REPORT OF THE FIRST MEETING OF 2000

RAPPORT DE LA PREMIÈRE RÉUNION de 2000

SCIENCE ADVISORY BOARD

LE CONSEIL CONSULTATIF DES SCIENCES

April 4-5, 2000

les 4 et 5 avril 2000

Health Canada
April 2000

Santé Canada
avril 2000

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Day 1 - April 4, 2000

1. Welcome and Roundtable Introductions - (Chair)

Dr. Bondar welcomed the members to the first meeting of the new Science Advisory Board (SAB).

2. Secretariat Roles and Responsibilities - (Kata Kitaljevich, Senior Advisor, SAB Secretariat)

The roles and responsibilities of the Secretariat to the SAB were reviewed.

3. Mandate of the Science Advisory Board - (Chair)

The Mandate of the Board was reviewed. The Minister of Health established the SAB in 1997 to provide him with independent advice on how best to position the scientific, technical and policy aspects of HPB programs now and in the future. The Board's responsibilities include the following; advising on ongoing measures required to ensure HPB science retains the confidence of the public; examining previous decisions to ensure the adequacy of the in house scientific base to meet current and future scientific challenges; reviewing and advising on the scientific and technical adequacy of HPB programs, procedures, methodologies, protocols, and tests; reviewing and advising on the adequacy and scientific basis of frameworks for proposed guidelines, standards or regulations under legislation administered by HPB; recommending, as appropriate, new or revised criteria or standards for setting priorities for public health issues and programs; reviewing and advising on new information needs and on future human resource needs for scientific and technical programs; providing advice on partnerships and strategic linkages with local, regional and international agencies; recognizing the particular importance of collaboration with provinces and territories; and reviewing and advising on scientific and technological trends in a global context and the issues and opportunities that are driving this change.

4. Approval of the November 1999 SAB Meeting Report

The members discussed the format and content of the report. They provided direction on the revision of the meeting report to make it more accurate and complete.

Conclusion:
The report will be revised and sent electronically to members for comments and approval.

5. Drug Review Process Report - (Doug Elliott, Chair, Sub-Committee)

The Report on the Drug Review Process will be formally presented to the Minister on April 4th and will be in the public domain the following day. The Chair of the Sub-Committee provided the new members of the Board with a brief outline of the background of the report and the activities of the Sub-Committee.

6. Peer Review - (Dr. Robin Hill, Project Manager, Science Platform)

The advice of the Board from previous meetings stressed the need for systematic peer reviews and for the integration of processes. Peer review is essential for public confidence and wise expenditure of public dollars.

For the recently conducted pilot project, HPB proposed a different way of doing peer review. A working group was established and looked for scientific work conducted across the branch, and chose the Endocrine Disrupting Substances Working Group for review. The Medical Research Council (MRC) assembled a panel and conducted a site visit last month. The review looked at how the group was managed, laboratory work linked to the regulatory process, and how the group work could be improved. The panel was also asked to review the process itself.

The lessons learned will be applied to a second pilot project on nutrition, a subject which has strong connections to the Health Promotion and Programs Branch and external organizations. After this pilot, the next step will be to develop a framework for peer review across the Branch.

Discussion included the following comments:

- Concerns were expressed about how the report will be presented. It is a review of peers to peers, not to managers. It is important that the report goes as quickly as possible to the investigators.
- ED group should receive official recognition by HPB, along with appropriate senior management and an effective management structure.
- The report should offer a summary overview of what and who is being peer reviewed, budget, organizational structure, who does what, outstanding achievement, to provide a sense of the object of the group being reviewed.
- HPB will need different models for peer review to be systematically applied. Responsibility for research cannot be compartmentalized in directorates and have it function.
- The Board would like to see lines of enquiry, responses, and follow-up.
- The Board expressed an interest in hearing an assessment of how the mixed peer review system worked.
- Since the second pilot on nutrition is more program development than research oriented, it might provide more and different information.
- Skill set in panel is vital. Issues to be addressed will differ from time to time.
- Defining the mission, objectives, and goals is essential; capacity needs will become

apparent and the direction and gaps will be identified.

Conclusions:
The SAB requested that:

- *The MRC report, apart from the section dealing with the evaluations of individual scientists, should be distributed as soon as possible, respecting the confidentiality of the material.*
- *The evaluations by the Review Team of the individual scientist's performance should be distributed as soon as possible, respecting the confidentiality of the material.*
- *Staff and managers should be invited to submit their comments on the MRC report which should be forwarded to Mark Bisby of the CIHR (MRC) for his consideration.*
- *At the September 2000 meeting of the Science Advisory Board:*
  - *the director of the EDSWG is to report back on how they have implemented recommendations 4, 5 and 6 of the MRC report. The Board requested that Mark Bisby of the CIHR (MRC) also be present; and*
  - *the Health Protection Branch update the Board on the implementation of recommendations 7 and 8 of the MRC report.*

The Board recognized the need to establish a well-structured office for peer review within HPB/Health Canada, both for coordinating external reviews that may be conducted within the CIHR context as well as for purely departmental purposes, including the review of program development.

The Board requested that an observer from the SAB participate as an observer in all future peer review processes.

The Board commended Dr. Hill and Mark Bisby for their efforts.

7. The Minister of Health - (The Honourable Allan Rock)

The Minister of Health, the Honourable Allan Rock, met with the members of the Board. He thanked the Board for their guidance and expertise, which have been instrumental in the efforts to strengthen Health Canada's role in protecting the health and safety of Canadians and to ensure that the department's science retains the confidence of the public. In his remarks, he highlighted recommendations of the Board that have been acted upon, including the Office of the Chief Scientist, the Office of Consumer Affairs and Public Involvement, peer review, the Canadian Institutes for Health Research, and the.Drug Review Process Report. Minister Rock welcomed future advice from the Board.

8. Overview of Issues and Events involving HPB - (Diane Gorman, A/ADM, HPB)

The Transition Initiative's five themes provided an opportunity to look at the way HPB does business.

- With respect to risk management, the Branch has been rigorous in using the Decision-Making Framework at its formal Risk Management meetings; the challenge is to ensure that discipline is brought to the ongoing work. Training programs for staff and managers are being developed.
- Program development is looking at programs which cut across the Branch and to other Branches.
- The status of Legislative Renewal will be discussed at a future meeting.
- The surveillance initiative originates with the Deputy Ministers of Health meeting in 1999 where they endorsed national surveillance. This issue will be discussed in more detail at a future meeting.
- The Science Platform work is continuing and members will be provided with status reports as work continues.

The Office of Consumer Affairs and Public Involvement (OCAPI) received funding in March 2000. It is now ensuring that it has the capacity, staff, tools, and focus on the types of public involvement before it opens for business.

9. Office of Natural Health Products – (Sharon Chard, Heather Throop, Office of Natural Health Products)

An update on the status of the Office of Natural Health Products was provided to the members.

Discussion included the following comments.

- There could be opportunities with health surveys to inject questions about use of NHPs, in addition to risk assessment.
- Board members expressed interest in following the regulatory process and how regulations will fit with legislative renewal.
- Concerns were expressed about reviewing monographs, proposals for research, and appropriate peer review.
- Standing Committee on Health focussed on availability, freedom of choice, safety, quality, accurate labelling which look to efficacy; however, safety is recognized to be paramount. Proper standards of evidence must be developed.

10. Risk and Health Policy - (Dr. Nuala Kenny)

(Because handouts were not provided to the Board, the record is presented here in some detail)

Dr. Kenny's presentation included the following comments:

- Science and technology offers so much benefit, but with a risk of harm.
- At the level of policy, when government makes a policy decision about benefits to the Canadian public, it is the same type of decision as between doctor and patient.

With the best scientific evidence, but dealing with a large population, it is more difficult to determine what risk/harm will be acceptable.

- What do we bring when we bring scientific information to the table? What are the values and how do we elicit them in the public? What is a reasonable risk, an acceptable harm?
- Risk assessment is discussed in medical literature as being the statistical significance of benefit. There is also the risk perception literature from psychology and the social sciences. Both are required for risk communications.
- Good health decision-making should be based on evidence and values. More attention must be paid to the values in the evidence – who chooses the research agenda and what are the outcomes?
- Risk is an adverse future event with two components – the magnitude of harm, and the possibility of occurrence. If you see a big benefit, you downsize the risk, and vice versa – sometimes to the point you don't see the other side at all.
- Excellent science is necessary, but not sufficient. In risk situations, we tried to make the numbers better, but it has to be seen in the context of public perception of risk. We too often think of risk as a mathematical construction rather than a social construction. It is about balance and implicit values.
- Risk assessment is not an exact science; it has inherent uncertainties. As we make a judgement of risk, facts, inferences and values on the meaning of the numbers – all of this involves values. Science is replete with values, including the value of empiric evidence.
- Presentation of evidence influences judgement. How it is presented and the language used are important. At the end of the day, it is trust in the one who delivers the message. What are the implications for government and regulators?
- Risk is about numbers, but not only numbers. When policy makers pass judgement on what is safe, it is replete with values.
- Personal experience helps define the risk perception, regardless of the numbers; some people are risk adverse, some are risk takers. Health care decisions must be respectful of the people; however, a common perception of a societal risk is more complex. Control of a risk becomes important; a paradox of modern life is that one might take risks like bungee jumping and smoking, but express concerns about a 10% chance of an adverse reaction of a drug.
- If there is trust in the media, the place where most get the information about their health risks, but not in those who control the risk, a result can be that when the risk managers try to convey there is no risk, people perceive there is. Openness about uncertainties in doctor/patient relationships can heighten trust. In the policy area, however, it heightens distrust.
- One must exercise care in the use of language and images of risk. If a risk is seen as uncontrollable or abnormal, the dread factor or perception of susceptibility is very high.
- Some empirical work has been done on factors affecting risk perception. Scientific data is the lowest of the most important factors in determining a personal

determination of risk; most important is trust in the credibility of who delivers the message. Caring and empathy are very important to risk communication, but are very difficult for a government to convey, especially in paper communication.

- There is a difference between expert and public language about risk. General public perception is that this works, or it doesn't; science talks in terms of comparative risk.
- There have been three "eras" in risk communication. First was the risk assessment, which stressed getting the numbers right. Then, governments became more aware that the issue was communications – how to tell the public that the numbers are right. Now, the challenge is not only good science, but how to deal with risk; this is centred on trust and community involvement.
- Media coverage is not related to the seriousness of the event. Media tells you what risk to think of, not what to think about the risk. Media frames the event; if the media decides something is an issue, there's a lot of coverage, usually alarming content or outrage, not about the analysis of the risk itself. Little technical information is in the story. Media makes a judgement about the meaning. The challenge for health communicators is to develop a better balance with the media.
- Perceptions are realities. The perception must be dealt with. Trust and credibility must be maintained, because the numbers can never be "right". Expectations have changed.
- The Krever Commission spoke of the precautionary principle; we cannot wait for science, and we have to pay more attention to the public perception and trust in government. We wait too late for public involvement of the risk and its meaning. There are huge resource implications – "HC should have known". The question has not been put to the public on the balance between freedom of choice and the resources required to mitigate other risks.
- Risk assessment must go forward; but early public involvement is essential; ultimate freedom and ultimate protection are mutually exclusive, but who represents the community in the decision? A potential consequence of hyper-vigilance can lead to paralysis.
- We must move from "we're the experts"; until we can engage risk that way, we cannot address how the public perceives risks.

Discussion included the following comments:

- Capacity in the government is often just firefighting instead of professionally thinking through the issues, what the messaging should be.
- Concern was expressed about use of the term scientist as a homogenous term; social scientists have accepted that research is value laden.
- Writing about science for public consumption can introduce the vocabulary which frames the discussion.
- Risk redefinition is where research is needed, where the new strategies are, power of language. Modern folklore and contemporary legends speak to what we know as a society, well evolved beyond risk perceptions. Need to bridge those two literatures

– how did this become a contemporary legend?
- Even "caution" can be value laden.

Conclusion:
The Chair thanked Dr. Kenny on behalf of the Board for her insightful, informative and exciting presentation.

Day 2 - April 5, 2000

10. Council of Science and Technology Advisors (CSTA) Report - Building Excellence in Science and Technology (BEST) - (Dr. Yves Morin, Vice-Chair, SAB)

The BEST Report is a report to Cabinet on the federal government's role in science and technology and its future capacity to perform this function. Because of globalization (harmonization), public expectations, knowledge-based economy and society, diversity of

options, the government is no longer the sole or leading player; it is now part of an innovation system. The primary constituents – government, universities and industry -- should collaborate. Capacity issues are extremely serious; human resources – lack of advancement opportunities, ageing work force, inflexible rules, wages; rust-out of facilities and platforms; ability to address mandates, forward look at new challenges; management information on science and technology activities is inadequate.

Three fundamental principles should be applied to all research conducted by the federal government: Alignment, Linkages and Excellence. Recommendations of the Report included integration of the three principles to the department's priority setting and delivery; annual planning and reporting mechanisms, including science and technology priorities; new models for science and technology that move away from vertical approach (e.g., CIHR); sufficient resources for federal science and technology, and, Science Advisory Boards to regularly assess departmental reports on implementation of the recommendations, to review with Minister and report to CSTA that recommendations are being implemented.

The next report of the CSTA will be on the role and functions of science advisory boards across the departments; a comparison of all the boards, and recommendations.

Discussion included the following comments:

- Concern was expressed about the concept of annual planning and priority setting; research development is a multi-year process that cannot be scrutinized only an annual basis.
- For government, annual priority setting is required. The suggested role of the Board in planning is to ensure it is being done; not to micro manage.
- Departmental officials said that growth in the Branch might not be in research science, but in regulatory science.

Conclusion:
The Board accepted the report and will review the recommendations and see if they are being implemented. The Board agreed that it should be more explicit in its review of priorities, on an annual basis, and in the review of its performance, it should ensure that the three principles are applied. With respect to the fifth recommendation, the Board should take an active role in assessing the implementation of the recommendations.

11. CIHR - (Dr. Joe Losos, former ADM, Health Protection Branch)

The Canadian Institutes for Health Research (CIHR) is an attempt to strengthen and transform the way research is done in Canada, in areas such as women's health, aboriginal health, ethics in research, genetics/genomics, infectious diseases. A discussion paper, using genomics as an example, was tabled in March; it was an operational proposal on how the CIHR might work.

Six levels of partnerships were suggested. Health Canada should sit on the advisory boards of institutes, to access the peer review and other mechanisms, tap into training, work with post doctorals. HC scientists should be able to be members of the teams applying for CIHR funding. CIHR should have access to HC facilities, e.g., Winnipeg lab. There should be an exchange and placement of personnel, and the use of CIHR expertise to support HC science capacity. CIHR would assist in the capacity of Canada to be available to the WHO (and others), to be an outreach for global response., e.g., outbreak, environmental spills – rapid mobilization to deal with crises; a good showcase and experience for Canadian researchers. A more long-term possibility would be to create a network of Canadian capacity for global response.

Next steps include the creation of a secretariat for academics relations; a formal agreement and commitment to various levels of collaboration, perhaps via a Memorandum of Understanding (MOU). Health Canada will sit on the advisory boards of relevant institutes. The department might choose areas of priorities in which to develop prototypes for linkages and program delivery, e.g., proteomics, genomics, population health and nutrition.

Discussion included the following comments:

- Health Canada must be involved in the relevant institutes from the beginning.
- A secretariat for academic relations is a good idea, and a MOU is a good starting point.
- Health Canada scientists must be allowed to apply for CIHR grants. Conflicts will be managed; there are already issues in peer review because of the science community's small size.
- Concern was expressed that the work of regulatory scientists will be divorced from scientific research; rotating fellowships were suggested as a way to mitigate this potential problem.
- Service research, such as Genome Canada which can bring forward new technology, new expertise, and provide it to others, is an important component.
- An issue to be considered is how to evaluate more targetted research.

Conclusion:
The Board accepts the document and approves the next steps: integration with CIHR at institute level of advisory board; scientist exchange, Health Canada scientists to participate in investigator-driven research and applying for grants.

12. Biotechnology and the SAB – (Joel Weiner, A/Director General, Policy, Planning and Co-ordination Directorate, Marc Le Maguer, Director General, Food Directorate)

The purpose of the presentation was to provide a context of what is currently underway and to identify gaps. GM Foods can be considered a case study, a surrogate for concerns about biotechnology in general and the regulatory system. There are profound questions that must be addressed: ethical, legal and social issues, trust in the regulatory system,

labelling and the definition of biotechnology itself.

Products of biotechnology on the market today are simple ones; foresight suggests a great increase in volumes and complexities. There are a number of activities currently underway to address these issues. Health Canada has contracted with the Royal Society to advise the department, the Canadian Food Inspection Agency (CFIA) and Environment Canada on forecasting, potential risks, gaps in current regulatory system; the report is due in eight months.

The Canadian Biotechnology Advisory Committee (CBAC) was established to broaden the range of advice to government, not to ignore scientific and regulatory elements, but to add other perspectives on the ethic, social and legal side. Their work plan is to broaden the debate beyond the science and the context of agriculture and food production; the report is due in the fall. The Royal Society plans to collaborate with the CBAC.

The Canadian Agri-Food Council has a biotechnology subcommittee which is looking at the economic impacts of mandatory labelling on consumers, industry and government.

Parliamentary hearings will be undertaken on the needs of Canadians for information on biotechnology and GM foods; more than one committee might review it jointly. Although this series of hearings may begin with focus on information needs, e.g., labelling, it is likely to become much broader.

Work is being done internally; funding was received in Budget 99, also Budget 2000, for regulatory enhancement. Knowledge acquisition is a fundamental part of strengthening the regulatory system. One of the proposals is to use disease surveillance capacity to look at the issue of long-term testing; there may be a need for an independent body for long- term testing to help public confidence.

Once all the reports are received, the Board could advise on their syntheses, priorization and implementation. There are issues which are not addressed – definition of long-term testing; public involvement in technical subjects; risk communication; recruitment and retention of scientific staff (competing with other departments, private sector, with US); engaging scientists in the debate, as a group, not just as individuals. It was suggested that the department could learn from the discussions of the Board recommendations for developing or improving the development of public policy profiting from learned debate.

Discussion included the following comments:

- A strong plea was made to initiate an open and transparent program of hands-on research and testing in food safety and not to rely solely on industry results.
- There is a need for openness on research, sponsored by other than industry and government. Science will not be the only factor in forming opinions.
- Concern was expressed that pending legislation, for legislative renewal and

reproductive and genetic technologies, will be an inhibitor of research. A diversity of scientific views should be debating the issue, a major lively open debate.

- A lesson from the Krever enquiry is about process and communication; as soon as people get the sense that the information is controlled and managed and packaged, and their anxieties are not addressed, it is a formula for disaster. This is not just about the substance; science is not the most important thing in risk communication.
- There is a need for research on communications, on public views, not just biomedical research. Input from and partnerships with consumer representatives would be useful, but must be done to ensure that consumers' diversity of opinion is taken into account.
- The quintessential element is trust – the government must be seen to be open and listening to the public and the scientific community.

Conclusion:
Biotechnology and related issues will be discussed at future meetings of the Science Advisory Board. The Board will provide advice on a policy framework, which will be based on the integration of analyses of current initiatives.

A forward agenda for the year 2000 was developed.

Meeting adjourned.

Next Meeting: June 2000