Health Canada Santé Canada

REPORT OF THE MAY 2001 MEETING

RAPPORT DE LA RÉUNION DE MAI 2001

SCIENCE ADVISORY BOARD

LE CONSEIL CONSULTATIF DES SCIENCES

May 7-8, 2001
les 7 et 8 mai 2001

Health Canada
May 2001

Santé Canada
mai 2001

---------- **Note:** Contents of the Meeting Report are a reflection of the discussions of the May 7-8, 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 7-8 mai 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 - Monday, May 7, 2001

In Attendance: Richard Lessard, Allan Ronald, Karen Grant, Rodney Ouellette, Stuart Macleod, Neena Chappell, Ardene Robinson Vollman, Stephen Strauss, Elizabeth Jacobson

Ex Officio Members: Ian Green, Marie Fortier, Diane Gorman, Kevin Keough, Dann Michols, Wendy Watson-Wright (for Robert McMurtry)

Secretariat: Kata Kitaljevich, Valerie Marshall

1. <u>Opening Remarks</u> - *(Acting Chair - Dr. Richard Lessard)*

The Chair welcomed members to the meeting, especially welcoming the new members to the Board. He noted he was standing in for the new chair, Dr. Judith Hall, who was unable to attend the meeting.

The Chair told the Board they must act as a new Board, noting the revised mandate of the Board would be discussed during the meeting tomorrow. He pointed out it was essential that everyone plays an active role in order to provide the Minister with the best advice possible.

In outlining the planned agenda, Dr. Lessard said the members' time was precious and must be used wisely. He pointed out the first day of this meeting would be spent giving an overview of the activities of Health Canada.

Dr. Lessard introduced Dr. Kevin Keough, Health Canada's Chief Scientist, to the Board and then the Deputy Minister, Ian Green..

2. <u>Welcoming Remarks</u> *(Ian Green, Deputy Minister)*

The Deputy Minister welcomed Board members, passing on best wishes from the Minister, as well as Dr. Judith Hall, the new Chair of the Board.

The Deputy Minister also said the Board was looking into appointment another new member who would be familiar with Aboriginal issues and asked Board members for any suggestions they might have.

He told Board members the first day of this meeting would be a series of briefings on the various branches of the Department. He pointed out realignment of Health Canada last July meant the Department now contains seven branches, six regions and two agencies. These changes were reflected in the revised Terms of Reference which the Board will

discuss later in this meetings.

The Deputy Minister told members responsibility for the Board would now come under the Chief Scientist's office. He thanked Assistant Deputy Minister Diane Gorman and her colleagues for the work done by them for the Board.

3. **Welcoming Remarks** - *(Dr. Kevin Keough)*

Health Canada's Chief Scientist welcomed the new members to the Board and said he was looking forward to the meeting to help him consolidate some of his ideas. Dr. Keough pointed out that he had been at Health Canada just over a month and said he was not in position at this time to present the Board with any action plan.

Dr. Keough noted his office had been looking at accreditation of Health Canada's laboratories and said his office would do an inventory of labs and activities to determine what the current status is. A determination of additional steps needed in accreditation or certification would need to be done.

He said there were any number of things the Chief Scientist could become involved in, but he wanted to maintain a focus. There were issues of quality, peer reviews, morale, internal and external communications. The issue of communication is an important one, he said, adding it was important to be able to tell good news and respond to bad news. He said he was still thinking about how his office might be able to help with issues of risk communication.

Partnerships were also important for the Chief Scientist, both internal and external. Another issue of importance was capacity: getting new people in to work at Health Canada is important. One of his main interests is for Health Canada to bring in more doctoral and post-doctoral trainees to the laboratories.

4. **Introduction of Board Members** - (*Dr. Richard Lessard*)

Encouraged by the Chair, members of the Board took time to introduce themselves and their areas of expertise.

5. **Healthy Environments and Consumer Safety Branch (HECS)** - *(Dann Michols)*
(Please refer to presentation slides)

Assistant Deputy Minister Dann Michols presented an overview of his branch, describing it as incredibly diverse in scope and responsibilities. The mission statement reads:

HECS exists to help the people of Canada maintain and improve their health by promoting healthy living, working and recreational environments, and by reducing the harm caused by tobacco, alcohol, controlled substances, environmental contaminants, and unsafe consumer and industrial products.

There are five programs within the Branch: Safe Environments; Product Safety, Tobacco Control, Drug Strategy and Controlled Substances, and Occupational Health and Safety. Mr. Michols is also the department champion for the Sustainable Development and Workplace Health Initiatives, the offices for which are located in his Branch.

Mr. Michols gave an overview of each of the programs within the Branch. In addressing challenges that face HECS, he noted that there is not a single aspect of the mandate of his Branch which does not require partnerships with other Branches in Health Canada or with other federal departments. The work also requires co-operation of provinces, municipalities, non-governmental organizations and other stakeholders. Developing a broader definition and capacity for science is imperative, as is long-term planning, focussing on recruitment and retention, and investing in facilities.

Discussion included the following points:

- Discussion of scientists must include social sciences as well and not be limited to bio-medical science.
- A substantial proportion of employees in HECS are professionals with degrees other than bio-medical.
- It is critical in areas such as tobacco control and water safety that partnerships be built between Health Canada and others so that the approach is truly a national partnership.
- Innovative approaches must be used to attract people to the Department, including executive interchanges, co-op programs with university students.

6. <u>Health Products and Food Branch</u> (HPFB) - *(Diane Gorman)*
(Please refer to presentation slides)

Assistant Deputy Minister Diane Gorman introduced her branch, noting that Board members would see some very similar themes throughout the presentations because of realignment.

The HPFB mandate is two-fold: promotion and maximization of safety and efficacy. Some people have difficulty with the first part of the mandate because the word promotion makes some people think of advocacy.

In describing the organizational structure of HPFB, the Assistant Deputy Minister said there were 1,600 people in the Branch and a budget of $144 million. The Canadian

consumer must be the focus of all this Branch does. Products represent a risk continuum, on the basis of which decisions should be made.

The ADM spoke to the challenges resulting from insufficient capacity in terms of science, policy, management or promotion in the Branch. There are only a handful of people who do any kind of social science, with investment to date being in bio-medical sciences.

Key challenges and opportunities for the Branch are in the areas of: increasing of new technologies, biotechnology and an increase in public demand for information and involvement.

The ADM pointed out staff in the Branch are very good in protection areas, but promotion and risk communication remains an area where work needs to be done.

Discussion included the following points:

- If you make decisions on what policy comes from bench science, you also want to draw on the best science to devise policy.
- Health Canada must push forward the debate on some issues. The Department must be forward-thinking and not reactive.
- For some researchers, finding statistics related to health in Canada is difficult. The World Health Organization seems to be a better source than Health Canada.
- The federal government's investment in biotechnology pushes forward bench science, while the social-ethical-legal considerations seem to be forgotten. There is a need for research to be integrated.
- Health Canada has to play a very strong role in this area. The Department's voice is one of the most important voices in this area.
- Technology has tended to outstrip ethical and legal issues.
- There remains a lot to be proud of in this Department and we need to showcase it.

7. **<u>Population and Public Health Branch (PPHB)</u>** *(Dr. Wendy Watson-Wright)*
(Please refer to presentation slides)

Dr. Watson-Wright, Senior Director General outlined the mission statement and vision of PPHB, as well as the strategic goals of the Branch. She noted the strategic goals, which are a work in progress, focus the Branch in several areas, including providing service and in policy and program development.

The third goal, which is to establish PPHB as a model and leader in multidisciplinary health research, highlights the Branch's new research capacity. As expressed by other Branches, one of PPHB's goals is to position the branch as a workplace of choice.

There are about 1,200 people in PPHB, which has responsibilities including:
The Centre for Healthy Human Development; The Centre for Chronic Disease Prevention and Control; The Centre for Infectious Disease Prevention and Control; the National Microbiology Laboratory; the Laboratory for Foodborne Zoonoses; the Centre for Surveillance Coordination; the Centre for Emergency Preparedness and Response; the Strategic Policy Directorate; Management Planning and Operations Directorate and Regional Offices.

The Branch also has responsibilities for the National Children's Agenda, including national programs such as the Canada Prenatal Nutrition Program. The key challenge for the Branch is to link everything together under the Wellness framework.

Dr. Watson-Wright outlined areas where she thought the Science Advisory Board could provide input to Branch initiatives, especially in the area of linkages external to Health Canada.

Discussion included the following points:

- Concerns about bioterrorism and its potential activity in Canada were expressed and are shared by those who work in that area in PPHB.
- The Board may be able to provide advice on how to attract scientists to Health Canada.
- Competition for scientists is going to be fierce over the next decade.
- Liaison with CIHR, in terms of understanding and knowing the direction being taken is important for Health Canada.
- Federal-provincial issues have a clear impact on the work done by people at Health Canada, especially since health is a provincial area.
- Health Canada is looked to for leadership.
- It is crucial for scientists to think outside the box and the Department will have to respond to, as well as encourage this kind of method.
- It is important to have a handle of what kind of research is being done, by whom and where.

8. Information, Analysis and Connectivity Branch - (*Kim Elmslie, Acting Executive Director)*
(Please refer to information package)

IACB is in the business of promoting access to the right information, to the right people, at the right time, by using appropriate tools, so that our health system is more responsive to the needs of Canadians and operates on an evidence-based decision-making model.

Two important partners for this branch are the Canadian Institute for Health Information and the Canadian Institute of Health Research.

Important aspects of the work of IACB are analysis, research and evaluation, highlighted by work done in areas such as the impacts of aging, globalization and technology on the health system in Canada.

Ms. Elmslie noted it was important to connect researchers with those making policy decisions, to create a link with targeted research.

Discussion included the following points:

- The ease of access to information because of the internet might change how information is collected and how Canadians use it.
- A discussion on access and who owns what research may be an important one in terms of Health Canada. If the people of Canada fund a research project, who owns the information?
- Communication is the key. It will require some changed thinking in terms of dealing with researchers.
- The Peer Review Process will determine scientific merit.

9. **<u>First Nations and Inuit Health Branch (FNIHB)</u> -** *(Ian Potter)*
(Please refer to presentation slides)

FNIHB's main focus is to assist First Nations and Inuit communities to improve their health, to ensure availability of, or access to, quality health services and to support greater control by First Nations and Inuit persons/ communities over health programs and services.

In support of these goals, Health Canada, through FNIHB, provides to First Nations and Inuit primary care services in remote and isolated communities, public health services, prevention and health promotion programs, addiction services and supplementary health insurance coverage.

There are specific challenges for FNIHB, including a population that is growing at a faster rate and that is much younger than the general Canadian population; serving a population that is highly mobile and providing health services and programs to communities that range from 100 to thousands in population size, often in very isolated and remote areas.

Over the past several years, improvements in health of First Nations and Inuit have been made, but FNIHB clients still have higher rates of heart disease, arthritis, diabetes, infant mortality, suicides and injury than the Canadian public at large.

The Canadian government is committed to transfer control of health care to First Nations, but the challenges of transfer include management of a wide range of services; human resources; reform of the system and provincial integration.

FNIHB currently has the lead in provision of what are considered public health and science activities with respect to First Nations and Inuit communities and populations and is responsible for their water, food, air and soil quality testing and assessment. Links with the Science Advisory Board could include direction, collaboration and suggested new areas of research.

Discussion included the following points:

- Local decision-making is a powerful issue, especially in First Nations and Inuit communities.
- Training and education are tools to help solve these problems.
- CIHR's Institute of Aboriginal People's Health will be working to help solve some of these problems.
- The aboriginal community is reluctant to be treated as research subjects because of past experiences and ethical standards will need to be stressed.
- The notion of partnership between the community and the researchers is an important one.
- Indicators of poor health include poverty, availability of medical care and road access.

10. Health Policy and Communications Branch (HPCB) - *(Ian Shugart, Assistant Deputy Minister)*
(Please refer to presentation slides)

There are three specific files with HPCB: health protection legislation, accreditation of ethics boards and assisted human reproduction.

HPCB provides support to the Department in terms of health policy, it has the lead in the Government of Canada's discussion on the precautionary principle, risk management and other areas.

A comprehensive review of Health Protection Legislation is underway, to update and modernize legislation in the face of new technology, globalization and societal changes. It is impossible to amend legislation to keep pace in a reactive way. The government would adopt a risk level approach and general safety approach.

Health Canada is a small player in the overall spectrum of science. But it is vitally important that the Department remain in the business of science. It is impossible to do everything in-house, so creative thinking about partnerships is essential. Health Canada sets the standards and the policy that is enforced by others. Letting the public know how we make decisions is equally important.

Discussion included the following comments:

- Legislative renewal is envisioned as a consolidation of all the legislation now on the books.
- Increasingly, more information is available to Canadians.
- The trend is to greater transparency, greater rigour in decision-making and more disciplined documentation.
- In some areas, there is increasing co-operation between the provinces and the federal government. In terms of public health, the federal government is needed and is expected to be there.

Day 2- Tuesday, May 8, 2001

In Attendance: Richard Lessard, Allan Ronald, Karen Grant, Paul Paquin, Rodney Ouellette, Stuart Macleod, Neena Chappell, Ardene Robinson Vollman, Stephen Strauss, Irv Rootman, Elizabeth Jacobson

Ex Officio Members: Ian Green, Marie Fortier, Diane Gorman, Kevin Keough, Wendy Watson-Wright (for Robert McMurtry)

Secretariat: Kata Kitaljevich, Valerie Marshall

11. <u>Health Canada: A Report on the Follow-up to SAB's Recommendations -</u> (*Ian C. Green)*

The Deputy Minister reported back on recommendations from the previous SAB meeting, noting that one of the challenges for Health Canada is the organization of the Department.

Looking ahead in the agenda, the Deputy Minister outlined some of the items the Board would be discussing, including aspects of food biotechnology, as documented in the Royal Society Expert Panel Report and Health Canada's response to the report's recommendation. The Deputy Minister also noted the Board would be hearing about post-market surveillance and related topics stemming from the recent Coroner's Report following the death of an Ontario teenager. The action plan is very important, he told the Board.

The Board's continued interest in the peer review process at Health Canada was recognized and the Deputy noted the second pilot project within the Nutrition Research Division would be coming forward to the Board at a future meeting.

As a follow-up to some of the recommendations from the previous SAB meeting, the Deputy said the Canadian Institutes of Health Research continues to be a priority not only for the government, but for Health Canada. The Board advised the Department not to rely solely on CIHR, but to build relationships with others. The Deputy said Health Canada was proceeding slowly on this front and will build the advice into the departmental planning processes with respect to research priorities and research capacity.

Health Canada is in the process of developing the policy framework, administrative centre and educational function for the Research Ethics Board, as discussed at the last SAB meeting.

At the last meeting, the Board expressed concern regarding the perceived lack of co-operation from the CFIA (Canadian Food Inspection Agency) in connection with recent public health concerns. As a result, a Canadian Science Centre for Human and Animal

Health Emergency Response Task Force has been established. The task force, which includes both the CFIA and facility management, will help develop a memorandum of understanding between the National Microbiology Laboratory and the CFIA.

The recommendations regarding Transmissable Spongiform Encephalopathy (TSE) have been taken to heart by the Department and Health Canada is seeking opportunities to pursue the possibility that the CIHR Institute of Infection and Immunity review the Canadian science capacity for prion research in viral and animal diseases.

In looking at current issues, the Deputy noted the establishment of the Commission on the Future of Health Care in Canada and said this exercise would be an important challenge for the Department. When the report is done in 18 months, it will be important to react quickly which will make for interesting policy discussions and dialogue. The Commission will be an interesting opportunity for public engagement.

The Deputy outlined for the Board the establishment of a special Health Canada Secretariat to help increase and co-ordinate safe organ and tissue donation in Canada.

He also reported back to the Board that a joint meeting was held on April 11 and 12th with Environment Canada's Science Advisory Board. The joint meeting proved valuable and it was agreed that further meetings of this nature should be held, the next one to be hosted by Health Canada.

In closing, the Deputy reiterated his support for the work done by the Science Advisory Board.

Discussions included the following points:

- Marie Fortier, the Associate Deputy Minister, noted the recent tabling of the Bill on Assisted Human Reproduction in the House of Commons. The bill will be sent to SAB members by the Secretariat.
- Dr. Richard Lessard and Dr. Karen Grant took the opportunity to brief the Board on the joint meeting held with Environment Canada. Dr. Lessard noted the presentation made to the joint board meeting were interesting and proposed the Board seek opportunities to meet with other departmental SABS, for example, agriculture.
- Dr. Grant proposed hearing more about the Longitudinal Study proposed by Health Canada which will track pregnant women and their children for 21 years. This study would be an important one for the Board to review.
- Dr. Grant also noted there was common ground between the two Science Advisory Boards, especially on topics such as safe drinking water and environmental pollutants. She suggested joint meetings be institutionalized.

12. **<u>Update on Research Ethics Boards</u>** - *(Dr. Kevin Keough)*

In terms of a Research Ethics Board for Health Canada, the Health Research Secretariat has been working since the last meeting to develop a framework. Dr. Keough would like comments back from Board members on the framework.

For research performed by Health Canada, Health Canada should have a research ethics board of its own, rather than relying on scrutiny through other REBs. Where Health Canada funds research externally, we would rely on existing REBs. It is suggested that Health Canada's REBs be composed of a majority of people from outside of Health Canada, although the exact size has not yet been established. The authority would be the Deputy Minister, although the reporting would be in the Office of the Chief Scientist.

The Chief Scientist requested that Board members suggest possible chairs of the REB to him. The person should probably come from the Toronto-Ottawa-Montreal triangle for ease of travel. He also solicited possible names of REB members. The Chief Scientist said it would be best to appoint the chair no later than the end of June, allowing for the final touches to be put on the policy document when the chair is in place.

Discussion included the following points:

- At this time, it is difficult to know what the workload will be for the REB members.
- From previous experience with REBs, it is important for Health Canada to spell out clearly what is subject to review and what is not.
- There were some concerns expressed about the authority of HC's REB: there needs to be clarification on what is meant by "advisory" and that it be clear that some research may be disallowed despite REB approval.
- The process needs to be clear and transparent so that researchers understand why they can or cannot go ahead with research.
- The researchers must also understand how monitoring is to be done.
- The issue remains on whether REB members are to be renumerated

13. **<u>Presentation of the Royal Society Report -Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada</u>** - *(Dr. Brian Ellis, Dr. Conrad Brunk)*

Dr. Conrad Brunk reviewed the Terms of Reference for the Royal Society Report, noting that it is important to understand the terms were very narrow. The terms required the members to look to the future, among other things, to forecast the types of biotech food products being developed for future review, the science likely to be used to develop these products and the potential short or long-term risk posed by development, production and use of the products.

The committee was not asked to evaluate the socio-economic benefits or to consider a broader range of ethical concerns.

The human health concerns identified by the panel were the potential toxicity of novel constituents, allergenicity of novel proteins and the difficulty of identifying new hazards in new products. The underlying issue is identifying unintended effects of single-gene insertion.

The four categories of recommendations included policies and principles, the precautionary principle, regulatory neutrality and benchmark standards.

An ongoing theme in the policies and principles area has been the struggle to maintain an adequate research base that has no ties to industry. A regulated peer review process within the regulatory process was recommended as one mechanism for building confidence in the process.

Fostering public acceptance of this technology and confidence in its safety remain challenges in a world where, within four years, 70 per cent of the North American food supply system has come to contain genetically-modified products.

Discussion included the following points:

- Retrospective studies will be difficult, given the variety of ways food may be used, for example, corn, corn syrups.
- Research has a long way to catch up to the changes.
- The scientific expertise exists in Canada. Scientifically, there is a consensus as to what needs to happen next. The political context is where the differences may lie.
- Labelling was the most contentious of the recommendations within the panel. It is an area where the public is making demands.
- There was some concern that the panel recommended voluntary, rather than mandatory labelling.
- There are some problems inherent in labelling: do you label the end product or do you label each of the ingredients?

14. **<u>Health Canada Analysis of the Royal Society Report</u>** - *(Dr. Karen Dodds)*

Dr. Dodds said Health Canada is working with other affected departments in preparing an action plan in response to the report. The intent is to make the action plan publicly available on the Department website. She reminded the Board the report was requested by the Ministers of Health, Agriculture, the Canadian Food Inspection Agency, Environment

Canada and Fisheries and Oceans.

The recommendations of the Royal Society Report target future needs. The recommendations help Health Canada to direct future developments and re-affirm that the regulatory system for GM foods needs to be continually reviewed, especially since the science and the application to products continue to evolve.

On the recommendation of substantial equivalents, Health Canada agrees that GM-foods should be subject to rigorous scientific assessment. Documentation will be revised and discussions will continue at the national and international level to develop effective tools to assess GM-foods.

The recommendation concerning the precautionary approach is also supported by Health Canada. With regards to transparency of the process, more work needs to be done. Health Canada acknowledges that it is not meeting expectations in this area. In action areas, the Department can publish all decision documents, ensure all documentation is complete and accessible and work with industry to achieve greater openness regarding specific product information.

Regarding external validation of the process, Health Canada agrees with the principle and the benefits of the recommendation and is working towards how best to ensure validation of assessments.

Other areas of agreement and further work include criteria regarding toxicological testing, safety evaluation of whole foods, alternatives to antibiotic-resistance markers, allergenicity and no approvals for feed-only.

Discussion included the following points:

- Some of the recommendations go beyond the four regulatory agencies. Better information would be available if resources were targeted specifically in these areas.
- In these cases, it would be beneficial to work with partners.
- Who pays for the testing when people's health needs to be protected? Can the industry be asked to pay?
- If there is labelling, it should be meaningful.
- The co-chairs of the panel are pleased with the response of the departments and agencies. The process is ongoing.

Recommendations:

- *The Board recognizes the quality and thoroughness of the report by the Expert Panel on the Future of Food Biotechnology.*

- *The Board recognizes the complexity of the issues and supports the proposed Health Canada actions.*

- *The Board would like to see a progress report on the Health Canada actions at its December 2001 meeting.*

15. **Health Canada Science Advisory Board - Terms of Reference** *(Dr. Richard Lessard)*

The Board examined new terms of reference for SAB which resulted from realignment of Health Canada in 2000. The initial mandate of the Board was to give advice to the Health Protection Branch. With realignment, it became obvious that the mandate should be broadened to provide advice to the whole department.

Recommendation:

- *The Board has reviewed the revised Terms of Reference and has proposed some minor modifications which will be considered by the Department and brought back to the next Board meeting as a final document .*

16. **Post-Market Surveillance: Issues Arising from Recent Coroner's Inquest** *(Dr. Robert Peterson)*

Before this discussion began, Dr. Stuart McLeod noted he had been an expert witness on behalf of the coroner at this inquest.

Dr. Peterson presented the action plan by Health Canada in response to recommendations from an April 24, 2001 coroner's jury report on the cause of death of Vanessa Young, 15, who died of cardiac arrest while on Prepulsid (cisapride). The verdict attributes the cause of Ms. Young's death to be brain damage following a cardiac arrest resulting from the effects of an eating disorder, Bulimia Nervosa, in conjunction with cisapride toxicity and a possible underlying congenital defect of the heart. The means of death was found to be accidental.

The jury made a total of 59 recommendations, including 14 recommendations directed at Health Canada. These recommendations were directed at Health Canada, the Pharmaceutical Industry, the Ontario College of Physicians and Surgeons, the Ontario College of Pharmacy, the Ontario College of Family Physicians, Ontario Medical Schools, the Ontario Colleges of Nurses, the Ontario Ministry of Health and the Ontario Coroner's Office.

Health Canada is committed to giving careful consideration to the recommendations provided by the Coroner's Jury.

Dr. Peterson provided perspective around the recommendations by outlining drug interactions with QT intervals. Drug interactions, dosages, genetic issues and other factors can have an effect on how individuals react to a drug. In pre-market studies, often these effects are not seen. When there are adverse drug reactions, the ADRs are often not reported for a variety of reasons.

With specific reference to Cisapride in Canada, there were 14 fatalities, including 10 cases with cardiac-related deaths. Most of these deaths involved elderly people on a variety of other medications. Canada was the first country to take Cisapride action. It was voluntarily removed from the market by the company.

Despite attempts to refine prescribing practices, the drug was widely utilized in Canada outside its approved indications. There are now several hundred patients getting Cisapride under the Special Access Program.

The Action Plan outlines several areas of possible changes given the recommendations, including improved communication at all levels, enhanced reporting of ADR's, a co-ordinated international ADR discussion forum and a proposed program on awareness of the seriousness of eating disorders.

Health Canada will fund appropriate recommendations and report back to the Chief Coroner in one year.

Discussions included the following points:

- Post-market assessment is problematic and it is essential that information be shared.
- Changes in how doctors record information, perhaps by computers, might facilitate improvements in reporting ADR's.
- There is a psychology in reporting problems, especially where there is blame that might be attached.
- It is important also for patients to understand ADR's.
- There are some actions that can be taken more quickly than others. Perhaps these should be phased in.
- The concern about health and medical errors is rising in the profession as a whole.

Recommendations:

- *The Board recognizes that Canada needs to continue to improve its post-market surveillance system and appreciates how difficult this area is.*

- *The Board urges Health Canada to continue to develop the proposed Action Plan and would like to review progress on the Action Plan at its October 2001 meeting.*

17. **Canada's Role in Global Health Research** - *(Dr. Allan Ronald)*

Dr. Allan Ronald presented his concept paper on Canadian Collaboration on Global Health Research to SAB, pointing out that the burden of disease falls on the less developed, less resourced, poorer nations and regions of the world.

Canadians are affected by global health problems in various ways: multi-resistant diseases and tropical diseases arrive via immigration and trade.

There are a number of agencies in Canada that are involved in global health research, notably CIDA (Canadian International Development Agency), CIHR, the International Development Research Centre (IRDC) and Health Canada, although most of the research has been of a fragmented nature.

Canada has a competitive advantage in the area of global health given our good reputation, bilingual capacities and good research expertise. What is needed is a strategy to work together in order to expand our involvement in global health research and to further develop Canadian expertise in this area.

Discussion included the following points:

- This is an extremely important initiative. Universities are increasingly ready for this.
- Most countries in the world are not financially able to conduct this kind of research.
- Ninety per cent of health research is being done on conditions that affect 10 per cent of the world's population.
- It is not that we are not active in research, it is just that there is no overall plan.
- The plan should include all developing countries, not just the continent of Africa, but Asia as well.
- The Chief Scientist will report back in the fall on an inventory of international activities.

18. **Forward Planning Agenda** - *(Monte Doyle, Intersol Consulting Associates Ltd.)*

Mr. Doyle presented the SAB with an overview of the results of a survey completed by the Board members the previous day highlighting various interests. (See Annex 1)

Members discussed adding various items to the list, which will be revised and sent back to them. Areas of interest will be included in upcoming agenda items.

Meeting adjourned at 3:15 p.m.

Annex 1

Health Canada
Science Advisory Board
Reflection on priorities for the S.A.B. agenda for 2001-2001

Based on your personal integration of the Agenda of the past year; of today's discussion of orientation and substantive issues; of the Terms of Reference as discussed today; and your own personal assessment of trends and factors, what are the agenda topics that you feel would be most important for the S.A.B. to address in the coming year. The idea is not to brainstorm a long list of potential topics, rather to identify the shortest list of top priorities in order to achieve a focused application of the value-added role of the Board. Simply put, the thrust of this reflection is to get your sense of the "vital few"priority issues which should form the core of the Board's agenda for the new year. For each topic, please complete the following template. There is no minimum number, but please limit your topics to a maximum of 5. Please be brief in your comments.

❶TOPIC NAME:	OVERALL PRIORITY:	❑ H = must do
		❑ M = important to do
		❑ L = nice do to
DESIRED OUTCOME (What is it about the issue that warrants the attention of the S.A.B. and what is the nature of the advice that the S.A.B. should develop. Said another way, what is the specific question that the advice of the Board would be intended to answer)		
LINK TO MANDATE (How does this topic link to the Mandate of the S.A.B.)		

WHEN IS THE ADVICE NEEDED - Are there aspects of timing, sequence etc. that are important for scheduling?

. . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . .

❷**TOPIC NAME**:	**OVERALL PRIORITY**:	❑ H = must do ❑ M = important to do ❑ L = nice do to

DESIRED OUTCOME (What is it about the issue that warrants the attention of the S.A.B. and what is the nature of the advice that the S.A.B. should develop. Said another way, what is the specific question that the advice of the Board would be intended to answer)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

LINK TO MANDATE (How does this topic link to the Mandate of the S.A.B.)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

WHEN IS THE ADVICE NEEDED - Are there aspects of timing, sequence etc. that are important for scheduling?

. . . . . .
. . . . . .
. . . . . .
. . . . . .

❸**TOPIC NAME**:	**OVERALL PRIORITY**:	❑ H = must do ❑ M = important to do ❑ L = nice do to

DESIRED OUTCOME (What is it about the issue that warrants the attention of the S.A.B. and what is the nature of the advice that the S.A.B. should develop. Said another way, what is the specific question that the advice of the Board would be intended to answer)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

LINK TO MANDATE (How does this topic link to the Mandate of the S.A.B.)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

WHEN IS THE ADVICE NEEDED - Are there aspects of timing, sequence etc. that are important for scheduling?

. . . . . .
. . . . . .
. . . . . .
. . . . . .

❶TOPIC NAME:	OVERALL PRIORITY:	❑ H = must do
. . . . .		❑ M = important to do
. . . . .		❑ L = nice do to

DESIRED OUTCOME (What is it about the issue that warrants the attention of the S.A.B. and what is the nature of the advice that the S.A.B. should develop. Said another way, what is the specific question that the advice of the Board would be intended to answer)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

LINK TO MANDATE (How does this topic link to the Mandate of the S.A.B.)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

WHEN IS THE ADVICE NEEDED - Are there aspects of timing, sequence etc. that are important for scheduling?

. . . . . .
. . . . . .
. . . . . .
. . . . . .

❺TOPIC NAME:	OVERALL PRIORITY:	❑ H = must do
. . . . .		❑ M = important to do
. . . . .		❑ L = nice do to

DESIRED OUTCOME (What is it about the issue that warrants the attention of the S.A.B. and what is the nature of the advice that the S.A.B. should develop. Said another way, what is the specific question that the advice of the Board would be intended to answer)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

LINK TO MANDATE (How does this topic link to the Mandate of the S.A.B.)

. . . . . .
. . . . . .
. . . . . .
. . . . . .

WHEN IS THE ADVICE NEEDED - Are there aspects of timing, sequence etc. that are important for scheduling?

. . . . . .
. . . . . .
. . . . . .
. . . . . .