Summary of Discussion
Science Advisory Board Meeting

February 28 – March 1, 2006

Participants

Science Advisory Board Members	***Ex-Officio* Member**
Arnold Naimark, Chair Linda Lusby (Co-Chair) Mark Goldberg Renaldo Battista Renée Lyons Arminée Kazanjian Keith Bailey Kathryn O'Hara Jacques Simard Howard Palley Stanley Vollant Mamoru Watanabe Rémi Quirion Stephen Bornstein Louise Lemieux-Charles Andreas Laupacis Chris Loomis	Morris Rosenberg Pierre-Gerlier Forest Neil Yeates Karen Dodds Bernard Dickens
Alternates	**Invited Guests**
Ray Edwards Katherine Stewart	The Honourable Tony Clement Cy Frank Richard Ellen Robert Clarke Theresa Tam
Secretariat	**Regrets**
Catherine Rotor Manal Bahubeshi	Lorne Babiuk Hélène Gosselin Marcel Nouvet Ian Potter Ian Shugart Susan Fletcher Chantale Cousineau-Mahoney Alan Bernstein

Boardroom 0115C, Brooke Claxton Building
Tunney's Pasture

Tuesday, February 28, 2006

1. Arnold Naimark, Chair

Arnold Naimark welcomed new members and noted the broad range of their interests and expertise.

He referred to the orientation package provided to members and invited new members to consult with him or members of the Secretariat on any matters related to the functions of the Science Advisory Board (SAB).

He noted that public health is one of the Board's main themes and that SAB's advisory functions include matters pertaining to the Public Health Agency (PHAC).

He emphasized that the term 'science' in the SAB's mandate is meant to include the social sciences as well as the natural and biological sciences.

He described the evolving format of the SAB's meeting agendas. He noted that there are four main sections to the agenda:

- formal presentations, discussions, briefings and updates on topics that fall under the SAB's main theme areas: public health; regulation of therapeutic and diagnostic products; health and environment; and, emerging technologies;
- formal presentations, discussions, briefings and updates on matters that don't fall under the above noted themes;
- briefings on developments of interest to the SAB by the Chief Scientist and, on occasion, by the Deputy Minister and Minister when their schedules permit; and
- operational issues.

He noted that the agenda also provides an opportunity for members to alert the SAB to developments of interest in relation to the SAB's mandate.

2. The Minister

The Minister welcomed the five new members of the SAB.

He noted the distinguished qualifications of the members of the SAB as a whole.
He referred to his engagement with health policy issues including his experience when he was Ontario's Minister of Health.

He outlined the health care priorities of the new federal government namely:

- wait times;
- Canadian Cancer Control Strategy;
- mental health;
- influenza pandemic; and
- science and technology.

He indicated that he looked forward to interacting with the SAB and to integrate its advice with other streams of input he receives on various issues.

In the ensuing discussion, the Chair and members of the SAB:

- Indicated that four of the five priority areas were already encompassed within the SAB's main theme areas and that it would certainly consider what role it might play in relation to the remaining priority area, wait times, and in particular the challenge of arriving at suitable benchmarks that can be related to improved outcomes.

- Flagged the importance of a cancer strategy for Canada but reinforced the importance of working together with other federal departments and agencies.

- Informed the Minister that the Kirby report on mental health is expected to be tabled in early May and would be useful background to the SAB's own deliberations on the matter.

- SAB members expressed their interest in contributing to the discussions surrounding a Science & Technology (S&T) strategy given the importance of innovation for the health sector.

3. The Chief Scientist

The Chief Scientist noted the appointments of new regular and *ex-officio* members of the SAB.

He described the changes in the Department with respect to Assistant Deputy Ministers (ADM) as well as the new governance structure (including the plan for the SAB Chair to engage monthly with Departmental Executive Committee (DEC-GEN).

He announced the dates for Health Canada's Science Forum; namely, October 30-31, 2006, noted that Kathryn O'Hara will be a member of the organizing committee and indicated the desirability for the SAB members to participate.

He reported on the progress of the Memorandum of Understanding (MOU) under development between PHAC and Health Canada and identified the desirability of a

separate MOU on science and research as there are mutual interests in several S&T issues.

He reported that Peter Nicholson has been appointed as President of the Canadian Academies of Science (CAS).

He indicated that the Lobbyist Registration Act (LRA) has migrated from Industry Canada (IC) to Treasury Board and that the Board is not in a position to respond to the questions raised with respect to the status of members of the SAB in relation to the Act. Further information is being sought and the members of the SAB will be kept abreast of the situation.

He noted that Arthur Carty, National Science Advisor, has a five year contract and is expected to remain in his position but may receive a new title.

In the ensuing discussion, the Chair and members of the SAB:

- Agreed with the importance of Health Canada developing a mechanism to track the adjunct professorships held by Health Canada scientists in academic institutions and other collaborative arrangements.

- Encouraged Health Canada to support efforts to remove barriers to and implement strategies that facilitate multi-disciplinary/interagency/interdepartmental collaboration.

- Noted the relatively small percentage of the Health Canada budget going to science and research activities other than those related to the regulatory mandate of Health Canada.

4. Round Table

Members identified developments of interest to the mandate and ongoing work of the SAB including:

- developments in telehealth and interplanetary travel;
- medical workforce issues and use of foreign medical graduates;
- nanoscience/nanotechnology and the implications for regulation;
- the forthcoming Kirby report on mental health;
- current work on a national system of accreditation of research ethics boards;
- a Council of Science and Technology Advisors (CSTA) report on management of S&T in the 21st century;
- biotechnology and sustainable development: Canadian Biotechnology Advisory Committee (CBAC) report, that includes material related to healthy communities, anticipated in late spring;
- the newly created centre for global research on environment and health;

- the CBAC report on Human Genetic Materials, Intellectual Property and the Health Sector;
- the work in Australia on building research capacity in aboriginal communities;
- the forthcoming report on the international review of the Canadian Institutes of Health Research (CIHR);
- integration of aboriginal students in the health sciences;
- the editorial crisis at the Canadian Medical Association Journal (CMAJ);
- private funding and private delivery of health services and other developments in Quebec;
- the need for a national approach to dealing with research integrity and research fraud; and
- vulnerable populations - care giving for elderly.

5. Public Health (Oral Health Strategy)

Peter Cooney, Chief Dental Officer, First Nations and Inuit Health Branch (FNIHB) presented "A Strategy to Improve the Oral Health of Canadians". The SAB was asked to provide advice/comments on the strategic approach, next steps and long term objectives of the strategy.

The SAB also received the following documents:

- "A Canadian Oral Health Strategy" (August 2005) prepared under the aegis of Federal, Provincial, and Territorial Dental Directors;
- A briefing note referring to the above document, the Office of the Chief Dental Officer, Health Canada (OCDO), the CIHR Institute of Musculoskeletal Health Arthritis that funds oral health research, and the Canadian Association of Dental Research (CADR); and
- "An examination of the oral health care system in Canada - Interim Report" prepared for the Chief dental Health Officer by J.L.Leake and S. Birch (December 2005).

Note: The comments and advice provided by the SAB were directed to Peter Cooney's presentation and the accompanying slide deck. They should not be regarded as reflecting a view of the SAB about the additional documents since they were not discussed by the Board. For greater clarity, any reference to an oral health strategy pertains to Peter Cooney's presentation "A Strategy to Improve the Oral Health of Canadians", particularly the part of his presentation headed "Proposed Strategic Plan, and not to the Federal/Provincial/Territorial (FPT) Dental Directors "A Canadian Oral Health Strategy" (August 2005).

In his presentation, Peter Cooney identified the lack of equality for support of dental care in comparison to general health care. He noted the links between oral health, general health and quality of life and indicated that a proactive strategy is needed to address the serious disparities of oral health care in Canada.

The goal of the proposed strategic plan is to improve the oral health of Canadians. The main elements of the plan are: needs assessment, health promotion, prevention and management of chronic oral health problems in vulnerable groups.

The key points made during the discussion were as follows:

- A convincing case was made for the development of a strategic plan to improve the oral health of Canadians.

- The SAB noted some of the historical and institutional factors that have influenced the current patterns of provision of dental health services and support of dental research (e.g. the removal of oral health care from the Canada Health Act (CHA) and the exclusion of dental research from eligibility for research infrastructure funds under the Canadian Foundation for Innovation's (CFI) research hospital fund). It was observed that it may be difficult to achieve a fully effective oral health strategy if dentistry and oral health aren't included in the Canada Health Act.

- Compartmentalizing health is problematic. To conceptualize oral health and general health as separate but linked entities is no more illuminating than thinking of "abdominal health" and general health as separate but linked entities. It is important to maintain a holistic approach.

- The elements of the strategic plan should be expanded to include two other elements: a research strategy and a knowledge transfer strategy. These two strategies would intersect with each of the other elements of the plan.

- The major emphasis of the research strategy should be on:
    - identifying the determinants of oral health and their respective weights including the roles of socio-economic status, educational level, occupation, access to and use of dental services, cultural factors, genetic factors, rurality, age, geography, immigration status, environmental factors etc.;
    - undertaking prospective intervention studies related to the efficacy of promotion and prevention studies; and
    - initiatives to identify goals and mechanisms for building research capacity especially in health services and population health.

- The knowledge transfer strategy should include:
    - synthesizing existing research from both national and international sources;
    - developing best practice guidelines; and
    - creating knowledge sharing networks.

- The further development of the strategic plan should involve the articulation of implementation steps. For example, if the strategy for management of chronic oral health problems in vulnerable groups is to overcome barriers to care, then which barriers will be addressed by what means?

- It is important to include portfolio partners (e.g. the National Cancer Institute (NCI), Canadian Institute for Health Research's (CIHR) Institute of Musculoskeletal Health and Arthritis (IMHA), and public interest groups) in the further development of the strategy as the issue of oral health cuts across organizational boundaries.

- The participation in the Canadian Health Measures Survey in relation to the needs assessment strategy is a welcome improvement over assessments based on self reporting.

- There was some concern expressed about the Oral Health Unit coming under the First Nations and Inuit Health Branch (FNIHB) since the issues involved affect all Canadians and certainly affect other vulnerable groups (children, the elderly and immigrants).

- A challenge that was identified was the unequal prominence given to general health over dental health. With respect to knowledge transfer, there is a bigger gradient in dental health as opposed to general health. More promotion and education is required starting with school age children. As well, a requirement is needed for school base policies with respect to the contents of vending machines. This would assist for both oral and general health. Provision of services is also encouraged on the part of dental health. Unfortunately, there are impediments to the provision of oral health services outside of dental offices.

- It was noted that a health disparities conference was to be held in Toronto the week following the SAB meeting and that an oral health component would have been appropriate.

6. Innovation and Emerging Technologies (Health and Innovation)

The SAB received a presentation from Charles Mallory, Director, Health Supply and Demand Analysis Division, Applied Research and Analysis Directorate (ARAD) of the Health Policy Branch of Health Canada, on the link between innovation and health costs.

He noted that substantial research links the growth of health care costs as a percentage of gross domestic products (GDP), in excess of what can be attributed to change in population size and age, to technological innovations. To the extent that these innovations result in better outcomes, they will result in lower quality adjusted prices.

The ARAD has hypothesized that:

- Over time as the total capital stock in the health sector increases, returns will tend to fall to the average of the economy as a whole.

- Growth in health care costs is going to continue until the return on investment slows down to the economy-wide average.

Charles Mallory then described a variety of initiatives to address the hypothesis consisting *inter alia* of cost-benefit and cost-utilization analyses, development of better measures of patient outcomes, and of productivity of investments in the capital stock. Charles Mallory was looking for input from the SAB on the next steps in the policy research agenda.

In discussing the presentation, the SAB offered the following general observations with respect to the rising costs of health care in relation to innovation.

- Growth in costs in excess of growth in the population may result from not only costs of technological innovation but also increased utilization of health services per unit of population. The presentation notes that aging of the population may be such a factor but there are several others including: an increasing demand for existing technologies and services; increasing capacity to service pent up demand; changing practice standards involving higher levels of servicing; and increasing regulatory costs (environment, safety, privacy protection).

- Technologically based innovation is not the only form of innovation that influences cost. Social innovations (organizational, managerial and logistical) can have both positive and negative effects on cost.

- The initiatives identified to address the hypothesis do not constitute a test of the hypothesis but rather represent attempts to get better measures of some of the variables that might be relevant to a test of the hypothesis. Indeed it would be helpful for the analysts to state in formal terms what an adequate test of the hypothesis would be.

- SAB members wished to have a better understanding of the assumptions underlying the method of quality adjustment of prices given the complexities in quantifying "quality".

- The SAB commended the ARAD for its efforts to tackle a complex and challenging issue and suggested, given the potential importance of the work as part of the context for policy-making in respect of innovation, that subjecting the project to rigorous review by a broadly representative group of health economists knowledgeable about the dynamics of clinical innovations would be helpful. As well, developing collaborations with clinicians and others involved in the introduction of health care innovations would also be helpful.

WEDNESDAY, MARCH 1, 2006

7. Regulation of Health Products (Special Access Programme)

The SAB's theme on regulation of health products includes: therapeutics; diagnostics; and natural health products and foods.

The Health Products and Food Branch delivered a presentation on Health Canada's Special Access Programme (SAP) to the SAB March 1, 2006. The SAP for drugs administers a provision in the *Food and Drug Regulations* allowing for the discretionary authorization of emergency access to drugs that are not approved in Canada, based on data supplied by the requesting practitioner or any other information the Branch may have in its possession. Under the SAP, a medical emergency is defined as a circumstance where a patient has a serious or life-threatening condition where marketed alternatives have either failed, were ruled out or were not available.

In the presentation, it was noted that the number of requests for special access has grown enormously creating intense pressures on the administrative capacity of the SAP and its information systems. The Science Advisory Board was advised that Health Canada is planning a comprehensive review of the SAP to assess systematically the ethical and regulatory framework for the SAP and its administrative policies and procedures in the context of current and emerging pressures. This review is part of a proposed regulatory modernization initiative for therapeutic products.

The advice being sought from the SAB was on how to establish a threshold of evidence for SAP requests that will reconcile meeting the intent of the drug regulatory framework, namely to ensure that Canadian patients have access to drugs that are safe, efficacious and of high quality with the desire of doctors and patients to have early access to new drugs in emergency or other special circumstances.

The SAB interpreted the term "threshold of evidence" to mean the evidence required to satisfy the criteria for authorizing special access. In discussing the presentation, the SAB noted the following.

- The assessment of the SAP, as a whole and of the robustness of the link between evidence and the application of criteria in particular, requires the ability to mine the data recorded in the SAP information technology (IT) system with respect to the applications approved and denied, the categories of drugs, diseases and circumstances involved, and outcomes, as well as trends in all of these categories over time.

- There is a need to review the criteria, and relevant evidence, for authorizing special access in relation to the particular categories of use (e.g. for experimental purposes and for use as a last resort in critically ill patients).
- The development of a contemporary, comprehensive ethical framework is important for developing policies on questions that bear on safety and efficacy.

The SAB identified the following points as the key messages to be included in preparing its advice to the Minister.

- The Branch is to be commended on its efforts in managing the SAP under heavy and increasing demands and on recognizing the need to review and modify the SAP to meet current and emerging challenges.

- The SAB urges that the review of the SAP be undertaken expeditiously.

- The development of a policy framework that is comprehensive in that it embraces both the ethical and scientific dimensions of regulatory functions includes wide consultations with leading experts in Canada and abroad and includes consideration of the question of cost of drugs provided under the SAP and its effects on access recognizing the role of provinces and territories in this matter.

- Urgent attention needs to be given to a significant expansion of the IT support for the SAP so that it can create the databases and data mining capabilities necessary to support evidence-based decisions about tailoring the SAP (criteria, regulations, policies, procedures).

- Consideration should also be given to:
    - the need for the development of a program for special access to medical devices and for hybrid products incorporating both drugs and devices;
    - the feasibility and desirability of introducing conditional/provisional licensing as a means of providing access to drugs for which there is an urgent demand while final evaluation is being undertaken;
    - the introduction of measures to prevent abuse of the SAP (i.e. using the SAP as a means of bypassing the regular process of drug approval in circumstances that do not warrant it); and
    - expanded requirements and rigorous enforcement thereof related to the provision of data by manufacturers of products approved for special access.

8. SAB Operations

The SAB reviewed several matters pertaining to its internal operations.

Declaration of Interest

- The Chair circulated a sample template of a Declaration of Interest form. The Secretariat will forward the template to members and they will complete, sign and return the forms.

Impact of the SAB's Advice - Draft Evaluation Framework

The draft Evaluation Framework, distributed with the agenda, was prepared following the SAB's agreement that the SAB should implement a systematic self-evaluation process that includes evaluation of the impact of its advice. The following points were made during the discussion.

- The draft Framework was approved in principle as a basis for further development taking into account the need for:
    - further consideration as to who should be asked to complete the questionnaire;
    - careful wording of items in the questionnaire; and
    - a carefully prepared covering memorandum that indicates clearly that it is a part of a process to evaluate the performance of the SAB and not the entities to whom it provides advice and that individual responses will be treated in confidence.

- In order to be able to decide which pieces of advice to track and how to track them, the SAB would have to know what the Minister's office did with the advice it received from the SAB that was not conveyed to the branches.

- Consideration should be given to follow-up discussions with evaluators as this would indicate the serious interest of the SAB.

- The Secretariat was requested to provide a list of items that were presented to the SAB along with the advice that was provided to the Minister.

Presenters' Guide

- The Chair asked the Secretariat to forward the presenters' guide to members for review and comment as the guide is in need of re-drafting.

Future Meetings

- The date of the last SAB meeting for the 2005-2006 SAB meeting year was confirmed as May 9-10, 2006.

- The new meeting year, 2006-2007, will commence in the Fall. The first meeting will focus on what the science/research strategy for Health Canada should be in the future. This meeting will take the form of a retreat. (Agriculture and Agri-Food Canada has completed this and should be considered as a framework for Health Canada). At the same time, the SAB expressed their interest in holding another reception with Health Canada scientists. As part of this retreat, it was suggested that representatives from the Council of Science and Technology Advisors (CSTA) be invited to discuss their new report that is to be released

shortly and the National Science Advisor could be engaged to participate in the retreat as well.