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Friends of Canadian Institutes
of Health Research

REMOVING TAX BARRIERS TO HEALTH INNOVATION

Proposals to Improve the Tax Incentives for
Scientific Research and Experimental Development
(SRED)

Submitted in response to requests from
The Department of Finance and the Canadian Revenue Agency
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**FRIENDS OF CANADIAN INSTITUTES
OF HEALTH RESEARCH**

with voluntary professional tax advice from
PricewaterhouseCoopers LLP

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INTRODUCTION

Friends of Canadian Institutes of Health Research is a national voluntary organization created to promote the value of health research and establish community-based partnerships. Since 2000, it has specifically supported the goals and initiatives of the Canadian Institutes of Health Research (CIHR) and has expanded its role to represent all health disciplines.

Friends of Canadian Institutes of Health Research is a national membership of volunteers broadly representing leadership in health research positions as Deans or Associate Deans of Medicine, Hospital and University Vice-Presidents of Research, and research team leaders in our major academic health centres.

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SUMMARY OF THE PROPOSALS

In our view, the Government of Canada's review of Scientific Research and Experimental Development tax incentives should:

- 1. *Provide the same tax regime for SRED expenditures, including "flow through shares" and "limited partnerships", as has been provided for Mining and Oil and Gas Exploration and Development" for more than 30 years.***
- 2. *Consider tailoring the SRED incentives to the health innovation sector by: considering the separation of "Health Innovation" expenditures from other SRED categories; allowing different levels of tax credits to differing categories of health innovation risk; increasing the expenditure limits eligible for tax credits; relying on peer review processes to confirm expenditures that qualify as health innovation; and/or relying on ownership retention policies comparable to the five year retention policies of oil and gas flow through shares.***

If Canada had adopted these policies 30 years ago, we would be a lot closer to having a thriving globally competitive health innovation industry today. The first objective is to remove the barriers to Canadians who might otherwise invest in health innovation by enabling them to access unusable or unused tax deductions, and then allow the incentives in the form of tax credits.

The uniqueness of health innovation expenses is in their high risks, long-term development life cycles, rapidly escalating cash requirements through that life-cycle, and the public policy desire to add more value from Canadian health innovations before they head into global markets. Our \$200 billion health care and research networks are capable of creating significant value for domestic and global markets. Canadians deserve to have at least as attractive and sensible an investment climate for making high-risk long-term investments in health innovation as we have for mining and oil and gas exploration and development: no more - no less. The risks and investment requirements are quite comparable.

To be internationally competitive in health innovations we have to bridge the gap between the public and private sectors. Multinational health innovation firms might be ready to consider investing hundreds of millions of dollars in basic science partnerships and Canadian led disease management studies if we could bridge this gap. We should be doing as well as the UK

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that represents about 6% of the international demand for health goods and services and 12% of the supply, versus Canada which represents about 4% of the demand but only 2% of the supply. Comparable results would turn our \$10 billion trade deficit in health goods and services into a \$10 billion trade surplus employing an additional 100,000 to 200,000 Canadians in knowledge intensive occupations. Genentech Inc. of California, a profitable firm headquartered in close proximity to three major universities, has a basic science investment program twice as large as the CIHR budget of \$1 billion – the type of bridging that we have never seen in Canada. We also need to stimulate investments in community and health services health innovation and administration such as those to provide fully integrated and electronically supported primary care services at the local level.

TODAY'S PROBLEMS FINANCING HEALTH INNOVATIONS

Canada has outstanding expertise in almost every disease and every technology and discipline at the publicly funded leading edge of the knowledge innovation life cycle. This ranges from health promotion, biomedical research, population health research, photonics, imaging, micro-engineering, nanotechnology and information technology. At the more mature end of the privately funded health innovation life cycle, global industries, developed countries and developing countries with huge populations are desperate for new, high quality health innovation goods and services. There is a gap between these two ends of the innovation life cycle that we have rarely been able to bridge in Canada.

Although it is always difficult to catch up to leaders with a thirty-year head start, it is not too late. Over the next thirty years, Canada is well positioned to take advantage of the current explosion of new knowledge and a predicted shift to personalized medicine that will open up many thousands of new opportunities for multi-disciplined integrated diagnostic, therapeutic and administrative products and services.

It is never easy for scientists: to shift their focus from intensely competitive grants or public budgets to commercialization; to extract even the most promising knowledge from the public sector research and clinical environments to protect intellectual property; to arrange financing for the first proof of concept or animal models; to build a multi-disciplined team of colleagues and contractors; to finance the early stage formulation, toxicity, feasibility testing, pre-clinical or Phase 1 trials; and to obtain ethics reviews from multiple institutions. It takes a heroic effort. The pre-clinical development support capacity of the Canadian public and private sector is relatively scattered and weak, and government and NGO funding at this level is rarely available.

There is always external pressure on the federal, provincial and even local governments and charity granting councils to provide seed money, but they are understandably cautious about taking on the risks, making economic decisions and diverting money from their primary objectives of basic science and knowledge translation. There is always external pressure on multinational health innovation companies operating in Canada to provide seed funding, but that is inconsistent with their global focus on selecting for development from thousands of opportunities, those few innovations that fit within their global strategies and have the highest potential to serve the most promising markets.

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Current SRED policies and tax credits are internationally competitive for mature and profitable companies who are the ones that carry out research that is related to the business. However, the current SRED and combined provincial tax incentives do not recognize the realities of early stage health innovation. There is no practical way of spreading the risks to individual investors in recognition that the failure rate will be very high. There is no practical way of allocating expenditures to third party investors for tax purposes. Experienced investors tend to avoid even thinking about early stage health innovations. Experienced investigators put their careers and competitiveness for grants at risk if they are distracted by commercialization initiatives.

For example:

- If an early stage health company is a non-profitable Canadian Controlled Private Corporation it can still get a 35% federal and an additional 10% to 15% provincial refund on its health innovation investment. Although that can be important source of cash flow, for example in a software company with a 2-year product development cycle, it is not a material incentive for health innovation. On the net investment of 50% to 55% the risks remain very high and any revenue potential is likely to be 10 to 15 years into the future. Tax policies limit expenditures to \$2 million before tax credits are reduced: not usually enough to get health innovations up to the 5 to \$10 million dollar level which true venture capital can reasonably assess the risks and financial demands of going forward. The reality of continuing losses creates an incentive to prematurely sell the investment to companies that can use the tax losses and before enough pre-clinical work has been done to properly assess the potential.
- If individual taxpayers such as family, friends, colleagues, inactive partners or so-called "angels" wish to invest in the work of a scientist, they are not eligible for SRED incentives and their entire investment is at risk and unlikely to produce returns for many years. Very real tax losses go unclaimed and their investment is not eligible for tax credits. Any such investors are likely to encourage scientists to sell their intellectual property as soon as it has value. Investments are likely to be sold prematurely. Individuals who gratuitously want to invest in health research are almost better to contribute to health charities where they at least get a 29% tax credit.

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- If corporations, ranging, for example, from public spirited financial institutions to groups of investors working through a corporate structures or partnerships, wish to invest in health innovations they are specifically blocked from deducting SRED expenditures and accessing tax credits (unless innovative tax advisors can create structures that look as if they are in the business of health research).

The lack of risk tolerant seed money has been identified in PricewaterhouseCoopers' studies as the biggest challenge facing Canada's health innovation sector. The net result is that Canadian scientists have to seek, almost beg for, venture capital too early, usually at less than the \$1 million level, before pre-clinical research has been done and before the risks are known. Many innovations fail at that level. Others proceed, but only after the equity and management responsibilities of the scientists have been prematurely reduced. Few innovations survive the steps of pre-clinical research. For those that do, the next round of financing, typically at the \$3 to 6 million level usually attract only tax-incentivized labour-sponsored venture capital or foreign investors with access to larger sources of clinical research moneys. Many Canadian discoveries are eligible for the US National Institutes of Health clinical research support once they are controlled by American investors. The Canadian Institutes of Health Research has been stretching its resources to the limit to try to strategically invest about 10% of its budget, or \$80 million per year, on clinical research whereas the NIH invests about 20% of its budget, or \$5 billion per year, on clinical research – about 60 times as much as CIHR.

Almost every month, the intellectual property of another very promising health technology is transferred out of the country for development by foreign investors. This month's example happens to be Zelos Therapeutics, an osteoporosis therapy company founded in Canada. Zelos had captured over \$75 million in private sector financing before consolidation to the USA for clinical development beyond Phase II. Every academic and research centre in Canada can provide examples of excellent research migrating to foreign owners for development. Canada has not had a billion dollar international health product since the invention of Pablum in the 1930's.

The biggest barrier to bridging the gap between our science knowledge and commercialization opportunities has been our SRED policies that:

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- Block potential investors who do not have health or health research as their principal business from investing in research or, as they do in oil and gas, in finding creative ways of sharing and spreading extraordinary risks among a wide range of investors;
- Block the very necessary fluidity in ownership among scientists, contractors, expert managers and investors which could and should change many times in the life cycle of a health innovation;
- Block the very real losses of the early investors from flowing through to be applied to other sources of income of subsequent investors - including those who do not have research as their principal business (unless innovative tax advisors can create a structure appearing to have health as the principal business).

The biggest mistake that the Canadian government has been making for years is considering SRED tax credits to be incentives for health innovation. The reality is that the investment risks and losses in health innovation are all too real and it takes more than the current SRED policies to attract investors into health innovation. Even the most carefully managed tax-incentivized labour-sponsored venture capital funds have not been able to build a history of profitable investment opportunities. To illustrate the risks, a Canadian review of the international literature of stroke research identified that of more than 120 promising stroke discoveries proven in animal models in recent years, not one produced a human therapy that made it to market. For those rare new molecules, biotechnologies or medical engineering products developed to serve a global market, the investment frequently involves no less than \$300 to \$500 million over 10 to 15 years. Even for outstanding niche technologies, such as Canada's Veritas surgical tools, it is extremely difficult to penetrate global markets dominated by exclusive supply contracts held by global suppliers.

IMMEDIATE BENEFITS OF THE PROPOSALS

The benefits of the above proposals focus on attracting individuals, corporations and partners who are not in the health business to invest in health research the same way that they can now invest in mining, oil and gas. With flow through shares and limited partnership structures, the tax losses can be passed through to investors as the expenditures are incurred. For example, in the simplest and best case scenario, a passive investor with a marginal tax rate of 40% would avoid taxes on other income equal to 40% of the investment, and with a 35% to 45% refund would recover a total of up to 85 % of the investment, comparable to the situation for mining, oil and gas exploration. Usually expenditures are incurred over a period of years and there are a variety of administrative rules that dilute the best-case scenario described above, but the concept is important. In the case of health innovation investments, each of the administrative controls has to be thought through in a consultative process with tax experts to ensure that quality of the health innovation investments and to prevent any potential abuse. The import principal is to err on the side of creating incentives for high-risk long-term health innovation investments rather than blocking risks across the full spectrum of SRED industries.

With these proposals:

1. ***The Canadian paradigm would change from our most productive scientists exhausting their time and energy searching desperately for small pockets of risk tolerant money, to a paradigm where large pools of smart money start searching for the best health innovation opportunities and programs for spreading their risks across many opportunities.***

This is comparable to the way oil and gas investors search for good prospects and meet the essential need to spread risks over many opportunities. If the definitions of "health innovation expenditures", "flow-through shares" and "limited partnerships" stay close to those used for oil and gas, there are already in place thousands of tax professionals, investment advisors, and investors totally familiar with their application. Their professional and social networks will all start to seek health innovation prospects and ways of sharing risk structuring partnerships and investment programs that are unheard of today. Investments will be targeted towards hundreds of multi-disciplined teams and the high risk but less costly pre-clinical and clinical levels of innovation that are not normally of interest to global corporations until the final stages of the development

life-cycle. We would start to bring the typical Canadian venture capital investment from today's \$1 million closer to a more realistic international level of 5 to \$10 million dollars per investment when the risks and needs for cash and professional managers and scientific advisors are better defined. It is easy to imagine that within a few years each of Canada's approximately 20 academic health centres and research intensive universities and hospitals could annually generate approximately 20 extra innovations capable of attracting \$5 million per year, representing \$100 million per year for each centre and close to \$2 billion per year for Canada.

2. ***Closing the huge gap between Canada's individual basic science and clinical investigators versus the business objectives of international life science industries.***

Now we have too many under financed stand-alone niche companies with few synergies and higher than reasonable risks. Outside investors with access to flow-through shares and limited partnerships are likely to find ways of pooling innovations to spread their risks and obtain synergies in the use of resources so that many small health innovations are consolidated, while they are still Canadian-owned, into mid-size innovative firms with 10 to 30 opportunities in the innovation pipeline under the direction of professional managers. Investment dealers and university industry liaison offices will have reasons to work together to help design investment programs.

To see synergies and help manage the risks, some programs may be disease based, others will be technology based, and others will be regionally based. Some of these programs will be able to attract major and institutional investors to become medium sized health innovation firms with global potential. The successful products of these pipelines will then attract the global firms with the resources, often hundreds of millions of dollars, to invest in developing and marketing these products and services globally.

As Canadian investors acquire a better understanding of the health innovation sector, some institutional investors and pension funds will be partners in these global development programs. With the use of flow-through shares and limited partnerships the investment pattern will parallel the 10 to 20 year development cycle of the oil and gas industry. At the front end of the oil and gas cycle, individual investigators ("land men") start to assemble property, seismologists and geologists assess its potential, and small exploration companies form

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exploration drilling partnerships, each taking a small share of the ownership.

As the risks start to decline but the costs escalate into the tens of millions of dollars, management changes, medium sized Canadian companies invest in development wells, and multi-national firms buy into the best of those opportunities for hundreds of millions of dollars to ensure global supply and meet global markets. The health innovation sector needs the same kind of fluid continuum of shared ownership, risk sharing and investment arrangements.

3. ***The culture of the health sector and its leaders, employing more than 400,000 Canadians, will become more open to sharing: innovative expertise; investment methods; commercialization objectives; access to patients; and access to improved methods.***

Those who live in a risk-averse public sector silo are likely to become more aware of the exciting but high-risk opportunities of innovation and commercialization. Industry is more likely to co-locate with academic centres. Public awareness of the importance of health research will rise. Patients and health professionals will benefit immensely from new diagnostics, therapies, clinical trials, and methods of providing and administering health services. One example: the health outcomes of patients in clinical trials are statistically better even if patients are in a placebo group, and privately sponsored clinical trials usually reduce the costs to the public health care system. Canada has the infrastructure to greatly help recruiting patients for trials if incentivized to do so.

Globally there are thousands of promising therapies and technologies waiting to be tested and developed in an environment as respected as the Canadian health care system. Instead of losing promising technologies, some technologies will migrate to Canada for development. Community health nurses, primary care providers, educators and clinicians would all benefit from better health information, methodologies, and therapies developed in their own environments. Much will depend on the inclusiveness of definitions of SRED or health innovation expenditures and the extent that participants are incentivized to pursue global opportunities in developed countries as well as in the developing world.

DEFINITIONS AND ADMINISTRATION OF THE PROPOSALS

Defining Health Innovation Expenditures

The current definitions of Scientific Research and Experimental Development seem to be inclusive enough to accommodate the spectrum of health innovations, including:

- a) basic curiosity driven science in all disciplines relevant to health research ranging, for example, from biomedical, to biotechnology, engineering, imaging; nanotechnology, bioinformatics, proteomics, environmental health and population health research;
- b) pre-clinical pre-product research including drug design and formulation, toxicity testing, design feasibility and early testing of engineered devices, animal testing and phase 1 trials;
- c) clinical research including innovations in disease prevention, diagnostics, therapeutics, rehabilitation products and services, and Phase II and III trials;
- d) health services innovation including best practices research, education and training content development; electronic health records and information systems;
- e) disease management studies; and,
- f) phase IV and V trials.

Some critical elements of the definitions should probably allow the Canada Revenue Agency to rely on publicly appointed and supported peer review processes to develop guidelines and then determine or arbitrate:

- a) whether the expenditures qualify as innovation – creating new knowledge or new tools of relevance to health – as compared to copies of existing tools that are widely available;
- b) the extent that foreign expenditures incurred by a Canadian taxpayer should qualify for the SRED pool in the event that they are deemed to be an essential component of the knowledge and products being developed; and,

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- c) the extent that a portion of the SRED expenses incurred by non-taxable entities such as Canadian universities and hospitals may be included in the SRED pool.

Accessing the peer review processes, or sub-committees, of existing organizations would further the objective of periodically applying the minds of Canada's best scientists to the health innovation agenda. Examples include the peer review committees of such organizations as the CIHR, Canada Foundation for Innovation, Canadian Health Services Research Foundation, Genome Canada, and Natural Science and Engineering Council.

Health Innovation Tax Credits

Current Investment Tax Credits, combined with provincial incentives, are 35% to 45% of current SRED expenditures incurred by Canadian Controlled Private Corporations "CCPC" up to a limit of \$2 million, of qualifying expenditures, and 20% on for all other expenditures including expenditures incurred by public companies. The limit should be increased closer to the \$5 to \$10 million level where the risks typically start to be predictable and more traditional sources of venture capital are appropriate. There may be better qualitative ways of limiting eligibility without arbitrary limits, and it may not always be constructive to limit eligibility to CCPCs.

Flow-through shares

A flow-through share is typically a common share with one important difference: when the shareholder purchases the common shares, the Corporation, by contract, agrees to "renounce" expenses that it could otherwise claim and pass them to the shareholder. Thus, the shareholder can claim the deductions as if they had incurred them directly. This is particularly useful for corporations that are not yet profitable as it allows the fast write-offs available for research and development expenditures to be used by the shareholders against their income from other sources.

The mining and oil and gas models are appropriate for health innovation. Investors may be individuals, partnerships or corporations. Investors subscribe for flow-through shares pursuant to an agreement whereby the corporation issuing the shares agrees to incur qualifying SRED expenditures within a specified period of time (24 months). They must be common shares without any requirement to redeem, acquire, or cancel the shares in any way within a specified period of time (five years). The expenditures renounced must not exceed the

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amount paid by the investors to subscribe for the share or the amount of the SRED (or Exploration and Development) pool. The investor is entitled to claim any related investment tax credits. Investors are required to hold the shares for a minimum of 24 months to help ensure a stable market for the shares. A tax-free transfer into an RRSP account, if held for an additional 12 months, provides a further incentive for investors to become long term supporters.

Limited Partnerships

Partnerships are currently prohibited as a means of allocating SRED expenditures to specified members of a partnership. Partnerships would provide a key step in taking health innovations through the lengthy, costly and high-risk development cycle. Over a typical 10 to 20 year health innovation cycle, ownership interests change as differing scientific and clinical disciplines and contractors are brought into the process. Managers change as the needs change. As in the oil and gas sector, investor tolerance for risk differs and investors need to have mechanisms to spread their investments and risks across as many innovations as possible. Active managing partners will often expect to have a proportionately higher ownership interest than their share of the financial investment, and limited liability partners will often be willing to accept a lower ownership interest than their share of the financial investment if they believe in the managing partners. Limited partnerships limit the liability of the partners to subscribed amounts and provide flexibility to allocate future economic benefits to investors contributing intellectual property, "sweat equity", cash or management capabilities using ratios that recognize and lever what each partner is bringing to each venture. Limited partnerships are a key to the success of the mining and oil and gas sectors, and can do the same for health innovation.

The limited partnership proposals are that:

- a partnership be considered to be a "person" for purposes of the flow-through share renunciation rules;
- the partnership losses resulting from the deduction of SRED expenditures may be allocated to limited partners;
- the investment tax credit to any partner should not be limited to the amount of the limited partner's at risk amount but to the amounts agreed to by the partners; and,

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- partners are entitled to the deduction only when the expenses have been incurred, even if they sell the shares before the expenses have been incurred.

MANAGING EXPECTATIONS AND IMPLEMENTATION

It will be difficult to assess these proposals, or measure their impact out of context of other public policy initiatives to address several chronic needs of the health innovation sector. For example:

- Visionary private and public sector leadership can go a long way towards optimizing the benefits of these proposals. Investment advisors, investors, clinicians, investigators, hospital and university administrators, politicians and public servants need to take the time to educate each other and understand the opportunities, communicate to the public, and support health innovation investments. Some investment advisors are likely to seek pan-Canadian disease or technology focused partnerships that will require considerable forethought and knowledge to put together. All initiatives will take a well thought out communications strategy.
- The extent that the investment communities and university-industry liaison offices and other knowledgeable intermediaries embrace the concept develop innovative and realistic investment programs will have a big bearing on the outcomes.
- Academic funding and programs are needed to increase the supply of human resources and the responsiveness of education programs, a limiting factor in the growth of the sector, including the urgent need for a new generation of clinician-scientists, technical staff in many newly emerging and relatively scarce disciplines, and management personnel.
- Canadian academic health centres need to acquire more experience and more robust decision-making and support programs to identify and respond to opportunities to put large scale multi-disciplined private-public health innovation partnerships together.
- Canadian investigators and investors need to acquire a much better understanding of the strategies, opportunities, pressures and capacities of the global health innovation industries. We need a "Team Canada" approach to helping Canadian executives attract investments into Canada when decisions are being made to allocate and rationalize international investment priorities.
- Ethics review and regulatory processes need to be seen by investors as ranking with the best in the world in terms of the quality of science knowledge, discipline, and efficiency designed into review processes.

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- Federal and provincial governments have to send out strong signals that they will be continuing their trends toward increasing the range and focus of public investments of all aspects of health innovation research. They would do well to find new means to ensure that the health innovation and health care bureaucracies are synchronized and remain ready and willing to play their appropriate roles in encouraging new program, partnership and funding models to support health innovation.

ECONOMIC IMPACT

There are too many contextual variables to accurately predict the economic impact of these proposals. Analysis is also complicated by the reality that Statistics Canada does not identify and bring together the academic, clinical and industry components that make up the health innovation sector. In the very best case, within a few years, a few broadly scoped national or regional partnerships each representing investments in the hundreds of millions could emerge to address particular diseases or technologies. These would likely draw significant matching investments from global health industries. In a far more pessimistic scenario, each of about 25 research-intensive universities generating at least one new health innovation per year would reach an investment level of \$5 million, representing more than \$100 million of new activity per year.

The simplest possible exploration of the economic impacts might suggest that each \$100 million of direct new investment by inactive investors in health innovation might cost the Crown about \$75 million in foregone taxes and refunds. New income and sales taxes paid by knowledge intensive workers might return to governments only about 33% of that amount. Just as in the mining, oil and gas sectors, the real economic justification for the investment will emerge in a few years when commercialization opportunities should be translating into hundreds of millions of dollars of investment each year by investors such as venture capital funds, institutional investors and global health industries. The global health industries are investing in excess of \$200 billion per year in health innovations, and if Canada ever achieved 4% of that amount it would exceed \$8 billion per year.

The “business case” does not come close to the “economic case” reflecting the value of the health benefits that may ensue to Canadians. A much more dynamic health innovation sector would produce huge improvements in primary health care administration, in disease prevention, acute care and rehabilitation relevant to the leading diseases. Thousands of patients would benefit from new diagnostics and therapies discovered or developed in Canada and from the new international partnerships that would emerge. The real test of the economic case will show up in relatively achievable and modest reductions in the economic burden of disease, now costing the Canadian economy in excess of \$400 billion per year.

Canada cannot afford not to pursue above proposals to remove tax barriers to health innovation.

END

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This submission may be posted on the web site of the Department of Finance.

FOR FURTHER INFORMATION

For further information, please contact any of the following:

Dr. Aubie Angel
President
Friends of CIHR
Massey College
4 Devonshire Place, Toronto ON M5S 2E1
416-506-1597
aubie.angel@utoronto.ca

Patrick Lafferty
Secretary, Board of Directors
Friends of CIHR,
31 Bittern Court, Ottawa, ON K1L 8K9,
613-745-1688
lafferty@rogers.com

Kent Davison
Partner
PricewaterhouseCoopers L.L.P.,
Suite 700, 99 Bank Street, Ottawa, ON K1P 1E4
613-237-3702
kent.davison@ca.pwc.com

Dr. Cal Stiller
Director, Friends of CIHR
Stilco Ltd.
528 Waterloo St.
London, ON N6B 2P9
519-858-1582 , ext. 236
crs@stilco.net

Dr. Pavel Hamet
Director, Friends of CIHR
Centre Hospitalier de l'Université de Montréal (CHUM)
Hôtel-Dieu, 2901 Rue Rachel Est, 4th Floor - Room 401 F
Montreal, QC H1W 4A4
514-890-8246
pavel.hamet@umontreal.ca