Summary of Discussion
Science Advisory Board Meeting

February 17 - 18, 2004

Boardroom 0115C Brooke Claxton Building
Tunney's Pasture Ottawa

Attendance

Members	**Ex Officio Members**
Judith Hall Lorne Babiuk Keith Bailey Robert Brunham Patricia Clements Mark Goldberg Karen Grant Chris Loomis Linda Lusby Kathryn O'Hara (February 18) Paul Paquin (February 17) Janet Rossant (February 18) Stanley Vollant Ardene Robinson Vollman	Ian Green (February 17) Janice Charette (February 17) Alan Bernstein (February 17) Patrick Borbey Scott Broughton Susan Fletcher Diane Gorman Kevin Keough Charles Mallory for Marcel Nouvet Wendy Sexsmith (February 17)
Secretariat	**Regrets**
Tammy Davies Meggan Davis André La Prairie Karoline Millson	John Kelton David Roy Dixie Snider Pierre-Gerlier Forest Ian Potter Ian Shugart

FEBRUARY 17, 2004

Opening Remarks
Dr. Judith Hall, Chair

Dr. Hall introduced new members Dr. Lorne Babiuk, Dr. Robert Brunham, Dr. Janet Rossant, and Dr. Stanley Vollant to the Board. She also announced the appointment of Dr. Linda Lusby as the Vice-Chair. In the coming year, the appointments of several members and the Chair will expire. She urged members to submit the names of possible candidates to the Secretariat.

Opening Remarks
Mr. Ian Green, Deputy Minister and Ms. Janice Charette, Associate Deputy Minister

Following up on their remarks at the November 2003 Board meeting, the Deputy Minister and Associate Deputy Minister spoke about the transition to a new Minister of Health, the possible changes to machinery and priorities, and the implications for science at Health Canada and the Science Advisory Board.

The Deputy Minister and Associate Deputy Minister shared their views on the creation of a Canadian Public Health Agency (CPHA), a Chief Public Health Officer, the range of options for the scope of their mandates, machinery, reporting relationships, and the possible implications for the structure of the Health portfolio and the broader public health network.

The creation of a CPHA and a Chief Public Health Officer reflect the views of many experts, including those expressed by Dr. David Naylor and Senator Kirby, as well as past recommendations by this Board. The Deputy Minister and Associate Deputy Minister believe that the CPHA should be based on a solid foundation of sound science. They committed to come to the Board with the plans for a CPHA as they are further defined, and would appreciate the Board's feedback on the Agency's scientific activities.

The Deputy Minister and the Associate Deputy Minister stressed a continued role for a Chief Scientist, the Office of the Chief Scientist, and the Science Advisory Board at Health Canada. The Deputy Minister also thanked Dr. Keough for his contribution to the Department and asked Board members to suggest individuals to replace Dr. Keough following his departure in July 2004. As a key advisor to the Deputy Minister, the Chief Scientist helps the Deputy manage the Department's science activities. Consideration is currently being given to how the Chief Scientist and OCS will provide science advice and support through activities such as peer review and the Research Ethics Board across the portfolio, including the CPHA and the Chief Public Health Officer.

Another important government and departmental priority is to improve Canadians' access to safe and effective therapeutics. Through the Therapeutic Access Strategy, Health Canada has an opportunity to build on a 'Canadian advantage' - a faster, more effective regulatory system, with decisions based on the best scientific data, provided to us in the most efficient manner.

One of the questions Health Canada must address is how to validate the quality of the data from pharmaceutical companies, or in the context of international harmonization, from foreign review agencies (e.g. the United States Food and Drug Administration). The Associate Deputy Minister invited the Board to advise on how Health Canada can ensure that judgements made elsewhere are consistent with those the Department would make.

The Associate Deputy Minister also invited the SAB's advice with regard to how Health Canada evaluates pharmaceutical research findings and ensuring the Department consistently uses the best available science.

The Deputy Minister informed the Board that they will continue to be called upon to provide timely and strategic advice on departmental and portfolio-related scientific activities. He also informed them that a strong science base will continue to be necessary to support decision-making.

Discussion Summary:

- The Board was interested to understand the specific role of the federal government in public health and how the new Agency would work with and support the broader public health network, including the provinces, territories, municipalities, and internationally to improve coordination, build national capacity, and improve information systems. There were also questions about how a new Agency would focus federal efforts in the public health domain and the possible advantage it offers over the existing system and structures.

- The Board supports an inclusive definition of public health and urges the Department to ensure that chronic diseases are reflected and included in the new Agency.

- Given the number of factors that affect consumers' access to drugs (e.g., provincial drug plans), it is important to define what "access" means

Natural Health Products Research Program
Philip Waddington, Director General, Natural Health Products Directorate, Health Products and Food Branch (HPFB) and
Michael Smith, Senior Advisor, Natural Health Products Directorate, HPFB

Dr. Waddington and Mr. Smith shared some of the challenges in developing a research program to support the new Natural Health Products Regulatory Framework. They outlined the operations, partnerships and research supported by the Natural Health Products Research Program, as well as efforts to establish research priorities through consultations with stakeholders, and ensure that Health Canada has the scientific capacity required to implement the new regulations.

Discussion summary:

- Post-market surveillance and information networks are essential to ensure that side effects, interactions with medications and foods (e.g. grapefruit), and long-term effects are reported and monitored.

- Given the high usage of natural health products in Aboriginal communities, and the potential for drug interactions with other medications, this issue should be studied further.

- Guidelines for physicians would be a useful tool for them to assist their patients in making informed choices about using natural health products.

- Particular attention should be paid to how certain segments of Canadian society, such as women, children at various ages, or ethnic groups use and metabolize natural health products. Gender and age-based analysis is required in accordance with departmental policy.

- The definitions of functional foods and nutriceuticals need to be clarified.

- Partnerships should be fostered with departments such as Agriculture and Agri-Food Canada, associations, and with universities where there is a cluster of expertise such as Laval University, the University of Guelph or the University of Manitoba.

- The Board expressed concern about the lack of common standards in the licensing or regulation of complementary health practitioners and their associations.

- The Board applauds the level of international collaboration and use of best practices to further the Natural Health Products Research Program.

First Nations and Inuit Health Research Agenda
Katherine Stewart, Director General, Strategic Policy, Planning and Analysis, First Nations and Inuit Health Branch (FNIHB)

Ms. Stewart presented the draft of the First Nations and Inuit Health Research Agenda. The

Research Agenda is intended to provide a guide to the work of the First Nations and Inuit Health Branch (FNIHB) on issues relating to science and research.

The Agenda details the current research capacity within FNIHB, the Department and external partners; identifies research priorities; highlights potential areas for collaboration; and suggests opportunities for the Branch to pursue international linkages and partnerships on issues relating to indigenous health research.

Discussion Summary:

- Research agenda should focus on four main priorities: surveillance/monitoring, public health issues, health service delivery, and knowledge translation.
- It is important to have "off reserve" research, as well as health research for on reserve and Inuit.
- These research activities represent a good research partnership between Health Canada and Canadian Institutes of Health Research. .
- The national research strategy presented is good, but buy-in and participation by local communities is equally important.
- Gender analysis is very important. As an example, there currently is very little gender-based analysis done on suicide. Different policy interventions may result.
- Sensitivity is necessary in how research is used (e.g. STD reporting). It is necessary to be aware of cultural sensitivities and overcome negative stigma.
- It is important to work with aboriginal communities at the beginning. Often the objectives have been determined in advance, outside the community. Must establish this at the beginning with the community.
- Newfoundland and Labrador have a 30 year history of a single institute as a portal for all aboriginal research (science and social science) and provide guidance for new researchers.

Medical Marijuana Research Program
Beth Pieterson, Director General Drug Strategy and Controlled Substances Programme, Healthy Environment and Consumers Safety Branch (HECSB)

Beth Pieterson provided a presentation on Health Canada's Medical Marijuana Research Program

(MMRP). MMRP is a partnership program with the Canadian Institutes of Health Research (CIHR), to which Health Canada has currently dedicated $7.5 M over 5 years for the study of the risks and benefits associated with the use of marijuana for medical purposes.

The MMRP solicits research applications for randomized controlled clinical trials (RCT) using smoked or non-smoked marijuana. To date, out of 18 applications submitted, the MMRP has funded one pilot study, through a $262,500 grant, to assess the use of smoked marijuana for the treatment of neuropathic pain.

The MMRP was subject to an evaluation in May 2003. The results (provided to the Board) indicate that the CIHR peer review process may be unsuitable for reviewing applications under the MMRP. Following discussions between HC and CIHR staff, attempts have been made to modify the process. To date there has not been an increase in the awarding of fundable applications.

Also in partnership with CIHR, Health Canada sponsors, the Marijuana Open Label Safety Initiative (MOLSI) focusing on safety studies. The ad hoc single RFA and review process for this initiative resulted in one $1.8M grant approved for a 3-year study in pain.

Discussion Summary:

- Randomized clinical trial processes are very standardized, yet there is a very low success rate for research teams seeking funding to do clinical trials.

- Providing medical marijuana whilst not having research to support its use is a challenge.

- There was some debate on the merits of concentrating researching on smoked marijuana. It was noted that smoked marijuana is preferred by many patients because of the rapidity and ease of titration to the desired level of effect through inhalation.

- There was a discussion on ways to improve the quality of applications and the CIHR review process.

Open House

The Board held an Open House to provide an opportunity to increase understanding and interaction between the Board and Health Canada's scientists and policy makers. The winners of the poster contest at the Health Canada Research Forum, as well as one poster from each branch, were invited to present and share their outstanding research with the Board.

Best Poster Competition Winners from the Health Canada Research Forum:

Development of the First High-Throughput System for Rapid Identification of Microorganisms Based on Rapid-Scan Focal Plane Array Fourier Transform Infrared Spectroscopy

- Jonah Kirkwood
- Dr. Ashraf Ismail – McGill University
- Dr. Jacqueline Sedman – McGill University
- Mr. Andrew Getler – McGill University
- Irene Iugovaz (HPFB)

Global Characterization of a Lung Epithelial Cell line derived using DNA microarrays

- Carole Yauk (HECSB)
- George Douglas (HECSB)
- Paul White (HECSB)
- Andrew Williams (HECSB)
- Lynn Berndt (HECSB)

The importance of mental health for healthy living: Evidence from the Canadian Community Health Survey 1.2

- Heather Orpana, Information, Analysis and Connectivity Branch (IACB)
- Carl Lakaski, Population and Public Health Branch (PPHB)
- Sylvie Moreau (IACB)

Quality of life in childhood cancer survivors (age <17 years): Comparisons of survivors with population controls

- Amanda Shaw (PPHB)

Other posters:

FNIHB

Overview of the Health Status of First Nations On-reserve in Canada

- Adam Probert

HECS

Metals in the Indoor Environment: Studies of House Dust in the City of Ottawa

- Pat Rasmussen

HPFB

Trends in Overweight and Obesity Among Adults in Canada: Clues From National Surveys

- George M. Torrance
- Michelle D. Hooper
- Bruce A. Reeder – Department of Community Health and Epidemiology, University of Saskatchewan

PPHB

Health Risk Assessment Model

- Elizabeth Ptasznik

February 18, 2004

Update from the Chief Scientist
Dr. Kevin Keough, Chief Scientist

Dr. Keough announced that he would be leaving the Chief Scientist position in July 2004. Given the Board's role in creating the position, he urged Board members to suggest candidates for the position. Dr. Keough shared some of the findings of a recent 360 degree review of the Chief Scientist and his Office (produced by Sussex Circle) and he invited members to consider the roles of the Chief Scientist and the Office of the Chief Scientist (OCS), and ways to ensure that science continues to support Health Canada's evidence base.

Dr. Keough provided an update on several OCS activities such as the Research Ethics Board, the second competition for the Postdoctoral Fellowship Competition, the Safe Food and Water Initiative, and the Innovative Science Competition.

Discussion:

- Members discussed ways to measure the effectiveness of OCS activities and the Office's impact on the Department's science. The use of performance metrics (e.g., publications) and the development of baseline data were suggested. Metrics should be applicable to the diversity of Health Canada's science activities, as well as capture the full extent of OCS's contribution and activities (e.g., Health Canada Research Forum).

- Members were interested in knowing how the priorities of the Chief Scientist and OCS will change as a result of this review. Dr. Keough and the Chair encouraged members to share their views on current priorities and to make suggestions for the future.

- Members felt strongly that the full spectrum of science, including the social sciences, should be included in the mandate of the Chief Scientist and that efforts should be made to engage the broad science community.

- Departmental science communication has improved as a result of some proactive initiatives, but work remains to be done to ensure that it is not focussed on responding to crises.

Public Health Agency and Plans to Address Potential Pandemics
Scott Broughton, Assistant Deputy Minister, and
Arlene King, Director, Immunization and Respiratory Infections Division (PPHB)

The suggestion for the creation of a c Public Health Agency is a response to the chronic public health under-funding, lack of emergency preparedness, and the highlighting of deficiencies by the recent series of very public infectious disease events. Considerations for the Agency include recommendations from Naylor, Kirby, Walker, Campbell and a strong desire to respond to public expectations.

The publication of the Canadian Pandemic Influenza Plan is the result of several years of collaborative work aimed at producing a document that conveys planning needs and achievements in addition to anticipated response activities. The goal is to minimize serious illness and overall deaths, and secondly to minimize societal disruption among Canadians as a result of an influenza pandemic.

The Plan describes the preparedness and response activities at all levels of government. Preparedness activities are ongoing, however, with a focus on the following unresolved issues: security of antiviral supply, estimating potential effects of interventions through modelling, testing of the manufacturing and regulatory processes for accelerated vaccine production, the role of new vaccine technologies, and the influenza research agenda.

Discussion Summary:

- Possible machinery models for the proposed agency include Canada Customs and Revenue Agency, Canadian Institutes of Health Research and the Pest Management Regulatory Agency. It is most likely that the Public Health Officer would report to the Minister.

- While the initial Agency may only include the Population and Public Health Branch, a broad definition of public health (infectious and communicable disease, chronic disease and health promotion) is preferred.

- There was some discussion on the real costs to society if there is a pandemic in Canada, and if these costs are adequately estimated in Health Canada's Pandemic Plan.

- It is important for Canada to have a robust vaccine strategy, including the means to shorten the time between development of a vaccine strain and production for use.

- It was recognized that antivirals may have limited therapeutic application, consequently the research agenda should focus on four main priorities: surveillance/monitoring, public health issues, health service delivery, and knowledge translation.

Therapeutic Access Strategy
Abby Hoffman, Executive Co-ordinator - Pharmaceuticals Management

Strategies (DMO)

Abby Hoffman presented an overview of the Therapeutic Access Strategy (TAS), highlighting the integration of regulatory and health care system policies in order to improve the delivery of health care to Canadians.

The TAS vision is to help ensure that human drugs and other therapeutic products are safe, of high quality, therapeutically effective, appropriately used and accessible in a timely and cost effective fashion. Objectives of the TAS policy framework are to improve regulatory performance, provide greater vigilance on safety in real world use through post-market surveillance and risk communication, improve access to therapies and contribute to the long-term sustainability of the health system.

Discussion Summary:

- The TAS Strategy covers all therapeutic products (including food, veterinary drugs, natural health products, vaccines, radiopharmaceuticals, biologics, drugs, medical devices). While the lead branch has been HPFB, the health care system aspects have been addressed by HPCB.

- While there is a possibility of a future structure change (i.e. an agency) that is not a central issue at this time.

- There was some discussion about the strong pressures for Canada to “rubber stamp” foreign reviews and the effect it may have on public confidence.

- The Board noted that the Department had made remarkable achievements in improving pre-market regulations, stakeholder consultations and in reducing the backlog of submissions.

- In discussing post market activities, the board stressed the importance for consumers to have reliable information about drugs. They highlighted the Department’s pilot project on product monographs as a good example of what was needed.

- It was noted that the advertising of drugs to consumers includes warnings such as "this may cause nausea, diarrhea" and other symptoms. This may affect post market surveillance, as such an expectation may result in under-reporting.

The Honourable Carolyn Bennett
Minister of State (Public Health)

After the SARS outbreak last year, the Federal Minister of Health appointed Dr. David Naylor, Dean of University of Toronto School of Medicine, to chair a Special Committee on SARS and Public Health.

In September 2003, Dr. Naylor urged the federal government to adopt a new approach to public health based on three new elements:

- a public health agency,
- a chief public health officer for Canada, and
- a pan-Canadian public health network

The plan called for the federal government to work closely with provinces and territories to strengthen the public health system across Canada while also providing a clear focal point for responsibility and accountability within the federal system for public health matters.

Subsequently, in the Speech from the Throne, the Government of Canada called for the creation of a Canada Public Health Agency and the appointment of a Chief Public Health Officer for Canada. The Throne Speech also underscored the federal government's commitment to working collaboratively with the provincial and territorial governments to strengthen Canada's public health system. The Prime Minister and the Minister of Health appointed Dr. Bennett to address this initiative.

Over the past several weeks, Dr. Bennett has been meeting with experts from every region of the country, and internationally, to discuss how to improve intergovernmental collaboration on public health and how a federal agency and chief public health officer should function.

Dr. Bennett has been focusing on three key issues:

- Cooperation between governments regarding public health
- Defining a precise mandate and mission for the Canada Public Health Agency
- Ensuring that the federal public health agency remains accountable to citizens

National Science Advisor
Dr. Arthur Carty

Dr. Carty has been named the National Science Advisor to the Prime Minister, a position that is scheduled to begin on April 1, 2004. This is the first time in Canada's history that there will be a national science advisor. While the job description has not been finalized, Dr. Carty believes the responsibilities will include an assessment of federal investments across Canada's Science and Technology. It will be a different exercise than the one done in 1992-94, and will emphasize our investments to date and ask key questions (such as "Has government invested in a balanced manner, and has it capitalized on the investments? Are there gaps? Why are we not as successful

as we want to be? How do we build a stronger science culture in Canada?).

Dr. Carty noted the important role of government science, including development and support of regulations, national standards, and health and environment challenges. He also noted that there is a significant role for government as creator of wealth. To fulfill these roles government science should be excellent in quality and funded to an appropriate level.