.73.
[71] Giovannetti and Jaggi, "Beyond Borders: Global Biotechnology Report 2010" p.72.
[72] Dellelce, "Developing Biotechnology and Life Sciences Companies in Canada," p.73-75.
[73] Investissement Québec, "IQ et la SGF fusionnent leurs activités," 2011, http://www.sgfqc.com/.

The counterargument would be that Quebec has perpetual budget deficits and relatively slow growth. Since the federal government is already in a severe budgetary shortfall, it may be difficult to argue for billions in investment for private companies. However, Quebec has managed to develop a vibrant life sciences sector despite these handicaps. The lesson to take away is that the federal government must balance this priority industry with other public investments.

The First Institution:

The first institution would provide G&C. NSERC and CIHR already provide hundreds of millions of dollars so the federal government is active in this regard. However, there is no guarantee that these subsidies for basic R&D will maintain current funding levels, especially as the federal government seeks to reduce the budgetary deficit. These subsidies should be locked-in so that there is a continual and predictable stream of revenue to academia to prevent a feast-or-famine climate.

Furthermore, the funding represents a pittance compared to the federal government's overall expenditures. While there are thousands of governmental priorities that must address all manner of societal issues, the proportion of funding could easily rise and would multiply throughout several other government priorities; from the financial world to the prosperity of municipalities to the health of Canadians to academia. But the financing would have to go beyond academia. Any small biotech company should be able to acquire G&C if they can demonstrate the significance of their assets under development to the federal government. Naturally, this will require project managers, either at Industry Canada or in a separate arms-length governmental agency.

There is an insatiable desire for scientific funding and it does of course have diminishing returns at a certain point, as with all investments. This policy may also be politically undesirable since it is not a populist measure and the benefits will not be seen until decades later. Nevertheless, a long-sighted federal government will invest in G&C to develop the roots of the pharmaceutical industry. Once the roots have been firmly established, biotech companies will no longer be at the mercy of Big Pharma and have to "out-license or enter collaborations earlier in order to complete development, and accept a lower return." [74] At the very least, Canadians would benefit from selling their equity later in the process and preserve "ownership until the late stage in order to retain a larger share of marketing revenue."[75]

The Second Institution:

The second institution would provide financial services and management expertise to make up for deficits present in the Canadian industry. In this instance, federal bureaucrats or government contractors would collaborate with researchers and business managers. This would provide Canadian-owned companies the option of growing and operating on a strategic level rather than relying on acquisition, which is the current anticipated outcome among industry stakeholders.[76]

The advantage is that institutional memory is created by a federal bureaucracy. The institution would accumulate best practices and be able to consolidate experience and resources to assist small and medium-sized firms, which are generally managed by

[74] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.96.
[75] Ibid.
[76] Jans, "Inflection point: Canadian Life Sciences Industry Forecast," p.21.

researchers rather than business managers. Canadian investors would have a Canadian alternative to relying on foreign investors for guidance and expertise:

> One consequence of the weakness of early- and mid-stage Canadian companies is that some Canadian investors look to the US and foreign locales to invest, since they can find companies with stronger patent positions and lower risk.[77]

A federal bureaucracy could replace this makeshift arrangement and mature the current business environment for Canadian-based firms so that they do not relinquish equity for the sake of fundamental business advice.

The Third Agency:

Finally, the third institution would allow companies with niche products or those that demonstrate great growth potential to go global through equity investments by the federal government. This economic investment strategy would deviate from the privatization trend of federal governments in the developed world.

However, this policy offers the best chance of temporarily injecting capital into promising Canadian-owned firms when experienced investors are too timid or inherently biased against the riskiness of life science firms. The government would invest in non-voting preferred stock in a company as an infusion of capital, and subsequently cash out upon maturity of the firm. In addition, the government could develop the talent and organisational structure necessary to broker strategic alliances during this period of ownership to assure a return on investment. The profits would be returned to the investment fund to assure its solvency and continued operation. Oversight and transparency would be paramount to avoid corruption since, in the end, the financing originates from taxpayers. Ultimately, the outcome of helping Canadian pharmaceutical

[77] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.108.

firms to globalize would prevent the concern raised in parliamentary committee of exporting Canadian IP.[78]

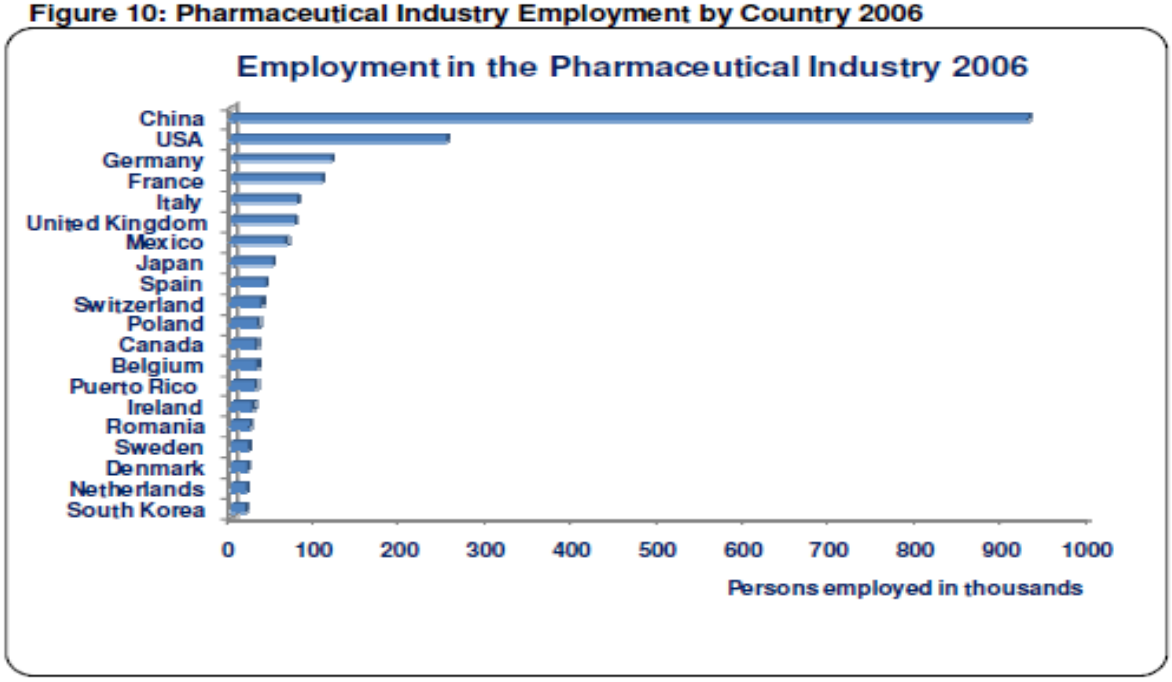
The province of Quebec has an exemplary strategy in place to foster innovative companies at each stage of development. Should the federal government establish the appropriate institutions, then disadvantageous M&A can be minimized, thereby keeping IP and firms in Canada, which will prevent the Canadian market from becoming a second-tier research area that has limited say over the direction and expansion of the industry.

3) Labour

The labour criterion of the pharmaceutical industry is significant because it requires highly skilled labour for scientific R&D on the one hand and highly skilled management for the high risk, high tech business side. Furthermore, the manufacturing side has to contend with international price pressures since it is occupied by low-skilled workers. Canada has a lower percentage than some smaller European countries but still employs a sizeable workforce in the pharmaceutical sector.

[78] Chong, "A Study of the Crisis Faced by Certain Industrial Sectors in Canada," p.44.

Figure 10: Pharmaceutical Industry Employment by Country 2006



Source: Oxford Intelligence, based on EFPIA data and National Statistics

[79]

The labour component of the pharmaceutical industry can be divided into three broad occupations: manufacturing labourers, scientific researchers, and business management. Each requires different policies to remain competitive in the international labour market.

I) Description of the Three Classes of Pharmaceutical Industry Workers

The manufacturing of pharmaceuticals employs relatively few workers in the overall economy, around 23-30,000,[80] but this is because it is a small percentage of the total national economy. The product design of pharmaceuticals is not complex compared to technological devices, machinery, or vehicles, so labour does not need to specialize to the extent of these more complex assembly lines.

[79] Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.24.
[80] Industry Canada, "Canadian Pharmaceutical Industry Profile," http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.html

As for scientific jobs involved in R&D, the number of employees for the entire biotechnology sector, of which the pharmaceutical industry is the largest sub-sector, is only around 12,000.[81] Statistics Canada does not have statistics on the number working on the management side of the industry because the positions are far more fluid. The management of a pharmaceutical firm must have "a combination of technical, financial, clinical, regulatory, business and marketing skills and experience"[82] to assure an efficient and effective path towards commercialization and the subsequent profits to justify the risky investment.

II) Analysis of the Quality and Quantity of Labour Available in the Labour Market

Canada is well positioned to dominate in the global labour pool. The US and Europe currently dominate the pharmaceutical labour markets in the developed world but they have become more hostile to immigration than Canada in recent years. Some developing countries, notably China, also employ many people in the pharmaceutical industry, but developing countries have inferior training and less efficient industries for the time being.

i) Low-Skilled Manufacturing Labour:

Advantages in the Canadian Labour Market for Low-Skill Manufacturing:

The safety and regulatory oversight in a country like Canada far outpaces that of the developing world. While some consumer goods like textiles can be made in a low-regulatory environment, medication, which is consumed with the express purpose of modifying how the human body operates, cannot afford flaws or contamination.

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[81] APPENDIX H
[82] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.82.

Low-skill labour in Canada is readily available and flexible. What should be noted is that pharmaceutical manufacturing is not a labour intensive industry and does not require the rock bottom low wages associated with other forms of low-end manufacturing because it is a value-added product that relies more on quality assurance than volume. This gives Canada an edge over developing countries.

In addition, Canada has an edge over European countries and the US. In the former case, the Canadian labour market is more flexible than the labour hiring and firing restrictions of Western European countries. In the latter case, an additional benefit in the Canadian market is the government-provided welfare system. Pharmaceutical companies do not need to provide extensive benefits to employees because universal healthcare is mandated by the federal government. This benefit also applies when competing with developing countries, whether it is against manufacturers in Central America[83] or R&D in China.[84]

ii) Deficiencies in the Canadian Labour Market for Low-Skill Manufacturing:

However, as developing nations improve the efficiency of their manufacturing facilities, pharmaceuticals will be acutely susceptible to outsourcing for labour cost reasons.[85] A survey of industry representatives ranks manufacturing outsourcing as the primary option for reducing exposure to risk, while they continue to regard R&D as too essential to outsource.[86] Despite the potential for outsourcing, over the past decade, the amount of workers employed in the manufacturing of pharmaceuticals in Canada has consistently ranged from around 23,000 to 30,000, even through the Dotcom crash and

[83] Oxford Intelligence. "Part 2 Corporate Location Benchmarking Analysis," p.12.
[84] Ibid., p.15.
[85] Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.79.
[86] Deloitte, "The future of the life sciences industries: Transformation and rising risk," p.14.

2007-2009 financial crisis, likely for reasons of quality control associated with producing value-added products that must face rigorous human health standards:

Yearly Employment in manufacturing portion of pharmaceutical sector (January 2000 to June 2010)

Source: Statistics Canada

Year	Employement
2000	23 796
2001	23 732
2002	25 029
2003	26 713
2004	28 213
2005	28 673
2006	30 032
2007	28 914
2008	28 697
2009	28 129
2010	28 464

[87]

The federal government cannot take the safety and quality standards of Canadian pharmaceutical manufacturing for granted. China, for example, has already demonstrated that it can operate high tech manufacturing facilities, and is growing more confident and able in the global pharmaceutical industry.[88]

ii) High-Skilled Labour:

The most basic organizational set-up has a rudimentary management team with key scientific employees working under contract for a larger company or through an asset acquired from academia or another pharmaceutical company. As more investors come along, the management team is likely to grow to include more specialized roles.

Advantages in the Canadian High-Skilled Labour Market:

[87] Industry Canada, "Canadian Pharmaceutical Industry Profile," http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn00021.html

[88] Giovannetti and Jaggi, "Beyond Borders: Global Biotechnology Report 2010" p.30.

In terms of ability to hire specialized scientific technical labour, Canada is already highly competitive in the North America context.[89] Scientific technical labour is not as pressing a concern as management in the Canadian economy because the education system for the life sciences is robust, and there are plenty of graduates available in the major clusters to feed into the life sciences industry on a regular basis.[90] Still, Canadian management has some advantages; Canada is fortunate enough to be next door to the US and share cultural affinities and regulatory harmonization, meaning Canadian managers can easily navigate the largest national pharmaceutical market in the world.

Tax policy regarding international labour is continually being reformed, which will ensure competitiveness in an increasingly global pharmaceutical industry. Most recently, the tax code was reformed to address double taxation resulting from income made by American investors in Canada.[91] This reform should encourage hands-on investors who specialize in biotech to come north and begin managing Canadian start-ups.

Deficiencies in the Canadian High-Skilled Labour Market:

Regarding scientific technical labour, the federal government could admit more immigrants who specialize in the pharmaceutical field and its related industries. The Conservative government has made economic immigrants and the recognition of their skills a plank of its mandate, which may or may not increase the number of scientific technical workers in the next few years depending on how well reforms are implemented.

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[89] APPENDIX I
[90] APPENDIX J
[91] Majewski, "Removal of Tax Barriers Opens Door to Flow of Foreign Capital for Biotech" http://www.biotech.ca/uploads/federal%20budget%202010%20biotecanada%20response_final.pdf

Management is the greater challenge. For one, there is a high turnover rate as it is more likely that management can flow between vary types of industries whereas a biopharmaceutical technician is unlikely to change industries. The business culture in Canada is different from the US. Risk and entrepreneurship are less sought after by Canadian managers and investors than in the US. The pharmaceutical industry culture, specifically, creates problems within this labour market; key management personnel move a pharmaceutical asset from a scientific invention towards a full-fledged market product but "Canada is lacking in these people because large pharmaceutical companies, where such skills are traditionally gained, do not spin off entrepreneurial executives." [92]

Consequently, since Canada has certain domestic labour shortfalls in businesses dealing in new technologies, many of these management positions may be filled by non-residents in foreign high tech business centres like Boston, Raleigh and Silicon Valley, which is not necessarily an issue since they are allowing Canadian-based firms to operate on a global-level. The fundamental issue is that:

> For both early- and mid-stage companies, the lack of experienced senior management with skills in developing products, designing the commercial business model and communicating it to investors, is […] a limiting factor in Canada.[93]

Ideally, though, Canadians would manage Canadian biotech start-ups since there is a better chance that ownership will remain in Canada and domestic management expertise will be developed for future projects.

III) Federal Government Investment in Labour Training and Incentives

i) Low-Skill Labour Policy:

[92] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.82.
[93] Ibid., p.108.

Maintaining Low-Skill Labour Competitiveness in a Global Market:

Canada's extensive welfare state is effectively a subsidy of worker benefits that allows it to compete despite having a relatively high global wage rate. Continued social welfare support will maintain this advantage over both developed and developing countries without an elaborate safety net, because the former spends a large total amount on benefits and the later spends a large amount relative to wages and salaries.

Canadian cities, in part because of these labour subsidies, have some of the least expensive R&D labour costs in North America.[94] The federal government could, as a manner of good industrial policy across the board, expand social services to Canadian workers, which would also contribute to the general welfare of the population. Of course, the new services would have to be weighed against budgetary concerns before they are implemented.

ii) High-Skill Labour Policy:

Several measures on immigration reform undertaken by the Conservative government, such as loans for validating foreign credentials and improving the points system to encourage skilled labour over family reunification, will increase the flow of immigrants into the pharmaceutical sector. However, these measures are economy-wide and do not address the unique needs of the pharmaceutical industry.

Training for Scientific Technical Labour:

The federal government should commit to training and attracting key scientific talent in two ways. The most obvious way is through funding to higher education. This policy would be an easy sell to the Canadian public and provincial governments. The concept of funding higher education is not difficult to market to voters, and provincial

[94] APPENDIX K

governments are always asking for education funding transfers. Therefore, this policy would satisfy the needs of the electorate and provincial governments while also fulfilling the intended objective of increasing scientific technical labour.

The second policy was outlined in the capital section: G&C. Beyond providing the necessary seed money for R&D at the academic level, a robust G&C arrangement with Canada's post-secondary institutions will improve Canada's reputation abroad as a centre of excellence in pharmaceutical research. This, in turn, will lead to an influx of foreign academics who are assured by the fact that G&C will continue to flow from federal coffers into academia.

The G&C will act as a springboard for researchers who wish to try their luck in the industry. Early and mid-stage companies rely on academic and government funding to continue operating and employing scientific technical labour, in a virtuous cycle:

> Most companies are small, with 352 or 72% having less than 50 employees; of these, 243 have less than 10 and 153 less than five employees. Many of the small firms receive only seed or angel capital, and operate within government or educational institutions. Their ability to grow is limited and the turnover rate is high.[95]

Stunted growth and a high turnover rate may seem antithetical to the notion of long-term training, but it is these early stage experiences that will allow scientific technical labourers to work across the industry, from start-ups to Big Pharma.

Furthermore, as previously mentioned, foreign subsidiaries in Canada do not encourage managers to be entrepreneurial. This includes managers with a scientific background. G&C can compensate for this deficit by providing an outlet for the innovative forces of scientific managers who wish to attempt the development of a pharmaceutical asset outside of the Big Pharma establishment.

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[95] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.72.

Management Incentives:

Scientific technical labour needs to be nourished, whereas management needs to be enticed, because the former operates in a highly specialized field and the latter can apply its skills in any industry. Also, while researchers can be slowly brought into the management-side of a biotech start-up, more specialized managers are absent until the mid-to-late stages of a firm's lifecycle. Management skills are obtained through:

> experience in designing strategy and implementing product development plans, obtaining financing, manufacturing and marketing. These skills are not typically available in most start-up companies, as they are initially staffed by researchers.[96]

The federal government, ideally in collaboration with provincial governments, should therefore institute a partial temporary waiver of income tax for managers, both foreign and domestic, who work at Canadian-owned pharmaceutical companies earning under a certain amount of revenue. This measure will increase the after tax income of managers at CCPC relative to Big Pharma managers. Once again, Quebec has successfully implemented such a waver, for a period of five years, to scientific technical and general high tech managers.[97]

There would be some costs associated with incentivising management in this way. The obvious one is reduced income tax collection from senior management. However, the revenue generated from these positions would represent a minuscule proportion of overall income tax collection and the waiver would be temporary. The costs would thus be minimal and recouped through corporate income tax when these biotech companies grow to maturity.

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[96] Ibid., p.82.
[97] Ibid., p.83.

iii) Promote Cluster Formation for All Class of Workers:

Finally, the formation of clusters can contribute to all three classes of workers. The major Canadian pharmaceutical clusters in Canada are Vancouver, Edmonton, Saskatoon, Winnipeg, Toronto, Ottawa, Montreal, Quebec, and Halifax.[98] Clusters cannot be formed with any one policy. They arise from multiple policies that foster a pro-business, pro-academia, pro-worker environment; Canadian clusters already excel in this regard[99] but competition is a constant.

Cluster formation should be considered a framework for all of the aforementioned policies, from capital financing to strategic alliances to labour policy. When government bureaucrats make decisions on how to address industry deficiencies, the decisions should always be filtered through the prism of cluster formation.

An industry and government emphasis on clusters is not altogether evident. In an analysis of Californian and Finnish biotech companies by Tanja Rautiainen, clustering is found to be important for business success[100] yet despite the implicit benefits of clustering as an external factor in business success and its casual promotion throughout industry strategies, industry stakeholders appear to disagree with the assertion that clustering is a vital factor in competitiveness.

Sandra Vanderbyl and Sherry Kobelak, two business professors with management experience in biotech companies, find in their survey of the industry that clustering and networking rank low in terms of success criteria.[101] This seems to be confirmed by a survey of Canadian pharmaceutical firms conducted by PricewaterhouseCoopers, in

[98] APPENDIX E
[99] APPENDIX L
[100] Rautiainen, "Critical Success Factors in Biopharmaceutical Business," p.10.
[101] Kobelak and Vanderbyl, "Critical Success Factors for Biotechnology Industry in Canada," p.76.

which clustering ranks near the bottom in terms of industry priorities.[102] One possible explanation is that the benefits of clustering are not as apparent to stakeholders as the more direct criteria of financing or subsidies.

On the governmental side, clustering is not as evident a success factor because of the structure of the Canadian government. The notion that clusters, rather than countries, compete in the international economy is a new one, spurred on by trade and capital liberalization. The federal and provincial governments are beginning to recognize the internationalization of all public policy but, for the time being, these same governments will continue to dominate in trade, education, finance and spending power. That being said, municipalities will at the very least need to build liveable and operational cities to attract and maintain the labour force by improving such areas as social services, infrastructure, and zoning regulation. Canadian clusters currently have high concentrations of pharmaceutical manufacturing compared to US clusters[103] thanks to effective municipal management.

Without liveable, innovative, economically viable cities, Canada will not be able to attract the most qualified immigrants nor retain students from local universities. Some pharmaceutical industry labour can be conducted remotely, such as the previously mentioned foreign managers operating out of global high tech centres. However, most of the labour will be done regionally, whether its lawyers for IP, investors for finance, or the three classes of workers discussed in this analysis of the industry.

The promotion of cluster formation by the federal government would benefit all three categories of workers, because while clusters are important for capital financing and

[102] Jans, "Inflection point: Canadian Life Sciences Industry Forecast," p.25.
[103] APPENDIX M

networking, capital is far more mobile than labour and networks now reach across the globe. Clustering is essential for pooling together labour. By attracting key personnel and establishing a positive operating environment for pharmaceutical activity, Canada's entrepreneurial culture will improve. Currently, "Canada […] lacks strong clusters of expertise and experience where people with all the skills assemble, creating an environment that encourages synergy and rapid progress."[104]

Canadian clusters rank high in North America but US clusters present comparable competition, so Canada faces constant competition from down south, not to mention competition from around the world whether from mature European pharmaceutical companies or up-and-coming developing countries hoping to break into this lucrative value-added industry and showcase the global reach of their cities. Canada will have to seize onto the momentum created by the clustering of labourers if it wishes to compete on a global level with the most efficient operations in the world.

Concluding Thoughts

The pharmaceutical industry is an exponential innovator. New techniques and technologies allow for ever increasing solutions to broad and niche human health issues, while contributing to the value-added economy. Canada, a nation obsessed with healthcare in policy and political discourse, continues to thrive in the highly competitive 21st century global life science industry. But there is always room for improvement. The three deficiencies listed by pharmaceutical industry stakeholders hold true in reality and must be addressed at the national level by the federal government.

[104] Noiseux and Schincariol, *The Canadian Biopharmaceutical Industry Technology Roadmap*, p.108.

The aforementioned policy proposals may not all be politically feasible given the new climate of fiscal restraint, but they should all be considered, at the very least. If Canada chooses to muster the full fiscal and organizational strength of the federal government, then it has a very real chance of occupying a premier place in the global pharmaceutical industry.

If, however, the government ignores industry complaints, there is an equally good chance that capital will be invested elsewhere, strategic partnerships will be dominated by foreigners who have minimal concern for the development of the Canadian industry, and labour will migrate to more favourable clusters. Investment in the pharmaceutical industry would be costly for the federal government but ignoring it altogether would be far more costly for the Canadian economy.

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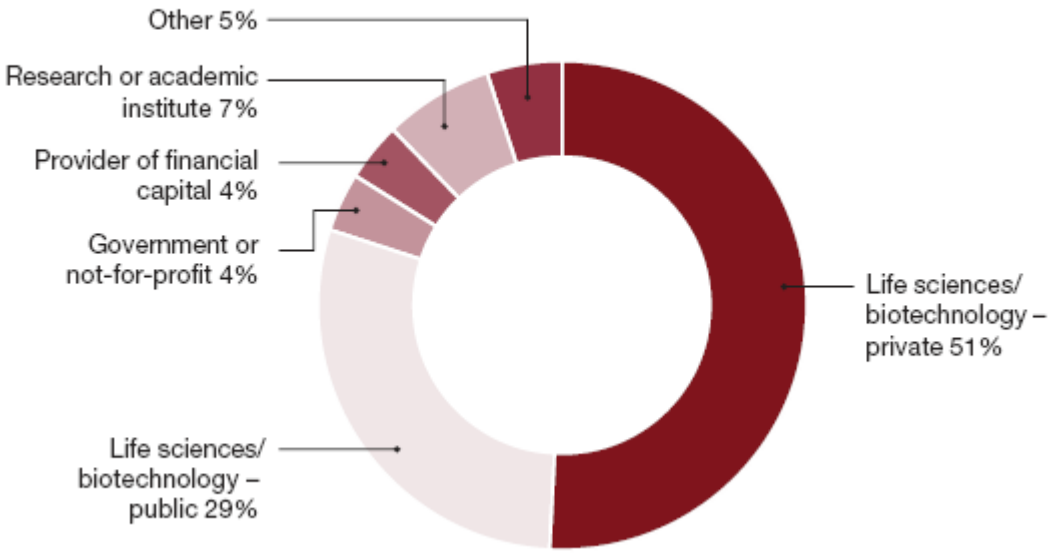
Appendices

APPENDIX A

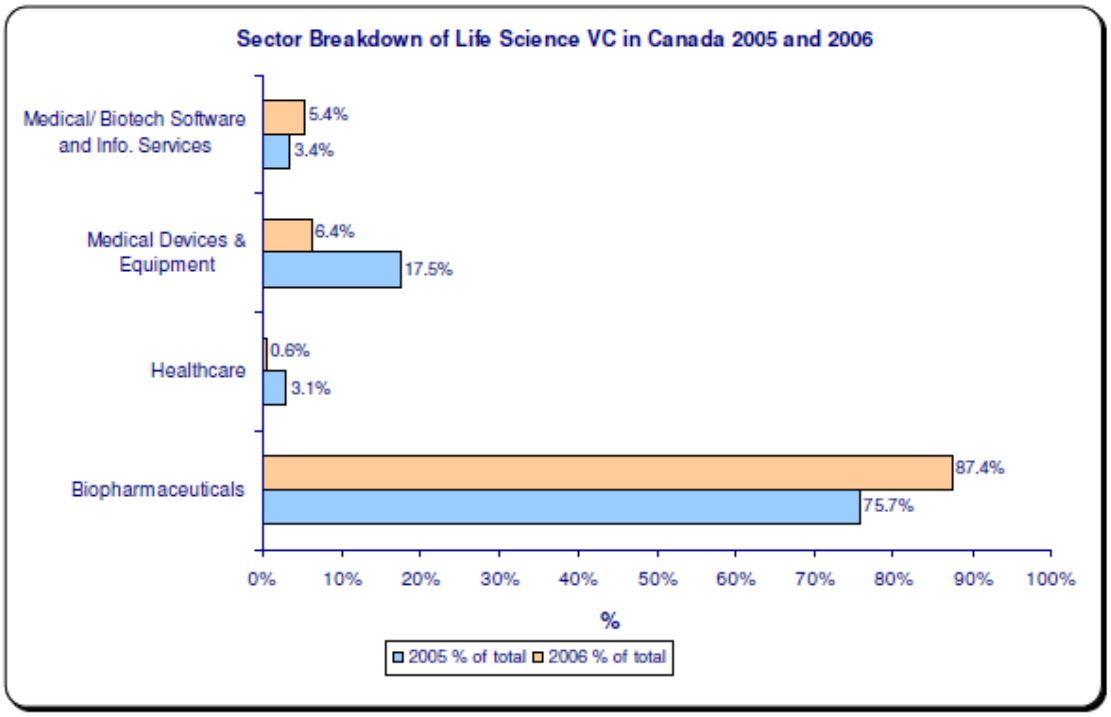
Figure 1: Respondent business



Source: Jans, Gord, "Inflection point: Canadian Life Sciences Industry Forecast," Prepared for BIOTECanada by PricewaterhouseCoopers, 2011, p.3.

APPENDIX B

Figure 67: Sector Analysis of Canadian MedTech Venture Capital Investment 2006 and 2007

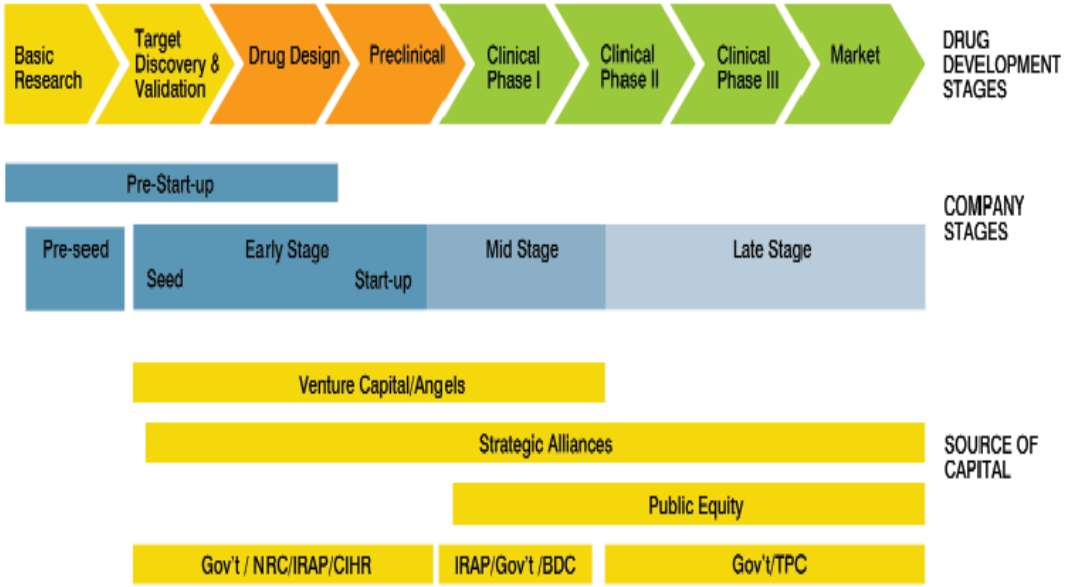


Source: Thomson Financial, Canadian Venture Capital Association

Source: Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p.68.

APPENDIX C

Figure 18: Sources of Capital relative to Product Development and Company Stage



Source: TRM Steering Committee.

Source: Noiseux, Michel and Anthony Schincariol. *The Canadian Biopharmaceutical Industry Technology Roadmap*. Industry Canada: 2010, p.96.

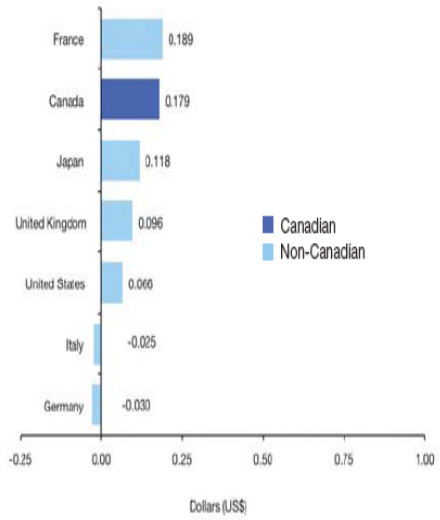
APPENDIX D

Generous R&D incentives

Canada understands that R&D and innovation are critical to the growth of biopharmaceutical firms; therefore billions of dollars are invested in R&D each year to ensure that investors have access to the best talent and infrastructure in the world. Canada provides a system of federal and provincial tax credits and accelerated tax deductions for a wide variety of R&D expenditures to allow global firms to significantly reduce costs.

Canada's Scientific Research and Experimental Development (SR&ED) program is an open-ended tax incentive initiative that covers 20 percent of various R&D-related costs, such as salaries, overhead, capital equipment and materials. The SR&ED incentive permits firms to reduce R&D costs through direct investment or subcontracting in Canada.

The rate of tax subsidies for US$1 of R&D, large firms and SMEs (G7 countries)**



Source: Invest in Canada Bureau. "Biopharmaceuticals," in *Invest in Canada*, Ottawa: Department of Foreign Affairs and International Trade Canada, 2009, p.8.

APPENDIX E

British Columbia

British Columbia's biopharmaceuticals sector consists of over 90 companies with a total of 2,200 employees and annual revenues of approximately $779 million. The province's biopharmaceutical sector is anchored by two of the world's first profitable biopharmaceutical companies: QLT and Angiotech. The B.C. Cancer Agency, the B.C. Centre for Disease Control and the University of British Columbia, located in Vancouver, house some of the province's world-leading research facilities.

Manitoba

With over 40 companies, 30 R&D establishments, 23 service firms, and 4,200 employees, Winnipeg's life sciences cluster offers significant capabilities in biopharmaceutical R&D and production, including three of Canada's top 10 life sciences companies in 2006: Diamedia, Kane Biotech and Samune. As Canada's third-largest exporter of pharmaceuticals, the region's manufacturing activity is centred on firms such as Cangene Corporation, Apotex Fermentation, Biovail and Vita Health.

Home to the Public Health Agency of Canada, Manitoba is a global centre of excellence in infectious disease identification and management, with Canada's only Level 4 containment laboratory. The biopharmaceutical cluster's areas of focus here include infectious diseases; cardiovascular and respiratory diseases; oncology; neuroscience; nutraceuticals and functional foods; and diagnostics.

Alberta

Edmonton hosts world-renowned researchers and publicly supported state-of-the-art facilities that provide a wealth of biomedical research capacity. Edmonton's University of Alberta and the universities of Calgary and Lethbridge offer an unparalleled environment for primary research. Successes include the Edmonton Protocol treatment for Type 1 diabetes, advanced cancer imaging and treatment, neurological imaging, and cutting-edge research into treatments for cardiac and infectious diseases.

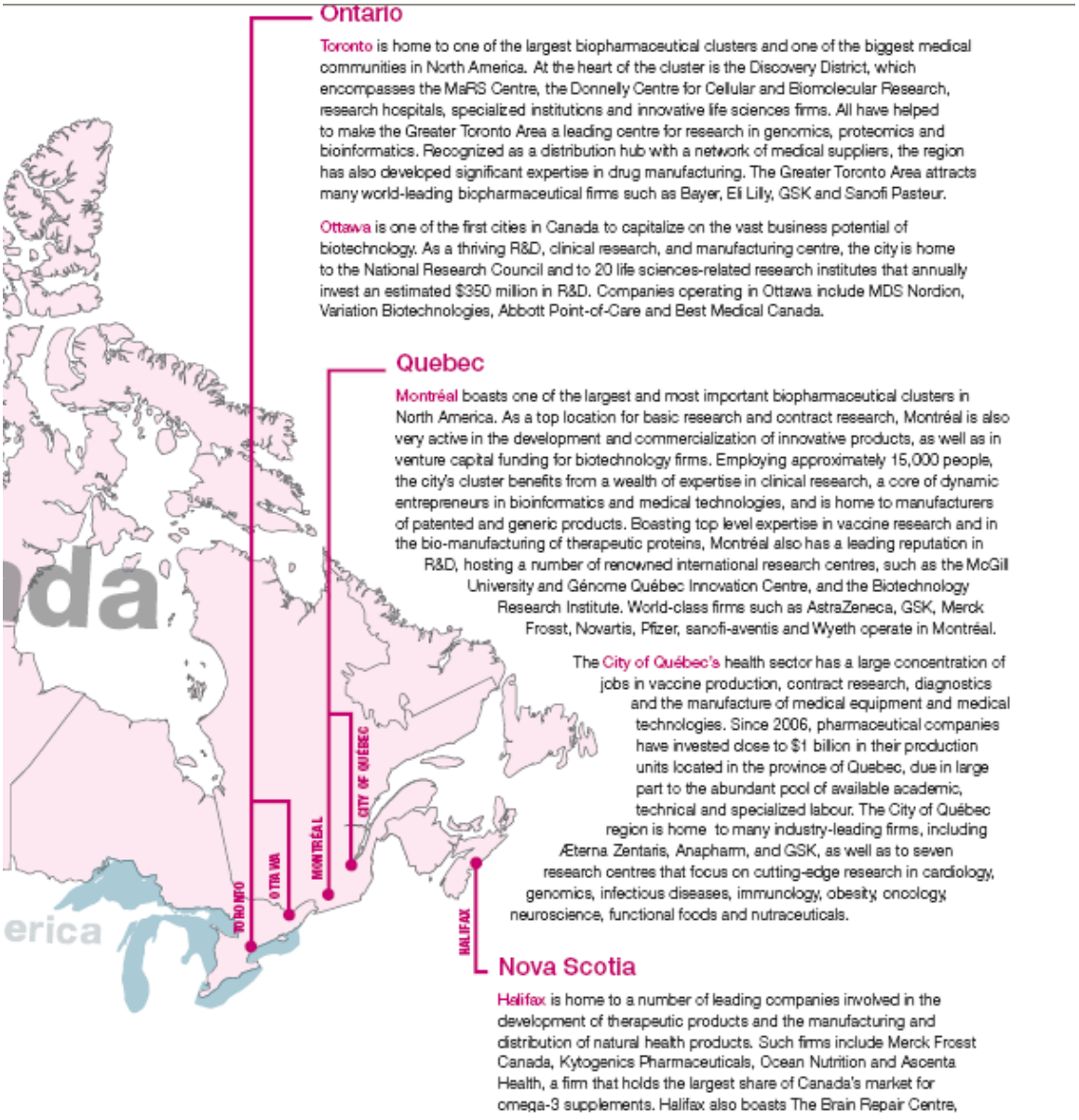
Private-sector companies add depth to the research environment in Alberta. Examples include BioMS Medical Corporation, developing therapeutics to treat multiple sclerosis; Oncolytics Biotech Inc., focusing on developing products to treat cancer; contract R&D firms NAEJA Pharmaceuticals and Chemroutes Corporation; and QSV Biologics, a GMP contract manufacturing (fermentation) firm. Gilead Sciences also operates a manufacturing facility in Edmonton.

Saskatchewan

A number of outstanding research facilities are located in Saskatchewan, many involved in clinical trials and cutting-edge work developing vaccines and finding cures for coronary disease, cancer, diabetes and viral infections. The province is home to many industry-leading firms, including Bioniche Life Sciences Inc. and POS Pilot Plant.

Saskatoon's National Research Council - Plant Biotechnology Institute focuses on developing plant-based products to improve the health and wellness of Canadians. The non-profit Vaccine and Infectious Disease Organization, credited with five world firsts in animal vaccine research, has expanded into human health applications in an effort to ease the suffering caused by influenza and hepatitis C and address the lack of effective vaccines for newborns and people in developing countries.

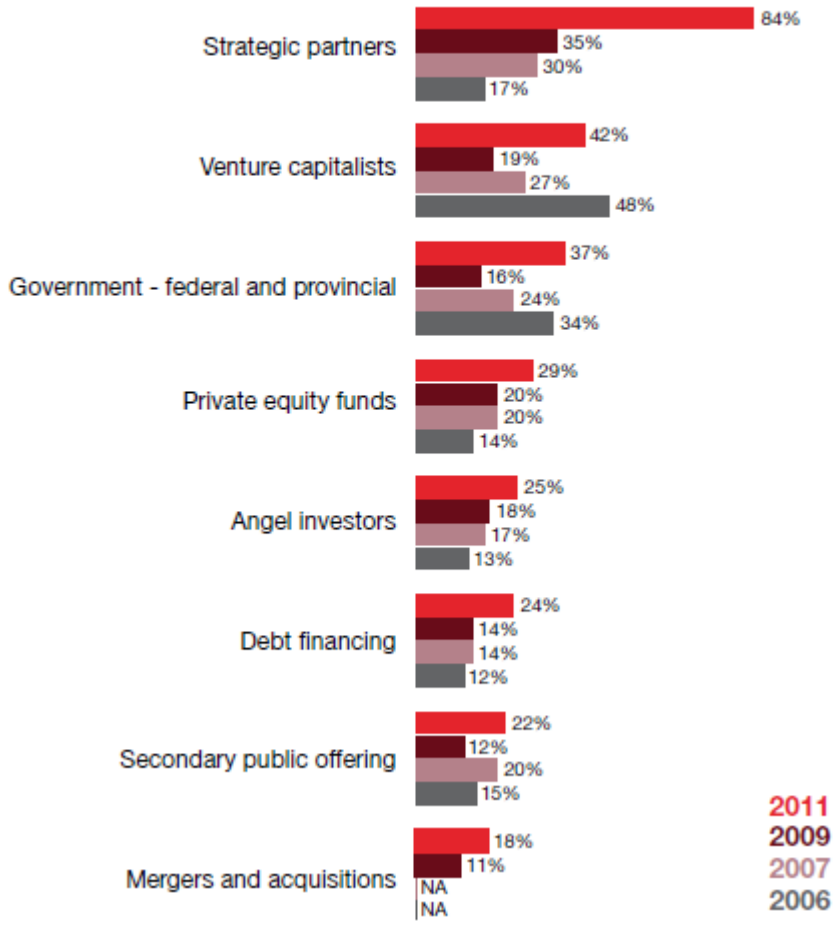
Source: Invest in Canada Bureau. "Biopharmaceuticals," in *Invest in Canada*, Ottawa: Department of Foreign Affairs and International Trade Canada, 2009, p.2.



Source: Invest in Canada Bureau. "Biopharmaceuticals," in *Invest in Canada*, Ottawa: Department of Foreign Affairs and International Trade Canada, 2009, p.3.

APPENDIX F

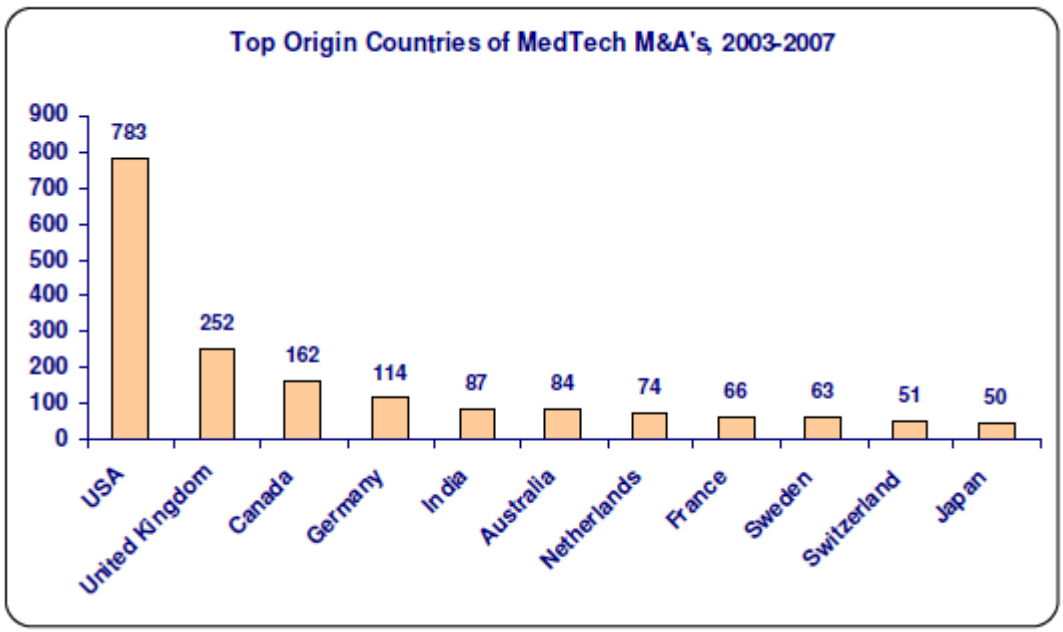
Figure 7: From what sources do you expect to get this funding? (respondents were asked to select top 3 choices)



Source: Jans, Gord, "Inflection point: Canadian Life Sciences Industry Forecast," Prepared for BIOTECanada by PricewaterhouseCoopers, 2011, p.12.

APPENDIX G

Figure 53: Leading Origin Countries of MedTech M&A 2003-2007



Source: Zephyr

Source: Oxford Intelligence, "Part 1 Industry Trends and International Investment Strategies," p58

APPENDIX H

Table 17: Distribution of Canadian Biotechnology Companies by Region, Size, Employees and Revenues, 2003

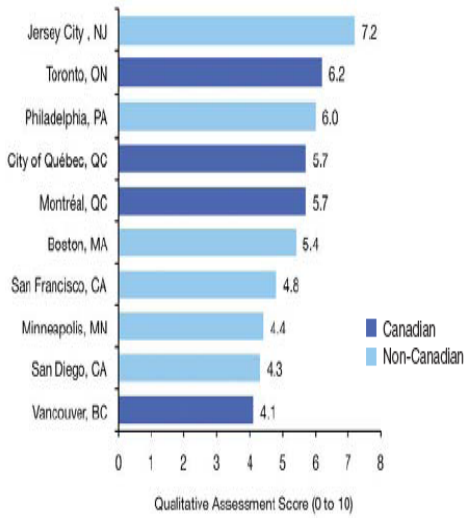
	Innovative Biotechnology Companies	Employees with Biotechnology-related Activities	Biotechnology Revenues (C$M)	Biotechnology R&D Expenditures (C$M)
Region				
Canada	490	11,863	3,842	1,487
Quebec	146	3,700	480	490
Ontario	129	3,508	2,026	453
Manitoba	21	1,213	145	56
Saskatchewan	34	337	94	23
Alberta	44	727	298	88
British Columbia	91	2,173	779	370
Atlantic	25	206	21	7
Size				
Small (0–49 employees)	352	3,619	468	495
Medium (50–149 employees)	77	3,746	909	699
Large (150+ employees)	61	4,498	2,466	293

Source: Statistics Canada, Biotechnology Use and Development Survey, 2003.

Source: Noiseux, Michel and Anthony Schincariol. *The Canadian Biopharmaceutical Industry Technology Roadmap*. Industry Canada: 2010, p.73.

APPENDIX I

Local potential to recruit skilled staff
(highest-ranking cities)*



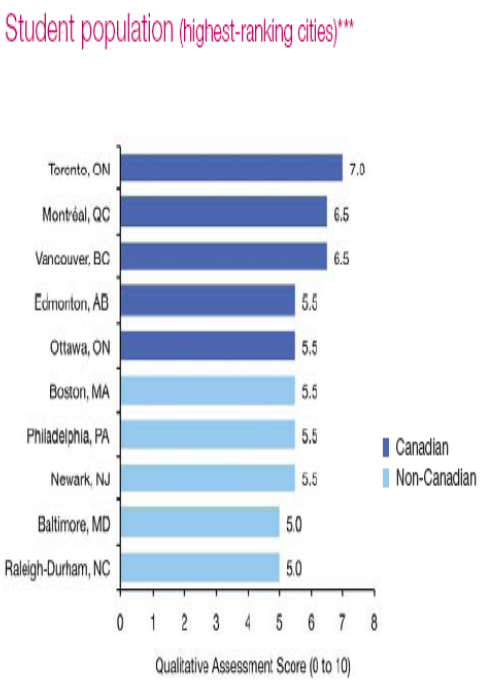
A deep talent pool

The presence of experienced clinicians and researchers contributes to the success of R&D activities. Proximity to universities and a student population are important in providing a source of educated labour, as well as individuals to serve as test populations for health research and studies. Ranked first in the world for higher education,[3] Canada is home to an exceptionally well-educated, motivated and diverse workforce.

Toronto, Montréal, the City of Québec and Vancouver all host large populations of experienced employees working in pharmaceutical and biomedical-related companies, as well as large student populations, ensuring a steady flow of new talent.

Source: Invest in Canada Bureau, "Biopharmaceuticals," in *Invest in Canada*, Ottawa, ON: Department of Foreign Affairs and International Trade Canada, 2009, p.7.

APPENDIX J



The people advantage

Canada believes in investing in people and welcoming talent from around the world. This helps explain why Canada has the world's highest percentage of college and university graduates and a well-educated, talented and diverse workforce, motivated to help businesses succeed.

IBM-PLI's benchmarking study rates five Canadian cities at the top of the rankings for the number of life science-related graduates. Toronto, Montréal, Vancouver, Ottawa and Edmonton all host sizeable universities with faculties in biological, biomedical and general life sciences, resulting in a large and constant flow of new talent for the industry.

Source: Invest in Canada Bureau. "Biopharmaceuticals," in *Invest in Canada*, Ottawa: Department of Foreign Affairs and International Trade Canada, 2009, p.8.

APPENDIX K

Estimated annual labour costs of a biotechnology R&D operation (highest-ranking cities) **

Favourable labour costs

A calculation of the estimated annual labour costs for a typical R&D facility focused on drug discovery and clinical trials shows the potential for significant cost savings of Canadian locations. All Canadian cities examined in IBM-PLI's study rank in the top 10 and have lower costs than prominent U.S. competitors such as Philadelphia, Boston and Jersey City.

An important component of Canada's labour cost advantage relative to the United States stems from the lower costs of providing employee benefits. Canada's national healthcare system implies that most medical insurance costs are publicly funded rather than paid by the employer, which can result in significant savings for employers.

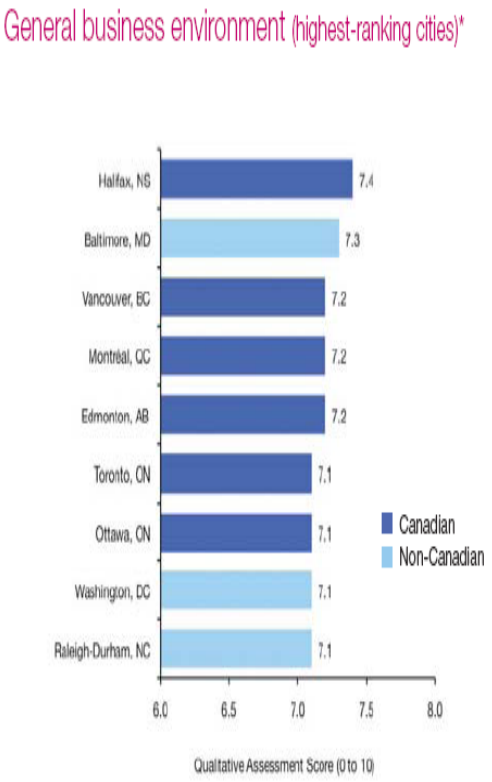
Source: Invest in Canada Bureau, "Biopharmaceuticals," in *Invest in Canada*, Ottawa, ON: Department of Foreign Affairs and International Trade Canada, 2009, p.7.

APPENDIX L

Best place to do business in the G7

Canada has a solid and dynamic economy, low corporate tax rates and generous R&D incentives. This, coupled with the support from local governments and development agencies, privacy regulations, information security and intellectual property rights, has helped to make Canada an advantageous business environment for companies to invest and flourish.

As the number one country among the G7 for GDP growth over the last decade and with the world's soundest banking system,[4] Canada provides a safe and strong business environment that offers tremendous growth potential and peace of mind for your investment.



Source: Invest in Canada Bureau, "Biopharmaceuticals," in *Invest in Canada*, Ottawa, ON: Department of Foreign Affairs and International Trade Canada, 2009, p.8.

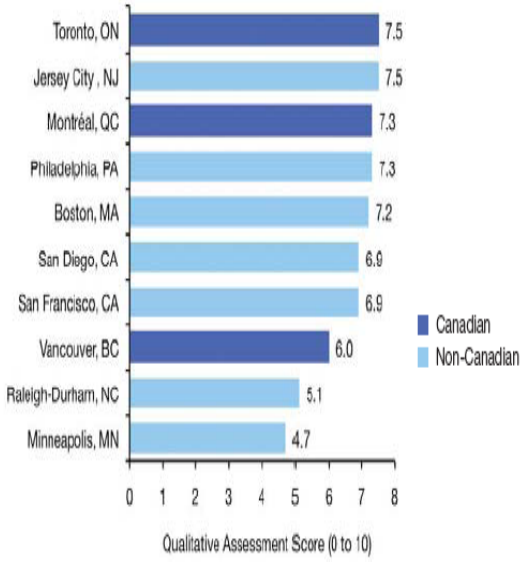
APPENDIX M

Thriving biopharmaceutical clusters

Clusters of pharmaceutical companies allow close linkages with buyers, suppliers and other institutions to offer advantages that lead not only to greater efficiency, but also to accelerated product improvement and innovation.

Canada has the second highest number of biotechnology companies in the world and is home to some of the largest established clusters in the pharmaceutical industry. Official counts of establishments classified as pharmaceutical manufacturing[2] show Toronto and Montréal comparing well to Jersey City, New Jersey, one of the most prominent pharmaceutical industry bases in North America.

Presence of pharmaceutical industry base
(highest-ranking cities)*



Source: Invest in Canada Bureau, "Biopharmaceuticals," in *Invest in Canada*, Ottawa, ON: Department of Foreign Affairs and International Trade Canada, 2009, p.7.