

Submission to ST&I Consultation Process:
***Moving Forward Through Leadership in Science, Technology and
Innovation***

Research Canada: An Alliance for Health Discovery
February 7, 2014
Ottawa, Ontario



About Research Canada

Who We Are

Research Canada is a national, broad-based alliance dedicated to increasing investments in health research through collaborative advocacy.

We believe health research is a shared benefit, shared responsibility and an investment in Canada's future.

We engage government, academia, industry and non-profit sectors to build support for balanced and long-term health research funding – investments that strengthen Canada's innovation system and lead to better health, sustainable healthcare, new commercialization opportunities, and skilled jobs for Canadians.

Our Mission

To improve the health and prosperity of all Canadians by championing Canada's global leadership in health research.

Stay Connected

www.rc-rc.ca #ResearchCda info@rc-rc.ca

Executive Summary

Research Canada: An Alliance for Health Discovery applauds the Government of Canada's Consultation on the S&T Strategy aimed at identifying solutions that reflect the realities of a dynamic global innovation landscape. A renewed ST&I Strategy offers our country the opportunity to maintain and build on Canada's strengths while addressing the threats to the competitiveness and effectiveness of our economy.

The S&T Strategy articulates the innovation and commercialization challenges Canada faces. It is the right time to build on Canada's core strengths as leaders in research and to continue to sharpen the focus and impact of ST&I investments by providing a new framework to guide federal ST&I investments and priorities.

As a national alliance of stakeholders drawn from the academic, private and public sectors, Research Canada could not agree more with the Government that every partner in the federal science, technology and innovation (ST&I) enterprise has a role to play. Supporting interdependencies among partners is the first step towards improving investment in R&D and innovation.

In its submission, Research Canada speaks to these interdependencies and explores recommendations to address business innovation, the development of innovative and entrepreneurial people and the excellence in public and post-secondary research. In particular, Research Canada recommends:

- Consistent and sufficient support of discovery research, which is the bedrock of innovation
- Improvements in regulatory approvals, intellectual property protection, and SR&ED tax policy
- Innovation incentives through a favourable procurement and reimbursement environment
- Longer-term government-funded programs that support multi-sectoral partnerships
- Re-instating publicly funded career development programs, extending programs like the CECRs and CRC, and implementing a multi-year fiscal framework for research funding

If Research Canada had one message that it would like the Government of Canada to remember, it would be that the ability to leverage Canada's strengths and address the challenges the country faces depends on the Federal Government's leadership in ensuring that all of the stages of the innovation system are supported, and that the government carries out *its* special role in funding discovery research consistently and sufficiently over time.

Business Innovation

1. Building on the advice provided by the Expert Panel on Federal Support for Research and Development, what more can be done to improve business investment in R&D and innovation?

Policy and financial support of initiatives that recognize the interdependencies among key sectors is the first step towards improving business investment in R&D and innovation, followed by support of the regional innovation system as the foundation of an innovation nation. Finally, improvements in regulatory environments, intellectual property and tax policy make Canada an attractive destination for business investment in R&D and innovation.

Canada's health research foundation is strong. Our per capita research productivity and impact consistently rank in the top five globally in major disciplines; many research trainees and professionals now view Canada as a health research destination; our research institutions and infrastructure are at the cutting-edge of technology and design; and, as consistently demonstrated through Research Canada's regular health research polls, the Canadian public places a high priority on—and faith in—our health research enterprise.¹

And yet Research Canada's members, drawn from the public, private and voluntary sectors, also confirm the disquieting truth that our health innovation system is increasingly struggling to capitalize on this foundation. Cash-starved governments are challenged by their traditional role in funding the high-risk, upstream science that fuels innovation at a time when policymakers are most concerned about strengthening our knowledge economy, accelerating innovation and overcoming Canada's increasing productivity gap.²

Academia, responding to the heightened expectations of policymakers, funders and the public, is increasingly facing pressure to demonstrate research relevance and impact, without reducing a fundamental commitment to exploratory science from which discovery and invention spring.³

Global industry, having entered an era of unprecedented consolidation and corporate re-engineering, faces reimbursement, productivity and competitive barriers that undermine the case for R&D investment in Canada—while our homegrown life sciences companies are unable to remain and thrive in Canada without the capital and commercial support of a diverse and integrated industrial cluster.⁴

And the not-for-profit/charitable sector, increasingly called upon to fill gaps in the research funding environment, must maintain its foremost accountability to patient impact in a highly competitive—and rapidly evolving—philanthropic environment.⁵

¹ Dr. Ryan Wiley, "Health Research in Canada: An Inflection Point," 2014 Annual Report, Research Canada, p. 4

² Ibid.

³ Ibid.

⁴ Ibid.

⁵ Ibid.

Rising to these sector-specific challenges will not be possible if we fail to act in a manner that recognizes how inextricably linked these challenges are.

Recognizing Interdependencies among key sectors is the first step towards improving business investment in R&D and innovation

Innovation is ultimately a social process in which new products and processes emerge from the ongoing interaction of a range of actors. What is essential for effectively upgrading an innovation system is to ‘embed’ the business sector in a broader system involving greater complexity of interaction and stronger links between the actors.⁶

In other words, improving business R&D in Canada requires integrated solutions that harness and strengthen the interdependencies across government, academia, industry and the not-for-profit/charitable sector; recognize that innovations in health technology cannot flourish without innovations in the structure of the health system and the context in which care is delivered; and take a balanced approach to investment in fundamental and applied health research across the discovery to practice continuum.⁷

The **Strategy for Patient-Oriented Research (SPOR)** initiated by the Canadian Institutes of Health Research (CIHR), is an excellent example of such an integrated solution. It is also a key instrument for healthcare innovation. SPOR is fundamentally focused on linking academic capacity to the health system. It proposes a national and multi-sectoral partnership (the provinces, the private sector, the academic sector, health charities and health professionals) aimed at applying research advances in healthcare and the economy.

The strategy will fundamentally transform how Canada translates the billions of dollars invested in medical research over the past decade into better outcomes for patients, new commercial technologies and cost savings for cash-strapped provincial governments. It should also provide Canada with a unique competitive edge over low-cost countries like China and India in attracting business investment in clinical trials to Canada.

Under SPOR, CIHR has held competitions for clinical research networks focused on community-based primary healthcare and mental health. The networks received \$25 million over five years, with half coming from CIHR and the remainder coming from partners including industry. Pharmaceutical companies tap into these networks to conduct multi-centre clinical trials in priority areas identified by CIHR.

Recognizing the regional innovation system

Further, policies for enhancing the national innovation system must also be designed with an eye to their impact at the local level within clusters in a regional innovation system. Research Canada has profiled, through its **Health Research Caucus**⁸ chaired by Senator Kelvin K. Ogilvie, a number of dynamic health innovation clusters at the regional and local levels. A common element in successful clusters is that the federal government is working with and through regional and local partners to stimulate their development.

J. Adam Holbrook and David A. Wolfe point out in their article, *The Innovation Systems Research Network (ISRN): A Canadian Experiment in Knowledge Management*, that a key virtue of this approach is the involvement of local stakeholders in thinking about effective innovation strategies within the framework of

⁶ David A. Wolfe and J. Adam Holbrook, “[The Innovation Systems Research Network: A Canadian Experiment in Knowledge Management](#),” *Science and Public Policy*, 32:2 (April 2005): 109-118.

⁷ Wiley, *Op.cit.* p 4-5

⁸ In 2009, Research Canada established a Health Research Caucus of Parliamentarians from all political parties to provide a forum to inform MPs about the social and economic benefits of Canadian health research and health innovation.

existing national and regional policies; and, clearly, the investment of the federal government at regional and local levels, recognizing that a national innovative capacity remains embedded in local networks and communities of firms and the supporting infrastructures of research and training institutions, financial intermediaries, government agencies and community and business associations.⁹

Enhancing Canada's innovation capacity therefore requires a broad mix of national, provincial/regional and local policies, including those providing support for upgrading the innovative capabilities of firms across a range of sectors; infrastructure (both physical and technological) and policies promoting the rapid diffusion of new technologies across a range of firms; policies building the market for new technologies; and policies supporting the growth of small- and medium-sized enterprises through increased networking and interaction.¹⁰

Examples of government working with regional partners

Thanks to a Government of Canada investment of nearly \$11 million by the Federal Economic Development Agency for Southern Ontario (FedDev Ontario), for example, the Ontario Brain Institute (OBI) has partnered with universities and private sector companies to help accelerate the commercialization of neurotechnologies in Ontario. By accelerating the development and application of innovative technologies, researchers will be able to produce a revolutionary picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both time and space, giving researchers the opportunity to seek new ways to treat, cure, and even prevent brain disorders. (See Appendix 1)

Federal investments through Western Economic Diversification and Genome Prairie/Genome Canada funding has made it possible for the Western Canadian Vaccine Network (WCVNet) to pull technologies from public and private laboratories across Western Canada in order to fuel the vaccine candidate pipeline. (See Appendix 2)

An excellent example of the Government of Canada working with and through a regional innovation cluster resulting in attracting business investments and creating jobs for Canadians is the Montreal Health Innovation Coordinating Center (MHICC). With funding from the CIHR, Genome Canada and the Canada Foundation for Innovation (CFI), the Centre has developed and coordinated already 70 multicenter clinical trials with 2,000 participating clinical sites in 20 countries in North America, Europe, Asia (China and India) and Australia. 40,000 patients from around the world have participated in these trials, and Canadian clinical sites are distributed across Canada.

The activities of the last decade have contributed to turn the MHICC into an organization with close to 200 employees, most of them being highly qualified personnel with university degrees. The total annual revenue of the MHICC has now reached \$40 million. (See Appendix 3)

First customer for R&D investments in Canada

Research Canada agrees that Canada must find ways to attract increased private sector investment while ensuring that the public interest is protected. In the health arena, this refers to three major private sector industries – pharmaceuticals, biotechnology and medical and assistive devices – each with its own requirements for doing business in Canada. Multinational pharmaceutical companies, for example, must convince parent companies to see Canada as an attractive environment for investment.

⁹ Op.cit. p. 110

¹⁰ Op.cit. p. 117

Increasingly, Canada's status as a target destination for global R&D investments is crucial to the success of our innovation system and requires improvements in the regulatory environment, intellectual property regime and tax policy. The federal government should:

- **Improve the quality and timeliness of regulatory approval times through enhanced reliance on established relationships with other leading regulatory jurisdictions;**
- **Following CETA, continue to enhance a G-7-leading, internationally competitive, intellectual property regime; and**
- **Introduce tax policy incentives (See SR&ED under Question 2, p. 9) to stimulate private sector and charitable investments in health research, innovation and commercialization. Further incentives for charitable giving by increasing the federal charitable tax credit from 29% to 39% could result in an upsurge of giving. Government should also consider removing the tax barrier for charitable gifts of private company shares and real estate.**

Attracting pharmaceutical investment to Canada through changes to IP, tax and regulatory policy is an important strategy to enhance business investment; however, it must be complemented by a plan that creates innovation incentives through a favourable procurement and reimbursement environment. Governments, for example, can adopt financial incentives, such as **"proof-of-concept" funding** that can stimulate and support the adoption of innovation. Such incentives are a key ingredient for creating a culture of innovation in Canada. In this regard, and cognizant of the stringent economic times, the Government of Canada might, nonetheless, consider increased investment in proof-of-concept funding through the launch of a federal matching program, analogous to the funding algorithm adopted by CFI. Given the growing provincial interest in extracting economic value from the investments made in discovery research, the time may be right for a federal-provincial partnership in supporting proof-of-concept, with strategies for adopting successful practices.

2. **What actions could be taken, by the government or others, to enhance the mobilization of knowledge and technology from government laboratories and universities, colleges and polytechnics to the private sector?**

Longer-term, government-funded programs that provide funding to de-risk discoveries emerging from academic and public sector labs will allow unimpeded uptake by private sector investors and/or companies.

A robust innovation enterprise requires a strong foundation of multi-sectoral partnerships. Partnerships promote collaboration, support shared responsibility and accountability and enable important efficiencies on the road to innovation.

CECR, POP and S²B Programs

Designed to bridge the challenging gap between innovation and commercialization, the Centres of Excellence for Commercialization and Research (CECR) program brokers the dynamic partnerships that match clusters of research expertise with the business community to share the knowledge and resources that bring innovations to market faster. Research Canada commends the government for creating this program as part of the internationally-recognized Networks of Centres of Excellence suite of programs.

MaRS Innovation was among the first CECRs to be created in 2008, largely based on the founding belief of its members that Toronto is a fertile research land for precisely this kind of translational activity.

Xagenic Inc., one of the first companies to enter MaRS Innovation's portfolio and access its seed funding and expertise, such as technology development, intellectual property protection and business development was able to attract Qiagen, a prominent European diagnostics tools developer, which recognized the value of Xagenic's technological approach by making a significant investment in the company.

The Pan-Provincial Vaccine Enterprise Inc. (PREVENT) is a Centre of Excellence for Commercialization and Research (CERC) as well, established in February, 2008 through the Networks of Centres of Excellence program. It has a mandate to fast-track veterinary and human vaccine development for diseases of major public health concern, and to address the commercialization challenges faced by Canada's biotechnology industry. As a unique pan-Canadian vaccine commercialization platform, PREVENT accelerates the most promising Canadian vaccine discoveries through preclinical and early clinical evaluation, catalyzing the commercially viable development of products that address significant public health needs. This reduces the risk shouldered by industry through the facilitation of time and labour intensive critical mid-stage vaccine development. PREVENT further supports this development as vaccine candidates are passed into the hands of receptor organizations, either in the private or public sector.

Through Research Canada's membership we have direct experience with the Centres of Excellence in Commercialization and Research (CECR) program, as well as CIHR's Proof of Principal (PoP) program. Both of these programs promise to accelerate the process of extracting economic value from knowledge through impressive centres such as MaRS Innovation and PREVENT.

The PoP program is an innovative approach to meeting the challenge of commercializing and mobilizing knowledge from research discoveries; at only \$5.7 million in grants for successful applicants; however, it is far from adequate to meet even current needs.

The S²B (Science to Business) program is also an excellent start to provide scientists with the business training to support the commercialization of their research and ongoing support is urgently needed.

Clearly, these programs have inherent sustainability challenges and it is not realistic to expect the new initiatives they fund to achieve financial independence within five years. Even if they do, they are more likely, in such a short period, to have become a Contract Research Organization (CRO), which was not the original intent of the program. **Research Canada encourages the Government of Canada to invest in these programs using a longer-term funding approach that reflects the temporal realities of knowledge translation and commercialization and the tremendous opportunity cost we will incur if we take a narrow and short-term view.**

Research Canada recommends that the CECR program continue to be extended, selecting those that have achieved commercialization and other high-impact milestones for continued support.

Research Canada recommends a federal-provincial matching grant program that could amplify support for the PoP program.

Industrial Research Assistance Program (IRAP)

A large gap exists in the funding of companies as they enter the order-fulfillment cycle. Changes to the IRAP program to reflect features of programs such as New York State's Strategic Partnership for Industrial Resurgence (SPIR) would be valuable. Encouraging investors through tax credits would be an innovative approach to ensuring SMEs have the capital they need to grow.

In addition, aligning various programs would be important; a great deal of time is currently required to put together applications that are similar in nature, but different enough to require significantly more work than is truly necessary. As well, many timelines are not appropriate for fast-growing businesses. Support in marketing Canadian innovative companies through awards or other forms of publicity can also be helpful.

SR&ED

The SR&ED tax credit, and in particular the refundable credit, is the lifeblood for small companies to conduct research investments in Canada. The continued investment that results from the SR&ED tax credit is essential in ensuring that a company can engage in research to extend and expand their product lines, thus ensuring a given company's sustainability.

The current structure, while encouraging investment for small and medium-sized companies (SMEs), cuts off investment once a company grows past a certain size or when a company loses its Canadian-controlled private company status, resulting in reduced investment at an artificial point. The loss of the tax credit, once a company can no longer benefit from it, has a detrimental impact on the amount of future investment in R&D. The loss of the refundable credit simply due to loss of a "Canadian-controlled" status is particularly troubling as the focus on the incentive should be to stimulate investments in research in Canada irrespective of the ownership status.

In addition to the eligibility of companies, the definition of eligible research for credits is similarly limiting. Research undertaken today goes beyond the definition written over 30 years ago. **Research Canada encourages the government to consider broadening SR&ED eligibility to include a broad continuum of health-related research, in alignment with the Organization for Economic Cooperation and Development (OECD). In addition, permitting milestone payments to biotechnology firms acquiring drug or biologic intellectual property rights would be a powerful support to a crucial emerging sector.**

In light of the increasing focus by regulators on the entire life cycle of drugs and biologics, **the federal government should permit research in areas such as health economics; health-care management; studies that address socio-economic factors; pharmaco-economic studies that build on known health outcomes; and studies to develop new methodologies and models for a broad continuum of health-related research.** Further, given the potential commercial impact of the hundreds of millions of dollars spent on R&D by research hospitals, **the federal government should review how SR&EDs apply to them, in particular examining the rules governing both the "expenditure limit" and who is deemed to be an "excluded corporation".**

These changes to SR&ED would encourage collaborative, interdisciplinary research and attract new capital for Canada's biotechnology sector.

Refundable portion of the SR&ED tax credit and the growth and commercial success of SMEs

In addition to the limitation of which type of company qualifies for refundable credits on research conducted in Canada, the timing of payment is also a problem. For small and medium-sized enterprises in particular, every month counts. Some banks will finance the cheque once certain conditions are met, but that typically happens at a later point. Another issue that has been identified is the capped value of the refund, as it does not encourage very significant investments and the credit does not apply to patent costs. Patenting of concepts should be funded in lock step with the development of technology. A strong intellectual property position is paramount for engaging further investment and defending a firm's position in the market. A final issue is that the SR&ED cannot be used in conjunction with other programs such as the Industrial Research Assistance Program (IRAP), making application to these programs less beneficial.

The strengths of the refundable credit are that it appears to be audited fairly, does enforce some structure to research programs and the funding is, ultimately, truly essential to maintaining a long-term technology development plan.

Other Innovative Programs

Businesses and universities have established several joint ventures over the years, including the Sanofi Pasteur Human Vaccine Challenge Unit at Dalhousie University, funded by the university, the Canada Foundation for Innovation (CFI) and Sanofi Pasteur; and the Wyeth Chair in Vaccinology at the BC Children's Hospital. This last initiative recognizes the key role that academic investigators played in taking research through clinical development and licensure of important life-saving paediatric vaccines in Canada.

Developing Innovative and Entrepreneurial People

3. How can Canada continue to develop, attract and retain the world's top research talent at our businesses, research institutions, colleges and polytechnics, and universities?

Attracting top-flight talent requires the government to develop a multi-year framework for research funding that extends and strengthens programs like the CECRs and CRC, and reinstates publicly funded career development programs.

A robust innovation system depends on a critical mass of health and other researchers. Highly qualified and innovative people – whose training is delivered in Canada's universities, hospitals and research institutes – are critical to each stage within the innovation cycle. A key factor that underlies the competitive advantage of successful regionally-based innovative networks is the talent pool located in the region. These trainees become a vital resource for industry—a material benefit that is recognized by Canadian businesses and is a draw to do business in Canada. Programs supporting the training of highly qualified Canadians must be increased—recognizing at the same time, however, the importance of balancing investment in salary support, infrastructure and operating grants.

Research Canada commends the government for continuing to support top-flight talent through the Canada Research Chairs (CRC) and Canada Global Excellence Research Chairs (CERC) programs that help attract and retain world-class talent so that we can benefit from their expertise and potential. At the same time, it is important for the government to recognize the enormous challenges young researchers face in finding public- or private-sector employment in relevant fields of study. We must be cautious not to squander our investment in training talented people by failing to support the critical early stages of their careers.

Researchers in clinical settings require support to balance their time among research, teaching and clinical care. Research Canada is of the view that we need to retain and promote career paths for clinician scientists. Our most outstanding applied health researchers deserve salary awards to compensate them for time spent on research rather than in the clinic.

Research Canada encourages the government to reinstate publicly funded career development programs providing support along the career development path from junior to intermediate to senior and clinician scientists. Sustainable funding models for salary support for health researchers are urgently required if we are going to protect our pool of talent for business innovation and productivity growth.

Government matching of private sector investments in highly qualified personnel (HQP) is one meritorious way to strengthen career development support and Research Canada encourages exploration of such a strategy; however, Canada needs integrated, sustained and comprehensive support across the career lifecycle. We do not want to inextricably tie the development of our future talent pool to current commercial interests alone. Research Canada underscores the importance of public sector leadership in supporting talent

development programs that serve Canada's broader interests.

Canada needs to be a more attractive centre for creative thinking in health research, where the best and brightest talents are encouraged to remain and reap training opportunities. In addition, Canadian health researchers need to keep up with the rapid changes in biomedical, clinical, health services and population health research; new technologies, new experimental approaches and the associated bioethical and social repercussions. Major research organizations that have the ability to be cross-disciplinary are working hard to capitalize on the opportunity to break down entrenched barriers. **Research Canada encourages the government focus on continuing cross-disciplinary, multi-professional training programs.**

Finally, it is our view that it is vital to develop a sustainable, multi-year fiscal framework. The research-to-market journey can take many years. In the absence of certain long-term support, we are distracted by the imperative of securing precarious year-to-year funding—sacrificing important advances because we are unable to plan for and capitalize on material investments already made. (See Question 5)

Excellence in Public and Post-Secondary Research

4. How might Canada build upon its success as a world leader in discovery-driven research?

Canada can build upon its success as a world leader in discovery-driven research through consistent and sufficient support of it over time, recognizing it as the bedrock of the innovation system in the context of adopting a full innovation system approach to policy development and funding of R&D.

We emphasize that research is a long-term process; investments made today in discovery research will likely take years to achieve impact. The most commercially successful products and services often begin as an idea and, through an unpredictable path of discovery, experimentation and hypothesis-testing, eventually emerge as a product of social or economic benefit.¹¹

Over the past ten years, Canada has made a concerted commitment to reinvigorating the public research enterprise through substantial investments in excellent research, world-class talent and cutting-edge research infrastructure. The S&T Strategy reflects the government's implicit recognition that these investments in knowledge creation have only occasionally resulted in strong commercial benefit.

The government, in response to this challenge, has rightly focused investment on programs that better capitalize on our nation's capacity to extract economic value from the federal investment in discovery research. While Research Canada agrees with this approach, it urges the government to pursue this strategy in tandem with ongoing, sufficient and consistent investments in discovery research, which is the foundation from which innovation arises. ***To capitalize on our success in discovery, we must not treat it as a conclusive success story awaiting the next phase of investment, but provide consistent and sufficient support of it over time.***

Research Canada underscores the essential role of governments in supporting discovery research. There is little market incentive for discovery health research so most of the opportunity must be borne by government. **Thus, Research Canada calls for a renewed ST&I framework that supports the entire cycle of R&D, from discovery, through to product development and commercialization, to the marketplace and to health-care settings.**

With this in place, it is possible to create a national economic environment and ST&I Strategy that enables the multi-sectoral partnerships required for a robust innovation enterprise that will enhance R&D capacity and accelerate the translation of discovery research into the health-care system and into the global marketplace.

In the case of the Ontario Brain Institute's initiative (see p. 6), it was the discovery research investments governments made in the first place that led to the sequencing of the human genome, the development of new tools for mapping neuronal connections, the increasing resolution of imaging technologies, and the

¹¹ Council of Ontario Research Directors/Ontario Health Research Alliance Baseline Information Survey 2003 (CORD), p. 8.

explosion of nanoscience, which positioned scientists to take the next step and develop these neurotechnologies.

Dr. Andrew Potter, CEO and Director of VIDO-Intervac points out that many of the platforms for the WCVNet (see p. 6) technologies trace back to discovery research grants funded through the Tri-Council, without which WCVNet would not be in a position to harness the continuum of vaccine development resources in British Columbia, Alberta, Saskatchewan and Manitoba.

It is important to note that Xagenic's technology strengths (see p. 8) are based on breakthrough scientific discoveries in two disciplines: genomics and nano-chemistry undertaken without direct commercial intent. This combined expertise, along with federal research funding that supported the foundational research, have produced an ideal tool for improved disease detection that may one day benefit all Canadians and is the basis for significant commercial development.

In the case of the Canadian Institutes of Health Research (CIHR), the country's premier funder of health research, Research Canada recommends increasing investments in CIHR's operating grants program in support of discovery research so that this research is consistently and sufficiently supported, while maintaining targeted investments in the SPOR program. Given their differing goals and objectives, investments in the latter cannot replace investments in the discovery research portfolio. Strong consideration should be given to additional funding in 2014-2015 to smooth the transition to the new funding model in CIHR. There is a real danger that this transition is going to result in a major loss of operating dollars to the system, which in turn could leave ongoing programs with funding gaps resulting in layoffs of research personnel—a situation from which it could take years to recover.

5. Is the Government of Canada's suite of programs appropriately designed to best support research excellence?"

While the innovation system is dependent on market forces, its success in delivering the social and economic dividends of health innovation reflects government commitment to supporting excellence in knowledge creation; to mitigating the investment risk in research and development; to supporting an innovation-focused healthcare system and policy environment; and to ensuring that new technologies and healthcare practices are ultimately made available to Canadians and the world. In other words, research excellence reflects government's commitment to supporting excellence in knowledge creation, but sufficient and consistent support of the latter requires a policy commitment to the full innovation continuum.

Since 2006, the Government of Canada has invested nearly \$8 billion in initiatives supporting science, technology and the growth of innovative firms in Canada, including \$5 billion for advanced research, education and training; \$2 billion for postsecondary infrastructure; and \$1 billion for applied research and financing. This funding has helped to make Canada a world leader in postsecondary education research and to create the knowledge and highly skilled workforce that are required for a prosperous economy.

Research Canada commends the government for taking these bold and necessary steps. It is also of the view that the research excellence that underpins the Canadian innovation system can only be sustained through long-term strategic programs that take a full innovation cycle approach to policy and program development and research investments.

Recently, the European Council for Health Research called for a pan-European strategic platform for health research and concluded that accelerating research in the biomedical field in Europe can only be achieved through long-term strategic research programmes capable of triggering global multidisciplinary partnerships and addressing the full innovation cycle. The Council recognized that the road that carries discoveries from bench to bedside is notoriously bumpy and complex; it involves many phases, stakeholders and regulatory barriers.¹²

Government plays a pivotal role in laying the foundation for knowledge creation, as there is otherwise little market incentive for discovery, clinical, health services and population health research; government investment in the form of infrastructure development, HQP training and incentives, operating funds and commercialization support are essential in galvanizing the contributions from other stakeholders.

Research Canada is of the view that all of the stages of the innovation system require support in order to achieve innovation from discovery, through to product development and commercialization, to the marketplace and to health-care settings. It also underscores the need to invest in a **balanced** fashion across the continuum of activities that, in aggregate, comprise an innovation system that is predicated on research and development.

Research

An innovative economy is built on excellence in knowledge creation and on the exploitation of the unpredictable fraction of that knowledge with commercial opportunity or direct social value. While

¹² Alliance for Biomedical Research in Europe, *European Council for Health Research Concept Paper*, p. 5

strengthening market-oriented programs to harness intellectual property arising from Canada's public institutions, **the government must also correct the operating budget shortfall that is jeopardizing Canada's global research competitiveness and ability to capitalize fully on existing investments in infrastructure and people.**

Research Canada is of the view that we must strengthen the commitment to basic science, which is the bedrock of other research, innovation, commercialization and patient-oriented research by ensuring the Tri-Council has consistent and sufficient budgets to retain top-flight talent. Over the past several years, Research Canada has advocated for increased investments in discovery research within the context of creating the balance required for a strong innovation system in Canada. Increasing investments in discovery research, often referred to as "curiosity-driven" research, through the Tri-Council's budgets would have given them capacity to respond to the growth in infrastructure and research capacity through the CFI and CRC programs. Failure to align these funding streams at the federal level has created a serious imbalance in the supply and demand in health research, which will affect our capacity to train, retain and recruit the best scientists. We cannot sit on our laurels content with the talent we now have.

A recent report in the *New England Journal of Medicine* demonstrates a decline in Canada's financial competitiveness in biomedical R&D, which has implications for the debate over appropriate federal policy in this area especially at a time when mature economies such as those in Japan and Europe have maintained their level of investment in this area. Canada's rate of decline in biomedical research funding "leads" the world. Australia now spends more on biomedical research than Canada.¹³

The OECD (2012) describes how Canada's granting agencies have been shifting funds away from curiosity-driven research and towards commercialization. The vision statement of NSERC on its website puts as much emphasis on fostering collaboration between industry and science as it does on fostering basic science.¹⁴

The C.D. Howe Institute's 2013 Commentary entitled, *From Curiosity to Wealth Creation: How University Research Can Boost Economic Growth* points out that federal granting agencies should reorient their system of allocating public funding of academic research to give more weight to overall academic excellence rather than immediate practical payoff. The universities and researchers that generate the greatest benefit to industry are those that are rated most highly on general academic grounds, and the best way the agencies can help attract top university scientists and engineers is to fashion a research environment that is focused on supporting the kind of research these academics like to engage in.¹⁵

Development to Market and Delivery

Successfully filtering ideas through the rigours of testing and validation requires a capital, regulatory and intellectual environment that values and supports the risk-taking involved in innovation.

Risk-taking defines entrepreneurship. To support this spirit of risk-taking and maximize the likelihood of commercial success—particularly for life sciences products whose protracted development cycles and intrinsic

¹³ Justin Chakma, B.Sc., Gordon H. Sun, M.D., Jeffrey D. Steinberg, Ph.D., Stephen M. Sammut, M.A., M.B.A., and Reshma Jagsi, M.D., D.Phil *Asia's Ascent — Global Trends in Biomedical R&D Expenditures*, *The New England Journal of Medicine*, January 2, 2014, p. 4

¹⁴ Howitt, Peter, C.D. Howe Institute, *From Curiosity to Wealth Creation: How University Research Can Boost Economic Growth*, *Commentary* 383, p. 14

¹⁵ *Op.cit.* p. 23

scientific risks can lead to unexpected exits—Canada must create an environment that attracts venture capital and enables the recruitment and training of highly qualified company builders.

With a strong knowledge base, Canada has the opportunity to become an innovation nation producing a range of innovative goods, products and services, more highly-skilled jobs, growing revenues, swelling pools of capital, increased foreign investment and an enhanced public revenue stream. To seize this opportunity in the life sciences and ensure investors can defend a decision to work with Canadian healthcare professionals, our priority must be to ensure a fast and smooth approval processes for new investors. **Canada needs to improve the quality and timeliness of regulatory approval times through enhanced reliance on established relationships with other leading regulatory jurisdictions. Health Canada needs to work efficiently and leverage the work done elsewhere.**

IP

To be a global player, **Canada must provide an operating environment that ensures intellectual property is protected. Building upon the recent CETA agreement, the creation of a world-leading intellectual property regime to protect capital investment, knowledge creation, publishing scale and creative capacity is essential for increasing private sector investments in Canadian R&D.**

Tax Incentives

Canadians' generous support of health charities is well known; however, further incentives for charitable giving could result in an upsurge of giving. This could be accomplished by increasing the federal charitable tax credit from 29% to 39%. Government should also consider removing the tax barrier for charitable gifts of private company shares and real estate.

Research Canada encourages the government to consider broadening SR&ED eligibility to include a broad continuum of health-related research, in alignment with the Organization for Economic Cooperation and Development (OECD). In addition, permitting milestone payments to biotechnology firms acquiring drug or biologic intellectual property rights would be a powerful support to a crucial emerging sector (see p. 8)

Conclusion

Canada has a strong record when it comes to the quality of its knowledge base. Its strong history and reputation for research excellence and scientific success are well documented. Canada's workforce is among the most skilled and well-educated in the world. Still, the country's innovative performance and its productivity growth continue to lag behind competing nations.

Policy and financial support of initiatives that recognize the interdependencies among key sectors is the first step towards improving business investment in R&D and innovation, followed by support of the regional innovation system as the foundation of an innovation nation. Finally, improvements in regulatory environments, intellectual property and tax policy as well as innovation incentives through a favourable procurement and reimbursement environment, make Canada an attractive destination for business investment in R&D and innovation.

Longer-term, government-funded programs that provide funding to de-risk discoveries emerging from academic and public sector labs will allow unimpeded uptake by private sector investors and/or companies.

Attracting top-flight talent requires the government to develop a multi-year framework for research funding that extends and strengthens programs like the CECRs and CRC, and reinstates publicly funded career development programs.

The ability to leverage Canada's strengths and address the challenges the country faces depends on the Federal Government's leadership in ensuring that: 1) all of the stages of the innovation system are supported so that we can move from discovery, through to product development and commercialization, to the marketplace and to health-care settings; and 2) it carries out its special role in funding discovery research consistently and sufficiently over time.

Appendix 1

Government of Canada Supports the Commercialization of Neurotechnologies in Southern Ontario: An Example of a Regional Innovation Cluster

The Ontario Brain Institute (OBI) has partnered with universities and private sector companies to help accelerate the commercialization of neurotechnologies. This is thanks to a Government of Canada investment of nearly \$11 million announced today by the Honourable Gary Goodyear, Minister of State responsible for the Federal Economic Development Agency for Southern Ontario (FedDev Ontario).

FedDev Ontario (www.feddevontario.gc.ca) is providing the Ontario Brain Institute (www.braininstitute.ca) with a non-repayable contribution of up to \$10,971,133 through its Technology Development Program to support 14 neurotechnology projects. The projects will bring together 28 partners from various sectors, including 12 not-for-profit organizations (universities, hospitals, and other research institutes), 11 private sector companies, all located in southern Ontario, and five international companies.

NEUROTECHNOLOGY PROJECT DESCRIPTIONS (Highlights of Five Projects)

1) Deep Brain Stimulation for Alzheimer's disease

Alzheimer's disease is a major and rapidly growing public health problem for which few effective therapies are available. However, recent findings have yielded disappointing results from several recent trials. Given this situation, consideration and development of novel therapies is critical to therapeutic success in Alzheimer's disease. Through funding from this project, Dr. Andres Lozano and his team will aim to determine the preliminary efficacy of deep brain stimulation (an effective treatment for motor aspects of Parkinson's disease which is now in development for epilepsy, major depression, and obsessive compulsive disorder) as a therapeutic strategy that may effectively, and with relatively low risk, to potentially improve Alzheimer's disease outcomes.

Highlights:

- Lead by Dr. Andres Lozano at Toronto Western Hospital of the University Health Network (Toronto, ON) (www.uhn.ca), a distinguished neuroscientist of international reputation in deep brain stimulation
- Project and partners are both located in Toronto (University Health Network and Functional Neuromodulation Inc.) (www.fxneuromod.com)
- Research aims to improve Alzheimer's disease, a disorder that affects millions worldwide

2) Home Diagnostic Tool for Sleep Apnea

Sleep apnea is a sleep disorder characterized by abnormal pauses in breathing or instances of abnormally shallow breathing during sleep. Sleep apnea is caused by collapsing of the airway during sleep (Obstructive Sleep Apnea) as a result of age or obesity, or defects in the brain's sleep control system (Central Sleep Apnea). It is normally diagnosed with an

overnight sleep test called a polysomnogram, or "sleep study" that is performed in a sleep lab. Sleep apnea is a high incidence condition, affecting seven to 10 per cent of the adult population with more than 80 per cent of those being undiagnosed. Untreated sleep apnea leads to three to four times increased risk of heart attack and stroke, and increased daytime sleepiness which leads to motor vehicle accidents, workplace accidents, and low productivity. A recent study also found a link between sleep apnea and an increased risk of cancer. This is a significant problem with serious health and economic implications.

The current method for diagnosing sleep apnea is through an overnight stay in a sleep lab. This requires that a patient go to a sleep lab and sleep in a strange bed while hooked up to over 20 electrodes and being monitored by the sleep lab staff. Not only is it difficult to sleep under these conditions, the patient must travel to the sleep lab which in rural or remote areas can be a significant journey. Testing in a sleep lab is expensive. In some regions there are few labs and long wait lists. In Ontario, the number of sleep apnea studies performed in 2006 was approximately 96,000 with a projected 1,800,000 patient screenings per year across North America.

The home diagnostic device being developed will dramatically change the detection and management of this disorder. The ApneaDx device is a simple, easy-to-use, portable design that can be given or sent to a patient for use at home. The patient wears the device while they sleep in their own bed and the device is then returned to a central location where the recorded data is downloaded and analyzed. A report is sent to the referring physician and the appropriate follow up is made. This device will be appealing to end-users because of its accuracy, comfort, availability, ease of use and convenience.

Highlights:

- Research led by Dr. Geoff Fernie, VP of Research at Toronto Rehabilitation Institute (Toronto, ON) (www.torontorehab.com)
- Industry funding from the Ontario Centres of Excellence (Toronto, ON) (www.oce-ontario.org) and Johnson and Johnson Inc. (www.jnjcanada.com) in the United States
- Research aims to diagnose sleep apnea at a much lower price and at greater convenience

3) Development of More Effective Methods to Identify Dysphagia

This project, led by Dr. Tom Chau at the University of Toronto (Toronto, ON), proposes development and commercialization of a tool to detect dysphagia (difficulty swallowing) that is common in older adults. It is estimated that about one in 10 people over the age of 50 have some type of swallowing disorder. This novel solution will serve as a valuable tool to help health-care practitioners to evaluate swallowing impairment.

Initial clinical evidence has demonstrated that the method has good sensitivity and specificity for detecting swallowing impairment in patients with neurogenic dysphagia, when compared to the gold-standard method. Currently, there are no non-invasive methods available for early detection of dysphagia, important for reducing clinical complications. Pneumonia and early death often arise when the condition is poorly managed.

Highlights:

- Research led by Dr. Tom Chau, VP of Research at Holland Bloorview Kids Rehabilitation Hospital (Toronto, ON)
- The proposed research involves the collaboration between Holland Bloorview Kids Rehabilitation Hospital and Toronto Rehabilitation Institute (Toronto, ON)

4) KINARM: A Robotic Virtual-reality Device for the Assessment of Brain Injury

Brain diseases and injuries impose huge medical, financial and social burdens on the daily lives of patients and their families. In Canada, one in four Canadians will suffer from a brain disease in their lifetime, with the attendant costs of medical care, loss of productivity and diminished quality of life. In the face of this growing economic issue, there is an urgent need to allay these consequences through more effective assessment, treatment programs and therapeutics. Currently, however, there is a distressing want of objective, quantitative tools for assessing brain injury and disease. BKIN Technologies, the leading developer of robotic technologies for probing brain function and dysfunction, will address this need by translating its pioneering KINARM™ research platform into mainstream clinical care.

Funding from FedDev will provide support for two integrated projects involving the translation of KINARM into a medical device. From Queen's University, Dr. Stephen Scott, who invented the KINARM Exoskeleton Robot in 1996, will be leading a project to quantify how healthy brains perform standardized behavioural tasks in the KINARM. This data represents a key enabler to the translation of KINARM to the mainstream clinic.

From the Sunnybrook Research Institute, Dr. George Mochizuki will introduce KINARM as a sensitive measure of sensory and motor function to assess the benefit of Botulinum toxin-A (BOTOX®) injections to stroke survivors with spasticity (stiff or rigid muscles that can interfere with movement).

Success of the study will further validate the utility of KINARM as a standard clinical tool resulting in improved patient care.

Companies providing matching contributions to the funding are Allergan Canada Inc. of Markham, and BKIN Technologies Ltd. of Kingston. BKIN has developed and sold KINARMS to scientists for eight years and has installed 35 KINARMS at internationally distinguished universities and institutes. The success of this project will allow BKIN to triple their workforce within three years following the project.

Highlights:

- Two integrated projects within the project using the KINARM lead by Dr. Stephen Scott from Queen's University (Kingston, ON) (www.queensu.ca) and Dr. George Mochizuki from Sunnybrook Research Institute (Toronto, ON) (www.sunnybrook.ca)
- Partnership between a hospital, university and an industry partner outside of Toronto
- Industry funding from BKIN Technologies (Kingston, ON) (www.bkintechnologies.com) and Allergan Canada (Markham, ON) (www.allergan.ca)

5) Novel Imaging of Carotid Plaque for Assessment of Stroke Risk and Real-Time Monitoring of Stent Placement

Stroke is a leading cause of death (15,000 patients/year) and disability (300,000 patients/year) in Canada, with a \$3.6 billion price tag to the Canadian economy. Current medical diagnostics, imaging and treatment selection for stroke management are decisively influenced by carotid stenosis (narrowing of the artery), which unfortunately is only a surrogate marker of the underlining disease process. Optical Coherence Tomography (OCT) may provide physicians the ability to image carotid plaques in-vivo at greater resolutions, previously not possible via existing techniques such as MRI, CT, or ultrasound.

This project aims to develop a disposable imaging catheter for use in the carotid artery for patient risk stratification in stroke patients and to attain real-time monitoring of stent placement (insertion of a tube into an artery to prevent its closure). This research lead by Dr. Victor Yang and Dr. Beau Standish will provide scientific insights to in-vivo imaging of the carotid vessel wall and the atherosclerotic plaque at resolutions previously not available to neurologists/neuroradiologists/surgeons involved in stroke care.

Highlights:

- Research is led by Dr. Victor Yang, from Ryerson University (Toronto, ON) (www.ryerson.ca)
- Industry partner is Colibri Technologies (Toronto, ON) (www.colibri.ca), a Canadian company dedicated to developing technologies that will improve patient quality of life, reduce healthcare costs and enable better treatment options for large patient populations
- Research aims to develop an improved method of imaging the carotid artery for patient risk stratification in stroke patients and in addition, attain real-time monitoring of stent placement (insertion of a tube into an artery to prevent its closure)

The FedDev project lead by Dr. Ting-Yim Lee aims to develop an imaging method to estimate the delivery of drugs through an opened Blood Brain Barrier (BBB). This project will develop a quantitative Computed Tomography (CT) imaging method to titrate the FUS opening of the BBB for the optimum delivery of drugs.

Highlights:

- Project is led by Dr. Ting-Yim Lee at the Lawson Health Research Institute (London, ON) (www.lawsonresearch.com)
- Industry partner is FUS Instruments, a Toronto-based spin-off company from the Focused Ultrasound Laboratory at Sunnybrook Health Sciences Centre (Toronto, ON) (www.sunnybrook.ca)
- Outcomes of the project are expected to provide improved imaging methods in order to optimize the effective delivery of drugs that target the brain

Appendix 2

Western Canadian Vaccine Network (WCVNet): An Example of a Regional Innovation Cluster

The aim of the Western Canadian Vaccine Network (WCVNet) is to harness the continuum of vaccine development resources in British Columbia, Alberta, Saskatchewan and Manitoba to enable the successful transition of potential vaccine candidates from late-stage discovery to clinical development and ensure uptake by appropriate receptors. Vaccines have had the greatest positive impact on human health in history and generate a return on investment of approximately 17:1 including social costs.

WCVNet will proactively pull technologies from public and private laboratories across Western Canada in order to fuel the vaccine candidate pipeline, and will take an integrated approach to coordinating development resources in order to ensure that candidate vaccines achieve a viable commercial outlet.

One of the key new infrastructures available to facilitate innovation in the cluster is the International Vaccine Centre. At a cost of over \$140 million InterVac is one of the largest and most advanced Containment level 3 facilities for the research and development of anti-infective and vaccines for humans and animals.

By harnessing the unique expertise and exceptional infrastructure in Western Canada, WCVNet will invest in projects that address a clear market need, offer strong commercial potential, and encourage interprovincial partnership. This will greatly enhance the capacity of Canada's research based pharmaceutical companies to perform world-class research and product development, and will strengthen Canada's reputation as one of the best countries to perform health related research. WCVNet will further strengthen Canada's economy by supporting the training of highly qualified personnel and employment of research scientists and training of graduate students.

Appendix 3

Montreal Health Innovation Coordinating Center (MHICC)

This regional cluster has existed for a decade. It is targeted to clinical research and in particular to the development and the coordination of multicenter and multinational clinical trials of phase III with large pharmaceutical and biotechnological firms. Most of the ideas and motivation for these trials have been generated from research results from the participating academic and research hospital institutions (mostly the Montreal Heart Institute). The MHICC has developed and coordinated already 70 multicenter clinical trials with 2,000 participating clinical sites in 20 countries in North America, Europe, Asia (China and India) and Australia. 40,000 patients from around the world have participated in these trials and Canadian clinical sites are distributed across Canada.

Most of the international pharmaceutical firms have now participated and founded trials with the MHICC as partners. The MHICC has been the basis for the creation of two national networks for clinical trials based on medical imaging (CAIN and MITNEC) that have respectively 5 and 14 member hospital research institutions across Canada. A single repository of medical images and patient data has been installed at MHICC where the data are transferred and communicated to MHICC from participating institutions across Canada using a rapid, efficient and secured electronic communication system part of it being based on the Canadian communication system, CANARIE. The resulting repository of advanced data is and will be a unique asset for further partnerships in international clinical trials with large pharmaceutical firms.

The activities of the last decade have contributed to turn the MHICC into an organization having close to 200 employees, most of them being highly qualified personnel with university degrees. The total annual revenue of the MHICC has now reached the level of 40 million dollars per year, with accumulated of 207 million dollars over the last decade.