

Report of the Deputy Minister, Health Canada to the Science Advisory Board

January 5, 2001

It has now been three years since the inception of the Science Advisory Board and within that period, much has been accomplished upon the advice of the Board, to improve the quality of science within the Department. The Science Advisory Board has striven to promote the integrity, quality, comprehensiveness and leadership of science in Health Canada. This report affords me the opportunity to demonstrate and report back to you, as members of the Board, on how Health Canada has heard your advice and used it to advance our work and reputation in the field of science, nationally and internationally.

Health Canada's Realignment

On April 17th, I announced the Realignment of Health Canada. The work since this time has been exciting, challenging and extremely energizing for the entire department. I want to reiterate my on-going commitment and that of my senior managers to proceed with what we began in a manner that is good for the organization as a whole, good for individual employees and, most of all, good for Canadians. This Department has a workforce that is dedicated to their work and who know that what they do each day is important for the health of Canadians.

Transformation

The Department is now continuing with a 'Transformation Phase' during which discussions will continue and issues and concerns around the detailed structure and operations of the organization will be addressed. At the Branch and Directorate level, newly-appointed management teams are working with employees and external stakeholders to determine how best to achieve common goals. I have also invited Health Canada staff from across Canada to participate in an employee advisory council named the Health Canada Transformation Forum which will advise me and the Departmental Executive Committee on sustaining the change.

As well, work will begin on the longer-term approach to change the way we work with each other and with our external partners. I realize that changes to the fundamental "culture" of our organization cannot happen overnight; it will require effort on the part of all to strengthen and enhance this organization's openness, trust, collegiality, flexibility and focus on results so that the Department is in a better position to deliver fully on its mandate and responsibilities to the health of Canadians.

Strengthened Risk Management in Health Canada

The protection of the health of Canadians is a core responsibility of Health Canada. In fulfilling this responsibility, management of risks to health is

fundamental. With Realignment, risk management expertise is now shared throughout the entire Department. This has afforded opportunities to strengthen the Department's risk management capacity:

- by enhancing greater integration and synergy between protection and promotion approaches within the Department
- by bringing together all of the evidence available to the Department across the full range of life sciences
- by providing a wide-ranging and adaptable internal capacity to identify and assess health issues in a timely manner
- by broadening perspectives and inputs to serve as a challenge function
- by discharging a reasonable and appropriate standard of care, including rigorous internal review and assessment of analyses, findings and recommendations
- by strengthening the Department's ability to identify and assess risks and make better risk management decisions by reducing "blind spots" which include not just unknowns, but "unknown unknowns"
- by seeking the advice of our key stakeholders across the Department
- by providing information to Canadians in a clear, coherent and timely fashion

To further strengthen the Department's capacity and increase high-level engagement with quality decision-making related to risk, I created a Departmental Executive Committee on Risk Management. This Committee is comprised of Assistant Deputy Ministers from each Branch, a Regional Director General representative, the Chief Executive Officer of the Pest Management Regulatory Agency, the Senior General Counsel, the Director General of Communications and the Chief Scientist. The Committee:

- provides expert leadership, horizontal co-ordination and strategic risk management discussion and advice at the senior management level
- brings clarity, focus, context and challenge to risk management and risk communications in Health Canada
- discusses options for optimal or most appropriate risk management action based on the best information available
- enhances risk management decisions with a common purpose and shared approach, ensuring that the co-ordination of issues is defined and verified
- identifies appropriate risk communications options and approaches based on risk management considerations

Strengthened Scientific Excellence in Health Canada

The last half of the twentieth century witnessed unprecedented advances in scientific knowledge and technology. We can expect even more spectacular advances in the twenty-first century. Scientific developments will vastly increase our knowledge about risks to health. Innovative health intervention approaches, analytical methods and medical technologies will provide numerous new ways to address those risks.

These and similar changes will require the Department to develop a greater capacity to respond rapidly to the increasing number, scope and complexity of evolving health issues. The Department will need to increase the size and diversity of scientific and other disciplines. They will be needed to properly understand, assess, select, integrate and apply available tools and evidence in the extremely complex environment of contemporary and future health needs. We will also require access to leading-edge research and knowledge in support of our health surveillance and health promotion and protection roles. We will have to rely not only on our own internal capabilities, but also on our participation in national, regional and local networks, and their international equivalents.

We have already made some progress in responding to the challenges in our environment. For example:

- we have internally reallocated resources to strengthen our surveillance, monitoring and disease prevention and control capacity to address public health blind spots;
- in health promotion, we adopted an approach that focuses on populations (as opposed to individuals), shared responsibility for health and the root causes of health;
- we have made important headway in harnessing the power of information technology to: facilitate the collection of comparable and compatible data across Canada, so that governments and health care providers can share best practices and assess the effectiveness of different approaches;
- the role of the Chief Scientist, peer review and the Science Advisory Board are key to ensuring the highest possible standard for the science conducted within the Department, by providing strong and credible internal scientific leadership that will articulate and promote the science vision of the Department, by ensuring systematic review of the science itself, and by providing independent external advice on the science programs and procedures.

In addition, we have taken a number of steps to improve the way scientific view points are expressed and debated. Science is changing rapidly and we need to have mechanisms to resolve differences. A recent Federal Court of Canada decision relates to this whole issue of freedom of expression and the need for an impartial and effective Public Service. The court confirmed the duty of loyalty owed by public servants and the restrictions that this may place on the making of public statement. But it also indicated that where public servants had tried to have their concerns

addressed internally, public criticism (for example, dealing with policies that jeopardize life, health or safety) will be justified if reasonable attempts to resolve the matter internally have not been successful.

There are a number of formal mechanisms which are already in place - or in development - for hearing and debating scientific and regulatory matters. For example:

- There are procedures in place for reviews of submissions from companies seeking approvals for drugs or food additives.
- Risk management reviews at the directorate and branch levels ensure the Department's Risk Management Decision-Making Framework is being applied.

The Department must continue to work together to ensure that differing viewpoints are aired and fully considered.

Science Capacity

Science Capacity is about building and improving the ability to conduct science that is relevant to the proper functioning of a given institution.

An institution's ability to undertake a particular task will depend on whether it has the right people with the right skills, education and training, and whether those people have the right facilities and equipment for undertaking that task.

In the case of science, these requirements translate into Health Canada having the right people to undertake its mandate e.g. disease surveillance, addiction prevention, community health service delivery, monitoring of the environment, risk assessment and management, regulation of food and therapeutic products etc. Science Capacity is about building and improving the *ability* to conduct science that is *relevant* to the proper functioning of the Department.

As the Board has pointed out on numerous occasions, having an excellent departmental science capacity to best serve the needs of Canadians is essential. Building such a capacity requires an examination of the relationship between science and policy, the direction and relevance of departmental science, and the ways in which branches of the department function both individually and in unison. I have taken the Board's advice to heart and, as you are aware, have initiated discussions with scientific staff across the Department, in the National Capital Region and in the Regions, on how best this can be achieved. My main objective is to develop an integrated departmental science capacity that would ensure the achievement of excellence across the Department. The purpose of these consultations was to identify and to recommend practical strategies for addressing the key challenges related to science in the Department:

- priority-setting and resource allocation and continuity of funding
- building and improving the ability to conduct science
- interaction with other capacities

- roles and accountabilities

Discussions were very productive and a wide range of useful ideas were brought forward to the plenary sessions. Over the next few months the Department will be attempting to transform some of these ideas from concept to reality. The enormously challenging task of synthesizing all the ideas received and developing implementation plans for a renewed and transformed science capacity for the Department is now under way.

Chief Scientist

With the recent announcement of the appointment of Dr. Kevin Keough, an internationally renowned biochemist, as the first Chief Scientist for Health Canada, we have someone to champion science within the Department, by exercising leadership to ensure its high quality, relevance to the mission of the Department and its integrity. The responsibilities of the Chief Scientist include:

- oversight of collaborative arrangements with external science organizations
- advice on and facilitation of external scientific relationships and collaborations
- professional leadership of departmental procedures for priority setting and resource allocation with respect to the Department's scientific responsibilities, including any foresight procedures to ensure horizontal linkages
- maintenance of systematic independent peer review
- coordination of science human resource planning
- advice on the optimal utilization of facilities, including regional labs

Peer Review

Peer review is one generally accepted mechanism to address the quality of scientific work. Recognizing the importance of peer review and on the advice of the Science Advisory Board, the Health Protection Branch entered into a partnership with the Canadian Institutes for Health Research (CIHR) to conduct peer reviews on Endocrine Disruptors Substances Working Group and Nutrition.

In April, 2000 the Board was briefed on the peer review of the Endocrine Disruptor Substances Working Group (EDSWG). A report on the response to the recommendations of the Peer Review Team was provided to the Board at the September meeting.

Peer review has been accepted as a valuable and important part of our departmental scientific processes. We will continue to work with the CIHR to find mechanisms by which the Department can draw on their established peer review processes.

Scientific Recognition in Canada and Abroad

Health Canada scientists have received numerous awards, internationally, nationally and within the Department, recognizing their excellence in science.

Recently, Dr. Chao-Mei Yu, of the Therapeutic Products Programme, has been conferred a title of Chinese National Expert from the Chinese government, which is China's most prestigious award for outstanding scientific achievements.

Excellence in Science awards from the former Health Protection Branch have recently been given to internationally-recognized scientists

- Dr. Hari Mohan Vijay, for dedication to the science of mould spore allergenicity and human health;
- Dr. Tine Kuiper-Goodman, for outstanding contribution to the risk assessment of mycotoxins and other toxicants, notably microcystins; and
- Dr. Peter M. Scott, for outstanding contribution to the field of mycotoxins, specializing in the development of methods of extraction and detection of mycotoxins in various food commodities and food products.

Over the past few years, Health Canada employees have been recognized for their achievements through formal awards, such as the Deputy Minister's Award for Team Excellence, the Deputy Minister's Award for Excellence in Diversity Management and in 1999 a new award was launched entitled, the National Mentoring Award. Health Canada employees have also been recognized with corporate awards, such as the Public Service Award of Excellence and most recently with the Head of the Public Service Awards.

Recently we were advised that the former Health Protection Branch will be sharing Vice President Al Gore's Hammer Award with the US FDA and other agencies from the UK, Germany, Australia, and the Netherlands. The Hammer Award is the Vice President's special recognition to teams who have made significant contributions in support of the National Performance Review principles of putting customers first, cutting red tape, empowering employees and getting back to basics. By collaborating and sharing resources, technology, and information, a team of 15 scientists has eliminated costly duplicative efforts involving worldwide sample collections, development of methodologies, and intelligence gathering to prevent the manufacture and sale of unsafe drugs and herbal products. Thanks to the team, patients in all countries are better protected against health fraud and hazardous medications.

Senior Management Appointments within Health Canada

In order to further strengthen the science capacity within the Department, I have made several recent appointments of science professionals to senior management positions:

- Dr. Robert McMurtry, the G.D.W. Cameron Visiting Fellow to the Department has now been appointed as Visiting Assistant Deputy Minister of the newly created Population and Public Health Branch. Dr. McMurtry was formerly the Dean of Medicine and Dentistry at the University of Western Ontario.
- Dr. Mohammed Karmali has assumed the responsibilities for the Laboratory for Food Borne Zoonoses located in Guelph. Dr. Karmali was formerly a Professor in the Department of Pathology and Molecular Medicine at McMaster University and a former member of the Science Advisory Board.
- I have also appointed Dr. Frank Plummer to the position of Scientific Director for the National Microbiology Laboratory in Winnipeg. Dr. Plummer was formerly a Professor at the Departments of Medicine, Medical Microbiology and Community Health Sciences at the University of Manitoba and a visiting Professor, Department of Microbiology, University of Nairobi.
- Another recent appointment was Dr. Judith Shamian as Executive Director of Nursing Policy. Dr. Shamian is an internationally respected health care and nursing leader who brings 20 years of experience to the position, which is intended to strengthen the focus on nursing policy issues within Health Canada. Dr. Shamian was the Vice-President, Nursing at Mount Sinai Hospital in Toronto and Associate Professor at the Faculty of Nursing, University of Toronto. She has served on the boards and committees of numerous professional nursing and health care organizations, and is immediate Past President of the Registered Nurses' Association of Ontario.
- The appointment of Dr. Robert Peterson as Director General of the Therapeutics Products Directorate is a further demonstration of the strengthened science capacity within the Department. Dr. Peterson comes to us from the Children's Hospital for Eastern Ontario where he most recently held the position of Chairman of the Department of Pediatrics and Pediatrician-in-Chief. He has authored numerous papers/chapters in pediatrics clinical pharmacology/toxicology and is qualified in hyperbaric medicine. He also completed a Master's of Public Health in the Department of Health Policy and Health Care Management at Harvard University.

The departure of Dr. Joe Losos as Assistant Deputy Minister of the Health Protection Branch was a loss to the Department. However, he has taken a position with the University of Ottawa as Director of the new Institute for Population Health. Our loss has turned into our gain. Exchanges of expertise between the Department and universities are very important mechanisms for building a strong and dynamic capacity for partnerships.

Partnerships and Collaborative Work

Health is a shared responsibility. No single

organization can hope to possess all the requisite capacity or knowledge to address health issues. Improved health outcomes requires collaboration, horizontal linkages and collective results. The pace of scientific progress and the public policy issues that are already on our radar screens require that we use our individual and collective strengths and networks to the fullest extent. Consequently, partnership and collaboration between Health Canada and other federal departments, other levels of government, academia, non-government organizations and other sectors and disciplines nationally and internationally are essential. I see it as breaking down artificial barriers in scientific activities so that we bring the most appropriate expertise to bear on any given issue.

The following are just a few examples of the collaborative work in which Health Canada is engaged.

The Canadian Institutes of Health Research, first announced in the 1999 federal budget, replaces the Medical Research Council of Canada. Along with a doubling of the research budget over three years, CIHR will create a series of virtual institutes linking investigators from all four areas of health research - biomedical research, clinical research, health systems and services research, and population health research - to better address the health needs and priorities of Canadians.

As they develop, CIHR Institutes will become a source of scientific leadership within their particular area of focus and establish priorities that will facilitate research efforts in this area. Led by Scientific Directors and guided by Institute Advisory Boards composed of various health stakeholders the Institutes will encourage researchers, voluntary health organizations, government and other partners to work together to shape the Canadian research agenda and translate research findings into practice within Canada's health system. Health Canada will be playing a strong role of the Advisory Boards on these Institutes. My goal is to have members of my Senior Management Team sit on the Institute Advisory Boards which are relevant to Health Canada's mandate.

As you are no doubt aware, the CIHR has already taken steps to broaden its eligibility criteria to include government scientists and scholars as eligible recipients of CIHR funding. This will help the Department better connect to academic health research communities in harnessing the national research capacities required to address complex health issues.

Another example of collaboration are the efforts of the Canadian governments and food industry to work together to maintain a safe food supply. To provide the public with information on the safe handling of food, consumer organizations, industry associations, and municipal, provincial, territorial and federal governments, through the Canadian Partnership for Consumer Food Safety Education, have produced an awareness campaign called Fight BAC!TM Incidentally, the FightBac!TM Food Safety Team at Health Canada were the recipients of one of the highest honours accorded to the members of Canada's professional Public Service, the Award of Excellence.

The Toxic Substances Research Initiative (TSRI) is a program managed by Health Canada and Environment Canada was launched in 1998. The TSRI reinforces the federal government's commitment to enhance the health and environment of Canadians through funding a variety of collaborative research projects on toxic substances.

An announcement of \$13.5 million towards 97 TSRI projects was made recently. These projects included several from Health Canada scientists:

- Developmental Neurotoxicity of Environmentally-Relevant Mixtures of Persistent Organic Pollutants
- Inhalation Toxicology of Air Pollutants: Pulmonary and Cardiovascular
- Minisatellite Mutations as Biomarkers of Environmentally-Induced Heritable Genetic Defects

Health Canada is working to maximize opportunities for collaboration internally and externally and in doing so, has placed great emphasis on networks, including the Canadian Institute of Health Information, the Canadian Health Network and the health surveillance networks, both nationally and internationally.

Human Resource Initiatives

At the June meeting of the Science Advisory Board, Members were briefed on issues and challenges facing this Department given the rapidly changing and increasingly complex environment. The scientific community within Health Canada is faced with significant challenges: it must give priority to dealing with future demographic changes which could weaken or compromise the department's science capacity; it must tackle the dual challenges of attracting and recruiting new scientists and other experts while retaining high-calibre employees to mentor and develop new recruits. New tools and measures are being developed and implemented to address these changes. Background material provided to Members contained a compendium of information on departmental human resource issues, initiatives and plans. It included a look at the current and anticipated future science demographics of Health Canada (i.e. rates of retirement, breakdown of scientific groups, etc.); reports and recommendations made by the Auditor General on science capacity; other reports on Visible Minorities, Science and Technology Management Development, Women in Science and Technology, and the Canadian Human Rights Tribunal Order; recruitment tools; student programs; and awards and recognition programs.

Also included was a proposal for a Scientific Emeritus Program for Health Canada. The program's intent is to provide an opportunity for former employees to continue to pursue their work in a non-employment capacity within a specific Health Canada science program, and also to allow the Department to recognize former employees for their significant contribution to the legacy of research knowledge. I thank the members of the Board for providing their insight and advice on this proposal.

In addition, the Department has sponsored a postgraduate fellowship program in partnership with the CIHR and Canada's Research-Based Pharmaceutical Companies. This fellowship is intended to provide recent health sciences postgraduates of Canadian universities with either a Ph.D., an M.D. degree or a relevant professional degree in health/medical sciences (e.g., Pharm. D., DVM) with the opportunity to acquire specialized research skills and experience in drug evaluation and monitoring within a unique regulatory environment.

A second postgraduate fellowship program is sponsored by the Drug Information Association (DIA), in association with the Therapeutic Products Programme. These fellowships are intended to provide an opportunity to acquire specialized skills and experience in drug evaluation and monitoring of marketed drugs, with focus on post approval surveillance. The Fellowship Program is intended for recent graduates who have successfully completed a Masters or Doctoral Degree program from universities of the Americas (except Canada, United States and Mexico) with a postgraduate degree in the health sciences (medicine, pharmacy, public health or a science applicable to drug development) or an MD degree from an accredited institution.

Health Canada has established a variety of partnerships with academia and industry to foster advanced learning in a scientific environment. The fundamental principle of these partnerships is that they must provide Health Canada staff the opportunity to participate in educational programs by world experts in order to maintain and enhance the program-specific knowledge required in our global regulatory environment. The following are examples for such partnerships:

- DESS Graduate Program in Drug Development with the University of Montreal, Faculty of Pharmacy
- Continuing Education Program with the Canadian Association of Pharmaceutical Regulatory Affairs (CAPRA)
- Ongoing exchange of information with the American Food and Drugs Administration

Public Consultation and Communications

One of the most pervasive messages that you have put forth, as a Board, throughout your tenure is the need to demonstrate clearly and consistently the Department's commitment to the health protection of Canadians, through communications, integrity and transparency. In response to this and other messages we have received through public consultations, the Department has established the Office of Consumer and Public Involvement (OCAPI).

OCAPI has been created to help the Department in general and more specifically, the Health Products and Food Branch (HPFB), develop a closer working relationship with the people it serves. At the same time, OCAPI will assist HPFB to better involve Canadians in Branch activities. The goal is to increase awareness and understanding of the public's views, attitudes and concerns so that these can be better reflected in the work of the Branch. OCAPI is also

engaged in the promotion of direct and meaningful public input into the development of a number of health protection policies and programs. As well, it serves to provide consumers with helpful information about our processes, decisions and activities.

In addition, OCAPI has been involved in assisting a number of Health Canada program areas in setting up public and stakeholder consultations. For example, OCAPI is helping the Natural Health Products Directorate with consultations on natural health products currently underway across the country; OCAPI is also assisting the Therapeutic Products Directorate with the design and launch of their planned national consultations on Xenotransplantation.

But involving the public is not a panacea for the ills of the Canadian health care system. We need to have a clear purpose and objective and then need to understand when, where and how to best use citizen involvement.

Conclusion

Since the Board was first appointed by the Minister of Health in 1997 to advise him on how best to position the scientific, technical, policy aspects and future directions of Health Canada's Health Protection Program, the Department has benefited from the knowledge and expertise provided by the Board. Now with a realigned Health Canada, the scope of the Board's mandate has been broadened to encompass all of Health Canada's programs and activities. This will present interesting challenges and opportunities for the Science Advisory Board in its future work.

On behalf of all scientific staff of the Department, I want to thank the Board for its many efforts to enhance science at Health Canada. Your advice is much appreciated and the Department looks forward to working with you in the future as we strive, through science, to maintain and improve the health of Canadians.