Health Canada Santé Canada

REPORT OF THE DECEMBER 2001 MEETING

RAPPORT DE LA RÉUNION DE DÉCEMBRE 2001

SCIENCE ADVISORY BOARD

LE CONSEIL CONSULTATIF DES SCIENCES

December 5 and 6, 2001
les 5 et 6 décembre 2001

Health Canada
December 2001

Santé Canada
décembre 2001

---------- **Note:** Contents of the Meeting Report are a reflection of the discussions of the December 5-6, 2001 Science Advisory Board Meeting. The points contained in this document are those of the Science Advisory Board and do not necessarily reflect the views of Health Canada and its employees./ Le contenu du présent rapport est le reflet des discussions de la réunion du Conseil consultatif des sciences tenue les 5 et 6 décembre 2001. Les points de vue qui y sont exprimés sont ceux du Conseil consultatif des sciences et ne reflètent pas nécessairement les points de vue de Santé Canada et de ses employés.

Canada

Day 1, Wednesday, December 5, 2001

Attendance: Judith Hall, Richard Lessard, Allan Ronald, Karen Grant, Rodney Ouellette, Stuart Macleod, Neena Chappell, Elizabeth Jacobson, Michel Bergeron, Lillian Dyck, Linda Lusby, Irv Rootman, Carol Herbert

Ex Officio Members: Ian Green, Kevin Keough, Dann Michols, Munir Sheikh

Guest: Dr. Bernard Dickens, chair of the HC Research Ethics Board

Secretariat: Valerie Marshall, Véronique Frenette, Janiece Walsh

1. Opening Remarks - *(Chair - Judith Hall)*

The Chair welcomed members to the meeting and announced that Dr. Richard Lessard had been appointed as vice-chair of the Board.

The chair noted because the Department had been preoccupied with emergency preparedness, the binders sent ahead of time were not complete. The Science Advisory Board encourages Health Canada to ensure materials are available ahead of time so the Board can give its best advice.

Dr. Hall passed on congratulations to Board member Dr. Neena Chappell, who will receive the Dunton Alumni Award from Carleton University on December 6, 2001.

The chair also filled Board members in on her attendance at the most recent meeting of the Canadian Science and Technology Advisors, noting the common problems of human resources and communications with all participants.

2. Office of the Chief Scientist *(Dr. Kevin Keough, Chief Scientist)*

Dr. Keough noted emergency preparedness and response have occupied a significant proportion of Departmental attention since September 11. The OCS has provided input on membership of the expert committee on bioterrorism struck by the Minister.

The OCS, along with CIHR, is co-sponsoring a workshop on bioterrorism in January, 2002. The workshop will identify the current state of research in viral agents; bacteriological agents; agriculture, veterinary and food; public health preparedness and response and vaccines and antimicrobials. The OCS is also exploring a modest targeted research program in this area, also sponsored by the CIHR.

The Chief Scientist reported that the first funds from the Strategic Science Fund were designated. A modified form of peer review for proposals for use of funds by year end.

Dr. Bernard Dickens has been appointed as Chair of the Department's Research Ethics Board (REB). The legal office has advised it may be important for the Department to consult widely for members, especially those who represent the non-specialist members of the Board. The Chief Scientist suggested the SAB membership might be able to advise on how to do that.

The Health Research Secretariat started extensive discussions with CIHR about knowledge transfer. This will mean more targeted contacts between the two organizations.

Dr. Keough updated the Board on a new activity within the OCS, that of a Science and Policy Co-ordination Unit which will be established in support of the ADMs, the Director of PMRA and the OCS in fulfilling roles in coordination of science and policy related to science. The objective of the Coordination Unit is to ensure that a full exchange of information occurs internally and externally.

The Chief Scientist reported on a trip made to Great Britain where meetings were held with representatives of the science and health research communities, including the former and current Chief Scientists. The meetings were informative and set the stage for future collaborations with the British Department of Health. Meetings with the Wellcome Trust may provide opportunities using Canadian expertise in infectious diseases and issues of global health research.

The Board was also told that the government Chief Scientist in the United Kingdom is developing a series of positions very much like the Health Canada's Chief Scientist. Since the SAB was responsible for developing the role of the Chief Scientist here, it seems SAB's recommendations are being picked up elsewhere.

Discussion included the following points:

- The sheer fact of having someone in the position of Chief Scientist has had a positive impact on the science community of Health Canada and Dr. Keough believes there are some things that are beginning to change and be modified because of the existence of the OCS.
- Projects which were funded through the modified peer review system were short-term items such as money for a post-doctoral student, monies for equipment and for library acquisitions.
- Discussions on the Romanow Report will be filtered through the Deputy Minister, but the Chief Scientist would want to have conversations with the research team on an unofficial level.

Action Item:

- *Kevin Keough will provide a list of the funded projects to SAB members before the next meeting.*

3. **Health Canada Update and Welcoming Remarks** - *(Mr. Ian Green, Deputy Minister)*

The Deputy Minister welcomed Board members, passing on best wishes from the Minister.

He briefed members of the Board on Health Canada's actions following the September 11 terrorist activities in New York and Washington, noting that the Government was in the final stages of developing a budget that would be influenced by the importance of public security. The DM said there were three priority areas: First Nations sustainability; research and information largely in the context of CIHR and CIHI; and the need for continuing investment in environmental health.

Health Canada has been active not only in the international area, but in the federal-provincial-territorial one as well. The action plan from September 2000 is being followed. In the area of pharmaceuticals management, a request for proposal is being developed to provide a permanent mechanism to assist in common drug reviews, best practises and a common template for assessing pharmaceuticals.

The DM suggested the new year would bring a renewed interest in health care reform, influenced by the Mazankowski Report, a provincial-territorial First Minister's meeting in January, the leadership campaign in Ontario, and the Romanow Commission's interim report. The Romanow Commission seems to be putting an emphasis on research with an emphasis on human resources, managing change and globalization.

Canada is leading the co-ordination the international effort on health security. The next meeting of the international Ministers and Secretaries of Health will take place in the United Kingdom in February. The questions about smallpox vaccines raise the issue about which government action needs to be planned for. Clearly smallpox is one of the risks, but there are other risks, such as designer bugs, dirty explosions and the safety of food and water supplies.

At this point, Health Canada has purchased sufficient pharmaceutical stocks to treat 100,000 people for 45 days for anthrax and protocols are being developed and endorsed. Other activities include acquiring detectors for a radio-nuclear event to be distributed at critical sites across Canada; inventories are being prepared on the capability of Tier One and Two labs across the country and bioterrorism research proposals are being developed to increase knowledge in the areas of concern.

Discussion included the following points:

- The appointment of Senator Yves Morin as special advisor to the Minister is a broadly-based charge. Senator Morin and the Chief Scientist talk to each other frequently.
- There is an argument to be made that if HC is to concentrate on public health, additional resources need to be allocated.
- The science of risk assessment and modelling becomes increasingly important in areas such as bioterrorism, as does moving forward new technology in terms of rapid tests and early identification. The science of detection and response could be helpful in areas such as natural disasters.

Major discussion point:

- *The Board is concerned about the level of risk the public accepts regarding chronic health problems such as smoking and the heightened level of risk it accepts about acute events such as terrorism. Driven by public and media concern, Health Canada puts time, energy and money into issues that may or may not be major public health risks. It is important that Health Canada be responsive and take leadership roles, but it is equally important that money should be put where health issues affect long term quality of life. It is important the public be protected, but real and perceived risks must be assessed and communicated.*

4. Approval of October SAB Meeting Report - *(Chair)*

The report is approved with changes made**.**

5. Research Ethics Board - *(Dr. Kevin Keough, Dr. Bernard Dickens, Kim Elmslie, Anne Malo)*

Kim Elmslie, of the Health Research Secretariat, outlined the progress made in establishing the Health Canada Research Ethics Board. The next steps for the REB include educating science managers and researchers about ethical issues, as well as completing the appointment process for Board membership.

Discussion included the following points:

- Specific expertise might need to be sought on different subjects while reviewing protocols.
- The new database of researchers will provide an insight into the kinds of research being done at Health Canada and expertise of REB members can be matched.
- The REB will need to be well-equipped to deal with a wide range of

proposals.
- Concerns were expressed regarding the REB's need for expertise to properly access research protocols for studies in Aboriginal communities and on topics concerning Aboriginal health. Issues about access to study populations and intellectual property take on a different significance in theses communities/populations and the Tri-Council Policy may not be sufficient to address the concerns of Aboriginal persons.

Dr. Bernard Dickens, the first chair of Health Canada's Research Ethics Board was introduced to SAB members. He described his role as a welcome challenge, noting Research Ethics Boards are not the repository of ethics, but are charged to monitor investigators' identification of and responses to ethical issues.

Dr. Dickens suggested challenges ahead include privacy and confidentiality while ensuring the protection of public health. REB members could be specialists and non-specialists, but need to be credible individuals.

Discussion included the following points:
- There needs to be some consideration about international projects Health Canada is involved and whether or not these projects should be reviewed by a REB.
- There is an overlap between ethics and privacy. There must be someone who has expertise in this area.
- The values of confidentiality are of primary importance and must always be properly protected.
- There may be a need to go back and re-visit regular Health Canada programs to see if they meet the standards that are established.

Discussion Summary:

The Science Advisory Board applauds the establishment of the Research Ethics Board and looks forward to a progress report.

Action Item:

- *By the Fall 2002, the Science Advisory Board would like an update on the composition of the Board and some indication of the kinds of proposals coming forward to the REB.*

6. <u>Communication</u> - *(Ms. Sheila Watkins, Director-General, Communications)*
(Please refer to presentation slides)

Ms. Watkins provided an overview of the Directorate and discussed the public environment within which the Department coordinates its communications program. The

presentation discussed the concepts of issues management, risk communications and crisis communications, using examples of three crises, an anthrax scare; Brazilian beef and a potential Ebola Virus case in Hamilton.

Discussion included the following points:

- Concern was expressed that HC communications tends to deal with high profile issues rather than chronic ones.
- There are three functions of communications: public relations, information and social marketing, which provides education for change.
- Information is not necessarily accessible to the Aboriginal community. When dealing with the Aboriginal community, some information must be targeted at children, rather than the adult population.
- The Health Canada website should be the gold standard that people can trust. It should be the site that Canadians go to for solid information.

Discussion Summary:
The Science Advisory Board believes that communication is important, but a balance is needed where communication does not just deal with crisis situations. The Board encourages Health Canada to offer more co-ordination and education.

Action Item:
The Board would also like to see the draft of the strategic communications plan as it relates to science and research.

7. **<u>Health Canada Surveillance: Inventory of Surveillance Activities</u>** - (Dr. Michael Goddard, Catherine Adam, Dr. Sheryl Bartlett, Dr. Robert Peterson
(Please refer to presentation material)

Dr. Michael Goddard introduced the Board to the Centre for Surveillance Co-ordination, noting that the centre doesn't actually perform surveillance, but rather draws together networks, develops tools and projects. One the tools of the CSC is access to information, which is available both within the Department and to public health officials.

Catherine Adam outlined some of the surveillance done by First Nations and Inuit Health Branch, including under the TB Elimination Strategy, tracking prevalence and using that information in program design.Surveillance is also done on diabetes, injuries and environmental monitoring.

Dr. Sheryl Bartlett presented some examples of surveillance done in the Healthy Environments and Consumer Safety Branch. Dr. Bartlett illustrated the value of environmental health surveillance using the National Dose Registry which contains records of radiation exposure for over 500,000 workers in Canada. A Federal-Provincial-

Territorial Committee is developing an inventory of environmental and occupational health surveillance databases in Canada.

Dr. Robert Peterson told SAB that the Health Products and Food Branch includes nutrition and dietary surveys, as well as foodborne disease surveys. Dr. Peterson also noted the Branch works with very interested patients' groups including arthritis, diabetes and HIV which allows for active reporting from patients regarding expectations for products.

Discussion included the following points:

- The people involved in surveillance may not necessarily consider themselves as doing research and may not be picked up by the database process in the Office of the Chief Scientist.
- If the surveillance database is accessible to other researchers, especially in surveillance involving First Nations peoples, it's critical how you define someone as aboriginal.
- The quantity of surveillance done by HC is extensive. Data quality for researchers is always an issue, especially if the information is voluntary.
- What does HC do with all this information? Health Canada might prioritize the kinds of surveillance it needs to do.
- There needs to be a more strategic approach to developing health surveillance systems in Health Canada.
- Despite best efforts, there are some gaps in the environment area and in population health that will cause problems in the future.
- The risk with this amount of surveillance is information overload.
- With limited resources, choices must always be made in the kinds of surveillance that's being done.
- Consultation with the provinces is constant, to ensure that their priorities are also covered.
- Health Canada wants to move from the disease-focussed approach and look through the lens of prevention.
- Surveillance systems should be developed to answer specific questions that are critical to managing health risks, developing policies that will assist in the prevention of health risks and promotion of health to Canadians, tracking the impact of interventions and developing health indicators.

Discussion Summary:
There is a rich resource of material here. The Science Advisory Board would like the material to be transparent and to be available to reseachers and the public. The Science Advisory Board would like to see whatever plan exists or is being developed for the use of this research material. The SAB would also like to see international comparisons.

8. **<u>Advisory Committee on the Management (ACM) for the Therapeutic Products Directorate</u>** - *(Dr. James Blackburn, ACM chair, Dr. Robert Peterson, DG TPD)*

The goal of the presentation is to provide SAB members with an overview of the role of the ACM and to pursue potential issues which are of common interest to both groups. Dr. Blackburn explained the purpose of the ACM, describing it as an advisory body to the Director General and a sounding board with the ability to evaluate new programs and initiatives.

One of the issues currently facing the committee is maintaining a core of qualified medical/health scientists within the Therapeutic Products Program to provide the necessary services to protect the public/consumer; the regulation of clinical trials of therapeutic products in Canada; the distribution of drug safety (scientific) information to health professionals and the public.

Dr. Stuart McLeod, a member of SAB and the ACM, suggested there was a real opportunity to identify areas where the two advisory groups could work together.

Discussion included the following points:

- Drugs are very much front and centre in the public's perception.
- There are areas of common concern between the two Boards.
- Technology is changing and the expertise that advisory bodies can provide is very important.
- Public involvement in this area is critical. There was some concern expressed over the membership of the committee in terms of the lack of consumer membership.
- There are patient advocacy groups that may have a differing point of view on the issue of speeding up the regulatory process and the licensing of drugs.

Discussion summary:
The Advisory Committee on Management is clearly an important committee in terms of the work it does. There is a challenge on several counts to make its membership more reflective of both the country (i.e., no current member from Quebec) and consumers. Steps are being taken to enhance consumer participation and regional representation.

9. **<u>Children's Health</u>** - *(Dr. Robert McMurtry, Claude Rocan, Catherine McCourt, Barbara Adams)*
(Please refer to presentation slides)

Child health is a priority for Health Canada, which addresses this issue through surveillance, research and policy and program development, including regulatory actions

and service delivery for First Nations and Inuit communities.

Health Canada partners with others, including provincial and territorial governments on issues involving children's health. Aboriginal children's health is also a responsibility. Health Canada's role is often consensus building.

Future directions include continuing to build scientific excellence in child health and further work in priority areas, including mental health, and health of adolescents and youth. New initiatives include the implementation of a National Immunization Strategy and a national congenital anomalies surveillance network.

Discussion included the following points:

- The Department has done a good job, but the emphasis on adolescent and youth is very weak.
- The feeling in the public health community is that children's health is not a priority of the federal government.
- The effects of smoking that can and will lead to cancer is beginning to have effects. Physicians are now seeing people in their 30s and 40s with lung cancer.
- Work needs to be done on clarifying areas of responsibility regarding research between Health Canada and CIHR.
- Data may need to be looked at differently. If you eliminate factors such as age and sex, the problems appear to be related to low income.
- Will privacy legislation have an impact on tracking children as they grow up?
- Child health is not just a responsibility of Health Canada, but needs to be coordinated among a variety of government departments.
- A core responsibility for Health Canada is child health surveillance, using that data to see how we compare internationally, to ensure appropriate information is being used.
- The federal role in programs is important, but engaging the local community is critical.
- Best practices need to be developed, so that communicating data influences change.

Discussion Summary:

There are a very large number of Health Canada programs involved in children's health. Perhaps the unique role for Health Canada is surveillance and evaluating the effect of health programs which then lead to new research and policy. There is a chance here to share and network. Health Canada plays a very useful convening role with importance needed to be given to youth, adolescents and socio-economic policy. The discussion

reflected that the Science Advisory Board did not have a sense of the priorities regarding Health Canada's work in this area.

Adjourned at 5:30 p.m.

Day 2 - Thursday, December 6, 2001

In Attendance: Richard Lessard, Allan Ronald, Karen Grant, Rodney Ouellette, Stuart Macleod, Neena Chappell, Elizabeth Jacobson, Linda Lusby, Lillian Dyck, Michel Bergeron, Irv Rootman, Carol Herbert.

Ex Officio Members: Kevin Keough

Secretariat: Valerie Marshall, Janiece Walsh

10. **Opening Remarks-** *(Chair)*

The Chair reported that she would be meeting with Minister Alan Rock later in the morning

11. **Aboriginal Health-Research Agenda and Collaborations Opportunities** - *(Dr. Jeff Reading, Scientific Director of the Institute of Aboriginal Peoples' Health, Canadian Institutes of Health Research)*
(Please refer to presentation slides)

Dr. Reading told Board members the health status of Aboriginal peoples in Canada is particularly poor and solving the problem is complicated by jurisdictional problems and health service concerns.

He pointed out that urban issues aren't something that have been dealt with in the past, but noted that there were 200,000 Aboriginal people living in Toronto.

Dr. Reading spoke about the ACADRE program (Aboriginal Capacity and Developmental Research Environments) with its major focus on developing an advanced health research capacity by supporting young Aboriginal health research investigators. The ACADRE program, working in pursuit of scientific excellence, would provide the environment necessary to encourage Aboriginal students to pursue careers in health research; provide an appropriate environment for scientists to pursue research opportunities in partnership with Aboriginal communities; provide opportunities for Aboriginal communities and organizations to identify important health research objectives in collaboration with Aboriginal health researchers and facilitate the rapid uptake of research results through appropriate communication and dissemination strategies.

He said there were four full ACADRE Centre awards, with $12 million committed over six years. This program embodies community relevance and community involvement

balanced with excellent science.

Dr. Reading said Aboriginal health is an area where Canada can be an international leader through innovation. There are co-operation possibilities with New Zealand and Australia and the enabling of links and information sharing.

Discussion included the following points:

- The excellence of this program will set the tone for the research.
- This Institute is the prototype for CIHR.
- The Americans are interested in the ACADRE program. The National Institutes of Health are looking at an exchange program, where they could send American students north and Canadian students to the NIH.
- The Aboriginal community is seeing this as opportunities to get work done.
- Integration with Health Canada in this area could be knowledge translation.
- Health profession educators have just not been able to attract aboriginal students. There is some thought about reaching younger students to identify people who have an interest and get them into a research career.
- There is also an interest in international health issues and the premise is if we could do a better job on aboriginal health, we could relate to developing countries.
- Canada can only be internationally competitive in a few areas. Indigenous health is one area where this country can be an innovator.
- There are linkages and opportunities with the United States, Mexico and the circumpolar countries where Canada can make a huge impact by leading by example.
- Reaching all young people with the possibilities of science is important.
- This Institute has a role in almost every health indicator. There are major problems in terms of stress, diabetes, poverty, the prevention of accident and injuries.
- There are exciting possibilities for the linking of Health Canada and CIHR in this area.
- The research community needs to train the next generation.
- In Aboriginal health, because it's a federal responsibility, there are the opportunities to forge a unique health care system by partnering.

Discussion summary:
The Board was concerned about the extent to which linkages were established between research and health needs of the First Nations. After listening to Dr. Jeff Reading, of the Institute of Aboriginal Peoples' Health, the Board is impressed by the research capacity building vision and plan of the Institute and is very satisfied to see the development of research is done very closely with the knowledge of health needs and health care needs of the First Nations. The Board also recognizes there is potential for Canada to become an international leader in the field of Aboriginal health.

12. **<u>Assisted Reproductive Technology: Update on legislative process</u>** - (Rhonda Ferderber, Lisa Lavoie)
(Please refer to presentation slides)

On May 3, 2001, Minister Rock presented draft legislation on Assisted Human Reproduction to the House of Commons Standing Committee on Health. The proposed approach includes prohibitions (e.g. cloning), and areas for regulations (e.g. embryo research).

The Minister asked the Committee to review the proposed approach and provide its recommendations, as well as its views on a regulatory body to oversee the legislation. The Committee's Report is due on or before January 31, 2002.

A summary of the draft AHR legislation was presented to the Science Advisory Board, as well as a brief overview of information presented by witnesses to the Standing Committee.

The Board was told one of the major objectives of the legislation is to provide reassurance to Canadians, as well as to provide a national regulatory environment for Assisted Reproductive Technology activities and researchers.

Discussion included the following points:

- The decision by the Minister to take the draft legislation to the Committee was unusual, but reflects the concern that Canadians have a say in the legislation.
- Inspection and enforcement are difficult areas to legislate and follow up.

13. **<u>Food Safety</u>** - (Dr. Karen Dodds)
(Please refer to presentation slides)

Dr. Dodds suggested SAB could provide guidance on two major issues for the Food Directorate of Health Canada:

1) Elements of the Health Canada action plan in response to the Royal Society Expert Panel Report: "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada."
2) Prioritization of the research needs related to enhancing the scientific basis of nutritional assessment of foods and mechanisms by which this work might be most effectively accomplished.

Dr. Dodds outlined several elements of the Action Plan, including substantial equivalents, developing tools to support the evaluation of more complex novel foods; whole food testing protocols; approaches for more public and expert consultation in the regulatory process and expert advisory panels on transgenic animals, fish and aquatic organisms/

Discussion included the following points:

- There is a continued relationship between members of the expert panel from the Royal Society and Health Canada.
- Food-related allergies are increasing, but there is no evidence that this is related to genetically-modified foods. The increase may be related to increased recognition.
- International discussions continue as other countries grapple with the same problems.
- Canada is considered one of the most expert internationally in safety assessment.
- Labelling remains a significiant barrier internationally. From a scientific perspective, the Expert Panel did not see need for labelling. The government of Canada position is that we would permit voluntary labelling and would inform consumers.
- The effect of agro-business on health is important. This could be a topic for a joint meeting with Agriculture Canada.

On the issue of Nutrients, Canada has limited data on food consumption and nutrient intakes and no national data on nutritional status. Dr. Dodds told the Board the last information on the nutritional status of Canadians was in 1972. Since that time, there is more diversity in food consumption patterns.

Discussion included the following points:

- It is astonishing that Canada does not have this information.
- There are potential roadblocks in asking Stats Can to collect this information as part of a census.
- This is a key aspect of surveillance that Health Canada is not doing.
- People react more strongly to a specific disease than general nutritional health, despite the fact nutrition has bearing on chronic diseases.
- Health Canada should take a leadership role on this issue.
- This is an area where CIHR should be involved.

Discussion summary:
The Science Advisory Board feels strongly that the issue of a nutritional survey of Canadians has been ignored for too long. The Board strongly advocates that Health Canada take action in this field.

Meeting adjourned at 3 p.m.