



Biotechnology Council of Ontario
PUBLIC POLICY FOR LIFE SCIENCES

Investing in the Life Sciences Sector: A Proposed Strategy for Innovation in Ontario

AUGUST 2006

Biotechnology Council of Ontario
MaRS Centre, Heritage Building
101 College St., Suite 120-C
Toronto, Ontario M5G 1L7
Tel: 1-866-342-4933
www.biocouncilontario.com



Biotechnology Council of Ontario
PUBLIC POLICY FOR LIFE SCIENCES

VOLUME 1

**Investing in the Life
Sciences Sector:
A Proposed Strategy
for Innovation in
Ontario**

**EXECUTIVE SUMMARY
&
RECOMMENDATIONS**

Biotechnology Council of Ontario
MaRS Centre, Heritage Building
101 College St., Suite 120-C
Toronto, Ontario M5G 1L7
Tel: 1-866-342-4933
www.biocouncilontario.com

AUGUST 2006



VOLUME 1 Table of Contents

Letter to the Premier	4
BCO Recommendations	7
Executive Summary	13
1. Introduction.....	14
2. Historical Overview	15
3. Advancing Ontario's Innovation Mandate	16
4. Driving Ontario's Health & Industrial Policy	19
5. How the Ontario Government Can Support the Biopharmaceutical Sector	23
Summary of Ontario Bio-Industry Position Papers	26
BCO Organizational Structure.....	28
BCO Working Committee 2006.....	30



VOLUME 2 Table of Contents

Appendix 1 - Introduction & Backgrounders	4
1.1 Introduction	5
1.2 Backgrounder: Biotechnology Solutions for Health & Everyday Living	7
1.2.1 Solutions for Health.....	7
1.2.2 Solutions for Everyday Living	8
1.3 Backgrounder: Ontario's Success Stories	9
1.4 Backgrounder: The Canadian Biopharmaceutical Industry	11
1.4.1 Pharmaceutical/Biopharmaceutical Sector	11
1.4.2 Biotechnology Sector	13
1.4.3 Medical Device Sector	16
Appendix 2 - Historical Overview	18
Appendix 3 - Advancing Ontario's Innovation Mandate.....	23
3.1 Biopharmaceutical Technologies Fit Within the MRI Mandate	24
3.2 The Threat of Unsustainability.....	25
3.3 Potential Solutions Provided by Biopharmaceutical Innovation	26
3.4 Life Sciences Clusters	33
3.4.1 Definitions and Key Elements of Clusters	33
3.4.2 Global Life Sciences Competition: Where does Ontario fit?	35



VOLUME 2 Table of Contents

Appendix 4 - Driving Ontario’s Health & Industrial Policy	41
<i>4.1 Improved Disease Management.....</i>	42
<i>4.2 Other Biotech-Based Approaches.....</i>	51
<i>4.3 Maintaining Wellness (Disease Prevention)</i>	53
<i>4.4 Opportunity Costs.....</i>	54
<i>4.5 Other Factors Affecting Health Care Costs</i>	55
<i>4.6 Summary.....</i>	56
Appendix 5 - How the Ontario Government Can Support the Biopharmaceutical Sector	58
<i>5.1 Success Metrics, Trends and Gaps.....</i>	59
<i>5.2 Limitations of Data Collection for Success Metrics.....</i>	63
<i>5.3 Enhancing Ontario’s Culture of Innovation as a Basis for Commercial Success</i>	64
Appendix 6 - Summary of Ontario Bio-Industry Position Papers.....	68
Appendix 7 - BCO Organizational Structure	70
Appendix 8 - BCO Working Committee 2006.....	72



Biotechnology Council of Ontario
PUBLIC POLICY FOR LIFE SCIENCES

Letter to the Premier



Letter to the Premier

August 1, 2006

The Honourable Dalton McGuinty
Premier of Ontario and Minister of Research and Innovation

Dear Premier McGuinty,

As Chair of the Biotechnology Council of Ontario (BCO), I am pleased to forward to you the 2006 strategy report for Life Sciences Innovation in Ontario. This report embodies a strategy for innovation that includes a series of recommendations to accelerate the commercialization of products in the Province's broadly-based biotechnology and life sciences sector.

As a province-wide council, the BCO acts to advise government on all public policy issues facing the life sciences industry and to advocate on behalf of the industry in Ontario. From its first biotechnology strategy tabled in 1994, the current BCO represents the evolution of more than a decade of work to advance the industry in the Province, including detailed consultation with industry, academia, key regions, and government.

On behalf of the BCO, I commend you, Premier, for your foresight and leadership in establishing the Ministry of Research and Innovation (MRI), and also for assuming the role of the first Minister of the MRI. The BCO endorses the vision of an Ontario in which the process of innovation becomes, in your words, inevitable. The Council firmly supports the Province in its ambitious goal of creating one of the leading life sciences industries in North America. Ontario has the potential to be a major player and provider in this global marketplace, building on its many strengths and cutting edge research capabilities. However, to ensure Ontario's prosperity and well-being for *tomorrow*, we must rely on our ability to innovate *today*, and to advance new ideas forward from discovery to commercialization.

Indeed, the Ontario government has a critical role to play in promoting life sciences research and innovation in the Province - by helping to address the critical needs of the sector. There is a broad consensus within the sector regarding these needs, and we have developed a number of specific recommendations to achieve the following four key goals for the Province.

The BCO recommends that the Ontario government should:

1. Support alignment of economic and health policy in serving the best interests of Ontarians,
2. Promote increased capital investment in Ontario's Life Science sector,
3. Improve commercialization and market environment for biopharmaceutical products in Ontario, and



4. Provide tax incentives to attract domestic, foreign and venture capital investment in Ontario.

Detailed recommendations and background information are laid out in the accompanying report, including an “Immediate Prescription for Growth”; these recommendations propose incremental short- and longer-term steps to position Ontario as a leader in the global life sciences business. In considering these recommendations, the government will be challenged to implement additional programs to augment Ontario’s leadership role in the life sciences industry - acknowledging innovation in this sector not only as a key driver of high-value jobs and future economic prosperity, but also as essential force in improving quality of life for Ontario families. Increased government investment in the latest innovative therapies will ensure patient access to leading-edge technologies that enable optimal health and productivity outcomes, while simultaneously contributing to cost containment within the provincial health care system. Thus in developing a life sciences innovation strategy as a primary driver of the Province’s economic and health agendas, the Ontario government has an excellent opportunity to align industrial policy with a sustainable economy.

We look forward to the government’s response and leadership in adopting these recommendations in partnership with industry, provincial ministries, and the federal government over the coming months. Please accept this submission as a formal request to meet with you and discuss how we can work together in implementing this multi-faceted plan.

I want to emphasize that this report is the collective work of a number of stakeholders - including representation from a broad group of life sciences companies and organizations - who believe that this industry offers a significant economic opportunity for Ontario. Participants of the 2006 BCO Working Committee have given generously of their time and energies over the past several months, for which I express my sincere gratitude. I am particularly impressed with the professionalism, industry knowledge, and dedication of Dr. Nora Cutcliffe in compiling the industry views endorsed in this paper in her capacity as lead writer.

In closing, we would like to thank you for the opportunity to respond to your challenge in preparing this report, and we hope the recommendations will be helpful to your government in promoting the Province’s culture of innovation. With continued government funding, and a renewed partnership with the industry, we believe that future growth of the life sciences sector will significantly enhance Ontario’s competitive and economic position, also driving health policy, in supporting a sustainable provincial economy.

Yours sincerely,

Dale Patterson
Chair, Biotechnology Council of Ontario



BCO Recommendations



BCO Recommendations

Ontario's biopharmaceutical industry, represented by the BCO, is committed to working with the provincial government to jointly address the following issues most critical to the industry:

Short Term Recommendations ("Immediate Prescription for Growth")

1

Support alignment of economic and health policy in serving the best interests of Ontarians

In order to coordinate the mandate and priorities of the provincial organizations responsible for economic, innovation and health initiatives within the Province, and to ensure consistent action across these fields in supporting a sustainable economy, the Ontario government should immediately:

a) Establish a Cabinet Committee, chaired by the MRI.

- Proposed Structure: The Cabinet Committee could be created as an Ontario Innovation Commission, led by elected members of the government caucus, and reporting directly to the Premier in his capacity as Minister of Research & Innovation.
 - The Commission would act in partnership with the newly appointed Ontario Research and Innovation Council (ORIC, June 2006).
 - Ideally, the Commission would comprise a group of 5 MPPs with a clear understanding of the Premier's vision for innovation, including representation from the Ministries of Research and Innovation (MRI), Economic Development and Trade (MEDT), Health and Long-term Care (MOHLTC), Finance, and Education.
 - The Commission would also include the Deputy Minister of MRI and a small Secretariat derived from staff in the MRI.
- Objective & Scope: The objective of the Ontario Innovation Commission would be to review existing and emerging policies through the lens of the Ontario government's innovation agenda, helping to foster the desired "culture of innovation". The Commission would be required to, but not limited to, review all policy initiatives, cabinet submissions, regulations, and legislation - to ensure that decisions made by the



government are aligned with and supportive of the Premier's innovation agenda.

- The Commission would thus represent an active "Innovation Filter" through which all government policy decisions would be vetted, to enforce appropriate business impact assessments and to balance desired social, economic and industrial policy outcomes.
 - As part of the Cabinet process, there could be a section in all submissions requiring consideration of the impact on innovation, including demonstration of how proposed changes will strengthen Ontario's position as a leading jurisdiction for innovative industries.
 - The comments and considerations of the Innovation Commission would be shared with Cabinet in their deliberations.
- **Timing & Announcement:** This initiative could be launched in the Fall of 2006, accompanied by a strategic announcement from the MRI and/or ORIC.

b) Recognize the Biotechnology Council of Ontario (BCO) as the lead public policy voice of the broadly-based biotechnology and life sciences industry, working in partnership with the Province on all public policy issues facing the industry.

Also consider the BCO as a catalyst for establishing a new structure and broader mandate for a pan-Ontario Life Sciences industry council.

- **Proposed Structure:** The new Life Sciences Council (potentially named the "Trillium Life Sciences Council") would include broad membership and participation from all existing provincial life science associations, organizations, and companies, with representation from the biotech, pharmaceutical, medical devices and financial sectors.
- **Objective & Scope:** A primary goal of the council would be to provide a permanent, official discussion forum for industry players, providing the government with a "one-stop-shop" to discuss industry needs and expectations in the context of government policies, also enforcing



mechanisms for industry, public, and stakeholder consultation.

- Public policy forums represent a fundamental component of the transparency process for future legislation that impacts on health and economic mandates in jointly encouraging biopharmaceutical innovation.
 - The council would act as a policy partner with the Cabinet Committee and/or ORIC to generate ideas, to participate in budget initiatives involving the “Innovation Filter” process, and to drive post-budget implementation of approved programs.
 - Other council activities would promote additional business development activities and branding of Ontario’s strengths in the Life Sciences.
- Timing & Announcement: This initiative could be launched in the Fall of 2006, accompanied by a strategic announcement from the MRI and/or ORIC.

Other recommendations:

2

Promote increased capital investment in Ontario’s Life Science sector

To increase investment in Ontario’s health innovation industries, primarily by facilitating access to risk capital from both private and public sector partnerships, it is recommended that the provincial government:

- a) **Provide incentives for pharmaceutical companies to contribute to the pool of risk-based investment capital.**
 - Create incentives for strategic partnerships between big pharma and early-stage biotech firms.
 - Promote “win-win” approach for Ontario and pharma sector, in which pharmaceutical risk is mitigated via early engagement (with or without VC involvement), with first opportunity to define investment strategy and realize return on investment. Ontario also stands to benefit from greater investment, job creation, improved health outcomes, and health care savings through enhanced disease management.



- b) **Encourage greater investment by institutional investors (pension funds, insurance funds) in the local biopharma sector.**
- c) **Restore the funding mechanism that the OIT and ORDCF programs represented, during the late 1990s, to promote research excellence.**
- d) **Work with federal government to eliminate barriers to foreign investment:**

Eliminate impediments preventing foreign financial institutions from investing in Ontario biopharmaceutical entities and/or venture capital funds.

3

Improve commercialization and market environment for biopharmaceutical products in Ontario

To attract investment through accelerated commercialization of biopharmaceutical discoveries, and in efforts to address regulations that restrict market access for innovative products, it is recommended that the Ontario government should:

- a) **Revise formulary/procurement policy to improve uptake of biopharma innovations, including drugs and novel medical diagnostics/devices.**
 - List more innovative drugs on provincial formulary (Ontario Drug Benefit Plan)
 - Reduce long time to listing (TTL) status
 - Set benchmarks and report progress on real time basis for Ontario formulary listings:
 - percentage of new products listed
 - TTL
- b) **Provide incentives to build bio-manufacturing facilities in Ontario, including local marketplace incentives.**
- c) **Evaluate and adopt international Best Practices to support a dynamic biopharmaceutical industry.**
- d) **Promote Ontario as a venue for biopharmaceutical activities (trade missions, networking and branding activities) in partnership with existing local programs and participants.**



4

Provide tax incentives to attract domestic, foreign and venture capital investment in Ontario

e) Work with federal government to reduce regulatory barriers to commercialization:

- Revise patent act to create a globally competitive environment for IP protection and enforcement.
- Streamline Health Canada review of new drug submissions to support an internationally competitive regulatory environment.

To leverage tax incentives in attracting and retaining new business investment and in sustaining a highly qualified provincial labour force to support Ontario's health innovation industries, the provincial government should:

- a) Consider changes to enhance provincial SR&ED tax incentive programs, providing additional and/or accelerated refunds of tax credits to businesses that establish biopharmaceutical facilities in Ontario.**
- b) Consider personal income tax reduction for international workers (e.g. during first 2 years in Ontario).**
- c) Consider flow-through shares for investors in Ontario-based biopharmaceutical companies (as is currently permitted for oil and gas companies), allowing certain tax deductions for qualifying expenses to “flow through” to the company's shareholders.**
- d) Work with federal government to:**
 - Review and enhance Ontario regulation regarding creation of pools of venture capital, with emphasis on early stage financing.



Executive Summary



Executive Summary

1. Introduction

The purpose of this paper is to present a business case as to *why* the Ontario government - through the new Ministry of Research and Innovation (MRI) - should support the broadly-based biopharmaceutical sector in its efforts to develop and execute a comprehensive life sciences strategy. By providing key recommendations, this report also attempts to answer the question of *how* the provincial government can encourage increased R&D investment and create supporting mechanisms for continued growth in this burgeoning sector.

The BCO is a nonprofit organization which acts to advise government on all public policy issues facing the life sciences industry and to advocate on behalf of the industry in Ontario. From its first biotechnology strategy tabled in 1994, the current BCO represents the evolution of more than a decade of work to advance the industry in the Province, including detailed consultation with industry, academia, key regions, and government. Operating under the key principles of inclusiveness and integration, the Council is open to all life sciences stakeholders in the Province, with the goal of fully integrating the interests of groups that span its geographic and functional boundaries.

Broadly speaking, life sciences encompass the fields of biotechnology, pharmaceuticals, biomedical diagnostics and devices, life systems technologies, animal health, agriculture, nutraceuticals, food processing, bioinformatics, and the environment. Within the human health sector, the focus of this report, the biopharmaceutical segment promises major social and economic benefits; its medicines, vaccines and other health-related devices and products have already helped to treat patients with many diseases and have improved their life expectancies. For the purpose of this report, the term “biopharmaceutical” is intended to represent the interface of a continuum, including both biotech and pharmaceutical firms (as well as their innovative health products) that are based on advances in biotechnology.

It is anticipated that biopharmaceutical technologies will lead to health innovations that are so extensive and pervasive in their application, or so powerful, that they will change the fundamental nature and direction of the health system. As a key transformative platform, biotechnology has been touted as the next big “shock”, with future advances expected to generate revolutionary change that will permeate the entire economy.



Many reports have documented Ontario's strengths in the biotech sector, with several examples and success stories presented in the supporting documents that accompany this report (provided upon request). Ontario is indeed in the midst of a tidal wave of scientific advances based on biotechnology; the Province has the potential to be a major player in this global marketplace.

2. Historical Overview

To provide historical perspective, previous provincial governments over the past two decades have increasingly acknowledged the importance of the biotechnology sector as a key driver of economic growth and job creation, with the need to coordinate discrete initiatives in industrial policy as parts of an integrated provincial innovation system. Essentially, Ontario government programs approved under provincial leadership during the period 1995-2003 stemmed from, and expanded upon, the nascent programs initiated much earlier by the previous Ontario governments. As the Ontario government strategy in the late 1990's significantly reinforced the initial foundation for accelerating biotechnology development, it continued to place emphasis on expanding the highly qualified labour force and investing in R&D to support knowledge-based industries, underscoring the need to cultivate and sustain an innovation culture. Similarly, the Biotechnology Cluster Innovation Program (BCIP), as originally announced under the previous government in 2003, eventually culminated in the development of 11 regional biotechnology consortia - known as Regional Innovation Networks (RINs) - under the current government.

Since the October 2003 election, the current government has announced several pivotal new initiatives to build on this positive momentum and to advance a thriving biopharmaceutical sector. Key among these has been the creation of the Ministry of Research and Innovation, led by Premier Dalton McGuinty, signaling the provincial government's unwavering commitment to research-intensive industries. As the biopharmaceutical (and more broadly, the life sciences) sector is now beginning to flourish under the recent wave of provincial government support, the current government has strategically positioned this sector to rise to the next level of success. The life sciences sector is currently poised to leverage Ontario's research capacity in achieving an international level of excellence, permitting competitiveness in world markets.



3. Advancing Ontario's Innovation Mandate

In his role as Minister of Research and Innovation, the Premier has announced two major goals: to support the process of innovation; and to create a culture of innovation. Given the priority the Premier has placed on developing an innovation agenda for the Province, and in continuing to reinforce the groundwork already laid by previous governments, this report aims to provide an analysis and recommendations for the broadly-based biopharmaceutical sector, specifically through the lens of innovation. Hence in building the business case to support the Ontario government's focus on this sector, it must be emphasized that biopharmaceutical technologies fit well within Ontario's MRI mandate. In fact, the health innovation industries - primarily biotechnology, pharmaceuticals and medical devices - collectively represent our country's largest investor in R&D as a research-intensive platform for growth.

Arguably, the health innovation industries also represent Ontario's best chance to compete successfully with other jurisdictions in the *new* global economy; one that is currently driven by knowledge, ingenuity and human capital as primary resources. This is critically important for Ontario, which is not endowed with the lucrative natural oil and gas commodities that help sustain other provincial economies. In contrast, Ontario's human capital and creativity are non-depletable, with enormous innovation and growth potential, particularly in the context of Ontario's strong education sector. In addition, as the Canadian dollar continues to surge, exceeding 90 cents U.S. by June 2006, many of Ontario's other leading sectors have suffered severely, including factory-based, manufacturing and exporting industries. Thus while the health innovation industries are poised to deliver vital goods and services for which global demand continues to escalate, they also represent an excellent fit for Ontario in positioning itself as an emerging leader on the supply side of the new knowledge-based economy.

While there is general consensus to support biopharmaceuticals as enabling, innovative technologies, one fundamental concern raised by governments has been that many of these products are anticipated to be expensive. Given that governments already face dramatically rising health care costs, these factors beg the critical question: How can new innovative technologies be accommodated, while sustaining the current provincial health system? Current spending on health care in Ontario is estimated to account for approximately 50% of the provincial budget, with future health spending expected to rise more rapidly than in the past, driven primarily by the aging "baby boomer" segment. Increasingly



however, arguments have been put forward to support the generation of economic wealth through biopharmaceutical innovation.

Dr. Henry Friesen, a pre-eminent Canadian thought leader, suggests that our health innovation sector should be considered as an “engine of economic growth that will contribute greatly to a sustainable health care system”. He believes that linking Canada’s health innovation and economic strategies will lead to national gain, providing substantial benefits to both sectors. His thinking has led to a pan-Canada, multi-stakeholder initiative known as CHIP (Canadian Health Industries Partnership). Ontario is supportive of the CHIP model in creating such a mechanism for collaboration and has nominated the Deputy Minister of Research and Innovation as Ontario’s representative.

As a key driver of future prosperity, biopharmaceutical innovation is already providing economic benefits in terms of increased numbers of viable companies, job creation, higher incomes, and enhanced competitiveness. These positive economic outcomes will augment a robust tax base - hence generating greater revenue for the Province to reinvest in social programs. To evaluate the more mature “big pharma” sector first, twenty-seven member companies of Canada’s Research-Based Pharmaceutical Companies (Rx&D) are located right here in Ontario. It is noteworthy that Rx&D members now directly employ 9,000 Ontarians, and are responsible for generating 25,000 additional indirect jobs. Together, these companies have contributed approximately \$2 billion annually to Ontario’s economy, making the Province a major centre for pharmaceutical research and development. It is particularly commendable that big pharma players have reinvested \$550 million in research and development in Ontario in 2005, representing the largest R&D investment across all provinces. Of this investment, over \$90 million has been directed towards university- and hospital-based research in 2005. While capital investment in Ontario by key pharmaceutical players has been substantial to date, these companies have also made significant contributions to provincial corporate taxes.

With regard to the emerging biotechnology sector, Ontario is home to over 140 of Canada’s biotech firms, employing over 8,000 people - approximately one third of the national biotech employment total. Based on the number of biotech companies, Ontario has recently been identified as the third largest biotech region (by state/province) in North America, trailing only California and Massachusetts. Ontario’s public biotech companies alone account for over 2,500 jobs, with over \$291 million reinvested in R&D in 2005; this corresponds to 34% of the annual R&D spend in Canada’s biotech sector. It has been argued that if Ontario currently makes relatively small investments in R&D and



commercialization, the Province will reap huge benefits within 10-15 years as the smaller companies built on those technologies begin to generate significant tax revenues. It may also be pertinent to speculate that if Ontario is successful in producing even one “mega company”, such as US-based Amgen, this would generate an exponential increase in provincial tax revenues. For perspective, Amgen was ranked as the largest biotech company in the world as of February 2006, with revenues exceeding \$US 10 billion in 2004 - almost double its revenues reported in 2002.

In evaluating the benefits of job creation from a broader perspective, recent U.S. data indicates that for every direct job created by the bioscience sector (including the biopharma, devices, medical research, and agricultural subsectors), the total increase in number of indirect jobs across all supporting service sectors is 5.7. This is known as the “direct-effect employment multiplier”. Hence a strong biopharma sector has both direct and indirect benefits that can substantially contribute to a region’s general economy, also bolstering personal income tax revenues. Dr. Friesen argues that future changes based on biotechnology have the potential to turn Canada’s annual health care trade deficit of ~\$8 billion into a trade surplus, thereby helping to address sustainability issues. Overall, by increasing the proportion of Canada’s investment capital in the life sciences, and by aggressively marketing Canadian innovations to other countries, this should assist in repatriating jobs, improving the balance of payments and adding billions of dollars annually to the Canadian economy. Parallel provincial strategies would also be expected to have a strong economic benefit for all Ontarians, while producing a net fiscal benefit for the government of Ontario.

Given adequate investment and government support, the Ontario’s biopharmaceutical sector also promises to deliver other positive economic outcomes to advance the Province’s innovation agenda. For example, a vibrant biopharmaceutical industry is anticipated to be instrumental in attracting new business, as well as additional domestic and foreign investment, to Ontario. A healthy, growing biopharmaceutical sector would also boost the Province’s efforts to attract and retain a highly skilled, knowledge-based work force, particularly in expanding other areas of the life sciences sector. Cross-fertilization of human capital among life sciences organizations - believed to be instrumental in accelerating discovery and innovation processes - would in turn be facilitated by increasing the size and quality of the provincial labour force base.

It is well acknowledged that a thriving pharmaceutical sector is one of the largest drivers in supporting a burgeoning biotech sector as an extended



“innovation arm”. In Ontario, as for other provinces, pharmaceutical companies have been a major source of funding for biotech firms, via basic or clinical research collaborations, licensing or other strategic agreements, and also through outright acquisitions. Sizable Canadian pharma-biotech deals are now being struck, as it becomes more fully recognized that synergies between pharmaceutical and biotechnology firms are not only advantageous, they are increasingly essential for corporate survival. In 2005, the U.S. biotechnology industry raised more than \$15 billion in partnering capital (in addition to \$17 billion through other financings) and analysts predict even more and larger partnering deals in 2006, with an emphasis on discovery-stage deals. Overall, pharma is now aggressively using buyout and partnership deals to gain access to drug candidates to fill the pipeline at all stages of product development, as part of portfolio management. Hence in general, government support for the pharmaceutical sector can provide significant economic benefits for the biotechnology sector, which in turn can facilitate the advancement of Ontario’s innovation agenda.

Another key avenue for biopharmaceutical companies to help drive Ontario’s innovation agenda is in the area of clinical trial research. Clinical research represents a central, crucial process in the development of innovative products to treat and improve the lives of Ontario residents. At the forefront of this research, Rx&D member companies have already enrolled over 40,000 patients in clinical trials in Ontario alone, and biotech companies have also conducted multiple early and late-stage clinical trials. Through the conduct of such clinical research, patients benefit from early access to novel therapies, as well as additional clinical monitoring. In addition, all Canadians benefit from acquired knowledge and collective advances in bench-to-bedside expertise of researchers, physicians and regulators in the study of new medicines. Clinical research also helps to propel job creation; trials conducted by Rx&D companies have supported employment of roughly 38,000 researchers and clinicians in Ontario.

4. Driving Ontario’s Health & Industrial Policy

As highlighted above, a well-supported biopharmaceutical sector holds the promise of enhanced employment, tax revenues, new business and clinical trial development. In addition to driving the Ontario’s innovation agenda in these key areas, investment in this sector may also help to advance the provincial health mandate by reducing health care costs overall. Typically, provincial policies concerning public drug benefit coverage of innovative medicines or diagnostics/treatments are aimed at



controlling acquisition costs, without considering the potential value of such novel therapies in terms of cost-savings in other government-funded programs. However, many new medicines and their associated disease management programs have untapped potential in reducing overall health care system costs, particularly by reducing the number of surgeries and/or hospital stays, while also enhancing patient health status.

According to Frank Lichtenberg, Professor of Business at Columbia University, the use of newer medicines (versus older medicines) saves up to \$7-8 for every dollar invested. Consistent with the main thrust of Lichtenberg's research, several other disease management studies in the areas of cardiovascular (CV) disease, diabetes, depression, peptic ulcer, and asthma - diseases that are most prevalent amongst Ontario Drug Benefit recipients - have demonstrated return on investment rates between 119% and 300%. Another compelling illustration of the impact of using innovative medicines over the past two decades has been the significant decline in hospitalization rates (per 100,000 population) for Canadian patients with ulcers (75%), AIDS/HIV (71%), diabetes (44%), respiratory disease (44%) and chronic liver disease (31%).

The power of reducing hospitalization rates must not be underestimated, particularly in the context of aligning innovation and health strategies. At present, the Ontario Drug Benefit Plan accounts for \$3.4 billion per year, approximately 10% of Ontario's health budget. However, the remaining 90% of the provincial health care budget is currently devoted to hospital expenses, physicians and nurses, as well as rehabilitation and homecare costs, and overhead administration. Hence by preventing patients from entering the hospital system through the use of innovative medicines, potential cost savings may be highly significant overall. In essence, with greater commitment and investment in bringing new biopharmaceuticals to market, the Ontario government has the opportunity to swing the balance of health costs away from expensive hospital-based care. Key pressing questions for the government to consider include the following: Without continued development of innovative medicines, how could the high costs of hospital-based care be adequately managed? In addition, how would the government efficiently deliver community care without future advances in innovative biopharma products and devices? Significant research efforts will be required in these areas to guide future health care policy.

Several large Canadian disease management programs have recently demonstrated great potential to reduce overall health care costs, i.e. by investing in evaluation, as well as in improvement and education, of best clinical practices - including the use of innovative medicines. Major public-private (or private only) sector partnerships include GlaxoSmithKline's



PRIISME™ initiative, Merck's ICONS study, the Pfizer/DaimlerChrysler "Tune Up Your Heart" program, and AstraZeneca Canada's REMEDY™ system. In particular, these programs have demonstrated significant reductions in hospitalization (or readmission) rates and emergency room visits, and thus in overall health care costs, through appropriate management of chronic conditions, including asthma, diabetes, and cardiovascular disease. Decreased costs in these key areas mean savings to the bottom line - savings that can be reinvested in the health care system and ongoing innovation. Fewer disability leaves and lower workplace absenteeism rates also contribute to a healthier, more productive work force.

In the U.S., results of the recent Pitney Bowes workplace disease management study have demonstrated that for diabetes patients, improving access to pharmaceuticals by enhancing prescription benefits can reduce pharmacy and overall costs. The decrease in costs for employees with diabetes is believed to result from a reduction in complications, and in turn, the avoided need for other even more expensive drugs. In the future, as more of the North American population is diagnosed with asthma, diabetes and CV disease, and as the workforce continues to age, cost pressures associated with managing these chronic diseases are anticipated to build even more intensely. For policy makers aiming to address these issues, the Pitney Bowes project appears to serve as a promising preliminary model. In Ontario specifically, additional budget should be assigned to the Ministry of Health, recognizing that required growth in the provincial drug budget (driven by emerging disease trends and the aging population) will contribute to both cost savings and improved health status through appropriate chronic disease management.

Apart from the economic benefits of implementing appropriate chronic disease management programs, other cost savings may be achieved through investment in novel biopharmaceutical technologies. For example, DNA-based diagnostics to detect pathogens are expected to be powerful tools for real time analysis, thereby reducing the spread and concomitant cost of infectious disease. The need for research in this area is further underscored against the backdrop of increased global travel, escalating the risk of disease migration, including avian influenza. Current evidence is highly encouraging however, suggesting that for every dollar invested in infection control - as a key strategy to attack health care costs - the return on investment is at least \$5 to \$7. Other biotech-based tests involving simple blood sample analysis, e.g. to diagnose prostate and ovarian cancer, can also eliminate the need for invasive and costly surgery, thereby reducing the potential cost of hospital stay, including the risk of post-operative infection.



Another recent focus for helping to reduce the strain on health care systems is the consumer-targeted approach of health promotion, i.e. by promoting the consumption of fresh fruits and vegetables to “maintain wellness”, rather than to “treat illness”. The main thrust of a new Ontario Agri-Food Technologies promotion will be to change consumer behaviour to prevent disease (and substantially lower or ultimately avoid treatment costs), with potentially far-reaching benefits for the Ontario economy. As advances in biotechnology continue to reveal key mechanisms underlying chronic illnesses (such as cancer, CV disease and obesity), the role of fruit- and plant-derived nutrients in attenuating such diseases will become better understood. Hence Ontario’s investment in research in biotechnology today should contribute to success in “maintaining wellness” and improving the overall health status of this province in the future.

At present, the Ontario government is urgently seeking solutions to temper health care costs, while balancing the need to provide safe, quality care. In the context of developing consistent provincial innovation and health care policies, investment in biopharmaceutical products must be viewed as a potential solution in offsetting rising health care costs, as driven by aging populations and emerging disease trends. While additional studies must be conducted to demonstrate additional economic benefits associated with biopharma innovations, net savings are expected to be significant. It is encouraging that the Ontario government, as part of Bill 102 Legislation (the Transparent Drug System for Patients Act, 2006), has recently announced its plan to invest in innovative health system research by establishing a \$5 million Innovation Research Fund. This funding will assist in investigating the value of medicines across the entire health system - taking a holistic view of the broad impact of new therapies - to support Ontario’s future drug policy. It is anticipated that results of this future research, taken together with data from currently available studies, will provide further motivation for fuelling the innovation cycle.

Overall, by investing in leading-edge biopharma technologies, the Ontario government can contribute to cost containment within - and hence sustainability of - the provincial health care system. Savings could then be redirected within the health care system in areas of priority need. For example, since increased investment and expenditure on the provincial drug budget are anticipated to reduce the number of surgeries and/or hospital stays, this will help to directly alleviate hospital waiting times. Net fiscal savings could also be reinvested to support the high-profile “Ontario Wait Time Strategy”, or other provincial programs to facilitate patient access, including the management of the 14 new Local Health Integration Networks (LHINs). Alternatively, net savings within the health care system



(which currently consumes 46% of the provincial budget) could also be deployed to enhance other provincial programs, e.g. within the ministries of Education, Transportation, or the Environment. In this way, Ontario's innovation and health strategies could also be aligned with the Province's broader industrial policy.

5. How the Ontario Government Can Support the Biopharmaceutical Sector

The biopharmaceutical sector promises major benefits, both in terms of driving Ontario's innovation agenda (by creating wealth via new companies, jobs, tax revenues, and innovative products), and in advancing the provincial health agenda (by providing cost savings through disease management programs, enhancing patient health status and work place productivity). Having established a firm business case regarding *why* the Ontario government should nurture and support this dynamic sector, it becomes pertinent to direct our attention to *how* this can be achieved.

Previously, the BCO's policy platform was based on the *OnTRAC* benchmarking framework, which identified four primary drivers of the biotechnology business model, including: Ontario's **T**alent and human resources; **R**egulatory and legal environment; **A**lliances and strategic partnerships; and **C**apital access issues. This framework, first proposed in 2003 and further refined in 2004, emphasized these key elements of public policy as a means of communicating the pathways by which the Ontario government could support the industry to optimize productivity and growth. There is excellent consensus across many studies that Ontario (like Canada) still faces an "innovation gap", and several analyses, including the BCO *OnTRAC* model, concur with regard to the major themes that need to be addressed. In general, many reviews of the biotechnology sector include a variety of metrics to indicate the level of maturity and stability that has been reached within this industry in the past few years. Typically, while such metrics are used for benchmarking purposes, they are also used as incentives to attract further investment and partnering activities in fuelling a steady stream of unique new therapies.

A key drawback in implementing and analyzing success metrics in the biopharma sector is that the vast majority of measures do not focus adequately on the commercialization and delivery of health care products as the final "end-game". Thus, while measures such as the number of



companies or jobs, venture capital financing, government funding, and R&D spending are often touted as measures of success, they should be more modestly considered as intermediate measures. Such intermediate measures should therefore be viewed as *necessary*, but *insufficient* conditions for ultimate success in this sector. Returning to the broader goals for research in this sector - namely to advance innovation and health strategy - there appears to be a need to develop a sharper set of metrics that are tied more directly to commercialization and health care delivery, more clearly articulating (and rewarding) return on investment. To further identify benchmarking trends and gaps, a new framework is presented in the supporting documents that accompany this paper. This framework partitions commonly cited metrics into four sequential categories, based on: 1) resources, 2) productivity, 3) commercialization, and ultimately, 4) health care delivery.

In evaluating its current success in supporting the biopharmaceutical sector, the Ontario government must acknowledge that the local business environment may not be enabling optimal commercialization and growth. Thus, in developing future policy for the life sciences, the provincial government must work hard to understand and remove any barriers to innovative research that may result in the stagnation or contraction of the local industry. Overall, in putting forth recommendations to help shape future policy, we must ask the critical question - how can Ontario's current innovation culture be improved?

If Ontario is to compete successfully with other provinces and countries, primarily the US and the UK, then the Province's life sciences sector will need to operate within a regulatory, legislative and policy framework that is competitive and conducive to increased R&D investment and its commercial exploitation. Building on its many strengths, Ontario needs to more aggressively foster an "innovator-friendly" environment by enhancing the attractiveness of local market conditions, i.e. by enhancing investment and tax incentives, and by reducing regulatory barriers to commercialization.

Interestingly, results from a 2006 PriceWaterhouseCoopers survey provide valuable insight regarding competitive positioning within the life sciences sector. A key finding of this forecasting study is that Canada stands to lose an astonishing 48% of its life sciences and biotech businesses (by relocating all or part of their business outside the country), if a more sustainable business environment is not established. However, respondents also indicated that governments can take a number of positive steps to influence this decision process. For example, more than 80% of respondents ranked the creation of more favourable corporate tax incentives in their top 3 choices. Increased funding of companies and



improved speed of the regulatory process followed as second and third choices (44% and 41% respectively).

With regard to Ontario specifically, these data suggest that government support in terms of improving tax incentives, encouraging capital investment, and enhancing opportunities to market biopharmaceutical products within the Province will likely play a critical role in the future well-being of the Province's life sciences industry. The identification of these key success factors also demonstrates strong overlap with (and hence support for) the recommendations put forward in this report. Furthermore, and more generally, the PwC survey results speak to the urgent need for constructive economic, health and industrial policy that will influence biopharma companies to stay within Ontario and Canada.

As alluded to above, Premier McGuinty, in his capacity as the first Minister of Research and Innovation, has carefully reinforced the foundation laid by previous provincial governments to advance the biopharmaceutical industry, i.e. by nurturing education and funding additional research capacity. At present, Ontario's thriving life sciences sector is now poised to seek world-class regional status. Clearly, much work remains to be done, with a sharper future focus, including the creation of appropriate incentive structures for innovation, continued high investment in R&D, and adapting government infrastructure to optimize commercialization.

Now, in considering the recommendations proposed by the BCO in this 2006 report, the current government will be challenged to implement additional programs to augment Ontario's leadership position in the life sciences industry - acknowledging innovation not only as a key driver of high-value jobs and future economic prosperity, but also as essential force in improving quality of life for Ontario families. Increased government investment in the latest innovative therapies will ensure patient access to leading-edge technologies that enable optimal health and productivity outcomes, while simultaneously contributing to cost containment within the provincial health care system. Finally, in developing a life sciences innovation strategy as a primary driver of the Province's economic and health agendas, the Ontario government has an excellent opportunity to align industrial policy with a sustainable economy.



Summary of Ontario Bio-Industry Position Papers



Summary of Ontario Bio-Industry Position Papers

Date	Committee & Chair	Report Title	Lead Author	Industries/ Scope	Outcome
1994	'Original' BCO (Graham Strachan)	Enabling Biotechnology: A Strategic Plan for Ontario	Lorne Meikle	Biotech (industry consultations/private meetings)	Recommendations submitted to government
1998	Biotechnology Task Force (Graham Strachan)	Ontario Biotechnology Task Force Report	Gord Surgeoner	Biotech (industry consultations/private meetings)	Recommendations submitted; several recommendations approved & executed
2002	BIOCouncil Ontario (Joseph Rotman)	Building Ontario's Biotechnology Corridor	Joseph Rotman	Biotech (industry consultations/private meetings)	Recommendations submitted; several recommendations approved & executed
2003	BCO (Dale Patterson)	Getting OnTRAC: Benchmarking Ontario's Biotechnology Sector	Kamal Gautman & Brian Gordon	Biotech (province-wide assembly; first event)	Industry consensus reached at BCO-hosted Public Policy Workshop and submitted to government
2004	BCO (Dale Patterson)	The Commercialization Agenda, Policy for the Ontario Biotech Industry, Final Report, 2004	Steven Ilkay	Biotech (province-wide assembly; second event)	Proceedings published from the first formal BCO Public Policy Forum and submitted to government
2006	BCO Working Committee 2006 (Dale Patterson)	Investing in the Life Sciences Sector: A Proposed Strategy for Innovation in Ontario	Nora Cutcliffe	Life Sciences (province-wide broadly-based biotech and life sciences industry consultation)	Comprehensive Life Science Implementation Strategy submitted to government August 2006

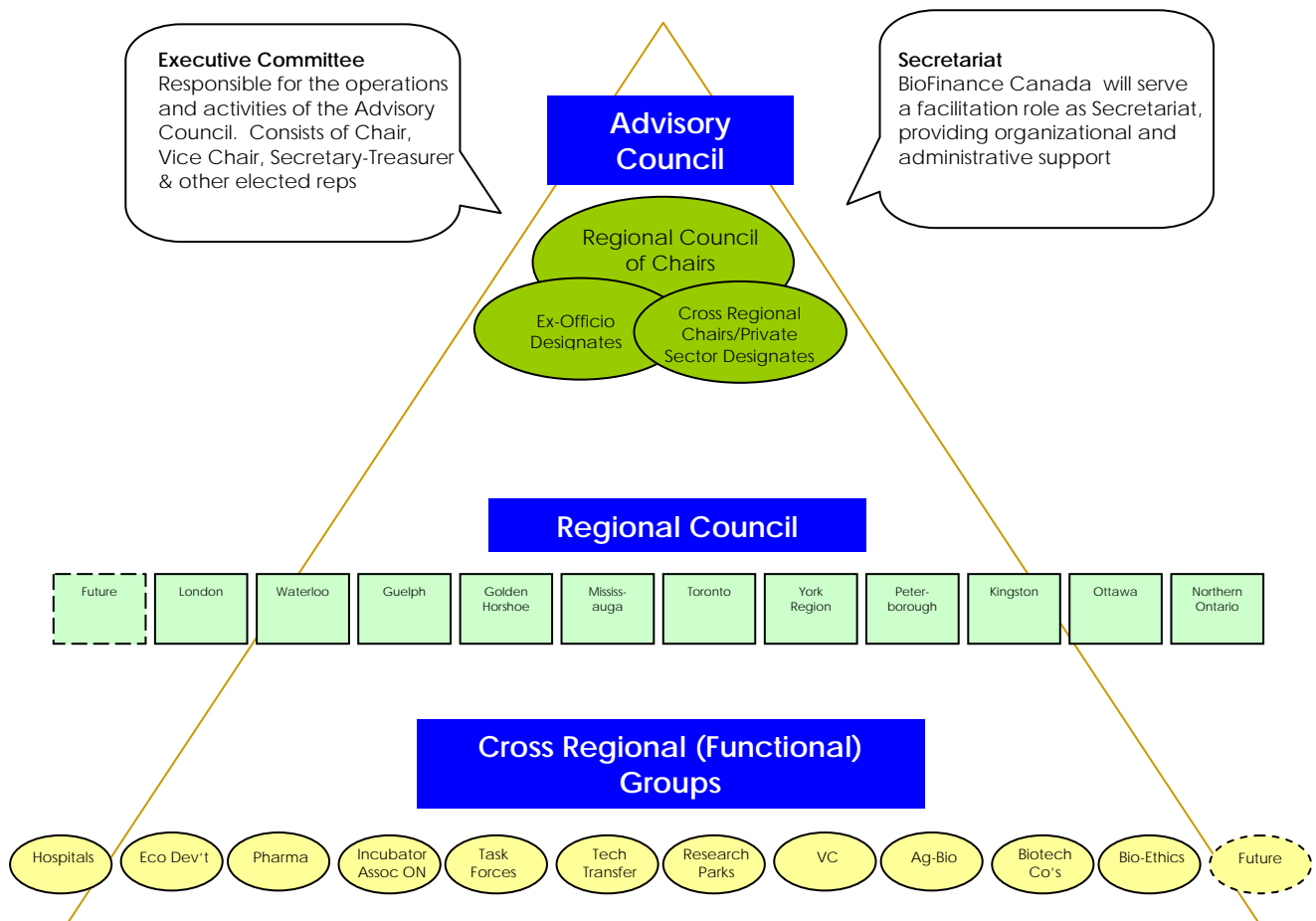


BCO Organizational Structure



BCO Organizational Structure

BIOTECHNOLOGY COUNCIL OF ONTARIO: ENVISIONED ORGANIZATIONAL STRUCTURE





Biotechnology Council of Ontario
PUBLIC POLICY FOR LIFE SCIENCES

BCO Working Committee 2006



BCO Working Committee 2006

Dale Patterson

Chair, Biotechnology Council of Ontario
Executive Vice President, Canadian Medical Discoveries Fund

Nora Cutcliffe

Consultant and Writer
BCO Life Sciences Strategy 2006

Tama Donoahue-Walker

Merck Frosst Canada Ltd.

Zenek Dybka

Canada's Research-Based Pharmaceutical Companies

Jeffrey Graham

Borden Ladner Gervais LLP

Gordon Jans

PricewaterhouseCoopers LLP

Sean Kelly

Pfizer Canada Inc.

Ken Lawless

Ottawa Life Sciences Council

Lisa Marsden

AstraZeneca Canada Inc.

Ross McGregor

Toronto Regional Research Alliance

Lorne Meikle

Toronto Biotechnology Initiative

Allan O'Dette

GlaxoSmithKline Inc.

Walter Robinson

Canada's Research-Based Pharmaceutical Companies

Michael Stinson

BioFinance Canada

Aimee Sulliman

Pfizer Canada Inc.

Gordon Surgeoner

Ontario Agri-Food Technologies

Grant Tipler

RBC Royal Bank

Ross Wallace

MaRS Discovery District

Matt Buist

City of Toronto



Biotechnology Council of Ontario
PUBLIC POLICY FOR LIFE SCIENCES

VOLUME 2

**Investing in the Life
Sciences Sector:
A Proposed Strategy
for Innovation in
Ontario**

SUPPORTING DOCUMENTS

Biotechnology Council of Ontario
MaRS Centre, Heritage Building
101 College St., Suite 120-C
Toronto, Ontario M5G 1L7
Tel: 1-866-342-4933
www.biocouncilontario.com

AUGUST 2006



VOLUME 1 Table of Contents

Letter to the Premier	4
BCO Recommendations	7
Executive Summary	13
1. Introduction.....	14
2. Historical Overview	15
3. Advancing Ontario’s Innovation Mandate	16
4. Driving Ontario’s Health & Industrial Policy	19
5. How the Ontario Government Can Support the Biopharmaceutical Sector	23
Summary of Ontario Bio-Industry Position Papers	26
BCO Organizational Structure.....	28
BCO Working Committee 2006.....	30



VOLUME 2

Table of Contents

Appendix 1 - Introduction & Backgrounders	4
1.1 Introduction.....	5
1.2 Backgrounder: Biotechnology Solutions for Health & Everyday Living	7
1.2.1 Solutions for Health.....	7
1.2.2 Solutions for Everyday Living	8
1.3 Backgrounder: Ontario's Success Stories.....	9
1.4 Backgrounder: The Canadian Biopharmaceutical Industry.....	11
1.4.1 Pharmaceutical/Biopharmaceutical Sector	11
1.4.2 Biotechnology Sector	13
1.4.3 Medical Device Sector	16
Appendix 2 - Historical Overview.....	18
Appendix 3 - Advancing Ontario's Innovation Mandate	23
3.1 Biopharmaceutical Technologies Fit Within the MRI Mandate.....	24
3.2 The Threat of Unsustainability	25
3.3 Potential Solutions Provided by Biopharmaceutical Innovation.....	26
3.4 Life Sciences Clusters	33
3.4.1 Definitions and Key Elements of Clusters	33
3.4.2 Global Life Sciences Competition: Where does Ontario fit?	35



VOLUME 2 Table of Contents

Appendix 4 - Driving Ontario's Health & Industrial Policy.....	41
<i>4.1 Improved Disease Management</i>	42
<i>4.2 Other Biotech-Based Approaches</i>	51
<i>4.3 Maintaining Wellness (Disease Prevention).....</i>	53
<i>4.4 Opportunity Costs</i>	54
<i>4.5 Other Factors Affecting Health Care Costs.....</i>	55
<i>4.6 Summary</i>	56
Appendix 5 - How the Ontario Government Can Support the Biopharmaceutical Sector	58
<i>5.1 Success Metrics, Trends and Gaps</i>	59
<i>5.2 Limitations of Data Collection for Success Metrics</i>	63
<i>5.3 Enhancing Ontario's Culture of Innovation as a Basis for Commercial Success</i>	64
Appendix 6 - Summary of Ontario Bio-Industry Position Papers	68
Appendix 7 - BCO Organizational Structure	70
Appendix 8 - BCO Working Committee 2006	72



Appendix 1

Introduction & Backgrounders



Appendix 1 - Introduction & Backgrounders

1.1 Introduction

The purpose of this paper is to present a business case as to *why* the Ontario government - through the new Ministry of Research and Innovation (MRI) - should support the broadly-based biopharmaceutical sector in its efforts to develop and execute a comprehensive life sciences strategy. This report also attempts to answer the question of *how* the provincial government can encourage increased R&D investment and create supporting mechanisms for continued growth in this burgeoning sector; key recommendations are presented with the accompanying Executive Summary. [Note that the Appendices presented here, in this series of supporting documents, follow the same sequence as the main headings of the Executive Summary report.]

The BCO is a nonprofit organization which acts to advise government on all public policy issues facing the life sciences industry and to advocate on behalf of the industry in Ontario. From its first biotechnology strategy tabled in 1994, the current BCO represents the evolution of more than a decade of work to advance the industry in the Province, including detailed consultation with industry, academia, key regions, and government. Operating under the key principles of inclusiveness and integration, the Council is open to all life sciences stakeholders in the Province, with the goal of fully integrating the interests of groups that span its geographic and functional boundaries. Appendix 6 provides an overview of the BCO's historical involvement in submitting BIO-industry papers and recommendations to the Ontario government since the early 1990's. Details of the BCO's organizational structure are presented in Appendix 7. Participants of the 2006 BCO Working Committee, including representation from a broad group of life sciences companies and organizations, are presented in Appendix 8.

Broadly speaking, life sciences encompass all research disciplines that contribute to the understanding of life processes, including plants, animals and human beings. Collectively, life sciences span the fields of biotechnology, pharmaceuticals, biomedical technologies, life systems technologies, nutraceuticals, food processing, biomedical devices, bioinformatics, and the environment.

Central to the life sciences, biotechnology has been defined differently to convey various meanings across various audiences and jurisdictions. In the simplest terms, if we break biotechnology into its root words, we have "bio" - the use of biological processes; and "technology" - to solve problems or make useful products¹. Another commonly accepted definition, including global acceptance, comes from Statistics Canada:

Biotechnology involves the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services².

¹ BIO 2005-2006, Guide to Biotechnology, Biotechnology Industry Organization, www.bio.org

² Biotechnology Use and Development Survey: Methodology, Issues and Responses, Statistics Canada, Feb. 2004.



The greatest impact of biotechnology to date, both in Canada and worldwide, has been in health care, including the development of novel biopharmaceuticals, diagnostics and devices. As of the year 2000, more than 90% of the advanced biotechnology products on the world market were health-related, and it is expected that about 75% of world biotechnology demand will continue to be in the health sector.³

This document focuses primarily on the enhancing the commercialization of human health care applications of biotechnology in Ontario. Within the health sector, the biopharmaceutical segment promises major social and economic benefits - its medicines, vaccines and other health-related devices and products have already helped to treat patients with many diseases and improved their life expectancies. For the purpose of this report, the term “biopharmaceutical” is intended to represent the interface of a continuum, including both biotech and pharmaceutical firms (as well as their innovative health products) that are based on advances in biotechnology. This report also touches briefly on other novel biotech applications, including examples in animal health, food processing, agriculture, and the environment.

In general, this document aims to provide an analysis of the biopharmaceutical sector through the lens of innovation, i.e. to provide added value within the context of Ontario’s Ministry of Research and Innovation mandate. Hence it is also useful to define innovation itself. The following is one of the many definitions of innovation that have recently been put forward:

Innovation is a process through which economic or social value is extracted from knowledge through the creation, diffusion and transformation of ideas to produce new or significantly improved products or processes⁴.

In terms of biotechnology’s potential to drive innovation processes, some experts contend new biotechnology tools will lead to health innovations that are so extensive and pervasive in their application, or so powerful, that they will change the fundamental nature and direction of the health system and/or of professional practice - in other words that they are “transformative⁵.” As a transformative technology, biotechnology is expected to serve as a platform for profound changes in both health care and economics that we are only beginning to imagine or comprehend.

Today, we can easily look back on the industrial revolution, with the internal combustion engine and electricity, and agree that these technological advances fundamentally changed our lives, our productivity, and our economy. Although hindsight makes this very easy to acknowledge, the long term impact was not as obvious at the early stages of the transformation. Hence if we accept that biotechnology is also a transformative technology that will have a huge economic impact over the next couple of decades, then we should collectively be working hard to make

³ Canada’s BioPharmaceutical Industry: Open for Global Business, V. Gupta, DFAIT, Oct. 4, 2000.

⁴ Conference Board of Canada, Biotechnology in Canada: A Technology Platform for Growth, Dec. 2005.

⁵ Biotechnology and Health Innovation: Opportunities and Challenges, A Discussion Document from the Canadian Biotechnology Advisory Committee (CBAC), March 2004.



our politicians and leaders understand what is at stake⁶. In addition, biotechnology has recently been touted as the next big “shock”, bringing revolutionary changes as profound as the computer⁷. It is anticipated that once the world has devised ways to incorporate biotech as it permeates the entire economy, a “payoff” or global boom will be the reward.

“Why does it matter that we enable biotechnology? And the answer... is that this is a transformative technology, a technology that is going to change everything. As much as steel or the steam engine or the computer, this is a strategically vital technology that will help determine the winners and losers in the global economy, while lifting quality of life in ways we're only beginning to imagine.”
James C. Greenwood, BIO President & CEO, 2005

Indeed, the purpose of this report is to provide an overview of the biopharmaceutical industry, with the goal of demonstrating that adequate provincial funding and support for this sector will be critical to our successful research and innovation pathways. These processes have the potential to generate products and services so new and exciting that we have great difficulty even imaging them today. These discoveries, in turn, hold the promise of creating wealth, raising our standard of living and enhancing the quality of life for Ontarians.

1.2 Backgrounder: Biotechnology Solutions for Health & Everyday Living

1.2.1 Solutions for Health

The first biotechnology medicine ever to be commercialized was recombinant human insulin, in 1982. Prior to that year, there were few options available for insulin-dependent diabetics who were allergic to insulin derived from animals. Recombinant insulin, known as one the “first generation” of biotech technologies involving recombinant DNA, is still saving lives today.

Since the early eighties, hundreds of millions of people worldwide have been treated with more than 200 biotechnology drugs and vaccines - this number of approved biotech medicines is up five-fold from 1995. There are currently more than 300 biotech drug products and vaccines in clinical trials targeting more than 200 diseases, and thousands more compounds and targets are in early-stage R&D⁸.

⁶ Are We Keeping Pace with the Knowledge-Based Economy? Brian Harling, BIOTECanada Conference, May 17, 2005, Toronto.

⁷ Richard Lipsey, Kenneth Carlaw & Clifford Bekar, Economic Transformations: General Purpose Technologies and Long Term Economic Growth, Oxford University Press, 2005.

⁸ James C. Greenwood, BIO President & CEO, Keynote Address: Enabling Conditions for Biotechnology, BioJapan 2005, September 7, 2005.



Cardiovascular disease is still the number one killer of adults in North America, although mortality rates are now declining, due in part to the introduction in 1987 of new biotechnology-based "clot buster" drugs that allow treating physicians to dissolve blockages causing heart attacks. The first drug approved in this class (tissue plasminogen activator) is now used to treat a stroke in progress, which may in turn reduce disability if this treatment is given quickly.

Biotechnology has advanced the treatment of cancer, particularly with the introduction of monoclonal antibodies that target specific receptors or cellular components in controlling the spread of breast cancer, leukemia, and colon cancer. A growing percentage of cancer patients are surviving and returning to good health, due to these biotech breakthroughs.

Vaccines against hepatitis B prevent the devastating liver damage that can lead to liver cancer. Hence these biotechnology-based hepatitis B vaccinations have been called "the first anti-cancer vaccine"⁹. In addition, biotechnology is responsible for hundreds of medical diagnostic tests, including the detection of the AIDS virus and home pregnancy tests.

New veterinary biopharmaceuticals have also enabled better disease treatment in animals, including anti-inflammatory drugs to treat arthritis or musculoskeletal pain. Other veterinary biotech products eliminate internal parasites, antibiotics are used to treat bacterial infections, and sedatives are used to calm animals during the administration of anesthesia.

What these biotech therapies all share in common is that they are based on biological substances or processes designed by nature, and they often rely on using the body's own tools for fighting infections and disease. These improvements in human and veterinary medicine are just a small sample of the benefits that biotechnology has already brought, and will continue to bring in the future. Other new products in advanced testing for human health include medications for HIV (both treatments and vaccines), sickle-cell disease, multiple sclerosis, psoriasis, macular degeneration and rare genetic diseases, just to name a few.

1.2.2 Solutions for Everyday Living

In addition to revolutionizing medical practice for human and animal health, biotechnology's impact extends to conventional manufacturing of everyday products, including paper, textiles, vitamins, plastics, detergents and dozens of other products. Biotechnology is rapidly replacing chemical technologies with cellular and enzymatic ones, thereby minimizing resource use and toxic pollution.

When you made coffee this morning, you probably didn't realize the filter was made with a biotechnology process that uses enzymes to bleach the paper, reducing the amount of chlorine and energy used in manufacturing.

⁹ Centers for Disease Control & Prevention, <http://www.cdc.gov/nip/publications/VIS/vis-hep-b.pdf>



With regard to biotech applications in food processing, the cornflakes we eat for breakfast are made with corn grown with fewer pesticides, due to the development of corn that is resistant to insects and disease. The bread in our toast contains natural biotech food enzymes that help the bread rise and keep it fresh. Biotech enzymes are also used to remove lactose from milk to help people who are lactose intolerant; they are also used in brewing beer and making cheese¹⁰.

In some cases, biotechnology can improve a food by removing an allergen. Scientists are working to isolate the specific proteins from foods (such as peanuts, shellfish, milk, soy, wheat or eggs) that trigger potentially fatal allergic reactions, i.e. with the goal of modifying such foods to eliminate the health risk.

As obesity rates continue to climb in Canada and other developed countries, biotechnology is helping to create a new generation of “trans fat free” oils from soybeans, canola and sunflowers. These oils should help to lower blood cholesterol levels in many Canadians, hence reducing their risk of heart disease. In addition, more than 70 percent of processed foods contain ingredients (such as oil and meal from soybeans, corn and cotton seeds) that have been improved through genetic alterations to improve disease and insect resistance. Biotech crops not only improve yields, cut costs and reduce pesticide use, they may also enhance quality of life for both farmers and consumers. As food and agricultural biotechnology applications have been gaining increased acceptance among consumers throughout the world, an enormous global milestone was reached just last year, when farmers planted the billionth cumulative acre of biotech crops in 2005.

Overall, recent advances in biotechnology have given rise to countless medicines, agricultural applications, as well as other products and devices to improve our health and enhance our everyday lives. These technologies have helped to reduce or eradicate many diseases and improve life expectancy. Collectively, they hold major promise for both social and economic benefits. In short, biotechnology is a health-oriented, environmentally friendly industry that is solving many of the problems that matter the most; it has the potential to transform vast swaths of the global economy¹¹.

1.3 Background: Ontario's Success Stories

Ontario's biotechnology industry was founded nearly a century ago, with the development of a landmark diphtheria antitoxin, and the Province has been recording one "first" after another ever since¹². Ontario is where the natural form of the hormone insulin was first discovered, helping to save the lives of countless diabetics. The T-cell receptor was also discovered in Ontario, allowing a better understanding of the fundamental immune processes involved in controlling chronic diseases.

¹⁰ Biotechnology Solutions for Everyday Life, www.bio.org

¹¹ James C. Greenwood, BIO President & CEO, Keynote Address: Enabling Conditions for Biotechnology, BioJapan 2005, September 7, 2005.

¹² <http://www.biotechontario.com/guides/overview.asp>



One of Ontario's key strengths in the biopharmaceutical industry has been the development and production of vaccines, which are widely accepted as effective therapies in helping the body recognize and fight infectious diseases. Ontario's vaccine research and business has been highly successful for over 25 years, including the development in the early 1990's of an acellular pertussis vaccine which is now recognized as a global gold standard¹³.

"PENTACEL™ ... (a combination vaccine) that provides protection to children as a single shot against five diseases - diphtheria, pertussis, tetanus, polio and Haemophilus influenzae type b meningitis - was developed right here in Toronto and is the envy of the world." Mark Lievonon, President, Aventis Pasteur Limited, 2004

More recently, Ontario has attracted additional international attention through Sanofi Pasteur's (formerly Pasteur Mérieux Connaught Canada) \$350 million investment in an international cancer vaccine program, based in Toronto¹⁴. This program has led to vaccine candidates now in clinical trials for melanoma and colorectal cancers. These new vaccines specifically target cancer tissue, with the goal of sparing normal tissue. Also, by analogy with vaccines that stimulate the immune system to fight against viruses or bacteria, cancer vaccines stimulate the body's immune system to attack cancer cells.

With regard to biomedical systems and devices, Ontario researchers are credited with developing automated systems for inexpensive DNA sequencing, as well as three dimensional imaging techniques. In addition, Ontario is home to the world's first regulated heart pacemaker and the original continuous passive motion (CPM) device for healing human joints, each of which has the potential to improve the quality of life for millions of patients around the world.

TM Bioscience, a Toronto-based biotech company, boasts another clear success for Ontario in the field of devices/diagnostics. This company is developing genetic testing platforms for mutations related to hematology, toxicology and other debilitating genetic disorders. The Company's Tag-It™ assay for detecting cystic fibrosis (CF) is the first such *in vitro* diagnostic to receive FDA approval¹⁵. This technology has been adopted by high profile institutions including the Mayo Clinic and Specialty Labs, a leading US hospital-focused clinical reference laboratory. The Tag-It™ CF assay, which is highly accurate and > 99.9% reproducible, will provide superior mutation coverage for CF screening in adults and also as an aid to diagnosis in newborns. Early detection is expected to play a major role in optimizing CF disease management and patient outcomes.

As an example in the field of leading-edge industrial biotech applications, Ontario is also home to the largest "fuel ethanol" producer in Canada (Commercial Alcohols Inc., Chatham), and a leading enzyme developer and innovator in the bioethanol field (Logen Corp., Ottawa)¹⁶. Logen's

¹³ Opening Address, Mark Lievonon, President, Aventis Pasteur Limited, BCO 2004 Public Policy Forum, BCO Final Report, 2004.

¹⁴ Engaging Innovation, Toronto Region Research Alliance (TRRA), October 2005.

¹⁵ US Genetics Diagnostic Markets, 2006 MaRS Emerging Technologies Briefings, Feb. 27 Event, 2006.

¹⁶ www.nrcan.gc.ca/regions/regions/ontario/index_e.html



primary research focus is to improve the efficiency of biotech enzymes that break down plant fibre (e.g. straw) into sugar molecules that can be turned into ethanol - as an environmentally-friendly alternative to petroleum-based gasoline for use in cars and other vehicles. Iogen has recently built a \$40 million EcoEthanol™ demonstration plant in Ottawa - the only one of its kind in the world¹⁷.

"We are the only company in the world up to now that has been able to take by-product fibre and turn it into a form of bioethanol with 90 percent lower greenhouse gas emissions than gasoline."

Brian Foody, President, Iogen Inc., 2006

Iogen has also developed an enzyme, BioBrite®, which breaks down the cellulose in wood fibers. BioBrite® allows pulp and paper companies to produce wood products more efficiently and with less chlorine, which significantly reduces the production of toxic dioxins known to pollute Canada's river and lakes.

The success stories summarized above are but a few of the promising examples that demonstrate Ontario's talent and momentum in biotechnology research and development, particularly in advancing health care and environmental applications. Much work remains to be done, but there can be no doubt that Ontario is a potential biotech powerhouse, poised to complete successfully in the global marketplace. As presented in the remainder of this document, Ontario's future success will depend heavily on adequate investment - and the government's shared vision in viewing biotechnology as an enabling, transformative platform with a crucial role in the Province's future prosperity.

1.4 Backgrounder: The Canadian Biopharmaceutical Industry

For additional background perspective, it is pertinent to examine the structure of the biopharmaceutical industry within the context of the today's Canadian landscape. For the purpose of this analysis, emphasis is placed on Ontario, where published data is available. The industry's key sub-sectors described below include: 1) pharmaceutical/biopharmaceutical 2) biotechnology, and 3) medical devices.

1.4.1 Pharmaceutical/Biopharmaceutical Sector

The industry association for Canada's research-based pharmaceutical and biopharmaceutical firms is known as Rx&D, which has a rich 90-year history of constructively interacting with all levels of government. This national association ensures that the innovative medicines discovered, developed and delivered by its members improve the health of Canadians and in turn, positively contribute to economic prosperity and improved quality of life.

¹⁷ www.iogen.ca/4100.html



Rx&D is comprised of over 50 member companies, including both Canadian-owned companies and Canadian affiliates of the global pharmaceutical and biopharmaceutical industry, whose members are responsible for developing in excess of 90% of the innovative medicines available in the world today. More than 23,000 Canadians are employed by Rx&D member companies. According to the federal Patented Medicine Prices Review Board (PMPRB), Rx&D member companies with active patented products in the Canadian market during 2004 invested \$1.17 billion in R&D activities that year in Canada¹⁸. The PMPRB also reports that total sales revenue of the Canadian research-based pharmaceutical industry was \$10.9 billion in 2004.

Key Rx&D Facts (re: Ontario)¹⁹:

- Member companies create approximately 9,000 direct jobs in Ontario.
- An average \$132,000 in taxes generated for every direct Rx&D job (net of R&D tax credits) in Canada.
- \$1.8 billion injected into the Ontario economy (2003)²⁰.
- \$4.5 billion has been invested in R&D in Ontario during the past 16 years, of which \$825.5 million has been spent in universities and hospitals²¹
- Over \$120 million invested in Ontario universities, hospitals and other institutions in 2004.²²

The Canadian pharmaceutical and medicine manufacturing sector is also a leading investor in capital projects, including plant equipment and engineering construction. According to Statistics Canada, total capital investments attributed to this sector were \$660 million in 2004. Investments in buildings and engineering construction in pharmaceutical manufacturing were 2.5 times higher in 2004 compared to the 1997 level. For the same period, annual capital investment decreased for all manufacturing industries by 9% in real terms. Overall manufacturing investments in building and engineering construction decreased by 46% during this seven-year period.

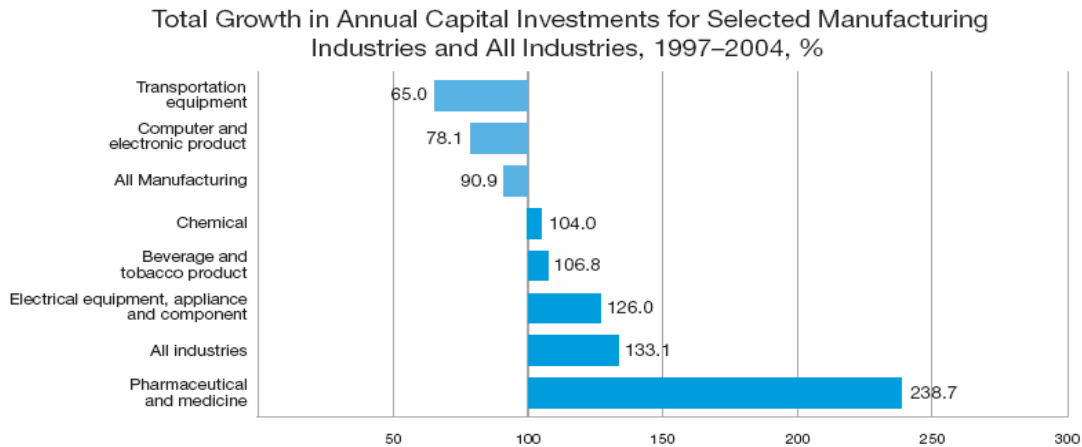
¹⁸ PMPRB Annual Report, 2004.

¹⁹ Price Waterhouse Coopers. Rx&D Companies: Driving a Better Stronger Canadian Economy, p. 4.

²⁰ Rx&D Website - Industry Publications (Fact Sheets), The Pharmaceutical Industry in Ontario, www.canadapharma.org.

²¹ *Ibid.*

²² PMPRB Annual Report, 2004, Table 19, p. 54.



Source: Statistics Canada, CANSIM table 031-0002, 2005

The pharmaceutical industry's share of total manufacturing investments increased more than 4.5 times to 13.5% in 2004 from just 2.9% in 1997. This sector is making greater commitments to building the long term infrastructure of Canadian industry than other industries.²³

1.4.2 Biotechnology Sector

At the provincial level, the Biotechnology Council of Ontario (BCO) was formed in November 2003 as a new permanent Council to advise government on all public policy issues facing the biotechnology industry²⁴. As a nonprofit corporation, the BCO acts as a central advocate on behalf of the industry in Ontario. Part of the BCO's mandate will be to support the Province in its goal of creating one of the leading biotechnology industries in North America.

At the national level, BIOTECCanada is the industry association representing biotechnology research organizations and biotech companies involved in health care, agriculture, environment, food processing, bioinformatics and aquaculture. About 67% of the core BIOTECCanada members are involved in health-related biotechnology (e.g. biopharmaceuticals, biosensors, biomaterials, stem cell technologies, biophotonics, nanotechnology and medical robotics). The number of biotech companies in Canada has increased from 282 in 1997 to about 450 by 2004; about 70% of these companies are focused on therapeutics and diagnostic product development.

According to several reports, the state of the Canadian biotechnology industry can be summarized as follows^{25,26,27,28}:

²³ Price Waterhouse Coopers, Rx&D Companies: Driving a Better Stronger Canadian Economy, p. 5.

²⁴ biocouncilontario.com

²⁵ BIOTECCanada, State of the Industry 2004.

²⁶ From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada's Innovative Health Industries, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.

²⁷ BIOTECCanada website, 4th Annual Forum on Pharma Patents, Presentation by Peter Brenders, October 18, 2005, Toronto, www.biotecanada.ca



- Over 450 companies (81 public + 378 private)
- Therapeutics companies have 540 products under development or on the market (22% of which are in Phase II or Phase III trials)
- Annual revenues of \$2.5 billion and an estimated market capitalization of \$13 billion
- R&D expenditure of approximately \$850 million
- Directly employs over 7,000 workers in public companies alone

Canada's biotechnology industry can be sub-divided, relative to biotechnology strengths in other countries, into the following sectors (all data in the remainder of Appendix 1.4.2 below, except where otherwise noted, is for 2003²⁹):

- Human Health
- Agriculture
- Food Processing
- Environment
- Natural Resources
- Bioinformatics
- Aquaculture

Human Health

- 262 firms representing 52.7% of the biotechnology industry in Canada
- \$1.999 billion in revenues and 9,194 employees

In this sector, biotechnology is applied to a range of products and services including vaccines, heart valves, blood products and pharmaceuticals.

Agriculture

- 89 firms representing 17.9% of the biotechnology industry in Canada
- \$448 million in revenues and 1,155 employees

In this sector, biotechnology is applied to introduce or integrate specific traits through genetic manipulation. In this area, "Canada has about the same number of biotech firms in agriculture as the United States, but just one-third the revenue."

Food Processing

- 54 firms representing 10.9% of the biotechnology industry in Canada
- \$1.266 billion in revenues and 761 employees

²⁸ Beyond Borders, Global Biotechnology Report 2006, Ernst & Young, p 41.

²⁹ Conference Board of Canada, Biotechnology in Canada: A Technology Platform for Growth, Dec. 2005.



In this sector, biotechnology can be used in food processing “to manipulate micro-organisms that improve process control, yields, efficiency and the quality, safety and consistency of bioprocessed products³⁰.” In this field, the Conference Board notes that “Canada appears to be a leader in the application of biotechnology to food processing, but this may simply reflect superior data collection capabilities.”

Environment

- 33 firms representing 8.0% of the biotechnology industry in Canada
- \$268 million in revenues and 709 employees

In this sector, biotechnology is applied in various ways including the use of bacteria to clean up oil spills, break down waste in landfills, reduce the need for chemicals and to produce alternate energy sources including ethanol and biodiesel. While Canada has a relatively small number of environment-related biotechnology firms, we are showing relatively strong results. With 20% fewer firms than the U.S., the total revenue of these companies exceeds those of the U.S.-based companies by almost three times.”

Natural Resources

- 21 firms representing 4.2% of the biotechnology industry in Canada
- Revenues: N/A
- 120 employees

In this sector, biotechnology is evident through genetic engineering of forests to protect against insect infestations. Other applications include bioproducts such as new fibres for construction materials or for use in the textile trade. While Canada is not focused in this area, neither are many other countries.

Bioinformatics

- 16 firms representing 3.2% of the biotechnology industry in Canada
- Revenues: N/A
- 244 employees

In this sector, biotechnology and information communications technology (ICT) converge. Bioinformatics involves the use of computer technology and databases to organize, store, and analyze health care, biological and medical information. This could become a key sector, should Canada or respective regions, especially Ontario or Québec, consciously choose to focus on life sciences in the health domain. However, the leaders in this field at the moment are the United States, United Kingdom and increasingly, India and Australia.

A primary example of Canada’s progress and potential world leadership position in health informatics and telehealth is occurring through *Canada Health Infoway*. *Infoway* was created in

³⁰ Electronic Forum on Biotechnology in Food and Agriculture: 11th Conference. Biotechnology applications in food processing: Can developing countries benefit? www.fao.org/biotech/C11doc.htm.



response to a commitment of Canada's First Ministers to "work together to strengthen a Canadawide health infrastructure to improve quality, access and timeliness of health care for Canadians." It has a mandate to accelerate the development and adoption of electronic health information systems in Canada. The deputy ministers of health for the federal, provincial and territorial governments are members of the *Infoway Corporation*³¹.

Aquaculture

- 15 firms representing 2.0% of the biotechnology industry in Canada
- Revenues: \$15 million
- 167 employees

In this sector, Canada appears to have carved out a niche and advantage. However, given the small size of the sector, the barriers to entry are few and other countries could - and likely will - easily compete with Canada in short order.

According to the Conference Board of Canada, we must better focus our efforts in a strategic and determined manner:

Canada's modest investments in biotechnology are spread across a range of industry sectors, including agriculture, health, environment, food processing, aquaculture, bioinformatics and natural resources. Meanwhile, other leading countries are making more strategic decisions about their investments in order to achieve international competitive advantages.

Given the absolute majority of Canadian biotechnology concentration in the field of human health, any strategic framework proposition must account for this factor along with the significant investment base - both public and private - that supports advancements in human health.

1.4.3 Medical Device Sector

The medical device industry in Canada has both a national trade association called MEDEC (Canada's Medical Device Technology Companies) and several provincial associations, including the Association of Health Technologies Industry (AITS) representing the Québec industry and the Trillium Medical Technology Association, formerly the Association of Ontario Medical Manufacturers (AOMM). MEDEC reports its members are responsible for over 50% of the almost \$4 billion in sales of medical devices annually in Canada³². Industry Canada data indicates that medical device exports in 2002 totaled \$1.9 billion, accounting for some 60% of the industry's total net sales revenue that year. The Department also reports that the Canadian

³¹ From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada's Innovative Health Industries, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.

³² <http://www.medec.org>



medical device industry invested about \$126 million in R&D in 2000 with the radiotherapy/medical imaging components of the industry being the most R&D intensive³³.

The highly profitable medical device industry consists of firms that manufacture products used for medical diagnosis and treatment including surgical and dental supplies, electro-medical equipment and related software, furniture, orthopedic appliances, prosthetics and diagnostic kits, reagents and equipment. In 2000, Industry Canada reports that the medical device industry consisted of 500 firms³⁴, most of which are engaged in manufacturing activities. A broader definition of medical devices that includes diagnostics, medical imaging and assistive devices would provide between 1000 and 1250 companies. Total employment in the industry ranges between 22,000 and 30,000 depending on the definition of medical devices used.

Some 90% of medical device companies operating in Canada are Canadian-owned. Of these, however, 80% are small firms with less than 50 employees. In terms of sales, the large firms with more than 150 employees, represent only 10% of the total number of establishments, but are responsible for nearly 50% of total net sales derived from medical device manufacturing in Canada. Nearly 60% of firms in the industry include distribution in their activities and almost half of all companies include research. The largest concentration of the medical device industry is located in southern Ontario and Québec.

³³ Industry Canada op. cit. Good Government is Everyone's Business, www.ppforum.ca

³⁴ Industry Canada, Canadian Medical Device Industry, [http://strategis.ic.gc.ca/epic/internet/inlsgpdsy.nsf/vwapj/Sector%20Profile%20-%20MedDev.pdf/\\$FILE/Sector%20Profile%20-%20MedDev.pdf](http://strategis.ic.gc.ca/epic/internet/inlsgpdsy.nsf/vwapj/Sector%20Profile%20-%20MedDev.pdf/$FILE/Sector%20Profile%20-%20MedDev.pdf)



Appendix 2

Historical Overview



Appendix 2 - Historical Overview

In promoting the biopharmaceutical industry in Ontario and making recommendations to guide future direction, it is useful to provide historical perspective by highlighting relevant initiatives taken by previous provincial governments over the past few decades. Despite a high degree of electoral volatility since the early 1980's, during which time Ontario has enjoyed five different governments involving all three major parties, policy makers have sought to address a number of common challenges. In general, the 1980s and 1990s represented a period of profound restructuring, also coinciding with the introduction of the Canada-US Free Trade Agreement (FTA) in 1989, and its successor the North American Free Trade Agreement (NAFTA) in 1993, signaling an ever more tightly integrated North American economy. In reaction to significant restructuring, provincial governments enacted a series of successive economic policies in an attempt to contribute to the process of economic renewal and to promote the transition towards more knowledge-intensive sectors within the Ontario economy³⁵.

Under the Liberal-New Democratic Party coalition government (1985-1987), which was then succeeded by the Liberal majority government (1987-1990), a key policy innovation was the Premier's Council Technology Fund, initially created by Liberal Premier David Peterson in 1986. The Fund financed a number of innovative programs under its umbrella, the most significant of which was the creation of seven university-based Centres of Excellence to strengthen research capacity in areas of key importance to the provincial economy. In addition to stimulating the production of basic research and the development of world class researchers, an explicit requirement of the Centres was that they engage in collaborative research with industry partners who would help to shape research priorities.

Following the election of the NDP government in 1990, a new centrepiece strategy - the Industrial Policy Framework - began to emerge under Premier Bob Rae. The most significant change embodied within this framework was its focus on working with specific industrial sectors, through the establishment of a Sector Partnership Fund (SPF). Initially announced in 1992, the SPF program was a multiyear initiative, budgeted at \$150 million, involving more than 15 sectors. In March 1994, Ontario's biotechnology sector was awarded financial support from the Ministry of Economic Development and Trade (MEDT) to develop a comprehensive strategy to move the sector towards higher-value activity and greater international competitiveness.

By September 1994, a report entitled "Enabling Biotechnology" prepared under the SPF program, as led by Graham Strachan with coordination by Lorne Meikle as the project team leader, was submitted to Frances Larkin at the MEDT³⁶ (see Appendix 6). Its recommendations focused on commercialization of products (seen as key to sector growth and job creation) and on the role of government in fostering the climate needed for industrial growth. Unfortunately, final consensus and Cabinet approval for biotechnology sector initiatives were not achieved prior to the NDP government's downfall in June 1995; the SPF program was subsequently terminated in July 1995. However, under both Liberal and NDP governments, there was increasing acknowledgement of the need to coordinate discrete initiatives in industrial and

³⁵ David A. Wolfe & Meric Gertler, *Globalization and Economic Restructuring in Ontario: From Industrial Heartland to Learning Region?*, NECSTS-99 Conference, October 2, 1999.

³⁶ *Enabling Biotechnology - A Strategic Plan for Ontario*, September 29, 1994.



technology policy as parts of a complex, integrated regional innovation system, particularly by encouraging linkages among the science and technology infrastructure, the educational system, business enterprises and government.

With the 1995 election of the new Progressive Conservative government, Premier Mike Harris' "Common Sense Revolution" called for an abrupt shift in the direction of government spending and economic development policies. Broad policy frameworks were introduced to reduce tax and regulatory burdens, with the goal of stimulating economic growth. Within the first six months of assuming office, the Harris government cancelled or wound down nearly all of the targeted spending policies of its predecessors, including the Premier's Technology Fund and the Sector Partnership Fund. Virtually all that remained were the Centres of Excellence, which were renewed in 1996 with a reduced budget and a consolidation of the seven centres down to four.

After a two year period of delay, as the Conservative government struggled with its broader mandate of tax cuts and expenditure restraint, the issue of innovation inevitably resurfaced on the industrial policy agenda in 1997. The budget that year introduced a major new spending program and several additional tax incentives. For example, the Ontario Research and Development Challenge Fund (ORDCF) was established as a \$500 million, 10-year initiative to promote research excellence, i.e. by increasing the R&D capacity of Ontario universities and other research institutions through private and public sector partnerships³⁷. With matching funds from three sources - government, academic institutions, and private companies - a \$1.5 billion fund was created while encouraging collaboration between academic research institutions and the private sector. Of the various tax incentives introduced in the 1997 budget, the most significant was the Ontario Business-Research Institute Tax Credit, a 20% refundable R&D tax credit for corporate-sponsored R&D conducted in Ontario by eligible universities or other approved educational institutes or research associations³⁸.

In 1998, motivated primarily by reports that entrepreneurs were relocating seedling businesses south of the border, the PC government also set up a Biotechnology Task Force, to recommend ways to improve conditions for science-based businesses in Ontario³⁹. The 16 member task force, chaired by Graham Strachan with coordination and preparation by Gord Surgeoner, submitted a report entitled, "Ontario Biotechnology Task Force Report" to Jim Wilson, Minister of Energy, Science and Technology, in December of that year⁴⁰ (refer to Appendix 6). Reiterating and expanding upon the key themes of the previous SPF report submitted to the NDP government, the focus of the recommended strategy was to build a foundation for biotechnology growth in Ontario by concentrating on the needs of people (in government, industry and academia), creating a culture of innovation, improving the business/finance climate, and establishing infrastructure⁴¹. It is noteworthy that this emphasis on human capital requirements planted the seed for joint public-private sector financing of executive director positions to encourage biotech community leadership, eventually culminating in the formation of

³⁷ Under One Roof, Part 3: Ontario's Biotech Community, Lesley McCarney, October 19, 2001.

³⁸ David A. Wolfe & Meric Gertler, Globalization and Economic Restructuring in Ontario: From Industrial Heartland to Learning Region? NECSTS-99 Conference, October 2, 1999.

³⁹ Hugh McIntyre, Ontario - Hot Biotechnology in a Cold Climate, Nature Biotechnology, Vol. 19, p 523-525, 2001.

⁴⁰ Ontario Biotechnology Task Force Report, December 31, 1998.

⁴¹ Ontario Biotechnology Strategy, Ministry of Energy Press Release, October 22, 1998.



the newly organized Biotechnology Council of Ontario (BCO), as later announced under the Liberal government in November 2003⁴².

The government responded rapidly to the Biotechnology Task Force report, implementing a key recommendation by creating the Ontario Science and Innovation Council (OSIC) to provide the government with long-term strategic advice and leadership on science and technology issues. As the Harris government recognized the increasing importance of the biotechnology sector as a key driver of economic growth and job creation, other major PC initiatives during the next 1-2 year window included⁴³:

- the Premier's Research Excellence Awards, an \$85 million, 10 year initiative established in 1998 to help Ontario attract and retain world-class researchers
- the Ontario Innovation Trust (OIT), created in 1999 as a one-time grant of C\$750 million to improve research infrastructure at universities, colleges, research institutes, and hospitals⁴⁴
- the Biotechnology Commercialization Centre Fund (BCCF), announced in 1999 to provide \$20 million over 4 years, conceived to create biotechnology commercialization centres, initially in London, Toronto, and Ottawa, with the goal of nurturing new biotech companies emerging from public research institutes and the private sector.

Building on the inertia of its programs initiated in the late 1990's, the PC government later announced the major Biotechnology Cluster Innovation Program (BCIP) under Premier Ernie Eves in 2003. The first (\$2-million) phase of the \$30-million program called for regional biotech partnerships to submit proposals for strategic plans to help build Ontario's biotechnology capacity. The second (\$28-million) phase focused on implementing strategic plans to support biotechnology infrastructure projects, including commercialization centres, research parks and other regional initiatives that demonstrate entrepreneurship and innovation⁴⁵. Essentially, Ontario government programs approved under PC leadership during the period 1995-2003 stemmed from, and continued to advance initiatives recommended much earlier by biotechnology advisors to the previous NDP government. Similarly, the Eves' BCIP strategy reinforced the initial foundation for accelerating development of Ontario's biotechnology clusters, which are now gaining further momentum as 11 regional biotechnology consortia, known as Regional Innovation Networks (RINs), under the current Liberal government's \$13 million program⁴⁶.

Since the October 2003 election, the Liberal party, led by Premier Dalton McGuinty has implemented several pivotal new initiatives - with full recognition of the need to prevent further opportunity loss, i.e. regarding the timeliness of bringing Ontario's innovation capacity to fruition. Key among these has been the appointment of the Premier himself as the first Minister of

⁴² Biotechnology Council of Ontario: New Province-Wide "Council of Councils" Formed, Press Release, Nov. 20, 2003.

⁴³ Under One Roof, Part 3: Ontario's Biotech Community, Lesley McCarney, October 19, 2001.

⁴⁴ The Ontario government has more recently placed a moratorium on funding via both the OIT and ORDCF programs, cited in: Biotechnology Council of Ontario Final Report, December 2004.

⁴⁵ Eves government launches Biotechnology Cluster Innovation Program (BCIP), MEDT Press Release, March 17, 2003.

⁴⁶ Remarks by Tony Wong, Parliamentary Assistant MRI, At the Opening of the Stiller Centre Convergence Laboratory, April 4, 2006.



Research and Innovation, signaling the provincial government's unwavering commitment to research-intensive industries. In addition, funding for the Medical and Related Sciences (MaRS) Centre, initially announced under the previous PC government, has remained strong under Liberal leadership. Specifically, an additional \$16 million will be contributed by the McGuinty government to support future expansion as the MaRS complex enters its second phase of development, on top of the \$66.7 million previously committed by the province of Ontario. The McGuinty government has also increased its support for research and development, announcing \$730 million for the Ontario Research Fund through 2007-08 and an additional \$142 million for cancer research through 2007-08. This is in addition to funding for RINs, MaRS, the Ontario Centres of Excellence, as well as the \$6.2 billion in funding for post-secondary education through 2009-10⁴⁷. Very recently, a four-year, \$24-million Innovation Demonstration Fund has also been created to assist early-stage technology companies developing new bio-based, environmental and alternative energy technologies - thereby addressing important concerns such as effective waste management and energy conservation⁴⁸. The Innovation Demonstration Fund is just one component of the McGuinty government's \$160-million "Ideas to Market" strategy, announced in the 2006 Budget.

Overall, during the past two decades, provincial governments (consisting of three different parties) have placed progressive emphasis on expanding the highly qualified labour force and investing in R&D to support knowledge-based industries. Together, Ontario's recent Liberal, NDP and Conservative parties have all contributed to higher education standards, provincial funding and/or R&D tax incentives, underscoring the need to cultivate and sustain an innovation culture. Building on what each party has accomplished in the past, the provincial governments over this multiyear term have increasingly nurtured the biotechnology industry, positioning this sector for continued growth.

As now beginning to flourish under the recent wave of provincial Liberal government support, the biotechnology (and more broadly, the life sciences) sector is currently poised to leverage Ontario's research capacity in achieving an international level of excellence, permitting competitiveness in world markets. Clearly, much work remains to be done, with a sharper future focus, including appropriate incentive structures for innovation and continued high investment in R&D. In his capacity as Minister of Research and Innovation, Premier McGuinty has carefully reinforced the groundwork to sustain a thriving life sciences sector; the Liberal government has strategically positioned this sector to rise to the next level of success. Now, in considering the recommendations proposed in the accompanying 2006 report and Executive Summary, the Liberal government will be challenged to implement additional programs to augment Ontario's leadership in the life sciences industry - acknowledging innovation in this sector not only as a key driver of high-value jobs and future economic prosperity, but also as essential force in improving quality of life for Ontario families.

⁴⁷ The Boston Consulting Group, *The Role of the Federal Government in the Development of the Public Research Base in the Toronto Region*, December 15, 2005.

⁴⁸ McGuinty Government Investing In High-Paying, Highly Skilled Jobs: New Program To Help Develop Technologies and Drive Economy Toward New Wealth And Jobs, Press Release, June 2, 2006.



Appendix 3

Advancing Ontario's Innovation Mandate



Appendix 3 - Advancing Ontario's Innovation Mandate

3.1 Biopharmaceutical Technologies Fit Within the MRI Mandate

On June 29, 2005, Dalton McGuinty, Premier of Ontario, announced the creation of the new Ministry of Research and Innovation (MRI). The rationale for establishing MRI was that “in the highly competitive global economy of the 21st century, places that invest in innovation - that successfully tap into the creativity of people and market their ideas most effectively - will be home to the most rewarding jobs, the strongest economies and the best quality of life.” By establishing the MRI, the Ontario government has signaled its commitment and support for research-intensive industries. In his role as the first Minister of the MRI, the Premier has announced two major goals: to support the process of innovation; and to create a culture of innovation⁴⁹. The members of BCO endorse the vision of an Ontario where the process of innovation becomes, in the words of the Premier, *inevitable*, rather than just creating instances of innovation⁵⁰.

Given the priority the Premier has placed on developing an innovation agenda for the Province, and in continuing to reinforce the groundwork already laid by past governments, this report (and its accompanying Recommendations and Executive Summary) aims to provide an analysis for the biopharmaceutical sector, specifically through the lens of innovation. Hence in building the business case to support the Ontario government's focus on the biopharmaceutical sector, it must be emphasized that biopharmaceutical technologies fit well within Ontario's MRI mandate. In fact, the health innovation industries - primarily biotechnology, pharmaceuticals and medical devices - collectively represent our country's largest investor in R&D as a research-intensive platform for growth. Arguably, the health innovation industries also represent Ontario's best chance to compete successfully with other jurisdictions in the *new* global economy; one that is currently driven by knowledge, ingenuity and human capital as primary resources⁵¹.

World leaders are also looking to biotechnology as a source of increased revenues, new companies, increased employment and a hedge against off-shoring. With human capital as its primary resource, nations do not have to be rich in natural resources to be players in biotechnology⁵². This is critically important for Ontario, which is not endowed with the lucrative natural oil and gas commodities that help sustain other provincial economies, including Alberta and Newfoundland. Instead, Ontario needs to rely much more on human capital, and as Premier McGuinty has said, “We're going to have to foster, nurture, stoke and tap into human creativity”⁵³. Fortunately, Ontario's human capital and creativity represent non-depletable

⁴⁹ Remarks by Dalton McGuinty, Premier of Ontario, at The Opening Of MaRS Discovery District, September 26, 2005.

⁵⁰ Remarks by Dalton McGuinty, Premier of Ontario, at The Ontario Centres Of Excellence Discovery 2006 Conference, February 7, 2006.

⁵¹ From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada's Innovative Health Industries, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.

⁵² Conference Board of Canada, Biotechnology in Canada: A Technology Platform for Growth, Dec. 2005.

⁵³ Remarks by Dalton McGuinty, Premier of Ontario, at The Ontario Centres Of Excellence Discovery 2006 Conference, February 7, 2006.



resources, with enormous innovation and growth potential, particularly in the context of Ontario's strong education sector. In addition, as the Canadian dollar continues to surge, exceeding 90 cents U.S. by June 2006, many of Ontario's other leading sectors have suffered severely, including factory-based, manufacturing and exporting industries⁵⁴. Thus while the health innovation industries are poised to deliver vital goods and services for which global demand continues to escalate, they also represent an excellent fit for Ontario in positioning itself as an emerging leader on the supply side of the new knowledge-based economy.

“Research, innovation and commercialization are a powerful means to a noble end of opportunity for all.” Dalton McGuinty, Premier of Ontario, 2006.

A key challenge and urgent matter for the Ontario government to address is that the biotech sector is highly competitive. Most of the world's developed and developing nations are also hard at work improving their novel technologies, along with their ability to attract biotech investment. Ontario therefore needs to move quickly and effectively, since those regions that are “fast to innovate, fast to produce and fast to market”⁵⁵ are also those that represent successful economies.

3.2 The Threat of Unsustainability

The examples presented in Appendices 1.2 and 1.3 illustrate that we are in the midst of a tidal wave of scientific advances in biotechnology. These new tools are addressing both emerging and longstanding health problems. In order to extract optimal benefit from these advances, while ensuring the financial sustainability of the system, governments must understand not only the nature and extent of the potential impact of these innovations on health care practices, but also their impact on the economics of the health care system. Spending on health care is already outpacing economic growth in most member countries of the Organisation for Economic Co-operation and Development, and Canada is no exception⁵⁶.

Given that bio-based health innovations (including new drugs) are major drivers of rising health expenditures, and that more than 80 percent of Canadian and global investment in biotechnology research and development is focused on the health sector, it is not unreasonable to expect that both the rate of generation and the complexity of bio-based health innovations will increase⁵⁷. The obvious question is this: How can we accommodate new products at affordable levels of health expenditure, given the difficulties already being felt in accommodating new developments?

⁵⁴ Heather Scoffield, Soaring Dollar Helps Fuel Record Jobs Boom, The Globe and Mail, June 10, 2006.

⁵⁵ Remarks by Dalton McGuinty, Premier of Ontario, at The Ontario Centres Of Excellence Discovery 2006 Conference, February 7, 2006.

⁵⁶ Organisation for Economic Co-operation and Development, Health at a Glance: OECD Indicators 2003, Health Policy Unit; Canadian Institute for Health Information, “Health Indicators 2003.”

⁵⁷ Biotechnology and Health Innovation: Opportunities and Challenges, A Discussion Document from the Canadian Biotechnology Advisory Committee (CBAC), March 2004.



“Allocating resources to competing health care demands is a challenge faced by every province and territory. Should we spend more on primary care? Do we increase homecare services for older people? ... When are we going to get an MRI scanner in our community? ... What priority will new biotechnology innovations get when plunged into this cacophony of demands?” Biotechnology and Health Innovation: Opportunities and Challenges, CBAC, March 2004

For the Ontario government, as for other jurisdictions, future health spending is expected to increase at a much higher level of growth than in the past. While current spending on health care in Ontario is estimated to account for approximately 50% of the provincial budget, health care expenditures are projected to increase to 70% of the provincial budget within the next 15 years, particularly with the aging of the “baby boomer” segment⁵⁸. According to a recent study by the Fraser Institute, Canadian individuals aged 65 years and over were reported to consume over 44% of provincial health care expenditures in 2002, while making up only 12.7% of the population⁵⁹. This data supports the alarming projections for increased health care costs in Ontario, as a greater proportion of the baby boom generation approaches age 65. On a global basis, health care spending is projected to triple in real dollars by 2020, consuming 21% of GDP in the US and 16% of GDP in other OECD countries⁶⁰. Based on these data and trends, how can our provincial health system be sustained, particularly in the context of competing demands for other services by Ontarians, including university and child care programs, as well as transportation infrastructure?

3.3 Potential Solutions Provided by Biopharmaceutical Innovation

Dr. Henry Friesen, an internationally known Canadian medical scientist and founder of the Canadian Institutes of Health Research, is optimistic in his views regarding the inter-relationships between health care and economics. His view is that our health care system and our health innovation sector can be an “engine of economic growth that will contribute greatly to a sustainable health care system”⁶¹. He argues: “It is time to see our health system not simply as a provider of health for Canadians, but as a generator of wealth for Canada”⁶². He believes there is a need for “holistic stewardship” in promoting health innovation, and he has identified public investment as an important dimension of such stewardship. Dr. Friesen’s vision of aligning health and economic strategies for national gain, as expressed below, can guide the development and execution of Ontario’s life sciences strategy.

⁵⁸ Dr. Gord Surgeoner, Fresh Fruit and Vegetables, Beyond Food, Ontario Agri-Food Technologies AGM, March 3, 2006.

⁵⁹ How Good Is Canadian Health Care? 2005 Report, The Fraser Institute.

⁶⁰ PricewaterhouseCoopers, Connectedthinking, HealthCast 2020:Creating a Sustainable Future, 2005.

⁶¹ Dr. Henry Friesen, New Models for Investing in Innovation in Health, Discussion Paper, Public Policy Forum Roundtable, August 2002.

⁶² From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada’s Innovative Health Industries, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.



“It is to see Canada’s publicly funded health system not as a cost to be endured, but as an opportunity to be explored. To align more effectively our social and economic policy directions; to put in place the right incentives; to reward entrepreneurship/innovation; to ensure that investment and regulatory regimes facilitate access to capital and markets; and to celebrate success.”

Dr. Henry Friesen, “Health care can be an engine of economic growth”, Public Policy Forum, *Newsletter* Vol. 4 No. 3 Summer 2003, p. 7.

Dr. Friesen’s thinking has led to a pan-Canada, multi-stakeholder initiative known as CHIP (Canadian Health Industries Partnership). CHIP is a proposed collaboration arrangement between the federal and provincial governments and the health innovation sector for developing and implementing appropriate strategies that are aimed at increasing investment in health R&D across the country and in strengthening the capability of Canadian health innovation industries to compete internationally in the commercialization of Canadian ingenuity⁶³. Ontario is supportive of the CHIP model in creating such a mechanism for collaboration and has nominated the Deputy Minister of Research and Innovation as Ontario’s representative.

Consistent with Dr. Friesen’s views, many arguments have been put forward to date to support the generation of economic wealth through biopharmaceutical innovation. Some of the general arguments presented include the following: improved economic conditions, including new companies, job creation, higher incomes, and increased competitiveness that would result in a robust tax base - hence generating greater revenue for the Province to reinvest in social programs^{64,65}.

To evaluate the more mature “big pharma” sector first, twenty-seven member companies of Canada’s Research-Based Pharmaceutical Companies (Rx&D) are located right here in Ontario. It is noteworthy that Rx&D members now directly employ 9,000 Ontarians, and are responsible for generating 25,000 additional indirect jobs⁶⁶. Together, these companies have contributed approximately \$2 billion annually to Ontario’s economy, making the Province a major centre for pharmaceutical research and development. It is particularly commendable that big pharma players have reinvested \$550 million in research and development in Ontario in 2005, representing the largest R&D investment across all provinces⁶⁷. Of this investment, over \$90 million has been directed towards university- and hospital-based research in 2005⁶⁸. While capital investment in Ontario by key pharmaceutical players has been substantial to date, these companies have also made significant contributions to provincial corporate taxes.

⁶³ *Ibid.*

⁶⁴ Building Ontario’s Biotechnology Corridor, Report of the BIOCouncil, Joseph Rotman, March 2002.

⁶⁵ Health, Healthcare and Nation-Building: A Three-Dimensional Approach to Innovation in Canada, Glenn G. Brimacombe, *Healthcare Quarterly*, Vol. 8, No. 3, 2005.

⁶⁶ PriceWaterhouseCoopers data, August 2005, cited in Bill 102: Unintended Consequences, Russell Williams, President, Rx&D, Bill 102 Information Session, Mississauga, May 15, 2006.

⁶⁷ PMPRB Annual Report, 2005, p 56.

⁶⁸ *Ibid.*



With regard to the emerging biotechnology sector, Ontario is home to over 140 of Canada's biotech firms, employing over 8,000 people, which represents approximately one third of the national biotech employment total. Based on the number of biotech companies, Ontario has recently been identified as the third largest biotech region (by state/province) in North America, trailing only California and Massachusetts⁶⁹. (A more detailed analysis of global life sciences clusters is presented in Appendix 3.4 below.) Ontario's public biotech companies alone account for over 2,500 jobs, with over \$291 million reinvested in R&D in 2005; this corresponds to 34% of the annual R&D spend in Canada's biotech sector⁷⁰.

At the most straightforward level of budget analysis, it has been argued that if Ontario currently makes relatively small investments in R&D and commercialization of biotechnology, the Province will reap huge benefits within 10-15 years as the companies built on those technologies begin to generate significant tax revenues. To evaluate such potential effects, Ontario's BIOCouncil has undertaken an economic modeling analysis in 2002 to assess the financial impact of several of the Council's recommendations⁷¹. Specifically, quantitative estimates of the economic impact were determined for Recommendations 1, 5 and 6, as described in Table 1 below. These analyses project that if the recommendations were implemented, both provincial tax revenues and jobs would be significantly increased both prior to, and after the year 2010. Collectively, the BIOCouncil recommendations are expected to have a strong economic benefit for all Ontarians, while producing a net fiscal benefit for the government of Ontario.

⁶⁹ Beyond Borders, Global Biotechnology Report 2006, Ernst & Young, p 24.

⁷⁰ *Ibid*, p 42.

⁷¹ Building Ontario's Biotechnology Corridor, Report of the BIOCouncil, Joseph Rotman, March 2002.



Table 1: Summary of Economic Modeling Results for Recommendations 1, 5 and 6.

Recommendation	Provincial Fiscal Impact	Provincial Jobs Impact
1. Accelerate the Development of Biotechnology Innovation Clusters	<ul style="list-style-type: none"> • Net tax revenue benefit of ~\$900 million from 2004-2010 • Plus annual tax revenue of ~ \$200 million after 2010 	<ul style="list-style-type: none"> • ~20,000 construction jobs • Almost 40,000 full time jobs when all new research park and incubator space is operational
5. Unleash Investment from the Ontario Pharmaceutical Industry	<ul style="list-style-type: none"> • Net economic benefit of ~\$1.3 billion over the next five years (based on increasing pharmaceutical investment from \$400 million per year to \$1.2 billion per year by 2006) 	<ul style="list-style-type: none"> • ~7,000 new full time direct jobs • ~18,000 indirect and induced full time and part time jobs
6. Become a Global Leader in Bioproducts R&D and Manufacturing	<ul style="list-style-type: none"> • Net economic benefit of ~\$300 million from 2002-2010 (including the provincial revenue lost due to a new fuel tax exemption for biodiesel until 2010) • Annual net provincial tax revenue of ~\$36 million when new plants are operational • Plus ~ \$50 million of tax revenue from construction activities 	<ul style="list-style-type: none"> • ~6,000 construction jobs • ~6,000 full time jobs when new plants are operational

It may also be pertinent to speculate that if Ontario was successful in producing even one “mega company”, such as US-based Amgen, this could generate an exponential increase in provincial tax revenues. To provide perspective, Amgen’s market capitalization is currently in the range of \$US 100 billion, which is larger than the combined value for three of Canada’s largest public companies (across all sectors), including the Royal Bank, Bell Canada, and Nortel⁷². These results are both shocking and inspiring. Amgen was founded in 1980; its key areas of therapeutic focus include therapies to treat blood disorders and arthritis. As of February 2006, Amgen was ranked as the largest biotech company in the world (and is now also the 8th largest global pharmaceutical company), with revenues exceeding \$US 10 billion in 2004, almost double the revenues reported in 2002⁷³.

⁷² Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, Dec. 2005.

⁷³ Med Ad News, *Top 10 Pipelines, Best Biotechnology Pipeline - Amgen Inc.*, February 2006.



“New transformative technologies produce mega companies and they do it fast. It would be nice to have some of that kind of wealth generation happening in Canada.” Brain Harling, BIOTECanada Conference, May 17, 2005

With regard to job creation, it has been previously reported that for every direct job created by biotechnology, roughly two additional indirect jobs are created in support services such as business supplies and legal services and in related consumer spending⁷⁴. Even more impressive data is presented in a recent US study, which reports that for each new job in the bioscience sector (including, in this analysis, the major subsectors of Drugs & Pharmaceuticals; Medical Devices/Equipment; Research, Testing & Medical Labs; and Agriculture), the total increase in number of jobs is 5.7. This is known as the “direct-effect employment multiplier”⁷⁵. Hence a strong biopharma sector has both direct and indirect benefits that can substantially contribute to a region’s economy, also bolstering personal income tax revenues.

Dr. Friesen has argued that future changes based on biotechnology have the potential to turn Canada’s annual health care trade deficit of ~\$8 billion into a trade surplus⁷⁶, thereby helping to address sustainability issues. He also submits the concept that linking Canada’s health innovation and economic agendas would provide substantial benefits to both sectors. In general, by increasing the proportion of Canada’s investment capital in the life sciences, and by aggressively marketing Canadian innovations to other countries, it has been stated that we could repatriate jobs, improve the balance of payments and add billions of dollars annually to the Canadian economy⁷⁷. While Ontario needs to support such federal strategies, it must also pursue parallel provincial strategies to maximize the economic benefits of biotech innovation.

Given adequate investment and government support, the Ontario’s biopharmaceutical sector also promises to deliver other positive economic outcomes to advance the Province’s innovation agenda. For example, a vibrant biopharmaceutical industry is anticipated to be instrumental in attracting new business, as well as additional domestic and foreign investment, to Ontario. A healthy, growing biopharmaceutical sector would also boost the Province’s efforts to attract and retain a highly skilled, knowledge-based work force, particularly in expanding other areas of the life sciences sector. Cross-fertilization of human capital among life sciences organizations - believed to be instrumental in accelerating discovery and innovation processes⁷⁸ - would in turn be facilitated by increasing the size and quality of the provincial labour force base.

⁷⁴ Massachusetts Biotechnology Council and the Boston Consulting Group, MassBiotech 2010, Achieving Global Leadership in the Life-Sciences Economy, 2002.

⁷⁵ Growing the Nation’s Bioscience Sector, State BioScience Initiatives 2006, Battelle Technology Partnerships Practice & SSTI, April 2006.

⁷⁶ Dr. Henry Friesen, quoted in Amber Lepage-Monette, Lifetime of Leadership, BioScience World.

⁷⁷ Biotechnology and Health Innovation: Opportunities and Challenges, A Discussion Document from the Canadian Biotechnology Advisory Committee (CBAC), March 2004.

⁷⁸ Dr. Diana Pliura, President & CEO, DELEX Therapeutics Inc., a wholly owned subsidiary of YM BioSciences Inc., cited in: BioBeat, WGTACC Newsletter, April 2006, Issue 1 Vol. 2, www.wgtacc.com



It is well acknowledged that a thriving pharmaceutical sector is one of the largest drivers in supporting a burgeoning biotech sector as an extended “innovation arm”. In Ontario, as for other provinces, pharmaceutical companies have been a major source of funding for biotech firms, via basic or clinical research collaborations, licensing or other strategic partnership agreements, and also through outright acquisitions. To evaluate U.S. statistics as a point of reference, the U.S. biotechnology industry raised more than \$17 billion through financings and \$15 billion in partnering capital in 2005, according to Burrill analysts⁷⁹. These analysts predict even more and larger partnering deals in 2006, much of it to come from “joining up with big drugs firms and other integrated firms in alliances”, with an emphasis on discovery-stage deals⁸⁰. Pharma’s biotech partnerships and acquisitions in the U.S. have already reached \$6.5 billion in the first quarter of 2006⁸¹. Pharma is now using buyout and partnership deals more strategically, not only to replace a product in the marketplace or near term, but also to gain access to drug candidates to fill the pipeline at all stages of product development, as part of portfolio management⁸².

“Overall, 2005 turned out to be an exceptional year for the biotech industry in terms of financings and partnering, bringing in a record \$32 billion for U.S. companies”. G. Steven Burrill, CEO, Burrill & Co., March 2006

Some large pharma companies, notably Philadelphia-based Wyeth and GlaxoSmithKline P.L.C., have already invested heavily in building formidable internal biotech capabilities and have launched biotech drugs. More recently, as additional evidence of pharma’s pursuit of biotech assets, companies such as AstraZeneca and Merck have also begun acquiring early-stage biotechnologies, apparently in attempt to vault themselves into the lead of biotech discoveries. Struggling to rebuild its product pipeline, AstraZeneca bought four companies in 2005, including British biotech firm KuDOS Pharmaceuticals Ltd. for \$210 million. In May of 2006, AstraZeneca announced it would acquire Cambridge Antibody, of Cambridge, England, for about \$1.07 billion, representing an extraordinary 67% premium above the firm’s market value⁸³. Just a few days earlier, Merck announced it had bought two biotech companies, GlycoFi, based in Lebanon, N.H., and Abmaxis, based in Santa Clara, for \$500 million - both deals are expected to close by the end of June⁸⁴. This flurry of recent merger and acquisition (M&A) activity confirms the enormous, vested interest of pharma companies in strategically advancing and marketing biotech product candidates. In addition, there is increasing recognition by pharma giants that the innovation demonstrated by biotech companies, in terms of generating new drug candidates, is something they find very difficult themselves⁸⁵. Overall, the lines between biotech and big pharma have been blurred dramatically⁸⁶.

⁷⁹ www.burrill.com, cited in Biotech Buyout, MedAd News, March 2006.

⁸⁰ Profitless Prosperity - The Biotechnology Industry Needs to Grow Up, The Economist, April 20, 2006.

⁸¹ Drugmaker Offers 67% Premium for Biotech, Thomas Ginsberg, Philadelphia Inquirer, May 16, 2006.

⁸² Neil Kurtz, M.D., CEO, TorreyPines Therapeutics, www.torreypinestherapeutics.com.

⁸³ Drugmaker Offers 67% Premium for Biotech, Thomas Ginsberg, Philadelphia Inquirer, May 16, 2006.

⁸⁴ The Associated Press, May 10, 2006.

⁸⁵ A Culture in Ferment: Why it's Kill or Cure for the World's Pharmaceutical Giants, Danny Fortson, The Independent Online Edition, May 21, 2006.

⁸⁶ Scott Morrison, Head of U.S. Life Sciences, Ernst & Young, May 2006, cited in: Philadelphia Inquirer, May 16, 2006.



"We expect that, by 2010, up to a quarter of our [drug] candidates for full-scale development will be biological therapeutic agents."

David Brennan, CEO, AstraZeneca International, May 2006.

In Canada, sizable pharma-biotech deals are also being struck, as it becomes more fully recognized that synergies between pharmaceutical and biotechnology firms are not only advantageous, they are increasingly essential for corporate survival. For example, a record biotech partnership collaboration has been announced in the first quarter of 2006, between Neuromed Pharmaceuticals Ltd., an eight-year-old biotech spinoff from the University of British Columbia, and Merck & Co., Inc.⁸⁷ This pharma-biotech deal has been valued at up to \$500 million (U.S.), and has been called "the richest collaboration ever in Canada". It is also believed that the deal could set the stage for Neuromed to go public in the near future.

Under the terms of this agreement, Merck has obtained exclusive rights to Neuromed's experimental drugs for chronic pain and anxiety, including NMED-160, which is currently in Phase II clinical trials for the treatment of arthritis pain. Merck has agreed to make an initial \$25-million payment to Neuromed and to finance its research for two years, with an option to renew for an additional two years. Should NMED-160 gain regulatory approvals globally, Merck would pay Neuromed an additional \$202-million. The payments would grow to \$450-million if the drug is later approved for a second use. Neuromed would also receive royalties on any sales by Merck.

The recent Merck-Neuromed deal represents an excellent example of Canada's potential within the global biotech industry, while also providing insight regarding future opportunities within the "converging" pharma-biotech market. The importance of such alliances to small and medium-sized biotech companies must not be underestimated; the government of Ontario needs to assist in creating an environment that encourages and facilitates such collaboration. In general, it must be acknowledged that government support for the pharmaceutical sector can provide significant economic benefits for the biotechnology sector, which in turn can facilitate the advancement of Ontario's innovation agenda.

Another key avenue for biopharmaceutical companies to help drive Ontario's innovation agenda is in the area of clinical trial research. Clinical research represents a central, crucial process in the development of innovative products to treat and improve the lives of Ontario residents. At the forefront of this research, Rx&D member companies have already enrolled over 40,000 patients in clinical trials in Ontario alone⁸⁸, and biotech companies have also conducted multiple early and late-stage clinical trials. Through the conduct of such clinical research, patients benefit from early access to novel therapies, as well as additional clinical monitoring. In addition, all Canadians benefits from acquired knowledge and collective advances in bench-to-bedside

⁸⁷ Neuromed Strikes Major Merck Deal, Leonard Zehr, The Globe and Mail, March 21, 2006.

⁸⁸ Bill 102: Unintended Consequences, Russell Williams, President, Rx&D, Bill 102 Information Session, Mississauga, May 15, 2006.



expertise of researchers, physicians and regulators in the study of new medicines. Clinical research also helps to propel job creation; trials conducted by Rx&D companies have supported employment of roughly 38,000 researchers and clinicians in Ontario.

3.4 Life Sciences Clusters

3.4.1 Definitions and Key Elements of Clusters

The Institute for Competitiveness & Prosperity (ICP), based at the University of Toronto under the leadership of Dr. Roger Martin, has identified the importance of clusters of traded industries in terms of closing Ontario's prosperity gap with its peer group of North American jurisdictions, as well as strengthening innovation and commercialization results⁸⁹.

Industry clusters can be defined as firms within a certain geographical proximity competing in the same goods or services market. The most robust industrial clusters are characterized by healthy competition, critical market mass and a suite of supporting suppliers from input goods and services to value added resellers to lawyers, finance, HR capacity, etc.

It is also important to note Michael Porter's more recent work on themes for regional competitiveness⁹⁰ as follows:

- the most important sources of prosperity are created not inherited;
- productivity does not depend on what industries a region competes in but on how it competes;
- the prosperity of a region depends on the productivity of all its industries; and
- innovation is vital for long-term increases in productivity.

At present, Ontario is considered to be "continentally competitive" in the following six clusters:

- Entertainment;
- Automotive;
- Pharmaceuticals / Biotechnology;
- Financial Services;
- Information and Communications technology; and
- Tourism / Hospitality⁹¹

⁸⁹ Institute for Competitiveness & Prosperity. Assessing the Strength of the Toronto Biopharmaceutical Cluster, September 2004, p. 3.

⁹⁰ Institute for Competitiveness & Prosperity. A View of Ontario: Ontario's Clusters of Innovation, April 2002.

p. 18.

⁹¹ *Ibid.*, p. 40.



Moreover, it is important to note that ICP found that ***“the pharmaceuticals and biotechnology cluster stands out as the only technology-intensive cluster in which Ontario has a comparable employment weighting”*** compared to Ontario’s peer jurisdictions (15 states and Québec)⁹².

It appears self-evident that anchoring a life-sciences economic development strategy around Ontario’s bio-pharmaceutical cluster is a logical, necessary and astute strategy. According to Porter’s analysis, Ontario’s biopharma cluster is currently ranked in the top 10 jurisdictions in North America, with the GTA placing among the top five metro-area broad life sciences clusters⁹³.

Narrow Biopharma Cluster

- Pharmaceutical Products
- Consumer Goods
- Containers

+

Broad Biopharma Cluster

- Biological Products
- Medical Devices
- Research Organizations
- Health Science Centres
- Specialty Chemicals
- Lab Instruments/Equipment
- Packaging
- Distribution

Ontario’s factor endowments as they relate to the broad biopharma cluster definition are immense, including government investments in:

- the MaRS Centre (a cutting-edge convergence centre and a prime regional asset located in Toronto, now home to one of the largest medical complexes in North America)
- post-secondary funding of \$6.2 billion over the next five years
- 22 teaching hospitals affiliated with five university medical schools (London, Hamilton, Toronto, Kingston and Ottawa), and
- the Northern Ontario School of Medicine (NOSM), a new medical centre in Sudbury with multiple teaching and research sites across Northern Ontario, including large and small communities.

This massive public investment, along with an annual public health care spend of \$33 billion annually, ***must*** be leveraged through a more favourable patient access environment. Furthermore, government collaboration with Rx&D member companies, as well as members of BIOTECCanada and the Biotechnology Council of Ontario and other related industries (medical devices, chemical producers, etc.) is essential if Ontario is to maximize the economic potential of the life sciences sector and to achieve world leading health outcomes to improve our enviable quality of life.

⁹² *Ibid.*, p. 29.

⁹³ Michael Porter, Cluster Mapping Project.



The following list draws upon conclusions and observations found from diverse sources including the work of the Milken Institute, Porter's Cluster Mapping Project, the ICP at the University of Toronto, the Burrill Group and internal Rx&D research documents. Common characteristics found across the most successful life sciences clusters include:

- Full scale diversity of firms or highly specialized (one technology, one sector) focus;
- Global linkages to HR talent and institutional capital are essential;
- Lead/anchor firms (i.e.: multinational enterprise) always present;
- Multiple stakeholder cohesion and political alignment (i.e. influential political champion);
- Enabling role of research institutes (usually government underwritten);
- Geographic (i.e. census metropolitan area) proximity of cluster participants;
- Accessible/continuous local pools of highly educated management and knowledge workers;
- Presence of serial entrepreneurs backed with access to non-institutional capital;
- Built around R&D activities; and
- Communication (int'l) of strategic biopharma/medical plan with outcomes measures.

3.4.2 Global Life Sciences Competition: Where does Ontario fit?

Life sciences competition, in the vernacular of the investment community, is a "global play." Several jurisdictions have established a clear lead by virtue of market size or cluster/clusters strength. While the U.S. is still the leader in the global biopharmaceutical market, other nations, most notably Singapore, Ireland, and Sweden are employing unique strategies to attract their "unfair" share of investment and market activity.

Singapore⁹⁴

The anchor of Singapore's biomedical sciences (BMS) strategy is the BIOPOLIS complex - a mere 20-minute drive from the business/financial district and 5 minutes from the MRT subway system. Phase 1 of this 7-building project (2 million square feet) opened in 2003 and is now 90% occupied.

- Biopolis (a state-of-the-art \$300-million facility, similar in concept to MaRS) is home to GSK's pre-clinical neurodegenerative diseases research facility, a \$62 million investment.
- Biopolis is home to the Novartis Institute of Tropical Diseases and Isis Pharmaceuticals research lab focused on new micro-RNA drugs to treat SARS, cancer and blood diseases.
- Biopolis houses six state sponsored institutes in the disciplines of molecular and cell biology, genomics, bioinformatics, bioengineering and nanotechnology.
- Singapore's effective marginal tax rate on capital (manufacturing sector) is 5.8% compared to Canada at 35.5%.
- Singapore has a solid IP regime (patent term restoration and data protection).
- Government commitment: By 2010, the Economic Development Board (EDB) aims for Singapore to become home to 15 international BMS companies and for the nation to become the regional centre for clinical trials and drug development.

⁹⁴ www.biopolis.com.sg.



Ireland⁹⁵

- Ireland's effective marginal tax rate on capital (manufacturing sector) is 14.1% compared to Canada at 35.5%.
- Corporate income taxes are 12.5%, lower than Canada's at 34.3%.
- A 20% R&D tax credit which includes provisions for university funding.
- Ireland has a strong IP regime including 20 years of patent protection, 5 years of patent term restoration and 10 years of data protection.
- Ireland is the highest net exporter of pharmaceuticals per capita in the world and these exports represent 44% of total exports.
- Solid access for patients as most drugs are reimbursed through the state formulary.
- Product pricing is largely unregulated.

Sweden⁹⁶

- Sweden's effective marginal tax rate on capital (manufacturing sector) is 12.8% compared to Canada at 35.5%.
- Corporate income taxes are 28% (2nd lowest in Europe), lower than Canada at 34.3%.
- Sweden has a strong IP regime including 20 years of patent protection, 5 years of patent term restoration and 10 years of data protection.
- Mature venture capital market, ranked 2nd behind the UK in the EU.
- 25% reduction in all taxable income for foreign executives, researchers, experts, etc. working for Swedish or international subsidiaries.
- Large biotechnology cluster in **Medicon Valley** is home to key facilities of global biopharma giants such as Novo Nordisk, Lundbeck, AstraZeneca and LEO Pharma.
- Medicon Valley is home to 3 million citizens (including a part of Denmark) with 41,000 biopharma/biomedical employees, 5,000 researchers and accounts for 6% of all of Scandanavia's life sciences output and contains 26 hospitals (11 of which are academic).
- Sweden ranks #1 globally for pharmaceutical R&D per capita and #1 globally for highest pharmaceutical R&D as a percent of GDP
- Biopharmaceutical R&D represents 20% of all business R&D and a 30% R&D to sales ratio for biopharma companies (Canada: 8.4%).

Life sciences are anchored around three industrial pillars - pharmaceuticals, biotechnology and medical devices. This section provides a cursory analysis of just three jurisdictions. Life sciences clusters are located, and continue to emerge, across the planet. Rx&D would be pleased to submit additional information and research sources regarding other global life sciences clusters, economic data and supportive policy frameworks, upon request.

According to the annual Milken Institute survey, the top five life sciences cluster regions in North America are ranked as: Boston; San Diego, San Jose, Raleigh-Durham-Chapel Hill, and

⁹⁵ OECD Health Data 2005 and Drug reimbursement systems in EU member states.

⁹⁶ OECD Health Data 2005 and Drug reimbursement systems in EU member states, OECD Main Science and Technology indicators, May 2005, and www.mediconvalley.com.



Philadelphia. Snapshot analyses for Boston, North Carolina and Philadelphia are provided below.⁹⁷

Boston Corridor

- Includes five MA counties (Norfolk, Plymouth, Suffolk, Essex, Middlesex) and two NH counties (Rockingham, Stafford).

Boston Corridor – Employment Table (vis-à-vis top 11 U.S. clusters)				
Sector	Employees	Rank	Location Rank	Growth Rank (1997-2003)
Core Life Sciences	34 864	6 th	5 th	9 th
- Pharmaceuticals	5 005	6 th	6 th	4 th
- Medical Devices	13 271	6 th	3 rd	11 th
- Biotechnology	3 043	6 th	4 th	8 th
Life Science R&D employment	13 544	4 th	5 th	6 th
Supporting industries employment	262 990	5 th	2 nd	3 rd
2002 Industry R&D to life sciences	\$ 1.8 billion	3 rd per capita		
2002 Academic R&D to life sciences	\$ 731 million	3 rd per capita		
Composite R&D index	1 st			

Raleigh-Durham-Chapel Hill

- Includes seven NC counties (Franklin, Chatham, Durham, Johnston, Wake, Orange, and Person).

North Carolina Triangle – Employment Table (vis-à-vis top 11 U.S. clusters)				
Sector	Employees	Rank	Location Rank	Growth Rank (1997-2003)
Core Life Sciences	15 922	9 th	1 st	1 st
- Pharmaceuticals	4 107	7 th	2 nd	3 rd
- Medical Devices	1 137	11 th	10 th	1 st
- Biotechnology	6 788	3 rd	1 st	4 th
Life Science R&D employment	3 890	9 th	3 rd	3 rd
Supporting industries employment	57 426	11 th	5 th	7 th
2002 Industry R&D to life sciences	\$ 326 million	9 th per capita		
2002 Academic R&D to life sciences	\$ 728 million	1 st per capita		
Composite R&D Index	3 rd			

⁹⁷ Data sourced from Milken Institute publication, The Greater Philadelphia Life Sciences Cluster: An economic and comparative assessment, June 2005.



Greater Philadelphia

- Includes five PA counties (Bucks, Chester, Delaware, Montgomery, Philadelphia), five NJ counties (Burlington, Camden, Gloucester, Salem, Mercer), New Castle county in Delaware and Cecil county in Maryland.

Greater Philadelphia – Employment Table (vis-à-vis top 11 U.S. clusters)				
Sector	Employees	Rank	Location Rank	Growth Rank (1997-2003)
Core Life Sciences	53 479	2 nd	2 nd	2 nd
- Pharmaceuticals	30 028	2 nd	1 st	5 th
- Medical Devices	6 681	7 th	8 th	3 rd
- Biotechnology	2 428	7 th	7 th	11 th
Life Science R&D employment	14 342	3 rd	6 th	1 st
Supporting industries employment	310 188	4 th	3 rd	2 nd
2002 Industry R&D to life sciences	\$ 2.6 billion	1 st per capita		
2002 Academic R&D to life sciences	\$ 632 million	6 th per capita		
Composite R&D index		5 th		

In the Milken Institute ranking of the top 11 U.S. life sciences clusters, many other factors are taken into account, including:

- National Institutes of Health Funding (NIH) to universities, hospitals and research institutes;
- Sector specific awards and federally sponsored “innovation” grants and programs;
- Venture capital activities in each region (investment and growth);
- Academic degrees awarded in entrepreneurship and life science (Bachelor, Master’s, PhD, and MDs); and
- Intensity of professional activity across 17 disciplines and sub-disciplines of management, engineering, physics, chemistry, and biology.

Within Canada, Ontario’s innovation corridor stretches from Windsor to Ottawa. In 2003, the government of Ontario introduced the Biotechnology Cluster Innovation Program (BCIP), a \$30-million initiative designed to accelerate the development of 11 regional biotechnology consortia known as Regional Innovation Networks or RINs⁹⁸ (see list below). Under this program, the government has committed to supporting commercialization initiatives in each region in an effort to facilitate entrepreneurship and innovation. The MaRS (Medical and Related Sciences) Discovery District in Toronto aims to act as a gateway to the RINs, providing a portal through which biotechnology innovation and commercialization will flourish.

It is noteworthy that in a very recent industry review, Ernst & Young reports that Ontario is the third largest biotechnology centre in North America, based on the number of biotech companies within the Province (Figure 1)⁹⁹. However, while Ontario has a tremendous number of small companies and a reasonable number of developed companies, current links between the two are not strong. According to John Cook, President and COO of MaRS, such linkages will be

⁹⁸ Kristine Archer, Ontario – The Gateway to Success, 2006 BioscienceWorld.ca

⁹⁹ Beyond Borders, Global Biotechnology Report 2006, Ernst & Young, p 24.



encouraged through the RINs program¹⁰⁰. Within the biopharmaceutical sector, big pharma will continue to bolster its pipeline, and some of the best pipeline products are likely to come from early stage biotech companies. Hence there is a need to drive the development of biotech in the same geographical area as the big pharma firms.

Cook believes that co-operation is the best path to victory, and that the focus should remain on building a globally competitive life sciences industry in Ontario. Overall, the RINs program is being viewed as one of the major drivers of the Province's commercialization framework, enhancing Ontario's competitive position on the global biotech stage. Yet Cook is cautiously optimistic, pointing out that the real impact of MaRS may not be felt for another five to 10 years. He believes that with the help of the RINs, and all regions working together, Ontario is very well positioned to face worldwide competition¹⁰¹.

“The reason we’re doing all this is because we’re absolutely in a global race to compete with other major innovations in the world. We’re now competing against a biotech initiative in all but one state in the United States - there are well over 200 MaRS-type initiatives around the world.”
John Cook, President and COO of MaRS, 2006

RINS - Full Names & Websites:

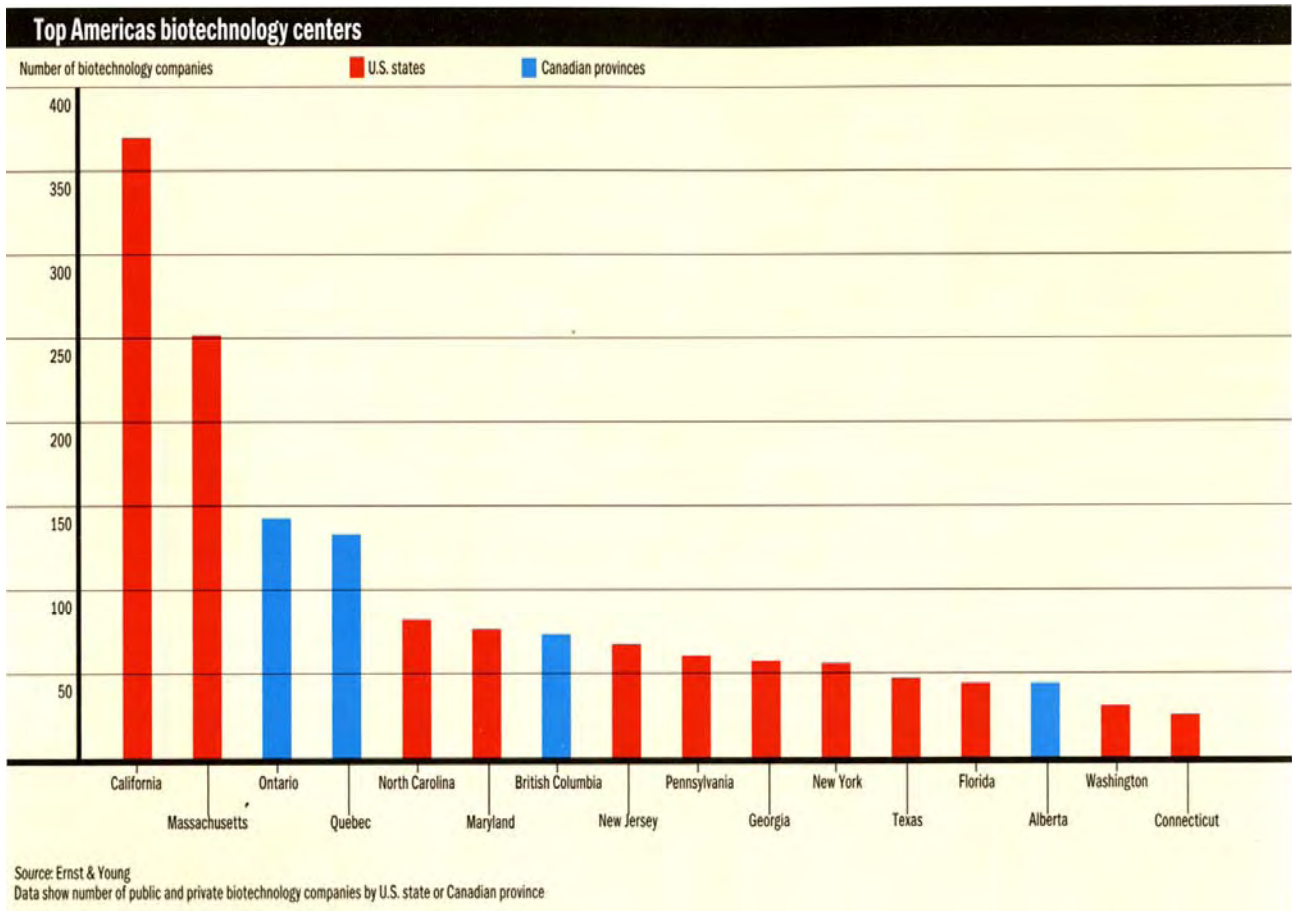
- 1) BioDiscovery Toronto www.biodiscoverytoronto.com
- 2) Eastern Lake Ontario Regional Innovation Network (ELORIN) www.kingstonbiotech.com
- 3) Golden Horseshoe Biosciences Network www.ghbn.org
- 4) Greater Peterborough Region DNA Cluster www.investpeterborough.ca
- 5) Guelph-Waterloo Partnership in Biotechnology Consortium www.gwpbiotech.com
- 6) London Cluster Consortium www.ledc.com
- 7) Northern Ontario Biotechnology Initiative Consortium (NOBI) www.thunderbay.ca
- 8) Ottawa Life Sciences Council (OLSC) (Ottawa and Eastern Ontario) www.olsc.ca
- 9) Southwestern Ontario Bioproducts Innovation Network (SOBIN) www.sobin.ca
- 10) Western Greater Toronto Area Convergence Centre <http://wgta.hal.ca>
- 11) York Biotech www.yorkbiotech.ca

¹⁰⁰ John Cook, President and COO of the MaRS Discovery District, Ontario - The Gateway to Success, 2006 BioscienceWorld.ca

¹⁰¹ *Ibid.*



Figure 1 - Top Biotechnology Centres in North America





Appendix 4

Driving Ontario's Health & Industrial Policy



Appendix 4 - Driving Ontario's Health & Industrial Policy

4.1 Improved Disease Management

Provincial policies and regulations concerning public drug benefit coverage of innovative medicines or diagnostics/treatments are typically aimed at controlling acquisition costs, without considering the potential value of such novel therapies in terms of cost-savings in other government-funded programs, including fewer surgeries and shorter hospital stays. However, many new medicines and their associated disease management programs are believed to have untapped potential in reducing overall health care system costs, while enhancing patient health status. By taking a holistic view of the broad impacts of new therapies, many health innovations have been shown to save lives, improve quality of life and enhance economic productivity¹⁰².

According to Frank Lichtenberg, Professor of Business at Columbia University, an \$18 increase in expenditures on “new drugs” is associated with a \$71 decrease in non-drug expenditures¹⁰³, supporting his view that, “the newer the drug in use, the less spending on non-drug items”. In an update to his initial study¹⁰⁴, Lichtenberg reported that reducing the mean age of drugs (from 15 years to 5.5 years) used to treat a condition increases the prescription drug spending by \$18, but reduces other medical spending by \$129, yielding a \$111 net reduction in total health spending. Based on these data, the cost/benefit ratio is 1 to 7.2, suggesting that the use of newer medicines (versus older medicines) saves up to \$7-8 for every dollar invested. While Lichtenberg's work has been questioned by other researchers¹⁰⁵, Lichtenberg claims that such criticisms are based on flawed methodologies, including inappropriate control of potential confounding variables¹⁰⁶. It should also be noted that Miller's recent critique of Lichtenberg's “cost-saving” premise is based solely on data from a cardiovascular patient population, and may therefore not bear relevance to Lichtenberg's large body of work (with largely consistent results) across other disease states, including cancer and HIV.

Consistent with the main thrust of Lichtenberg's research, several other disease management studies in the areas of cardiovascular disease, diabetes, depression, peptic ulcer, and asthma (diseases that are most prevalent amongst Ontario Drug Benefit recipients) have demonstrated return on investment rates between 119% and 300%¹⁰⁷. Another powerful illustration of the impact of using innovative medicines over the past two decades has been the significant decline in hospitalization rates (per 100,000 population) for Canadian patients with ulcers, AIDS/HIV, diabetes, respiratory disease, and chronic liver disease, as shown in Figure 2 below.

¹⁰² From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada's Innovative Health Industries, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.

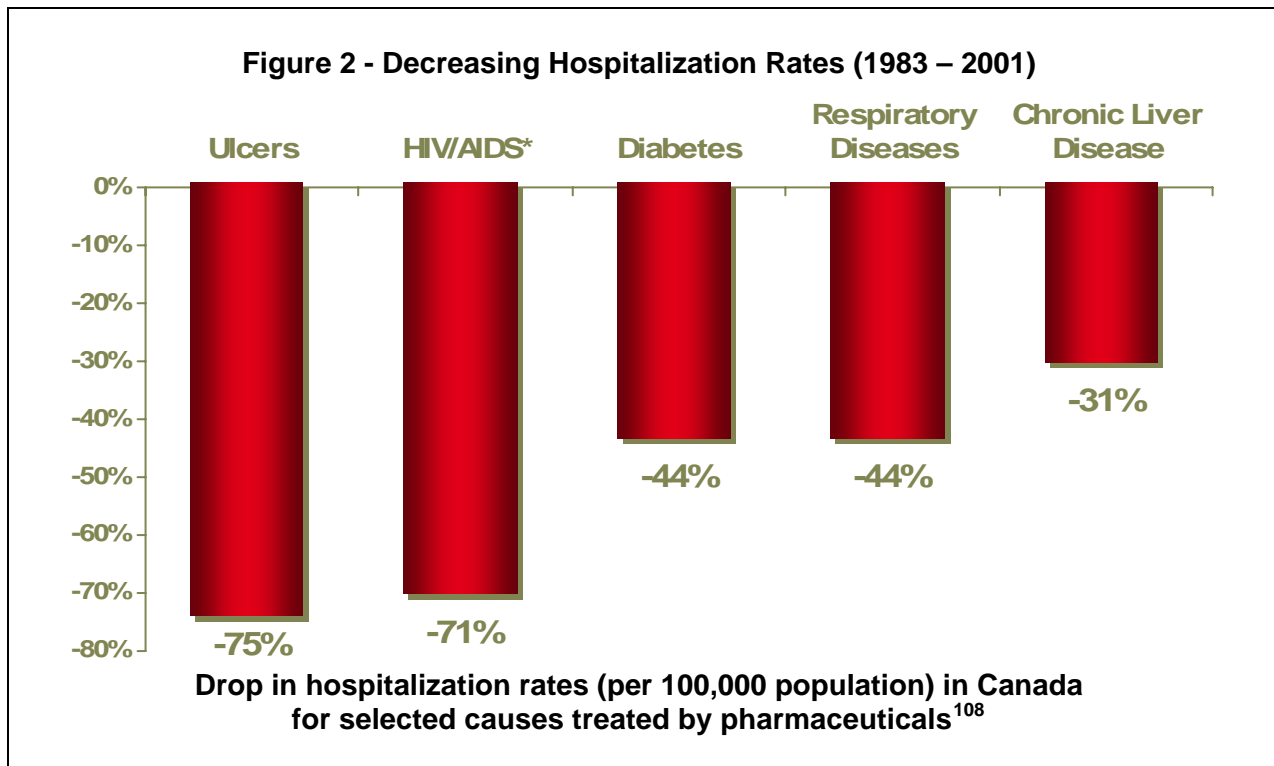
¹⁰³ Lichtenberg, Frank R. Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS, Health Affairs, September, October 2001.

¹⁰⁴ Lichtenberg, Frank R., Benefits and Costs of Newer Drugs: An Update, National Bureau of Economics Research Working Paper 8996, 2002.

¹⁰⁵ Miller, G., Moeller, J., and Stafford, R., New Cardiovascular Drugs: Patterns of Use and Association with Non-Drug Health Expenditures, Inquiry, Vol. 42, Winter 2005/2005.

¹⁰⁶ Lichtenberg, F., Letter to the Editor, Inquiry, Vol. 43, Spring 2006 (in press).

¹⁰⁷ Kuriakose, B., “Disease Management Literature Review”, Agro Health Associates, December 2003.



The potential economic implications of reducing hospitalization rates must not be underestimated. To provide perspective, total health care spending in Canada is the range of \$130 billion per year, with total expenditures on new medicines reaching \$22 billion in 2004¹⁰⁹, corresponding to only 17% of the total health care burden. In Ontario, the total health care spend is roughly \$34 billion¹¹⁰, yet the Ontario Drug Benefit Plan accounts for approximately \$3.4 billion per year¹¹¹. While drug expenses currently account for only 10% of the Ontario government's health budget, they represent the single fastest growing cost component, with Ontario Drug Benefit program costs soaring 140% since 1997¹¹². The remaining 90% of the provincial health care budget is currently spent on hospital expenses, physicians and nurses, as well as rehabilitation and homecare costs, and overhead administration.

Hence by preventing patients from entering the hospital system through the use of innovative medicines, potential cost savings may be highly significant overall. In essence, with greater commitment and investment in bringing new biopharmaceuticals to market, the Ontario government has the opportunity to swing the balance of health costs away from expensive

¹⁰⁸ OECD Health Data 2004. *HIV/AIDS Data 1993-2001.

¹⁰⁹ PMPRB Annual Report, 2004, citing Canadian Institute for Health Information (CIHI) data.

¹¹⁰ Karen Howlett, So Many Patients and Too Few Dollars, The Globe and Mail, June 5, 2006.

¹¹¹ House Statement by George Smitherman, Minister of Health and Long Term Care, April 13, 2006, www.health.gov.on.ca/english/media/speeches/archives/sp_06/sp_041306.html

¹¹² *Ibid.*



hospital-based care. In this context, key pressing questions for the government to consider include the following: Without continued development of innovative medicines, how could the high costs of hospital-based care be adequately managed? In addition, how would the government efficiently deliver community based care without future advances in innovative biopharma products and devices? Significant research efforts will be required in these areas to guide future health care policy.

Several pivotal examples of disease management programs are presented below, with emphasis placed on quantitative Canadian data published to date (see summary presented in Table 2). These examples draw on learnings acquired through recently established public-private sector partnerships, including high-profile initiatives supported by GlaxoSmithKline (PRIISME™), Merck (ICONS) and AstraZeneca (REMEDY™), now successfully underway in conjunction with provincial hospitals and health care teams in Ontario, Québec, B.C., Alberta, and Atlantic Canada. In addition, two examples of effective workplace disease management programs are described, including Pfizer's "Tune up Your Heart" program in Canada, and Pitney Bowes' diabetes prescription benefits program in the United States. Other strategies for disease management, including infection control and biotech-based diagnostics and pharmacogenomics therapies are also briefly discussed.



Table 2 - Leading Disease Management Programs

Program	PRIISME™	ICONS	Tune up Your Heart	Diabetes Prescription Benefits Design
Disease Focus	Asthma, COPD, Diabetes	Cardiovascular Disease	Cardiovascular Disease	Diabetes
Broad Program Objectives	Education, optimal management of chronic disease, improved clinical practice guidelines	Evaluation of evidence-based practices to improve CV health	Education and intervention to improve CV health	Improve diabetes management by enhancing drug benefits (to lower barriers to care)
Program Participants	n=30,000	n=12,500	n=580	n=656
Location	Québec, Ontario B.C., Alberta, Atlantic Prov.	Nova Scotia	Windsor, Ontario	U.S.
Sponsor/ Partners	GlaxoSmithKline, Québec and Ontario Regional health authorities, governments, institutions, community groups, hospitals, private medical clinics, and health professionals ¹¹³	Merck Frosst Canada Inc., N.S. Government, Community Health Care Professionals, Division of Cardiology, QEII Health Sciences Centre	Pfizer Canada, DaimlerChrysler Canada, CAW, Windsor-Essex County Health Unit, Green Shield Canada, Solutions in Health	Pitney Bowes
Program Type	Public/Private partnership (disease management in provincial health care system)	Public/Private partnership (disease management in provincial health care system)	Public/Private partnership (workplace disease management)	Employer-initiated program (workplace disease management)
Investment	> \$9 million	> \$6 million	Undisclosed	Undisclosed
Topline Results	<ul style="list-style-type: none"> • 33% reduction in hospitalization • 50% fewer emergency room visits (asthma related illnesses) [Québec data] 	<ul style="list-style-type: none"> • 16% decrease in rehospital-ization (1 yr after MI) • 9% decrease in rehospital-ization (1 yr after all CV events) 	<ul style="list-style-type: none"> • 40% of participants lost weight • 11% quit smoking • 19% moved to a lower-risk category • 100% increase in compliance with CV medications 	<ul style="list-style-type: none"> • 7% reduction in average total pharmacy costs • 26% reduction in emergency department visits • 6% reduction in overall direct health care costs per plan participant with diabetes

¹¹³ Including, in Québec: Acti-Menu, the Québec Association of Hospitals and Long-term Care Facilities, Québec Federation of Specialists, Québec Order of Pharmacists, Bayer HealthCare, Diagnostic Products Division, Québec Lung Association, Association of CLSC (Local Community Service Centres) and CHSLD (Residential and Long-Term Care Centres) of Québec.



PRIISME™ Program

A major Canadian initiative in disease management is GlaxoSmithKline's PRIISME™ program, more formally known as "Programs to Integrate Information Services and Manage Education". As an excellent example of public-private sector partnerships, PRIISME™ is focused on optimal management of chronic diseases, taking a comprehensive, multidisciplinary approach to integrate all steps of patient management. The PRIISME™ concept involves education of patients, primary care physicians and other allied health professionals to ensure optimal use of medication, particularly through the dissemination of clinical practice guidelines.

From 1999 to 2004, PRIISME™ has implemented more than 25 projects in Québec, focusing on asthma, chronic obstructive pulmonary disease (COPD) and diabetes, through which 3,000 health professionals have been trained and 30,000 patients have received personalized disease education. During the initial four year period from 1999 to 2003, GSK invested over \$9 million in PRIISME™ projects. These visionary partnerships have clearly shown that such investment in innovative disease management programs has significant value; the PRIISME™ approach has been highly successful in promoting better patient outcomes and health care cost effectiveness. For example, a Regional Board in Québec found their PRIISME™ project demonstrated a 33% reduction in hospitalizations and 50% fewer emergency room (ER) visits for asthma related illnesses¹¹⁴. In addition, PRIISME™ has been identified in a 2000 report given by the *Commission d'étude sur les services de santé et les services sociaux in Québec* (the Clair Commission) as a positive health care solution for the Province¹¹⁵.

Based on its success in Québec, the PRIISME™ concept was more recently expanded to help manage chronic diseases at five Ontario hospitals, beginning in 2004. Preliminary in-house data at Credit Valley Hospital is very impressive, suggesting that asthma patients in the PRIISME™ program experience an 80% reduction in hospital admissions, with a 60% reduction in ER visits¹¹⁶. Currently, PRIISME™ projects are also underway in Alberta, British Columbia and the Atlantic provinces. In addition to decreasing hospital and ER visits, more widespread participation in the PRIISME™ initiative is expected to demonstrate continued increases in quality of life, reduced absenteeism rates, and more appropriate use of medications for patients with chronic diseases across the provinces¹¹⁷.

"We've got an overburdened healthcare system and frequent users are patients with chronic diseases. We need innovative, new ideas of how to help patients have consistent, good medical care to lessen the number of times they present to acute care hospitals to manage chronic diseases." Dr. Diane Flood, Head of Respiriology, Credit Valley Hospital, Mississauga, Aug. 2004

¹¹⁴ http://www.gsk.ca/en/about_gsk/health_policy/gsk_reports/innovationcrossroads/GSK32865_PublicPolicy.pdf

¹¹⁵ *Ibid.*

¹¹⁶ Border Crossing, Canadian Healthcare Manager, August 2004, www.chmonline.ca

¹¹⁷ Hospital News, PRIISME™ helps primary care providers and patients manage chronic disease, Dr. Terri Paul, Aug. 2004.



These positive outcomes are anticipated to significantly impact health care costs. To focus specifically on asthma in Québec alone, roughly 760,000 asthma patients visit their doctor every year, and an additional 100,000 patients visit emergency rooms. In Québec, asthma causes roughly 56,000 hospitalization days, 325,000 lost working days, 4,000 ambulance services calls and 150 deaths each year. The annual cost of asthma on the Québec health care system exceeds \$150 million¹¹⁸.

In a very recent Ontario study, the total number of ER visits for asthma exceeded 12,500 (including over 7,800 children and 4,600 adults) at participating clinical sites, with approximately 11% of children and 7% of adults subsequently being admitted to hospital¹¹⁹. Overall, approximately 12% of Ontario children and 7% of Ontario adults are currently being diagnosed with asthma, which is the leading cause of hospitalization for Ontario children and is also a significant cause of school and work absenteeism¹²⁰. For its part, the government of Ontario should encourage and support investment in the latest innovative therapies and educational programs as exemplified by PRIISME™, i.e. to optimize health care outcomes, including the control of hospitalization and ER admission rates as key cost containment issues.

ICONS Program

Another landmark Canadian disease management initiative is Merck's ICONS (Improving Cardiovascular Outcomes in Nova Scotia) project. The ICONS program was conceived as a province-wide, partnership-measurement model of disease management, with a focus on patients with both acute and chronic heart problems. It is one of the largest Canadian studies ever undertaken to measure and improve cardiovascular (CV) health care. Nova Scotia was chosen for this study since approximately 40% of Nova Scotians die from CV disease - a slightly higher rate than the national average of 38%. In addition, the N.S. population of close to 1 million is stable enough to support long-term evaluation, large enough to ensure appropriate statistical power, and yet is small enough to enable adequate tracking and documentation of CV treatments and outcomes. Overall, CV disease is responsible for billions in direct and indirect costs each year in Canada, estimated at \$18 billion in 1994 alone¹²¹.

Launched initially as a 5 year project in February 1997, the purpose of the ICONS study was to examine whether using the most effective evidence-based practices to treat heart disease would measurably improve the health of Nova Scotians. Other objectives included the evaluation of which interventions would best improve health outcomes at the most reasonable cost¹²². Partners in this study include the N.S. Government (Department of Health), Community Health Care Professionals (physicians, nurses, pharmacists), the Division of Cardiology, QEII Health Sciences Centre, and Merck Frosst Canada Inc. (Patient Health Management Division). The budget devoted to this study was \$6 million dollars over five years, as contributed by Merck Frosst Canada Inc.

¹¹⁸ <http://www.newswire.ca/en/releases/archive/May2004/04/c8661.html>

¹¹⁹ M. Diane Loughheed et al., The Ontario Asthma Regional Variation Study, Emergency Department Visit Rates and the Relation to Hospitalization Rates, *Chest*. 2006; 129:909-917.
<http://www.chestjournal.org/cgi/content/abstract/129/4/909>

¹²⁰ http://www.health.gov.on.ca/english/public/pub/ministry_reports/asthma/asthma.html

¹²¹ <http://www.theberries.ns.ca/archives/ICONS.html>

¹²² *Ibid.*



Over the first 5 yrs, ICONS enrolled 12,500 patients to long-term follow up, and examined over 70,000 patient hospitalizations. As a result of the program's beneficial impact on provincial cardiovascular health, as well as its successful integration of community-based administrative culture and processes, ICONS became an operational program of the Department of Health of Nova Scotia in 2002¹²³. Overall, ICONS data has shown an improvement in patient response to treatment and a reduction in hospital readmissions. For example, there was an overall 16% reduction in rehospitalization at one year following a heart attack¹²⁴, and the one year hospital readmission rate for N.S. patients following all cardiovascular events declined from 41% (1998) to 32% (2003)¹²⁵. From the perspective of health policy makers and others primarily concerned with administration of health care, this successful disease management initiative was a major innovation and achievement in organizational behaviour in primary health care¹²⁶. The ICONS program may also serve as a model to expand beyond coordination of hospital-to-home care, by also including primary intervention strategies. For example, such a model may make sense in adult-onset diabetes - a clinical population which shares high-risk for CV, brain and kidney diseases.

"This is a first for the province. Never before have we had such a concentrated focus, provincewide, on preventing, treating and managing cardiovascular disease. It is critical that we continue to build on the ICONS initiative if we are to reduce the number of Nova Scotians impacted by heart disease."

Jamie Muir, N.S. Health Minister, 2002

Tune Up Your Heart Program

A third example, in terms of Canadian disease management programs, is the "Tune Up Your Heart" project, undertaken by Pfizer Canada in partnership with CAW (Canadian Auto Workers Union), DaimlerChrysler Canada and its insurance and benefit service providers. This landmark initiative, the first of its kind for a Canadian manufacturer in the field of workplace disease management, was launched in April 2003¹²⁷. Under this program, the entire Windsor-based workforce was offered a comprehensive educational program consisting of seminars on CV health-related topics, such as diet, exercise, compliance with medications, smoking cessation and informed grocery shopping. In total, 1,180 employees underwent risk assessments; 580 of these individuals who were found to be at-risk chose to enroll in a 12-month intervention program.

At the end of the one year study period, results of the "Tune Up Your Heart" program demonstrated that, of the 580 employees enrolled, 40% had lost weight, 11% quit smoking (36% in the higher-risk group) and 19% moved to a lower-risk category (50% in the higher-risk

¹²³ <http://www.terrymontague.ca>

¹²⁴ Canadian Council for Research in Disease Management, April 2006.

¹²⁵ <http://www.icons.ns.ca/beta/home.html>

¹²⁶ Montague T. et al., Improving Cardiovascular Outcomes in Nova Scotia (ICONS): a successful public-private partnership in primary health care. *Hospital Quarterly* 2003; 7: 32-38.

¹²⁷ [http://www.chmonline.ca/conferences/ho2004/images/Renaud%20\(session%207%20pres%20\).pdf](http://www.chmonline.ca/conferences/ho2004/images/Renaud%20(session%207%20pres%20).pdf)



group). Compliance with CV medications has also increased by 100%. Furthermore, 89% of the participants agreed or strongly agreed with the statement that they plan to maintain healthy changes adopted as a result of the program¹²⁸. An independent actuarial analysis was conducted to assess the direct cost impact of these results in five key areas of direct benefit costs: short- and long-term disability, casual absenteeism, prescription drug costs and group life insurance. The analysis estimates the results could save over \$2 million in 10 years if implemented across DaimlerChrysler Canada¹²⁹.

"It's really encouraging to see organizations like DaimlerChrysler and Pfizer taking steps to help employees stay healthy and active on the job. Corporations that invest in the health and well-being of their employees know the benefits of promoting workplace wellness. It is also encouraging to see innovative partnerships being formed to help develop these healthy strategies." Jim Watson, Ontario's Minister of Health Promotion, May 2006.

REMEDY™ Communications System

AstraZeneca Canada has also initiated several disease management programs, particularly in the treatment of asthma, CV, and gastrointestinal disease. As one key example, AstraZeneca's REMEDY™ communications system involves the use of an automated patient management and tracking software program. REMEDY™ is a 'patient-centric' healthcare management solution that permits self-management outside of a medical facility, be it at home, work, school - with interactive 24/7 monitoring. The system allows for confidential, secure data entry and results tracking through the convenience of mobile cellphones, PCs, laptops or PDAs. The REMEDY™ system has potential use in monitoring cardiovascular disease, diabetes, cancer, respiratory illnesses, arthritis, and obesity; its main goals are to promote individual health, wellness and disease self-management - thereby preserving independence, preventing illness and injury.

REMEDY™ was initially launched in February 2005 as a pilot program for asthma sufferers at Stonegate Community Centre, in conjunction with St. Joseph's Health Centre, Toronto¹³⁰. The main objectives of this program are to enhance communication between patient and caregiver - particularly in terms of asthma-inhaler use and emergency room visits - that may otherwise go unreported. Manual administration is also reduced with bi-directional data flow, including alerts, notifications, and prompts (in the form of local weather reports and pollen counts), as well as reporting of new symptoms/triggers, to improve patient compliance. The digital, internet-based REMEDY™ technology helps overcome one of the greatest challenges of earlier disease management programs, most notably the difficulty in aggregating accurate patient information.

¹²⁸ Canadian Council for Research in Disease Management, April 2006.

¹²⁹ Improved Health of Employees and Financial Bottom Line Demonstrated Through Innovative Pilot Program at DaimlerChrysler Canada's Windsor Assembly Plant, Pfizer Press Release, May 10, 2006.

¹³⁰ Kira Vermond, Right on Track, Software Helps Doctors Monitor Patients Between Visits, Canadian Healthcare Manager, April 2006, <http://www.chmonline.ca/issuearchive/April2006/innovations.pdf>



“We’re eventually going to shift to a paradigm where the physician and patient are looking at the same screen”.

Dr. George Tolomiczenko, Director, Research and Knowledge Management, St. Joseph’s Health Centre, Toronto, 2006

While the REMEDY™ system has been implemented too recently to demonstrate its full impact in asthma patients, it is anticipated that this disease management software will provide a powerful means to control costs, improve the delivery of care, and enhance employee productivity. Whether this tool is used to digitize an existing health, wellness or disease management program (i.e. for greater effectiveness and efficiencies), or if it is used to facilitate the implementation of such a program, REMEDY™ is expected to generate substantial cost savings and reduce emergency room visits by promoting patient education, compliance, and timely treatment intervention.

Diabetes Benefits Program

Another excellent example that demonstrates the value of workplace disease management programs is the program introduced by Pitney Bowes Inc.¹³¹ to manage diabetes in the United States. Pitney Bowes provides integrated mail and document management services, with over 23,000 employees in the U.S. (58% male), with an average length of service of 8.1 years. Concerned about rising prevalence and costs of diabetes among its employees, the Company revamped its drug benefit design in January 2002 to synergize with its other disease management and patient education programs. The Center for Disease Control and Prevention estimates the annual direct costs for diabetes and related complications at \$92 billion per year, with health expenditures for an individual with diabetes estimated at triple those of the average consumer. From the US employers’ perspective, the burden of diabetes extends even further to include the \$40 billion annual cost for indirect expenditures due to disability, work loss and premature mortality¹³².

Based on data from an internal study commissioned by Pitney Bowes, the Company became aware that lack of adherence to diabetes treatment contributes to disease-related complications, and hence that non-adherence is a cost driver. The evidence that low prescription fill rates are associated with high subsequent costs led the Company to question its fundamental assumptions regarding cost sharing and drug accessibility in the company prescription benefit plan. Hence in this study, Pitney Bowes shifted all diabetes drugs and devices from their previous Tier 2 or 3 formulary status to Tier 1. This single change in pharmaceutical drug benefit design immediately made critical brand-name drugs available to most Pitney Bowes employees (and their covered dependents) for 10% coinsurance, versus the previous cost share of 25% to 50%. The rationale was that by reducing patients’ out-of-pocket costs, this should eliminate

¹³¹ John J. Mahoney, MD: Reducing Patient Drug Acquisition Costs Can Lower Diabetes Health Claims, The American Journal of Managed Care, August 2005, S170-176.

¹³² Centers for Disease Control and Prevention, www.cdc.gov/diabetes/pubs/estiamtes.htm, April 21, 2005.



financial barriers to preventive care, thereby increasing adherence and reducing costly complications, thus in turn, slowing the overall rate of rising health care costs.

After 2-3 years, preliminary results for plan participants with diabetes demonstrated that medication possession rates had increased significantly. Use of fixed-combination drugs had increased (possibly related to easier adherence), yet average total pharmacy costs had decreased by 7%. This overall decrease in pharmacy costs for employees with diabetes was thought to result from a reduction in complications and the avoided need for other even more expensive drugs. In addition, emergency department visits decreased by 26%, and hospital admission rates, although increasing slightly (a potential result of the aging of the workforce), remained below the demographically adjusted Medstat benchmark. Total direct health care costs per plan participant with diabetes decreased by 6%¹³³.

“As indicated in this preliminary project, health managers may be able to improve care and limit overall costs for diabetes by selectively lowering barriers to appropriate pharmaceutical access.”

John J. Mahoney, M.D., American Journal of Medical Care, 2005

Overall, Pitney Bowes' simple modification in benefit design highlights the fact that such changes can significantly impact disease management, facilitating wellness in long-term care. Furthermore, the sharp increase in diabetes prevalence at Pitney Bowes during the last few years (36 episodes per 1,000 employees by 2005, a rate increase of 50% over 2001), makes these findings all the more compelling. In the future, as more of the population is diagnosed with diabetes and the workforce continues to age, cost pressures associated with diabetes and CV care will build even more intensely. For policy makers aiming to address these issues, the Pitney Bowes project appears to serve as a promising preliminary model.

4.2 Other Biotech-Based Approaches

Another major strategy for attacking health care costs through enhanced disease management is in the area of infection control. Hospitals are notoriously dangerous places - this year alone, 200,000 Canadians will acquire (and 8,000 to 12,000 Canadians will die from) a hospital infection. The mortality rate ranks with those for breast and colorectal cancer. Hospital infections are also expensive, including the cost of additional hospital stay. A crude estimate of the annual direct costs of hospital infections in Canada (such as pneumonia, surgical wound infections, blood stream and urinary tract infections) is about \$1.5 billion. Yet there is ample evidence that for every dollar invested in infection control, there is a return of at least \$5 to \$7¹³⁴.

In this context, it is noteworthy the PMPRB reported that general anti-infectives for systemic use and parasitic products accounted for a major portion (10.5%) of sales of patented drugs in Canada in 2004. As a single class, anti-infectives/parasitic products fall within the top 4 drug

¹³³ Canadian Council for Research in Disease Management, April 2006.

¹³⁴ Knowledge Transfer and Management in Health Care: Quality, Safety, Accessibility and Affordability – Finding the Balance, Queen's School of Business, 2005.



classes for total sales in 2004, as well as the top 4 classes that contribute to growth in total expenditure in 2004, relative to 2003. Thus the Canadian and Ontario governments should be highly motivated to support R&D towards future development of new biopharmaceutical diagnostics, e.g. as made possible through advances in proteomics and genomics techniques. Exquisitely sensitive (DNA-based) diagnostics that can rapidly and definitively detect pathogens will be powerful tools for real time outbreak analysis and disease surveillance, thereby reducing the spread, and concomitant treatment cost, of infectious disease. The need for research in this area is further underscored against the backdrop of increased global travel, escalating the risk of disease migration, including avian influenza. The World Tourism Organisation predicts global tourism will triple by 2020 as low-cost air travel is aided by ever-larger commercial jets that can travel farther and faster¹³⁵.

Apart from applications in infectious disease, biotech-based tests are now being used to diagnose certain cancers, including prostate and ovarian cancer, by taking a simple blood sample¹³⁶. This eliminates the need for invasive and costly surgery, and also reduces the potential cost of hospital stay, including the risk of post-operative infection and treatment. In addition to diagnostics that are cheaper, more accurate and quicker than previous tests, biotechnology is allowing us to diagnose diseases earlier in the disease process, greatly improving a patient's prognosis¹³⁷.

Another key area in which advanced biotech and disease management systems may reduce health care costs is within the branch of genomics research termed "pharmacogenomics". Pharmacogenomics is the study of how genes affect the way an individual responds to drugs. It refers to products that use biomarkers for diagnosis, prescription and patient treatment. Pharmacogenomics has the potential to diagnose diseases earlier in their development and to aid physicians and patient decisions regarding therapies for serious diseases.

Many experts anticipate that pharmacogenomics research will generate highly targeted therapies, with significantly improved efficacy rates. For example, as of 2006, it is not uncommon to have success rates of only 20%-80% in treating lung or breast cancer patients with chemotherapy, particularly for patients with metastatic disease.^{138,139} This means that a large fraction of treated patients are receiving no health benefit, and may also be experiencing undesirable side effects. At the same time, treatment costs for these patients represent a huge economic drain on the health care system.

In contrast, the practice of "predictive, preventive and personalised" medicine, via investment in tailored pharmacogenomic therapies, is expected to reduce the overall economic burden, primarily by maximizing efficacy (e.g. in patients who are most likely to respond to drug treatment)¹⁴⁰. Pharmacogenomics therapies are also anticipated to minimize side effects (e.g. in

¹³⁵ PricewaterhouseCoopers, Connectedthinking, HealthCast 2020:Creating a Sustainable Future, 2005.

¹³⁶ Women sought for Cancer Trial, The Australian, Amy 14, 2006.

¹³⁷ BIO 2005-2006, Guide to Biotechnology, Biotechnology Industry Organization (www.bio.org).

¹³⁸ Improving the Odds in Lung Cancer, OncoLog, January 2006, Vol. 51, No. 1.

¹³⁹ Dr. Uri Sagman, Executive Director, Canadian Nanotechnology Business Alliance, Toronto Biotechnology Initiative Breakfast Meeting Presentation, Jan. 19, 2006.

¹⁴⁰ *Ibid.*



patients with specific gene variants), and to optimize dosing in general¹⁴¹. In addition, it has been argued that improved drug-targeting could reduce the massive marketing costs vital to previous-generation blockbuster drugs, hence reducing the purchase price of these novel pharmacogenomics products¹⁴².

Overall, predicting the economic impact of pharmacogenomics is currently a controversial subject, especially since major differences in cost outcomes are expected if only high-risk persons are tested (potentially generating net savings), versus implementing an unfocused screening program (that could result in adverse financial impact on the health care system)¹⁴³. A broad fundamental challenge of public policy will be the need to guide genomics innovation in directions that will materially improve the health of Ontarians, Canadians, and other patients around the world.

4.3 Maintaining Wellness (Disease Prevention)

A recent focus for helping to reduce the strain on health care systems is the consumer-targeted approach of health promotion, i.e. by promoting the consumption of fresh fruits and vegetables to “maintain wellness”, rather than to “treat illness”. For example, a recent study reports that a diet high in vegetable products helps to prevent high blood pressure and related chronic diseases¹⁴⁴. Consistent with other recommendations that vegetable products be part of a healthy lifestyle, it has also been shown that smoking, alcohol use, and low fruit and vegetable intake are leading risk factors for cancer-related deaths worldwide and in low-and-middle-income countries¹⁴⁵. Another recent study reports that a high dietary intake of antioxidants, including beta carotene, vitamins C and E, and zinc (as provided by vegetables such as asparagus, carrots, and broccoli) is associated with a substantially reduced risk of age-related macular degeneration in elderly persons¹⁴⁶.

Dr. Gord Surgeoner, President of the Ontario Agri-Food Technologies, presented the concept of promoting the “health” of fresh fruits and vegetables at the recent Annual General Meeting, March 2006¹⁴⁷. The concept of “Verified Health Quality” or VHQ¹⁴⁸ (which builds on consumer identification and acceptance of VQA wines), and which will also involve Foodland Ontario, will be used to aid such promotion. By enlisting resources within the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA), as well as the Ministries of Education, Research and

¹⁴¹ Pharmacogenetics: Ethical Issues: Nuffield Council on Bioethics, 2003
(http://www.nuffieldbioethics.org/go/ourwork/pharmacogenetics/publication_314.html)

¹⁴² Pharmacogenomics to Replace Pharma’s Business Model
(<http://drugresearcher.com/news/ng.asp?n=58360-pharmacogenomics-to-replace>)

¹⁴³ Miller, F., “Predictive Genetic Tests and Health Care Costs”, Final Report prepared for the Ontario Ministry of Health and Long-term Care, Jan. 2002.

¹⁴⁴ Eating vegetables lowers blood pressure - study, Reuters, January 10, 2006.

¹⁴⁵ Causes of cancer in the world: comparative risk assessment of nine behavioural and environmental risk factors, Lancet, 2005, Nov 19; 366 (9499):1784-93.

¹⁴⁶ Dietary Intake of Antioxidants and Risk of Age-Related Macular Degeneration, R. van Leeuwen et al., JAMA 2005; 294: 3101-3107.

¹⁴⁷ Dr. Gord Surgeoner, Fresh Fruit and Vegetables, Beyond Food, Ontario Agri-Food Technologies AGM, March 3, 2006.

¹⁴⁸ www.vhqfood.com



Innovation, Health Promotion, this campaign intends to eventually promote processed fruits and vegetables, whole grains, specialty dairy and eggs, as well as specialty meats and fish, although not promoting specific brands or individual companies. The main thrust of this promotion will be to change consumer behaviour to prevent disease (and substantially lower or ultimately avoid treatment costs), with potentially far-reaching benefits for the Ontario economy.

“My father taught me that it’s better to buy health at the grocery store than the drug store”. Leona Dombrowsky, Ontario Ministry of Agriculture, Food and Rural Affairs, Royal Winter Fair, 2005

As advances in biotechnology continue to reveal key mechanisms underlying chronic illnesses (such as cancer, cardiovascular disease and obesity), the role of fruit- and plant-derived nutrients (including antioxidants) in attenuating such diseases will become better understood. Hence Ontario’s investment in research in biotechnology today should contribute to success in “maintaining wellness” and improving the overall health status of this province in the future. Research in these promising areas also represents another example of convergence within biotechnology - in this case across the human health, agriculture and food industry sectors.

4.4 Opportunity Costs

As noted earlier, biopharmaceutical innovations are likely to exert pressure on the health care system by creating new tests and treatments, many of which are anticipated to be expensive. To what extent are R&D investments in biotech-related innovations fueling this pressure, particularly within Ontario? Another way to look at this question is to ask: If the provincial government provided less support to the biopharmaceutical sector, would it ease the pressure on our health care system? The answer is a definitive “No”.

Despite the growth of the biotech industry both in Ontario and in Canada, the vast majority of advanced and expensive bio-based products entering our health system are developed in other countries. If Canada or Ontario reduces its commitment to R&D, the research would continue to happen elsewhere. Hence, when a product is developed, we would end up importing it, because physicians are not generally concerned with the origin of a new therapeutic or diagnostic product. If it comes on the market and is better than current products, physicians and their patients will demand it¹⁴⁹. In fact, a recent international study reported that the internet has made a huge jump in importance as a source of health care information, and as patients become better educated, over 54% of all patients are now visiting their health care provider with a specific treatment or brand of medicine in mind¹⁵⁰.

According to Statistics Canada, total shipments by Canadian drug manufacturers amounted to \$7.8 billion in 2003, with Canadian plants supplying only about \$4.4 billion of these shipments. Given that total drug sales were estimated by PMPRB to be \$15.1 billion in 2003, it can be

¹⁴⁹ Biotechnology and Health Innovation: Opportunities and Challenges, A Discussion Document from the Canadian Biotechnology Advisory Committee (CBAC), March 2004.

¹⁵⁰ Global Research Report, Vision & Reality 2005, Capgemini Consulting.



readily calculated that roughly 29% (4.4/15.1) of Canada's drug sales are supplied domestically by Canadian plants¹⁵¹. Conversely, this implies that Canada is currently importing over 70% of total drugs utilized. Also, the import share becomes even higher if the calculation is restricted to brand name products, since most generic drugs sold in Canada are produced domestically. These data underscore the magnitude of Canada's drug importing operations to supply current health care demand. They also highlight the need for Canada and Ontario to actively promote and develop domestic drug products to support adequate delivery of health care (and pricing control) within our own borders.

"...is Canada prepared to simply import what is needed - with scarce capital flowing out of the country? Or are we looking to invest in the infrastructure and mechanisms that are required to ... capture the economic rent that can accrue from world-class, leading-edge innovations, while improving our quality of life? Do we want to 'make' or 'buy' more of the goods and services produced by the health sector? How can Canada move from being more a "price taker" to more a "price maker?"

Glenn Brimacombe, CEO, Association of Canadian Academic Healthcare Organizations (ACAHO), 2005

The reverse argument can also be made - that many Canadian firms may specifically target US and other foreign markets in distributing biopharmaceutical products. The decision to market products in foreign countries is typically based on the fact that R&D investment is typically too high to be recouped domestically, but may also reflect perceived and/or real advantages of foreign regulatory systems. Interestingly, while such strategies taken by Canadian firms might impede the availability of novel therapies within Canada and/or Ontario, government investment in such firms would still generate domestic tax revenues.

With regard to potential job loss, it has been asserted that while provincial efforts and progress to date have been commendable, Ontario cannot afford to sit by and watch biotech companies and talent leave for other jurisdictions. To do so would risk letting other regions take the lead and surpass Ontario, drawing desirable jobs, resources, companies and dollars away from our economy¹⁵². In a similar vein, if the businesses are there but the graduates are not, Canada fails. If the graduates are there, but the businesses are not, we may be training the next generation labour forces of our competitors¹⁵³.

4.5 Other Factors Affecting Health Care Costs

Rising levels of health care costs do not necessarily imply rising prices of biopharmaceutical products, diagnostics, or therapies (or the reverse). Several other factors, i.e. those that affect

¹⁵¹ PMPRB, Annual Report 2004, p 27.

¹⁵² Getting OnTRAC: Benchmarking Ontario's Biotechnology Sector, Biotechnology Council of Ontario, 2003.

¹⁵³ Conference Board of Canada, Biotechnology in Canada: A Technology Platform for Growth, Dec. 2005.



the volume and composition of drug utilization, can produce high cost increases even when drug prices are constant or declining¹⁵⁴. These factors include:

- changes in total population or changes in the demographic composition of the population (e.g., movement in age-distribution towards older persons with more health problems);
- increased incidence (within particular demographic groups) of health problems calling for drug therapy;
- changes in the prescribing habits of physicians (e.g., shifts away from older, less expensive drugs to newer, more expensive medications treating the same condition, possibly more effectively);
- greater use of drug therapy rather than other treatments (e.g., instead of surgery);
- use of innovative drug therapies to treat conditions where no effective treatment existed previously; and,
- greater propensity on the part of physicians and patients (e.g., in response to new medical findings) to use drugs to treat conditions not previously considered problematic.

In addition to the factors outlined above, it should be borne in mind that the cost of drugs represents only 17% of total health care spending in Canada¹⁵⁵, and accounts for only 10% of the Ontario government's health budget, as noted in Appendix 4.1. In Ontario, additional budget should be assigned to the Ministry of Health, recognizing that required growth in the provincial drug budget (driven primarily by emerging disease trends and the aging population) will contribute to both cost savings and improved health status through appropriate chronic disease management. Higher drug utilization should actually be considered a success story for the health system, with fewer doctors and surgeons required to treat hospital-based illnesses.

4.6 Summary

At present, the Ontario government is urgently seeking solutions to temper health care costs, while balancing the need to provide safe, quality care. In the context of developing consistent provincial innovation and health care policies, investment in biopharmaceutical products must be viewed as a potential solution in offsetting rising health care costs, as driven by aging populations and emerging disease trends.

With regard to disease management, several large, high-profile Canadian programs have demonstrated great potential to reduce overall health care costs, i.e. by investing in evaluation, as well as in improvement and education of best clinical practices, including the use of innovative medicines. In particular, hospitalization/readmission rates and emergency room visits, and hence overall health care costs, can be reduced through appropriate management of chronic conditions, including asthma, COPD, diabetes, and cardiovascular disease. Decreases in hospital and emergency room costs mean savings to the bottom line - savings that can be reinvested in the health care system and ongoing innovation¹⁵⁶. Furthermore, investment in novel biopharmaceutical diagnostic tools (e.g. for real time infection control or early stage cancer detection) as well as in disease prevention programs may also contribute to a healthier,

¹⁵⁴ PMPRB, Annual Report 2004, citing Canadian Institute for Health Information (CIHI) data.

¹⁵⁵ *Ibid.*, p 6.

¹⁵⁶ Speaking Notes for Paul Lucas, President & CEO, GSK, Mississauga Board of Trade, April 27, 2006.



more productive work force, with fewer or shorter hospital stays. In the U.S., results of the recent Pitney Bowes study have clearly demonstrated that for diabetes patients, improving access to pharmaceuticals can reduce overall costs. This study may serve to guide other policy-makers dealing with rising costs and other long term diseases on both sides of the border.

While additional studies must be conducted to demonstrate additional economic benefits associated with biopharma innovations, net savings are expected to be significant. It is encouraging that the Ontario government, as part of Bill 102 Legislation (the Transparent Drug System for Patients Act, 2006), has recently announced its plan to invest in innovative health system research by establishing a \$5 million Innovation Research Fund. This funding will assist in investigating the value of medicines across the entire health system to support Ontario's future drug policy. It is anticipated that results of this future research, taken together with data from currently available studies, will provide further motivation for fuelling the innovation cycle.

Overall, by investing in leading-edge biopharma technologies, the Ontario government can contribute to cost containment within - and hence sustainability of - the provincial health care system. Savings could then be redirected within the health care system in areas of priority need. For example, since increased investment and expenditure on the provincial drug budget are anticipated to reduce the number of surgeries and/or hospital stays, this will help to directly alleviate hospital waiting times. Net fiscal savings could also be reinvested to support the high-profile "Ontario Wait Time Strategy", or other provincial programs to facilitate patient access, including the management of the 14 new Local Health Integration Networks (LHINs). Alternatively, net savings within the health care system (which currently consumes 46% of the provincial budget¹⁵⁷) could also be deployed to enhance other provincial programs, e.g. within the ministries of Education, Transportation, or the Environment. In this way, Ontario's innovation and health strategies could also be aligned with the Province's broader industrial policy.

¹⁵⁷ Karen Howlett, So Many Patients and Too Few Dollars, The Globe and Mail, June 5, 2006.



Appendix 5

How the Ontario Government Can Support the Biopharmaceutical Sector



Appendix 5 - How the Ontario Government Can Support the Biopharmaceutical Sector

In the context of countless exciting new advances, we are probably beyond the stage of discussing **why** Ontario should embrace the biopharmaceutical technology as a platform for growth. It would be akin to asking whether or not we should embrace electricity or the Internet.

"It is no longer a matter of if we should establish a biotechnology platform, but how we will establish it." Conference Board of Canada, Biotechnology in Canada: A Technology Platform for Growth, Dec. 2005

5.1 Success Metrics, Trends and Gaps

In previous reports^{158,159}, the Biotechnology Council of Ontario (BCO) has identified four key drivers in building a successful biotech sector: talent, regulatory environment, alliances, and access to capital. In looking at the many regions around the world that are seeking to grow their biotech sectors, each of these regions is also focused on these major themes, including methods to maintain or improve these four key elements. The BCO reports provide a framework, aptly named "Getting *OnTRAC*", as an excellent mechanism for benchmarking Ontario's competitiveness in terms of **T**alent, **R**egulatory Environment, **A**lliances, and **C**apital, relative to other regions. Emphasis is placed on methods to strengthen these key components of public policy as means of communicating the pathways by which the Ontario government can help support the biopharmaceutical industry to optimize its productivity and growth. For the complete data and analysis supporting the *OnTRAC* framework, the reader is encouraged to refer to the comprehensive BCO reports. It is noteworthy that consensus was reached on the conclusions of the 2003 BCO report at a Public Policy Workshop, and a subsequent BCO Public Policy Forum involving over 200 participants led to published proceedings in 2004.

Many reviews of the biotechnology sector include a variety of metrics to indicate the level of maturity and stability that has been reached in this industry within the past few years. While such metrics are typically used for benchmarking purposes, they are also used as incentives to attract further investment and partnering activities, i.e. to fuel a steady stream of unique new therapies.

"Dozens of metrics mark the coming of age of the biotech industry."
Karen Bernstein, Editor of BioCentury, 2006

The most common metrics quoted within the biotech industry include the number of companies, jobs, venture capital financing, government funding, and R&D spending associated with a

¹⁵⁸ Getting OnTRAC: Benchmarking Ontario's Biotechnology Sector, Biotechnology Council of Ontario, 2003 (www.biocouncilontario.com).

¹⁵⁹ The Commercialization Agenda, Policy for the Ontario Biotech Industry, First Annual Public Policy Forum, Biotechnology Council of Ontario, Final Report, December 2004 (www.biocouncilontario.com).



particular geographic region or sub-sector (e.g. see sample data presented for Canada and Ontario in Appendices 1.4.1 & 1.4.2). However, a number of other success metrics are also used, many of which are presented in Table 3 below.

Table 3 - Success Metrics (by Category)	
1) Organizational	<ul style="list-style-type: none"> • Number of private/public companies • Average headcount per firm • Industry associations/organizations/clusters/collaborations • Corporate partnerships
2) Finance	<ul style="list-style-type: none"> • Venture capital (VC) financing • Initial public offerings (IPOs) and follow-on financing • Market capitalization • Government funding, grants & awards (“public investment”) • Industry/corporate investment (“private investment”) • Burn rate or survival time • R&D investment/spending • Scientific Research and Experimental Development (SR&ED) tax claim refunds • Sales/Revenues
3) Human Capital	<ul style="list-style-type: none"> • Number of employees/employers • Placements (and degrees awarded) in undergrad/graduate university programs • Networking forums, national meetings, association memberships
4) Technology Transfer	<ul style="list-style-type: none"> • Academic/industry alliances • Scientific publications • Licensing deals • Spin-off companies • New patents filed/granted
5) Regulatory	<ul style="list-style-type: none"> • Products in Phase I/II/III clinical trials • Number of Health Canada approvals (NOCs) • Approval time • New formulary listings (full/restricted) • Time to listing (TTL) • Total prescriptions (\$ value of Rx) • Reimbursement
6) Manufacturing	<ul style="list-style-type: none"> • Number of new plants • Square footage of research space



Figure 3 - Framework for Success Metrics

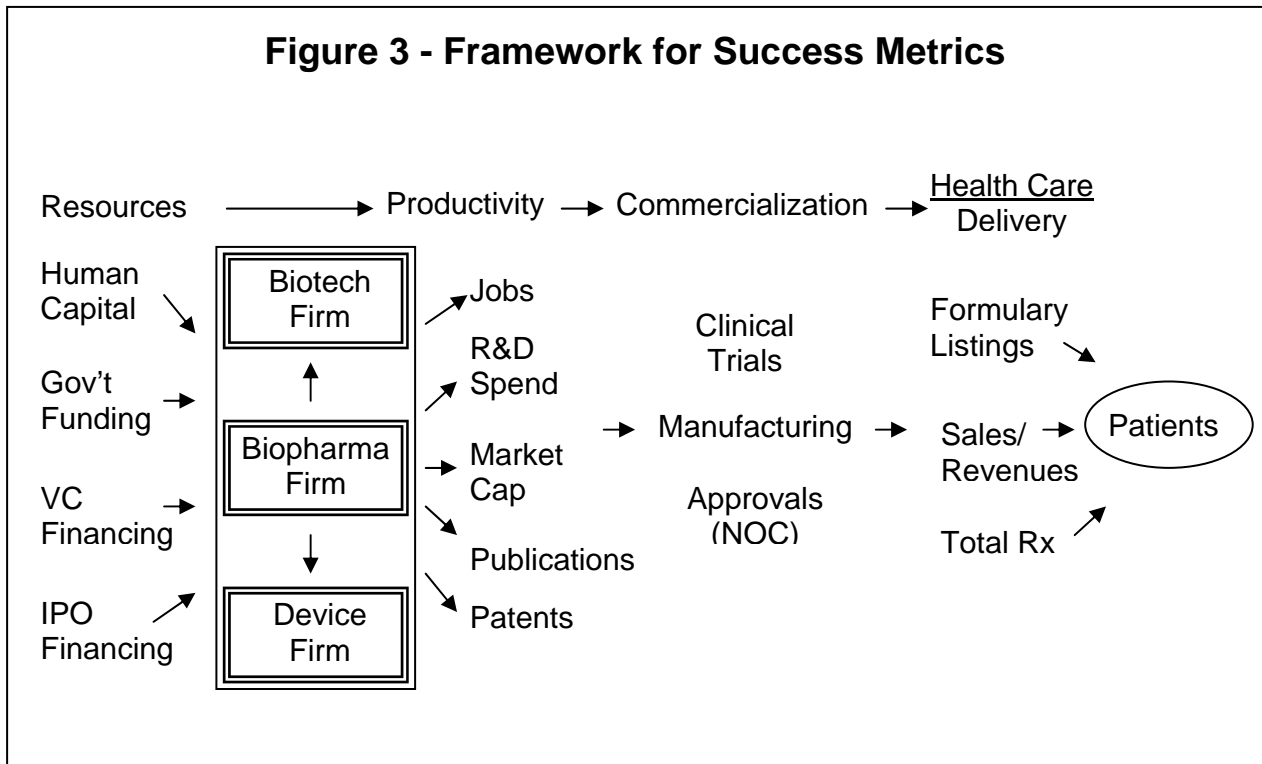


Figure 4 - Framework for Success Metrics

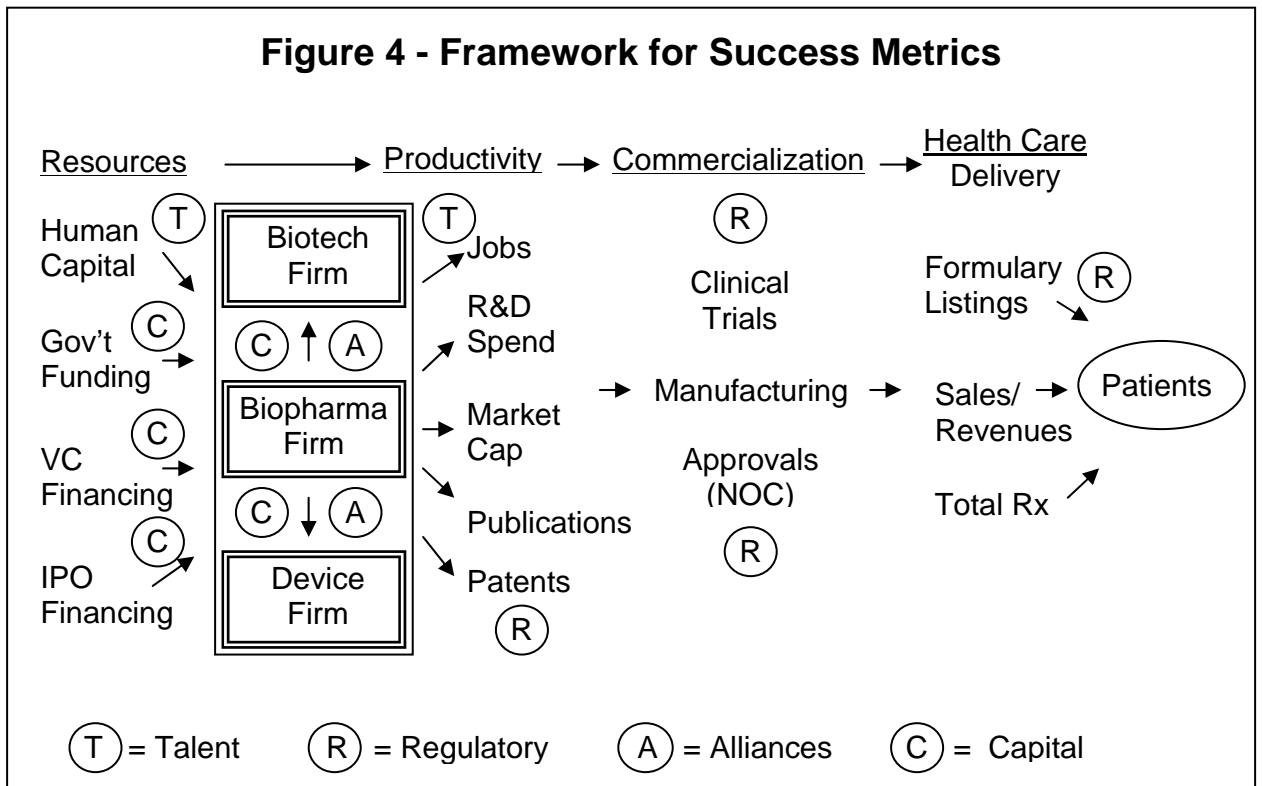




Figure 3 presents an alternative scheme for illustrating success metrics along a different dimension. It shows the inter-relationships among the relevant entities (research organizations) and several common measures of success. This framework also attempts to position these metrics within an appropriate sequence along the pathway from the initial investment in research, towards innovation and growth, and ultimately, the delivery of new therapeutics for health care applications. For the purpose of this analysis, success metrics are grouped into four categories: 1) resource-based measures, 2) productivity-based measures, 3) commercialization-based measures, and 4) health care delivery-based measures. It should be emphasized that this report is not intended to describe (or provide data for) each of these metrics in detail, but instead to provide more general tools to identify relevant categories, trends and gaps.

In Figure 4, an attempt is made to identify those metrics which are associated with the four key categories presented in the *OnTRAC* framework described above. Essentially, this process involves the simple overlaying of the 4 key elements of the *OnTRAC* benchmarking system onto the framework in Figure 3. It should also be noted that Figure 4 illustrates key players and relationships mainly within in the biopharmaceutical's industry/private sector, within which the companies are ultimately positioned to provide health care applications to patients. Potential alliances (see A = alliances) are shown between biopharmaceutical, biotechnology, and device firms; such relationships could include partnerships or licensing agreements for product development, clinical trials, manufacturing, and/or sales. Although equivalent infrastructures for government, academic, and hospital sectors are not represented in Figure 4, many potential collaborations between/among these other sectors (not shown) and the industry players (as shown) already exist and will continue to be nurtured and expanded in the future.

A key drawback in implementing and analyzing success metrics in the bio-pharmaceutical sector is that the vast majority of measures being reported do not focus adequately on the commercialization and delivery of health care products or applications as the final "end-game". In large part, this observation reflects the fact that many firms in this sector, especially those biotechnology firms not affiliated with established pharmaceutical players, are in early stage of their development cycle. Hence, many Canadian biotech firms are unlikely to have any commercial products or revenues. Thus, while measures such as the number of companies or jobs, venture capital financing, government funding or R&D spending are often touted as measures of success, they should be more modestly considered as *intermediate* measures for actual success and ultimate growth.

"Some health innovations may be based on biotechnology inventions, but a biotechnology invention is not in itself a health innovation until it is introduced and applied." Biotechnology and Health Innovation: Opportunities and Challenges, A Discussion Document from the Canadian Biotechnology Advisory Committee, March 2004

Specifically, parameters such as firm count or company headcount, and even R&D spending should be considered closer to the "input" side of the spectrum, in terms of bringing products to market. Hence these measures are categorized as earlier stage "resource-based" or



“productivity-based” metrics in Figures 3 & 4. Overall, such intermediate measures should be seen as **necessary**, but **insufficient** conditions for success in the biopharmaceutical sector¹⁶⁰.

Returning to the broader goals for R&D in this sector, namely to advance innovation and health strategy, “there is a demand to move up the value chain”, by asking¹⁶¹:

- Was the new product commercialized?
- Was it profitable?
- Did it provide benefits to its users?
- Did it contribute to the well-being of Canadians?

At present, both the federal and provincial governments appear to be seeking a sharper series of metrics that are directly tied to commercialization and health care delivery, more clearly articulating “the rate of return” that their investments are generating. This is an important point, especially given the lack of current consensus regarding how to measure return on investment¹⁶². Clearly, more work must be done in this area.

5.2 Limitations of Data Collection for Success Metrics

In general, biotechnology data collection in North America is considered rudimentary, with data-gathering practices still in a relative state of infancy¹⁶³. Other problems inherent in data collection methodologies include the following:

- Data is often reported for jurisdictions of different scope, e.g. the US¹⁶⁴ versus Canada^{165,166}, Ontario¹⁶⁷, or the greater Toronto region innovation corridor¹⁶⁸, and as such, may not be directly comparable. In addition, the sophistication of data collection, the types of success metrics, or the definitions used for success metrics, may not be consistent across the regions considered, making it difficult to draw clear comparisons and conclusions.
- The sector(s) under evaluation may represent very broad fields (e.g. life sciences, innovation industries) or more narrow disciplines (e.g. pharmaceutical or biotechnology sectors), some of which may be overlapping. Hence it may be difficult to align or “tease out” specific elements for analysis, even within a single region.

¹⁶⁰ Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, Dec. 2005.

¹⁶¹ *Why Conduct R&D?*, Innovation Analysis Bulletin Vol. 8, No. 1, Statistics Canada, February 2006.

¹⁶² *Health, Healthcare and Nation-Building: A Three-Dimensional Approach to Innovation in Canada*, Glenn G. Brimacombe, *Healthcare Quarterly*, Vol. 8, No. 3, 2005.

¹⁶³ Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, Dec. 2005.

¹⁶⁴ BIO 2005-2006, *Guide to Biotechnology*, Biotechnology Industry Organization (www.bio.org).

¹⁶⁵ *From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada’s Innovative Health Industries*, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.

¹⁶⁶ *Follow the Leaders, Celebrating Canada’s Biotechnology Innovators*, Government of Canada, Second Edition, 2003.

¹⁶⁷ <http://www.biotechontario.com/guides/overview.asp>

¹⁶⁸ *Engaging Innovation*, Toronto Region Research Alliance (TRRA), October 2005.



- For any given success metric reported for a specific region, trend analysis over a period of 5 or more years is not often provided. With the exception of BIO's 2005/2006 "Guide to Biotechnology", which provides comparative data over at least a 10 year window, the critical context of timeframe (as other known changes occur in the economy) is frequently missing.
- Counting the number of firms in a given sector is at best a rough measure of activity. Firm count should not be considered an accurate reflection of the size, sustainability or success of those firms, or of a successful biotechnology sector. Furthermore, any activities undertaken outside dedicated biotechnology firms can be difficult to capture. As a result, conventional businesses that are employing new biotechnology processes may not be reflected in the count of firms.

"Canada is developing an environment in which ideas flowing from scientific discovery are being generated at an unprecedented rate. Now we must focus on bringing these ideas to market; to realizing their commercial potential. That is what will drive our economy forward, increasing investment and employment."

Federal Budget Speech, March 2004 (cited in: Engaging Innovation, Toronto Region Research Alliance, October 2005)

5.3 Enhancing Ontario's Culture of Innovation as a Basis for Commercial Success

In evaluating its current success in supporting the biopharmaceutical sector, the Ontario government must acknowledge that the local industry and business environment may not be enabling optimal commercialization and growth. Thus, in developing future policy, the provincial government must work hard to understand and remove any barriers to innovative research that may result in the stagnation or contraction of the local biopharmaceutical industry. Failure to be at the forefront of future treatment and diagnostic innovations would also mean that we will fail in our objective to provide state-of-the-art health care to patients in need. Overall, in putting forth recommendations to help shape future policy, we must ask the critical question - how can Ontario's current innovation culture be improved?

If Ontario is to compete successfully with other provinces and countries, primarily the US and the UK, then the Province's life sciences sector will need to operate within a regulatory, legislative and policy framework that is competitive and conducive to increased R&D investment and its commercial exploitation¹⁶⁹. Building on its many strengths, Ontario needs to more aggressively foster an "innovator-friendly" environment by enhancing the attractiveness of local market conditions, i.e. by enhancing investment and tax incentives, and by reducing regulatory barriers to commercialization.

¹⁶⁹ From Discovery to Market: Creating a Multi-Stakeholder Partnership in Support of Canada's Innovative Health Industries, Canadian Health Industries Partnership (CHIP), Public Policy Forum, Conference Report, July 2005.



“Marketplace rewards and reimbursement policies that ensure patients have access to our breakthroughs are absolutely critical to the health of our industry. Without these incentives, biotech companies can’t raise the money they need from investors to fund R&D of the next generation of therapies.” James C. Greenwood, BIO President & CEO, 2005

While Ontario struggles with current and future policies, the province of Québec represents an excellent example, particularly in terms of developing policies that support a dynamic pharmaceutical industry, including accessibility of medication, fair and reasonable prices, and optimal drug use. The Québec government acknowledges the pharmaceutical industry as a major player in the provincial economy, and hence the importance of linking health and industrial policy in order to ensure that the provincial government acts coherently in these fields. As an outcome of industry meeting held in May 2004, which culminated in a consensus Pharmaceutical Policy Consultation Paper¹⁷⁰, three main proposals have been put forward to support a dynamic pharmaceutical industry in Québec.

The first proposal for Québec is to maintain the 15-year rule, to ensure manufacturers of new medications are guaranteed their product will remain fully refundable for 15 years after being included in the formulary, even if the patent expires and a less expensive generic equivalent enters the market. The second measure is for agreements to be signed with the pharmaceutical industry in order to promote optimal drug use and reduce risks of using medications. Finally, in order to maintain balance between health and economic development policies, a permanent discussion forum is proposed, bringing together the MSSS, the Ministère du Développement économique et régional et de la Recherche (MDERR), and manufacturers of innovative and generic drugs. Overall, Québec’s inclusionary process for drug policy review, with public hearings held prior to legislation¹⁷¹, serves as an excellent model for Ontario in supporting and reaffirming the pharmaceutical industry as an engine of provincial economic development.

Looking to British Columbia (B.C.) as another example, BC Biotech - a not-for-profit, non-government, industry-funded association - has recently published an industry report¹⁷², in which the views and recommendations of B.C.’s biotech stakeholders are publicly presented. Like the life sciences industry in Ontario, the B.C. biotech industry is breaking new ground in research and innovations that have the potential for improving health outcomes and the provincial economy. The BC Biotech report aims to demonstrate that B.C.’s biotechnology industry is critical to the economic growth and diversification of the provincial economy. Similar to the arguments presented in this paper for Ontario, it is posited that the B.C. biotech industry plays a key role in turning the inputs of innovation into the commercial products and applications, with the potential to transform B.C.’s economy, making the Province a leader in Canada for Health and Life Sciences. In addition, consistent with this report (and its accompanying Executive Summary and Recommendations set out for Ontario’s life sciences industry), B.C.’s biotech

¹⁷⁰ Pharmaceutical Policy Consultation Paper, Québec, Dec., 2004.

¹⁷¹ Ontario Bill Shackles Brand-Name Drugmakers, G. Tipler, L. Meikle, J. Graham, The National Post, May 27, 2006.

¹⁷² BC Biotech - Building World-Class Biotech Businesses in British Columbia: The Industry Position, 2006.



stakeholders believe that by working together, they can make changes to the business environment that will allow the Province to compete globally with the many other jurisdictions aggressively developing biotech industries and innovation economies.

In evaluating Canada as a whole, results from a recent PwC survey have also shed light on the opinions of key stakeholders from commercial business, academia, government and capital providers in the life sciences industry. These data provide excellent insight regarding future directions in improving Canada's competitive positioning¹⁷³. A key finding of this 2006 forecasting study is that Canada stands to lose almost half of its life sciences and biotech businesses if a more sustainable business environment is not established - an astonishing 48% of commercial business respondents reported that they are considering or planning to relocate all or part of their business outside of Canada. While this result indicates a considerable risk to the future of Canada's life science and biotech industry, respondents also indicated that governments can take a number of positive steps to influence success. For example, more than 80% of respondents ranked the creation of more favourable corporate tax incentives in their top 3 choices. Increased funding of companies and improved speed of the regulatory process followed as second and third choices (44% and 41% respectively). Another 39% of respondents also ranked the implementation of positive changes to product pricing regulations in their top three choices.

With regard to Ontario specifically, the PwC study suggests that government support in terms of improving tax incentives, encouraging capital investment, and enhancing opportunities to market biopharmaceutical products within the Province will likely play a critical role in the future well-being of the Province's life sciences industry. The identification of these key success factors also demonstrates strong overlap with (and hence support for) the recommendations put forward in the summary document that accompanies this report. Furthermore, and more generally, the PwC survey results speak to the urgent need for constructive economic, health and regulatory policy that will influence biopharma companies to stay within Ontario and Canada.

In returning to the central theme of this document - advancing research in the life sciences for human health applications - it must be kept in mind that health care is ultimately about patients, not organizations¹⁷⁴. Given that the focus for biopharmaceutical innovation is better patient outcomes, we must ensure that the views of patients, health care providers and administrators are also taken into account. In particular, in the current environment of highly complex drug pricing and procurement modalities, it is critical that patient impact is not forgotten. In striking the right balance between cost containment and the quality of health care delivery, future policy solutions will also need to involve the public, hospitals, regional health networks and provincial legislators.

In considering the recommendations proposed in this 2006 report and Executive Summary, the current government will be challenged to implement new programs to augment Ontario's leadership position in the life sciences industry - acknowledging biopharmaceutical innovation

¹⁷³ Canadian Life Sciences Industry Forecast 2006, PriceWaterhouseCoopers, BIOTECanada, 2006.

¹⁷⁴ Knowledge Transfer and Management in Health Care: Quality, Safety, Accessibility and Affordability - Finding the Balance, Queen's School of Business, 2005.



Biotechnology Council of Ontario
PUBLIC POLICY FOR LIFE SCIENCES

not only as a key driver of high-value jobs and future economic prosperity, but also as essential force in improving quality of life for Ontario families. Increased government investment in the latest innovative therapies will ensure patient access to leading-edge technologies that enable optimal health and productivity outcomes, while simultaneously contributing to cost containment within the provincial health care system. Finally, in developing a life sciences innovation strategy as a primary driver of the Province's economic and health agendas, the Ontario government has an excellent opportunity to align industrial policy with a sustainable economy.



Appendix 6

Summary of Ontario Bio-Industry Position Papers



Appendix 6 - Summary of Ontario Bio-Industry Position Papers

Date	Committee & Chair	Report Title	Lead Author	Industries/ Scope	Outcome
1994	'Original' BCO (Graham Strachan)	Enabling Biotechnology: A Strategic Plan for Ontario	Lorne Meikle	Biotech (industry consultations/ private meetings)	Recommendations submitted to government
1998	Biotechnology Task Force (Graham Strachan)	Ontario Biotechnology Task Force Report	Gord Surgeoner	Biotech (industry consultations/ private meetings)	Recommendations submitted; several recommendations approved & executed
2002	BIOCouncil Ontario (Joseph Rotman)	Building Ontario's Biotechnology Corridor	Joseph Rotman	Biotech (industry consultations/ private meetings)	Recommendations submitted; several recommendations approved & executed
2003	BCO (Dale Patterson)	Getting OnTRAC: Benchmarking Ontario's Biotechnology Sector	Kamal Gautman & Brian Gordon	Biotech (province-wide assembly; first event)	Industry consensus reached at BCO-hosted Public Policy Workshop and submitted to government
2004	BCO (Dale Patterson)	The Commercialization Agenda, Policy for the Ontario Biotech Industry, Final Report, 2004	Steven Ilkay	Biotech (province-wide assembly; second event)	Proceedings published from the first formal BCO Public Policy Forum and submitted to government
2006	BCO Working Committee 2006 (Dale Patterson)	Investing in the Life Sciences Sector: A Proposed Strategy for Innovation in Ontario	Nora Cutcliffe	Life Sciences (province-wide broadly-based biotech and life sciences industry consultation)	Comprehensive Life Science Implementation Strategy submitted to government August 2006



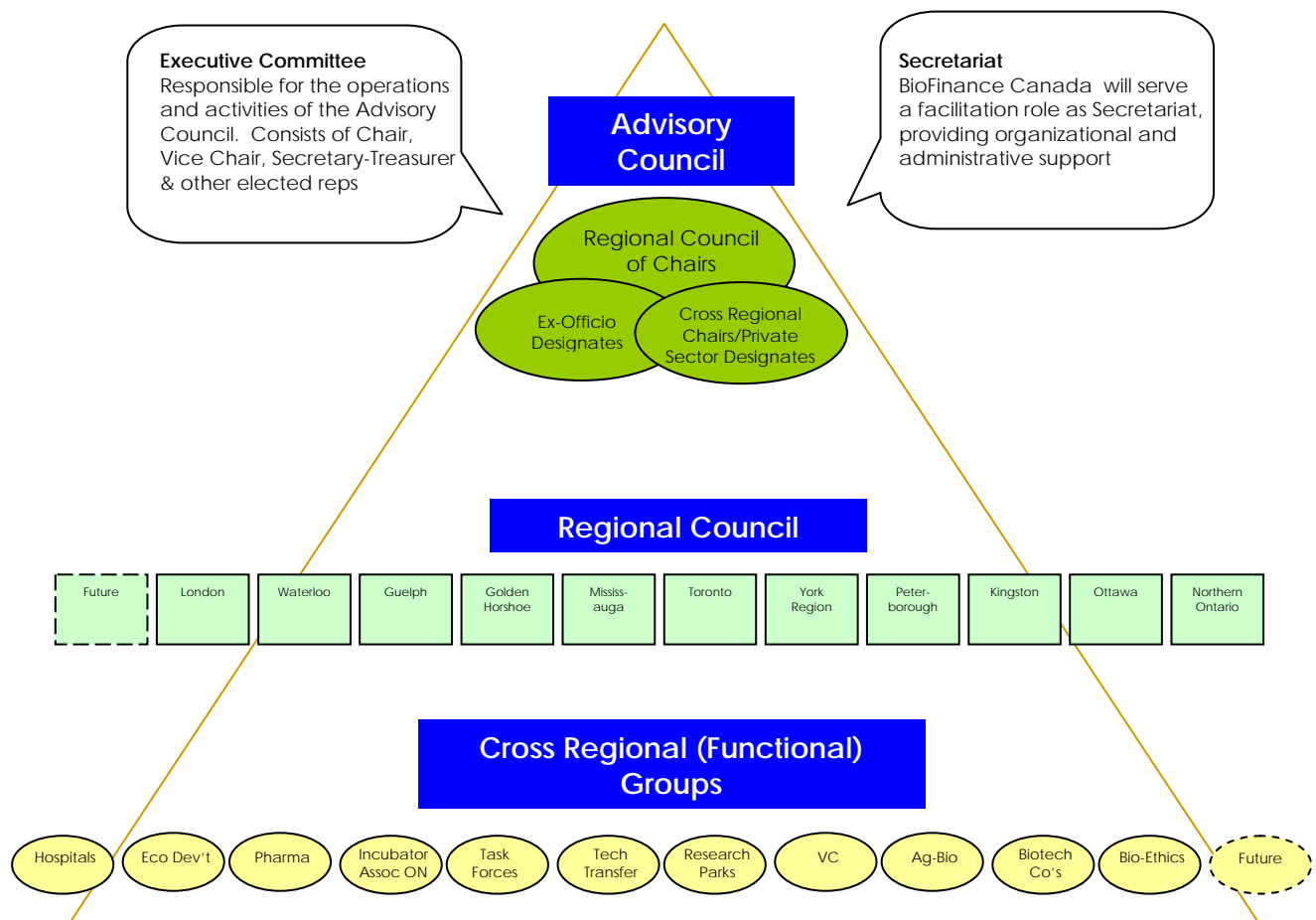
Appendix 7

BCO Organizational Structure



Appendix 7 - BCO Organizational Structure

BIOTECHNOLOGY COUNCIL OF ONTARIO: ENVISIONED ORGANIZATIONAL STRUCTURE





Appendix 8

BCO Working Committee 2006



Appendix 8 - BCO Working Committee 2006

Dale Patterson

Chair, Biotechnology Council of Ontario
Executive Vice President, Canadian Medical Discoveries Fund

Nora Cutcliffe

Consultant and Writer
BCO Life Sciences Strategy 2006

Tama Donoahue-Walker

Merck Frosst Canada Ltd.

Zenek Dybka

Canada's Research-Based Pharmaceutical Companies

Jeffrey Graham

Borden Ladner Gervais LLP

Gordon Jans

PricewaterhouseCoopers LLP

Sean Kelly

Pfizer Canada Inc.

Ken Lawless

Ottawa Life Sciences Council

Lisa Marsden

AstraZeneca Canada Inc.

Ross McGregor

Toronto Regional Research Alliance

Lorne Meikle

Toronto Biotechnology Initiative

Allan O'Dette

GlaxoSmithKline Inc.

Walter Robinson

Canada's Research-Based Pharmaceutical Companies

Michael Stinson

BioFinance Canada

Aimee Sulliman

Pfizer Canada Inc.

Gordon Surgeoner

Ontario Agri-Food Technologies

Grant Tipler

RBC Royal Bank

Ross Wallace

MaRS Discovery District

Matt Buist

City of Toronto