

Life Sciences

DAVID EMERSON:

Industry Minister David Emerson on his top priorities on the life sciences file, on GMOs, and on some of the ethical dimensions of life sciences.

Pages 26, 31

James Rajotte:

The Conservative Party aims to create a responsible public framework under which the life sciences sector can develop and prosper, says Conservative MP James Rajotte. **Page 24**

Paul Crête:

We need a greater transparency, especially in the case of GMOs, where Quebecers are strongly in favour of mandatory product labelling, says Bloc MP Paul Crête. **Page 28**

Jean Crowder:

Canadians want mandatory labelling now so we can choose which foods we want to consume, says NDP MP Jean Crowder. **Page 28**

Arthur Carty:

The 21st century health challenges are global, complex problems that will necessitate a new approach to scientific research, says Canada's Science Adviser Arthur Carty. **Page 29**

Arnold Naimark:

We must develop a comprehensive national strategy to promote the commercialization of biotechnology here in Canada, says CBAC's Arnold Naimark. **Page 30**



Photograph by Jake Wright, The Hill Times

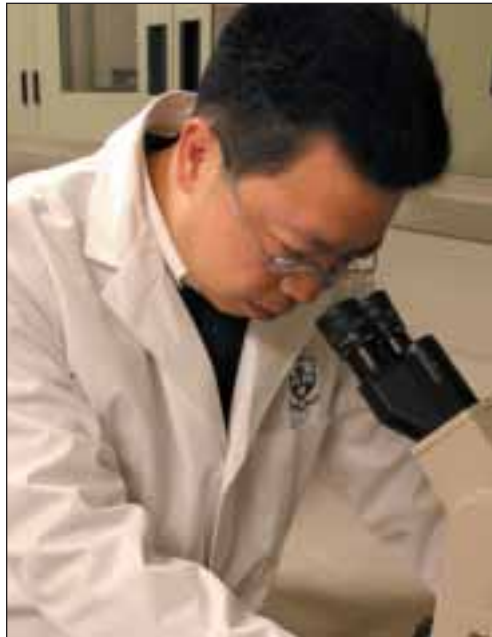
It's life sciences: Industry Minister David Emerson, above with reporters, talks to *The Hill Times* this week about the latest on life sciences.



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Jun Liu –
Outsmarting drug-resistant infections

Jun Liu, a professor of Medical Genetics and Microbiology, is developing new drugs to battle antibiotic-resistant strains of tuberculosis and a new vaccine to halt the disease's spread.



Peter McCourt –
Creating drought-resistant plants

Canada Research Chair in Plant Molecular Genetics Peter McCourt discovered a gene that controls drought resistance — a development that could increase crop yields in arid environments and alleviate world hunger.



Molly Shoichet –
Can spinal cord injuries be reversed?

As Canada Research Chair in Tissue Engineering, Molly Shoichet is developing techniques to promote regeneration of nerve tissue after spinal cord injuries.



Janet Polivy –
How chronic dieting lowers self-esteem

Psychologist Janet Polivy of the University of Toronto at Mississauga looks at the negative effects of chronic dieting on behaviour and how unrealistic weight loss expectations lower self-esteem.



Rudy Boonstra –
Stress and the snowshoe hare

Zoologist Rudy Boonstra of the University of Toronto at Scarborough established the link between predator stress on the snowshoe hare and dramatic swings in its population — knowledge that is being applied to the broader study of ecology.

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POLICY BRIEFING - LIFE SCIENCES



Addressing the needs of life sciences sector in Canada

Conservatives aim to create public framework for life sciences sector to develop and prosper

By CONSERVATIVE MP JAMES RAJOTTE

Canada is a leading performer in agricultural and therapeutic biotechnologies. The quality of life sciences research being conducted in Canada is highly regarded.

The life sciences sector needs to continue to grow and prosper in Canada not only because it inherently seeks to improve our lives, but also because a successful life sciences sector creates wealth for the entire economy. In fact, some argue that the life sciences sector is the natural successor to the information technology revolution of the last 20 years.

Research is the key first component in supporting our life sciences sector. Canada remains a minor player in research spending when compared with our international competitors. After the Liberals initially made deep cuts to all federal research spending in Canada, gross expenditures on R&D (GERD) have increased since 1994, although total spending has leveled off since 2002. Clearly our research policy framework must continue to be reviewed and Canada must commit to improving our capacity to perform and fund public and private research.

At our recent policy convention in Montreal, the Conservative Party passed resolutions that recognize the importance of both public and private sector investment in research. They are:

A Conservative government will uphold funding of innovation, technology and research through the granting councils. The Conservative Party supports a

competitive peer review process and enhanced transparency and accountability to determine who shall receive grants through these councils. A Conservative Government would continue to fund the indirect costs of research with particular attention to small universities.

The Conservative Party recognizes the importance of private sector investment in research and development of commercial applications. We recognize that the Scientific Research and Experimental Development (SR&ED) tax credit has been successful in spurring private investment in R&D. We will work with stakeholders in all fields of research and various industry sectors to expand this tax credit. A Conservative Government will also eliminate the capital tax and reduce the capital gains tax because the effectiveness of the SR&ED tax credit relies upon the general level of tax on capital and investment.

From the research being conducted in both the public and private sectors, organizations create innovative products and processes that are eventually delivered to Canadians through the marketplace. This is the development side of R&D. In my role as industry critic for the Conservative Party, I have had the opportunity to meet with many companies, academia and individuals who represent the life sciences sector. An interesting discussion has emerged around how to support the transition from the research to development.

While we have many government organizations and programs that support research, comparatively, precious little resources and attention has been spent by the federal gov-

ernment on development. Indeed, some industries argue that Canada has fallen so far behind in the development process that other countries are much better positioned to take the research conducted in Canada and transfer it to the marketplace.

The most prominent development program in Canada is the Technology Partnerships Canada program (TPC). TPC is poorly run, highly-politicized and actually devotes scarce resources to pure development. I would argue that, in its current form, TPC is not a development program at all.

Aside from TPC, much of the development framework in Canada is focused on commercialization. There is no doubt that a great deal of commercialization is inherently a responsibility of the private sector. As such, the government must create an economic climate where the private sector can support its own commercialization processes without any direct interference from the federal government.

However, I also recognize that in some cases, the federal government will be required to assist both businesses and not-for-profit organizations with commercialization and development strategies. Therefore, I believe the underlying approach to commercialization should be balance—a balance between when government should engage in the commercialization process and when they should step back.

A recent survey by BIOTECANADA concluded that the barriers to businesses that want to commercialize their products have not changed since 2001. Access to capital continues to be the biggest challenge for Canadian life sciences companies. In addi-

tion, they continue to face significant regulatory challenges and hurdles in accessing skilled human resources.

I believe that development and commercialization should be a part of a larger economic strategy. We must: improve venture capital financing and review the role of the Business Development Bank of Canada; create a clear intellectual property framework and commit to enforcing it; reduce and streamline the regulatory burden; re-examine our commitment to education and training at both universities and colleges such as the Northern Alberta Institute of Technology; review immigration credentials; review the government's role in infrastructure—both in science infrastructure funding and in supporting the natural clusters that have developed in places such as Montreal (biopharmaceuticals), Edmonton (nanotechnology) and Saskatoon (synchrotron and spin offs); and engage in an open dialogue concerning the ethical challenges in areas such as the genome and reproductive technologies. Good government policies result in better products and advanced lifestyles for Canadians. The life sciences sector offers opportunities to both improve our economy and to address many of the current health, food and environmental challenges facing Canadians. Public support of the sector is essential. The Conservative Party aims to create a responsible public framework under which the life sciences sector can develop and prosper.

Conservative MP James Rajotte, his party's industry critic, represents the riding of Winnipeg South, Man.

The Hill Times



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POLICY BRIEFING - LIFE SCIENCES

Emerson says government must do more on life sciences R&D

■ *Industry Minister David Emerson says he wants to see more life sciences R&D in both the public and private sectors because there are far too few of these firms and he wants to see the 'picture change in a very substantial way over the next few years.' Sounds like a challenge.*

By THE HILL TIMES

Canada's Industry Minister David Emerson says Canada's small, medium and multi-national enterprises need to become globally competitive through growth and reinvestment which is partly why he's looking at establishing an upcoming "commercialization panel."

Mr. Emerson (Vancouver Kingsway, B.C.), a rookie to federal politics, who recently publicly stated that he would indeed run again in the next election, despite being discouraged by the sensational revelations coming out of the Gomery Inquiry into the \$250-million now defunct sponsorship program, also said the government is trying to make the regulatory process more competitive for life sciences.

Declared Mr. Emerson: "We're following through on Smart Regulations, with particular attention to biotechnology. Previous commitments to improve the regulatory approval process are already bearing fruit in the area of drug approvals, but more needs to be done for all life science products. We've also made specific life science infrastructure investments in the B.C. Cancer Foundation, the Medical and Related Sciences Discovery District (MaRS) in Toronto, and the Atlantic clusters initiative, which has a significant life sciences component."

Mr. Emerson said he wants to see "more sustainable, globally competitive Canadian companies in the biopharmaceutical industry, and in other life science industries."

And he said Canada's life sciences industries "could offer solutions to key development priorities such as food security, a cleaner environment and sustainable economic development."

Mr. Emerson conducted an email interview last week with *The Hill Times* for this week's life sciences policy briefing.

What are your three top priorities on the life sciences file?

"Industry Canada focuses on industries in the health sector, such as pharma, biopharma and medical devices, and those firms in industrial sectors that are beginning to adopt biotechnology to reduce waste, develop alternative sources of energy and pursue new processes in the chemicals industry. And, in some of the more traditional economic sectors, such as agriculture, forestry and fisheries, life science firms are essential innovators.

"Our priorities on the life sciences file are to sustain the major increase in federally-funded research, which has doubled since 1997-98, improve the commercial opportunities for innovations coming out of the research community, and facilitate a significant improvement in the competitiveness of Canadian-based life science firms. Ultimately, I want to see many more life science firms holding their own in the global marketplace. This will not only be good for the economy but will also provide health and environmental benefits to all Canadians."

How much does the Canadian government invest annually into "life sciences" total, across the board?

"In 2004, the government invested \$513-million in R&D on biotechnology, alone, both in research and in programs such as Technology Partnerships Canada. The government also makes significant

life science investments through funding to the Canada Foundation for Innovation (CFI), the Canadian Institutes of Health Research (CIHR) for non-biotechnology life sciences research, and to the Natural Sciences and Engineering Research Council of Canada (NSERC) related to medical devices and environmental programs. There are also programs such as the Industrial Research Assistance Program and the Business Development Bank of Canada (BDC) that invest in life science firms, including biotechnology companies.

"We often view the government's investments as being at the front end without appreciating the much larger and related investments made by the private sector. These industries directly employ 68,000 Canadians, spend about \$2.9-billion annually in R&D and have revenues of over \$21.8-billion."

Is that enough?

"In the last budget we committed an additional \$165-million (on top of the \$435-million previously invested) to Genome Canada to maintain Canada as one of the leaders in genomics research. We provided an additional \$375-million to the three granting councils (CIHR, NSERC and the Social Sciences and Humanities Research Council of Canada) and increased funding by \$15-million, to a total of \$260-million annually, for the indirect research costs in universities and research hospitals. We're finalizing plans to implement \$75-million toward pilot projects to better commercialize university and government lab research, and we're following through on our \$250-million investment in BDC to encourage technology transfer and to strengthen venture capital investments.

"However, we must keep in mind that government efforts are intended to complement the larger investments made by industry. Most life science firms face unique business challenges because they are highly regulated, R&D intensive, and have long product development times with high risk of product failure. Many within the health sector are seeking to reposition themselves as the pace of discovery increases and global competitiveness becomes more intense. The make-up of these industries—a large number of Small-Medium Enterprises (SMEs), a small number of large Canadian firms, along with a significant presence of Multi-national Enterprises (MNE)—creates both challenges and opportunities. As a result, many companies are seeking innovative ways to work in partnership with other companies, between industries, with public research institutions, and with governments.

"These firms need to become more globally competitive through growth and by reinvestment in Canada. Increasing the private sector's R&D investment is a key challenge. As part of that challenge, I see the need to pursue additional measures to improve the competitiveness of these and other industries in Canada that are increasingly utilizing leading-edge technologies. That is partly the reason why I am looking to establish a commercialization panel."

Has the federal government lived up to its life sciences direction and funding?

"The government has made a major investment in life sciences as part of its broader commitment to research and research infrastructure. We're strengthening our efforts to get discoveries out the door and to facilitate greater early stage investments within the private sector.

"In addition, the government has a significant initiative underway to make the regulatory environment more competitive for life sciences. We're following through on Smart Regulations, with particular attention to biotechnology. Previous commitments to improve the regulatory approval process are already bearing fruit



Photograph by Jake Wright, *The Hill Times*

It's the life sciences file: Industry Minister David Emerson, who recently announced that he will run in the next election, says, "in some of the more traditional economic sectors, such as agriculture, forestry and fisheries, life science firms are essential innovators."

in the area of drug approvals, but more needs to be done for all life science products. We've also made specific life science infrastructure investments in the B.C. Cancer Foundation, the Medical and Related Sciences Discovery District (MaRS) in Toronto, and the Atlantic clusters initiative, which has a significant life sciences component.

"The Government also has in place the Canadian Biotechnology Strategy to help better coordinate federal efforts in biotechnology and to leverage external advice. The bio-industrial element of that strategy is expected to be strengthened through the Budget commitment to pursue a \$200-million Sustainable Energy Science and Technology Strategy to develop/commercialize leading-edge environmental technologies."

What's the federal government's stand on

genetically modified foods right now?

"Industry Canada—along with five other departments and agencies—worked with representatives from industry, academia, consumer groups and other levels of government to develop a national voluntary standard for the labeling of genetically engineered foods. I'm pleased to say that this new national standard was published early last year.

"The Government of Canada has always supported a voluntary standard as a market-based solution to meeting the information needs of consumers, while conforming to obligations under international trade law. It's important to note, however, that when there are health or safety concerns, ALL foods—including genetically engineered products—are

Continued on Page 28

POLICY BRIEFING - LIFE SCIENCES



BQ: Canada must err on side of caution in life sciences

Quebecers are strongly in favour of mandatory product labelling on GMOS, says Paul Crête

By BLOC MP PAUL CRÊTE

The term biotechnology refers to a series of techniques that use living organisms or their constituent parts to create products or implement processes. This type of technology offers outstanding economic possibilities and biotechnology has a wide range of applications, because it will radically transform the traditional approaches to health care, agriculture and environmental protection.

In Canada, the number of firms increased by almost 40 per cent between 1997 and 2001. Quebec has 130 firms, 35 per cent of the total, while the Western Canadian provinces have 31 per cent; Ontario, 27 per cent; and the Atlantic provinces, seven per cent.

Montreal, with some 200 specialized centres, is first in Canada and ninth out of 25 major North American cities in the number of university R&D centres. The Montreal laboratory is the best performing of Merck's 11 research centres around the world. A number of drugs were invented there, including three of Merck's six best-sellers around the world.

Although Quebec has 23 per cent of Canada's population, it has:

- 68 per cent of the Canadian patents for prescription drugs;
- 42 per cent of the pharmaceutical investment in R&D;
- 41 per cent of the biotechnology investment in R&D;
- 32 per cent of the peer-awarded research grants in Canada.

Quebec researchers receive a larger share of Canadian research funding for health care:

- Neurosciences 59 per cent
- Immunology 48 per cent

- Genomics 45 per cent
- Health services 45 per cent
- Cardiology 44 per cent
- Paediatrics and obstetrics 42 per cent

There are more than 31,054 people working for companies linked to the biotechnology field in Quebec, including 4,710 in highly specialized positions, primarily in the Greater Montreal Region. However, Quebec also has two major regional centres, Sherbrooke, where the emphasis is on the environment, and Saint-Hyacinthe, which specializes largely in animal and human food. Of the rest, a third biotechnology region seems to be on the point of emerging. This region, which intends to focus on harvesting the marine biomass, is the Lower St. Lawrence/Gaspé region.

The challenges for Quebec

The Quebec industry, which has shown that it intends to be fully involved in the great biotechnology adventure, has as its main assets:

- a solid network of universities and research centres;
- a pool of educated workers and qualified researchers;
- financial and tax incentives;
- proximity to major markets;
- a base of quality government research on health care with almost 10,000 employees;
- an increasing level of government research funding thanks to new initiatives, Génome Québec and the Canadian Institutes of Health Research;
- specialized degrees in manufacturing (pharmaceutical research and biotechnology);
- generous tax measures for Research & Development and biotechnology development;
- international events: BioContact and Le Carrefour des biotechnologies;

- a cohesive community that facilitates partnership and leadership within the sector.

The revenues for this industry inside Quebec exceeded \$1.5-billion in 2001; more than 92 companies reported revenues in 2001 out of the 252 Canadian firms generating revenues. Of the \$980-million in supplementary capital in 2001, Quebec obtained \$467-million.

As solid as these assets and Quebec's cost competitiveness are, we must not forget certain problems that, in the medium or long-term, could mortgage the future of the Quebec biotechnology industry.

Thus, the shortage of scientists and managers, during a period of estimated annual growth of 15 per cent, could prove very harmful to the industry. As well, there is limited funding available. For these firms to be competitive at the international level, they must have equipment on the cutting edge of technology, which is not always the case. Finally, the industry is grappling with a legal framework that is too imprecise and that limits its ability to plan for the long term, and thus to secure long-term funding.

Resolving the fiscal imbalance would give Quebec the necessary resources to provide better funding to the advanced research and university network, incidentally solving part of the labour problem. As long as the federal government refuses to resolve the fiscal imbalance, the Bloc Québécois will ensure that the Quebec biotechnology industry has adequate and predictable funding and that it receives its fair share of federal funds.

Clearer ground rules should also be established to allow the industry to predict the future with greater clarity. This does not necessarily mean that the rules should be relaxed, because it is best to remain cautious in the field of biotechnology. The Bloc



Photograph by Jake Wright, The Hill Times

Biotechnology: Bloc Québécois Leader Gilles Duceppe, above. Montreal is first in Canada in the number of university R&D centres.

Québécois is very attached to the principle that we must err on the side of caution in this sector more than any other. Ethics remain a priority and it is imperative that we listen to the public, which is calling for greater transparency, especially in the case of GMOs, where Quebecers are strongly in favour of mandatory product labelling.

The federal government could integrate the precautionary principle by ratifying the Cartagena Protocol on Biosafety. At present, 119 countries have ratified this agreement that recommends oversight of the transportation, handling and use of GMOs in order to avoid any adverse effects on human health and biodiversity.

Bloc Québécois MP Paul Crête, who represents Rivière-du-Loup-Montmagny, Qué., is his party's industry critic.
The Hill Times



Canadians want public debate about new biotechnology

And Canadians want mandatory labeling now so we can chose which foods we want to consume

By NDP MP JEAN CROWDER

Although biotechnology has developed some amazing breakthroughs in laboratories, Canadians are justifiably a little leery of what those breakthroughs mean in the real world.

Genetically-modified organisms are the most recognized products coming out of the life sciences sector.

Agriculture Canada is promoting GM food as a boon to farmers, as a boon to food aid and as a boon to the environment.

But there is a lot of opposition to the widespread use of GM crops. From farmers who now worry they will be prosecuted for growing GM crops that seeded naturally on their farms; to consumers who want to know if GM ingredients are in their food, Canadians want a public debate about this new biotechnology.

Adding to Canadians' concern about GM foods is the lack of transparency in Health Canada. That was compounded last year by the firing of four scientists who spoke out regularly on an institutional culture at Health Canada that pushed scientists to approve drugs and technologies.

Health Canada has the ignoble distinction of winning the Canadian Association of Journalists award for being the least transparent agency in the Canadian government: ahead of the Department of National Defence or the Computer Security Establishment.

Canadians need an agency that shows through action, reports and its hiring and

retention practices that it is in the business of protecting Canadians' safety. That is not the case with Health Canada today. Changes are being made but not fast enough.

Once GM foods enter the ecosystem, we do not know what the long-term effects may be. That led one country, Zambia, to refuse food aid that contained genetically-modified food.

"Despite pressure from around the world, the Zambian government maintains that it has made a responsible decision by not accepting GMO food aid. We argue that the long-term impacts of GMOs and products derived from them are not fully understood and, therefore, safety and caution should take precedence over other interests including international trade agreements," said Dr. Mwananyanda Mbikusita Lewanika, executive director of the National Institute for Scientific and Industrial Research in Zambia.

The main risk assessment used to evaluate genetically-modified organisms is "substantial equivalence." There is no hard and fast definition of substantial equivalence; it basically means if the genetically-modified organism shares most of the same characteristics as another variety of the organism, one can assume it is safe.

This flies in the face of the 2001 Royal Society of Canada report for Health Canada, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada" whose first recommendation was: "That approval of new transgenic organisms for environmental release, and for use as food or feed, should be based on rigorous scientific assessment of their potential for

causing harm to the environment or to human health. Such testing should replace the current regulatory reliance on 'substantial equivalence' as a decision threshold."

Another interesting recommendation, especially in light of Canadians' wariness of approvals done in secret was: "That the Canadian regulatory agencies seek ways to increase the public transparency of the scientific data and scientific rationales upon which their regulatory decisions are based."

In April 2004, Canada adopted a voluntary standard for labeling GM foods. But manufacturers do not have to label products with less than five per cent GM ingredients. No consumer or environmental group supports the voluntary labeling. In contrast, six of the G-8 countries already have mandatory labeling laws.

My colleague, Judy Wasylycia-Leis, has once again introduced a private member's bill calling for mandatory labeling. Bill C-317 will amend the *Food and Drugs Act* to provide that the Minister of Health is responsible for establishing that a food or one or more of its components are genetically modified.

Once this has been established, the minister is required to have the name of the food published in the *Canada Gazette*. The minister must also prepare a list of all such foods and have a copy sent at no cost to any person who requests it.

Any food and food products containing this GM food cannot then be sold in a package unless a label is affixed to the package containing the following notice: This product

or one or more of its components have been genetically modified.

In addition, any food and food products containing this GM food cannot be sold without a package unless a sign in the prescribed form is posted near the food containing the following notice: genetically modified.

When she introduced the bill, Ms. Wasylycia-Leis said, "Mr. Speaker, this bill flows from numerous attempts before me to introduce mandatory labeling legislation, vis-à-vis genetically modified foods, in the House. It also flows from the government's continued refusal to act on the express concerns of Canadians about the rapid entry of GM organisms into the marketplace.

"Our knowledge of the impacts of genetic modification is far from complete and mandatory labeling to identify and trace these items is the only way, at this time, we can know for certain that safety is verified."

Canadians do not want to wait to find out a food was not safe. We need to introduce mandatory labeling now so Canadians can chose which foods they want to consume.

And we need a full public debate on the science around GM foods and how best to ensure that any potential harms are identified before an organism is taken out of the laboratory and onto our farms or into our homes and bodies.

NDP MP Jean Crowder, who represents Nanaimo-Cowichan, B.C., is her party's industry critic.

The Hill Times

POLICY BRIEFING - LIFE SCIENCES

Canada still ranked 15th in knowledge-based productivity

'Other countries are making significant investments,' says rookie Industry Minister Emerson

Continued from Page 26

required to be labeled under existing Canadian regulations."

What are some new and exciting research and development projects going on in the life sciences industry?

"That's a difficult question because there are so many important projects going on in the over 1,000 life science companies across the country. From the health perspective, in drugs and other therapeutics along with medical devices, there is a lot of great R&D in the areas of cancer, Alzheimer's disease, Type 2 diabetes and heart disease, not to mention strong Canadian leadership in the area of vaccines.

"We've got medical devices companies with world-leading expertise in a number of areas, including medical imaging, radiation therapy, dental implants and *in vitro* diagnostics for diseases such as cancer, hepatitis, HIV and heart attacks. Outside of the health field, there are companies making a difference in bio-chemicals, bio-materials, and in the effort to introduce more sustainable energy products such as ethanol, bio-diesel and bio-oil."

What are some of the ethical dimensions of life sciences that you deal with as Canada's Industry Minister?

"As the Minister of Industry, I have an interest in seeing the growth of industries in Canada, and that this occurs in a responsible manner. In that regard, I am encouraged that there is an active dialogue in this country on many levels. For example, last year, the Canadian Biotechnology Advisory Committee published a report on the issue of privacy and genetic information. And, as part of our investment in Genome Canada, there is a dedicated research program on the ethical, environmental, economic, legal and social issues related to genomics. These and other efforts mean that as we move forward on bringing the health, environmental and economic benefits of life sciences to Canadians, we do so while being informed by this ethics dialogue."

Can you talk about some current opportunities for nanotechnology in Canada?

"Canada has recognized the importance of nanotechnology with the establishment, in partnership with the Government of Alberta, of the \$120-million National Research Council (NRC) nanotechnology institute in Edmonton, Alta. Through the Canada Foundation for Innovation and the NRC, an additional \$300-million has been invested in nanotechnology related projects. But I think the real opportunities for nanotechnology are through industry adoption of these technologies.

"Over 100 Canadian firms are engaged in nanotechnology R&D and manufacturing. One of the remarkable characteristics of life science industries is that they are leaders in the convergence of emerging technologies, particularly biotechnology, information and communications technologies, and nanotechnology. Within the health sector, nanotechnology is already being used to explore the development of new and innovative means for diagnostics and treatments."

How much is the federal government investing in revolutionary research in health, environment, biodiversity, genomics?

"The government is investing widely in revolutionary research. Perhaps the most obvious example has been in the field of genomics, where we have invested \$600-million in Genome Canada, \$15-million annually in federal lab genomics research, and are providing significant support through the granting councils.

"We have made investments in other critical life sciences research through the NRC institutes in the areas of biotechnology and nanotechnology, CFI and through the Networks of Centres of Excellence (NCE) in leading-edge research in genes, stem cells, genetic diseases, vaccines and photonics.

"From the environmental perspective, we can expect to see uptake in life sciences research in industrial sectors as part of recent budget commitments—\$1-billion to encourage emission reductions and \$200-million for a Sustainable Energy Science and Technology Strategy to develop and commercialize leading-edge environmental technologies."

Back on Sept. 18, 2003, Paul Martin said that Canada should develop a specific and "perhaps commercial expertise here in Canada, and create new technologies, new therapies, and new services that can be taken advantage of by developing countries" to help fight diseases. What's going on with that?

"Our challenge is to leverage the R&D being done in Canada to address developing country challenges and help improve health outcomes. The Canadian biotechnology sector, for example, can make important contributions.

"HIV diagnostic test kits produced by MedMira Inc. in Halifax, are being used in China's public health campaign. The University of Manitoba received nearly \$22-million from the Bill and Melinda Gates Foundation to expand its work on HIV and AIDS prevention in Kenya and India. International Bio Recovery Corporation in Vancouver is an environmental biotechnology company that is currently constructing a waste management processing plant in China.

"Looking to the future, as global markets develop, these projects could become the seeds of new trading partnerships. Life science industries could offer solutions to key development priorities such as food security, a cleaner environment and sustainable economic development.

"Canada is also well-placed to share its policy, scientific, and regulatory excellence with the world. For example, through funding provided by Genome Canada, Dr. Peter Singer of the University of Toronto, and partners have been exploring models for institutional collaboration as part of a 'genome diplomacy' approach that aims to position Canada as a leader in genomics research for international development. Another good example is the partnership between the Montreal-based pharmaceutical company Sanofi-Aventis and the CIHR, in which Canadian researchers will provide mentoring assistance to developing countries—an effort that has begun with a pilot project with South Asian researchers."

Where does Canada stand (what is its ranking) in the biopharmaceutical sector internationally? And where do you want to take it?

"Well, just in terms of biotechnology, Canada ranks in the top tier of countries for the number of products under development. However, only a handful of the Canadian companies developing these products are making significant revenues and have products in the market. I want to see more sustainable, globally competitive Canadian companies in the biopharmaceutical industry, and in other life science industries."

Do you think the government should be fostering R&D partnerships in Canada such as the pharmaceutical and biopharmaceutical industries?

"These partnerships already exist and

are growing among firms within the private sector. They are a critical part of the success of any biotech company in the health field, whether in Canada, the U.S., or internationally.

"Over a recent four-year period, there have been over \$1.4-billion in partnership investments made by multi-national pharmaceutical firms and other large firms with Canadian biopharmaceutical companies. The challenge for the private sector is to ensure that these alliances occur at the right time in a company's development or in the development of the company's products. In a way, you could say that government has already been fostering these partnerships through its strong support of publicly funded research, which has been a big asset to Canadian biopharmaceutical companies."

Some say from a health policy and a regulatory perspective, one way that Canada could become more attractive as a place for the multinational pharmaceutical companies to get involved with the biopharmaceutical industry, is enhanced intellectual property (IP) protection, or "patent term restoration." Do you agree?

"Canada meets its international obligations for intellectual property protection and I suspect that the interaction between these two industries will increase for a number of other important reasons. Certainly, a competitive environment will help attract investment but Canadian firms, first and foremost, will attract investment because they have leading-edge products under development, they have a strong business plan in place, and they are well situated in life science clusters in Canada.

"The goal for both industries is to develop globally competitive products. The government's goal is to ensure as much of that development as possible occurs in Canada. Of course, it's Canada's goal to ensure that we provide a balanced regulatory environment for our industries, one that simultaneously protects the interest of consumers and inventors."

Access to market is also key for Canada's affiliated companies to attract investments. What's your take on this?

"Access to market is a reality for all industries. And while you may be referring only to the Canadian market, and to issues regarding the regulation of health products at the federal and provincial levels, I'm thinking about the North American and global markets. In my view, life science industry investments in Canada, whether by domestic or foreign firms, should be constantly targeting those broader markets.

"The U.S. is currently the world's biggest market and it's right next door. If Canadian life science firms want to be successful, they have to target that market by taking out patents in the U.S., going through that country's regulatory approval process or possibly using U.S. distributors for Canadian-made products."

Canada is still 15th in its ranking in the knowledge-based productivity. What's gone wrong?

"I'm not sure if it's a matter of what has gone wrong or rather that other countries are also making significant investments. Let's look at some notable statistics related to Canada's performance.

"Canada has established the fastest rate of growth in the number of workers devoted to R&D, in external patent applications and in business R&D expenditures among G-7 countries. By 2006-07, annual federal support for research in the higher

education sector will be almost \$2-billion more than in 1997-98, representing a cumulative incremental investment of more than \$11-billion over that period. Canada now ranks among the world's top five nations, in terms of publicly performed research as a proportion of gross domestic product (GDP), according to the Organization for Economic Co-operation and Development. Canada's productivity growth has also improved, rising on average 1.7 per cent per year over the past eight years, compared with average growth of 1.1 per cent per year between 1980 and 1996. And, between 1997 and 2004, Canada ranked first in the G-7 in average real GDP per capita growth due to stronger employment and productivity growth."

The Millennium Ecosystem Assessment last month released a report that said the human race is exacting such a deadly toll on the global environment that we are endangering our own future well-being. As Canada's Industry Minister, what do you think of when you read a report like that? And is there anything you can do to help prevent that in some way?

"On matters of the environment, our government believes that the status quo is unsustainable, and that improvements must be made now or we risk more painful adjustments in the future. That's why we launched Project Green, a national project to create a healthier environment by engaging business, consumers, governments, and Canadians generally in making sound decisions to deliver environmental improvements. As a government, we're playing our part by offering incentives, initiatives and regulations that will accelerate this transformation.

"As Minister of Industry, my particular focus is on building and enhancing Canada's competitive position, and our environmental plan reflects this focus. It is comprehensive, fair and balanced, and treats Canada's economic future with the same respect as our environmental sustainability. As discussed earlier, biotechnology holds the promise of environmental benefits through cleaner processes and reduced reliance on carbon-based fuels and chemicals.

"We have set ambitious targets, and by marshalling the efforts of Canadians, we intend to meet them. The first instalment in Project Green demonstrates our commitment, and sets Canada on the right path to move forward."

What accomplishments are you proud of on this file?

"I am particularly proud of the amount of life sciences R&D going on in both the public and private sectors. I'm also pleased to see some life science companies getting to the market entry stage and demonstrating their global competitiveness. However, there are still far too few of these firms, and I want to see the picture change in a very substantial way over the next few years.

"On the government side, I'm pleased with recent efforts that have begun to address challenges at the early stages of development. But, again, more will need to be done to ensure life science firms are on the right commercialization track to becoming globally competitive.

"Finally, I'm particularly encouraged to see the increasing amount of engagement and partnership between stakeholders (government, industry and the research community) in the life sciences field. Strengthening and expanding these partnerships will be key to the future success of Canada's life science industries."

The Hill Times

POLICY BRIEFING - LIFE SCIENCES

A life sciences saga and Canada's vaccine story: Carty

The 21st century health challenges are global, complex problems and necessitate a new approach



By ARTHUR CARTY

On April 12, 2005, the world celebrated the 50th anniversary of the introduction of the Salk vaccine for polio, one of the true milestones in the history of medicine and public health. I had occasion to be invited to head a Canadian delegation to Lyon, France to help celebrate the 50th anniversary and to demonstrate Canada's excellence and talent in vaccine and immunization.

The story of the development by Jonas Salk of the Salk vaccine has been well-told. In the United States, there were 58,000 cases of polio in 1954, an epidemic which created polio hysteria and drove the massive and successful field trials of the Salk vaccine.

Back in Canada, the successful adoption of the Salk vaccine owes much to the Connaught Labs and scientific leadership and vision of Armand Frappier and that of the then federal minister of health, Paul Martin Sr., father of the current Prime Minister of Canada.

I had the privilege and honour of presenting the original correspondence between these two great Canadians to Prime Minister Martin in January of this year following a visit I made to the Institut Armand Frappier in Laval, Qué.

Today, l'Institut Armand Frappier is a thriving scientific and industrial hub in Canadian biosciences, housing some 300 researchers and sharing a research park with 70 companies.

Another significant component of Canada's scientific contributions to vaccine R&D was the development of the Meningococcal vaccine to treat meningitis. Meningitis has a 10 per cent fatality rate among infected Canadians and many of those who survive are faced with permanent brain damage and deafness. More tragic is the fact that two-thirds of the victims are children under the age of five.

Harold Jennings, a chemist at the National Research Council of Canada, used spectroscopic techniques to determine the structures of the polysaccharides found on the cell surface of the bacteria. This work was instrumental in the invention of the first generation group-C meningococcal polysaccharide vaccine.



Photograph by Jake Wright, The Hill Times

Message: PM Paul Martin, above, with reporters last week on the Hill. Canada is still ranked 15th in the world in knowledge-based productivity.

The CIHR is investing heavily in research and vaccine development for infectious diseases such as SARS, West Nile Virus and Influenza A and has recently announced a Clinical Research Initiative on vaccines. In addition the Canadian Network for Vaccines and Immunotherapeutics (CANVAC), one of 21 Networks of Centres of Excellence, is dedicated to the search for new vaccines to counter AIDS, cancer and hepatitis C. Another promising initiative, funded by CIHR, CANVAC and the U.S. NIH at the University of Nairobi, led by Dr. Frank Plummer of Health Canada and the University of Manitoba is examining the transition dynamics of HIV in Africa, routes of mother to child transmission and the underlying basis for natural immunity to HIV observed in small groups of highly-exposed sex workers.

The Vaccine and Infectious Disease Organization (VIDO) is yet another example of this world-class effort. VIDO, located at the University of Saskatchewan, is credited with five "world firsts" including the first genetically engineered animal vaccine. VIDO was also the first to demonstrate that DNA immunization could be effective in cattle. Lately it has been expanded by the addition of a \$62-million International Vaccine Centre for work on

emerging human and animal diseases.

Despite the remarkable scientific advances in medical science over the past five decades, the incidence and impact of aggressive viral and bacterial diseases is still growing in developing countries that have neither the economic nor scientific resources to address the problems.

Clearly many health issues in the developing world go well beyond scientific research. Sound education, economic development and government health policies and systems are of fundamental importance in this regard. As one example, Canadian efforts are being mobilized around health systems and research for Africa through the unique Global Health Research Initiative—a partnership involving CIDA, Health Canada, Canada's International Development Research Centre and CIHR.

The scientific and knowledge communities in the advanced economies, in partnership with countries in Africa, Asia and Latin America, can play a crucial role.

For example, it is now possible to develop a vaccine to wipe out the deadly group-A meningococcal meningitis, the most deadly of the serogroups, particularly in Africa, where it affects thousands of infants and kills hundreds of children each year.

The 21st century health challenges are

global, complex problems that will necessitate a new approach to scientific research. We need to bridge the boundaries between scientific fields, institutions and geographic location to effectively mobilize scarce resources and global expertise. A prime example of this form of collaboration is the International Consortium on Anti-Virals (ICAV) which has evolved from Canada's Protein Engineering Network of Centres of Excellence's (PENGE).

ICAV is a not for profit, large-scale international consortium established to discover and develop new therapeutics that target host functions crucial to the infectivity of many viruses. By linking scientists and practitioners from universities, institutes, hospitals and industry from around the world, ICAV will facilitate knowledge transfer and accelerate the development and delivery of drugs that target viral diseases worldwide.

The message in all of this is that Canada has a strong role and well-earned reputation in the application of the life sciences for Canadians and their well-being as well as supporting the global efforts in this area.

Arthur Carty is Canada's National Science Adviser.

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POLICY BRIEFING - LIFE SCIENCES

Putting life sciences to work for the health of Canadians

Canadian inventions are often exploited elsewhere, need national strategy on commercialization

By ARNOLD NAIMARK

Rarely a week goes by without news of yet another remarkable advance in biotechnology (defined as technical knowledge about living things). Spurred by revolutionary discoveries in the life sciences, applied biotechnology has become one of the fastest growing sectors of the knowledge economy. Biotechnology is pervasive, touching many more aspects of society than most Canadians realize—food and nutrition, health, the environment, industrial development, the economy and international trade. Maintaining a strategic focus on biotechnology is essential because the vast majority of the economic, social, ethical and legal issues of concern to the public and to legislators, related to the life sciences, involve applications of biotechnology. This is abundantly illustrated by the role of biotechnology in the health sector.

Biotechnological advances have produced powerful new tools to promote health and to aid in the prevention, diagnosis and treatment of disease and disability. Knowing the genetic make-up of plants, animals and microbes helps us to create new vaccines, to identify disease susceptibility of individuals and populations, to tailor the development and use of therapeutic drugs to the specific characteristics of individuals; and to use advanced methods of gene transfer and stem cell transplantation to restore normal structure and function to diseased or malfunctioning organs and tissues. Add to these developments the convergence of biotech-

nology and nanotechnology to produce microscopic diagnostic probes or precisely targeted molecular delivery systems and it is easy to understand why many believe that bio-based health innovation (BHI) will have profound effects on the practice of medicine and on healthcare systems generally.

The promise of BHI does not come without significant challenges for policy makers and legislators as they seek to promote innovation and exercise responsible stewardship of the nation's human and material resources. The intensity of the challenge is magnified by both the pace of change and by the social and ethical issues associated with life-altering technologies. The opportunities and challenges of BHI, and policy initiatives for dealing with both, are analyzed and discussed in *Biotechnology and the Health of Canadians*, a report by the Canadian Biotechnology Advisory Committee (CBAC) (<http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00488e.html>). In the report, we call for action across a broad front involving four major overlapping sectors of activity: research and development; regulation and commercialization; technology assessment; and health system uptake and diffusion of BHIs.

For example, in research and development we identify the need for continuing enhancement of Canada's investment in the life sciences as the well-spring of future practical innovations and for strategies to encourage collaboration among biologists, social scientists and humanists in exploring the interaction of the scientific and social dimensions of BHI. Concerns about the stor-

age and use of genetic information derived from research, and the special implications of genetic research for the human subjects involved in it, led us to recommend the creation of a national body to set standards and to accredit organizations with responsibilities for research ethics boards and the use of repositories of data or biological specimens for research purposes.

Canada is an active player in industrial biotechnology with a relatively large number of firms; but many of them are small and, given the expense and time required to bring products to market in a highly-regulated environment, require readier access to capital and a hospitable environment to remain viable and to grow. Too often, Canadian inventions are exploited elsewhere and thus we urge the development of a comprehensive national strategy to promote commercialization here in Canada—a strategy that involves enhancing links among researchers, developers and users, increases the options for financing industrial research and development, and streamlines regulatory processes to make them timely, efficient, cost-effective and forward looking.

Beyond federal regulation to ensure product safety, technological innovations need to be assessed to ensure that they are appropriate for adoption by the health system. Optimum health technology assessment (HTA) requires intensified collaboration among the federal, provincial and territorial governments aimed at broadening the range of products being assessed, extending the reach of HTA to include social, ethical, economic and organizational impacts of BHI

on the health system, and enhanced integration across jurisdictions and regions.

Healthcare providers face a daunting task in introducing new technology into an already heavily-burdened system. Linking an enhanced system of HTA effectively into the decision-making process about the adoption of biotechnological innovations can help, but there is also a need for much more research on the management of technological change in the health system (perhaps by a body such as the newly-formed Health Council of Canada) to identify barriers to adoption of beneficial innovations and best practices to remove or reduce them.

Realizing the opportunities and managing the challenges associated with biotechnological innovations clearly require concerted action. Ignoring the pressures for change will not make the complexities involved disappear—more likely it will simply compound the costs of dealing with them later. With careful planning we can build on investments already made, expand on initiatives already taken and move in new directions that will make biotechnology work for all Canadians, now and in the future.

Arnold Naimark is chairman of Canadian Biotechnology Advisory Committee. The CBAC is a body of experts, external to government, which provides advice to the Government of Canada on current policy issues associated with the ethical, social, health, regulatory, scientific, environmental and economic aspects of biotechnology.

The Hill Times



HARNESSING THE BENEFITS OF HEALTH RESEARCH AND INNOVATION

Association of Canadian Academic Healthcare Organizations (ACAHO) is the national voice of teaching hospitals and regional health authorities responsible for the academic mission - service provision, the education & training of the next generation of Canada's health professionals, and supporting and conducting research & innovation.

Health research and innovation - the oxygen of an evidence-based health system, benefits Canadians in at least three substantial ways:

- Improves our individual and collective health status
- Introduces more cost-effective ways of delivering quality health services on a timely basis, and,
- Contributes to our collective ability to prosper on a sustained economic basis

To ensure this, the federal government must:

- Create a multi-year fiscal framework that supports all components of the health research and innovation value chain
- Continue to increase funding for the Canadian Institutes of Health Research (CIHR) to a minimum of \$1.0 billion by 07/08
- Increase base funding for the indirect costs associated with research, and,
- Continue to support initiatives that accelerate the commercialization of health research.

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Sciences, engineering research a major player in life sciences

By TOM BRZUSTOWSKI

Natural Sciences and Engineering Research Council of Canada (NSERC) supports university research in many areas of the life sciences. Discovery grants support basic research in animal biology and physiology, psychology, cell biology, molecular and developmental genetics, plant biology, and evolution and ecology. Many results of this work find application in agriculture and primary food production, biotechnology, and the environment. In 2004-05, NSERC will have spent \$68 million on the direct costs of basic university research in these areas.

This activity is authorized by NSERC's founding legislation, which calls on it to "...promote and assist research in the natural sciences and engineering, other than the health sciences..." That last distinction was easier to make in 1977 than it is to apply today, when advances in many aspects of health care are made possible by advances in basic life sciences and the other natural sciences.

Consequently, applicants for research support in the areas of the life sciences that are close to human health are faced with the challenge of determining whether NSERC or the CIHR is the more appropriate agency to fund their research. Obviously, all involved believe that any excellent proposal for such research should be eligible for funding by one or the other of these federal granting agencies.

In addition to basic research, NSERC also supports project research in partnership with industry. This is university research done in areas where industry has found problems that can't be solved with existing knowledge. University-industry research helps solve such problems, and the results often lead to innovations—new or improved products, processes or practices

implemented by the industrial partner. University-industry research has the added benefit that it also provides advanced training for people who become highly qualified in the technology issues of the industry and ready to function as employees.

In 2004-05, NSERC will have spent about \$13-million on university-industry research in the life sciences, most of that in biotechnology. This was combined with another \$23-million of contributions from industry, to provide a total of \$36-million to support project research in the universities in those areas of the life sciences that are of direct interest to industry. Beyond the research in life sciences described above, NSERC supports work in other disciplines that may be proven to support developments in the life sciences and their applications.

Life science research supported by NSERC has obviously been of great interest to Parliamentarians. The monthly "Bacon and Eggheads" breakfast, which NSERC sponsors with The Partnership Group for Science and Engineering (PAGSE) and the Speakers of the House and Senate, is always well attended. The most recent life-science topic, "The Bar-code of Life," by Paul Hebert of the University of Guelph, promoted a particularly lively period of questions.

Other recent topics show the broad range of Canadian research in the life sciences. They included "Invasive species: coming soon to lake near you," by Hugh MacIsaac, Great Lakes Institute, University of Windsor, "Fighting climate change with biology," by David Layzell of Queen's University, "Pollinators in a Genetically Modified World," by Mark Winston of Simon Fraser University, and "The Human Genome Project, Heading for payoff..." by Tom Hudson of the Montreal Genome Centre. And there's much more to come.

Tom Brzustowski is president of NSERC.
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