FINAL

REPORT OF THE THIRD MEETING OF 2000

RAPPORT DE LA TROISIÈME RÉUNION de 2000

SCIENCE ADVISORY BOARD

LE CONSEIL CONSULTATIF DES SCIENCES

September 12 - 13, 2000
les 12 et 13 septembre 2000

Health Canada **Santé Canada**
September 2000 **septembre 2000**

---------- **Note:** Contents of the Meeting Report are a reflection of the discussions of the September 12-13, 2000 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 12 et 13 septembre 2000. 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.

D R A F T

Day 1 - Tuesday, September 12, 2000

In Attendance: Roberta Bondar, Yves Morin, Doug Elliott, Lynn McIntyre, Allan Ronald, Elizabeth Jacobson, Russ Graham, Karen Grant, Rodney Ouellette, Carol Herbert, Stuart McLeod, Michel Bergerson, Leslie Millin, Gabriel Plaa, Neena Chappell, Richard Lessard.

Ex Officio Members: Diane Gorman, Robert McMurtry, Dann Michols, Mark Bisby (for Allan Bernstein

Secretariat: Kata Kitaljevich, Suzanne Bassett

1. <u>Opening Remarks</u> - *(Chair - Roberta Bondar)*

The Chair welcomed the members to the September meeting of the Science Advisory Board (SAB). She briefly reviewed the business and agenda for the meeting. The Chair also reviewed the Science Advisory Board's mandate to provide advice to the Minister. She stressed the importance of having a general discussion on the issues, coming to a conclusion and providing clear advice from the Board to the Minister. Members of SAB were requested to bring forward issues they feel should be dealt with before the end of the year. It was agreed that members were to let the Secretariat know their language preference with regard to mailouts, while ensuring copies in the other language will be available.

2. <u>Approval of April 2000 SAB Meeting Report</u> - *(Dr. Yves Morin, who chaired last meeting)*

Members were requested to provide comments by the end of the meeting; the records will be deemed approved with amendments.

3. <u>Health Canada Realignment - Progress Report</u> - *(Dr. David Dodge)*

On the topic of Realignment, the Deputy Minister said by the end of June, Health Canada had met its target for proceeding. He described the period of time between April 17 and the end of June as a very productive time. Health Canada is now in the second part of the endeavour, which is to bring about the cultural change that must occur if Health Canada is to perform well in the 21st century. The Deputy Minister also updated the Committee on the search for a Chief

Scientist. Other senior appointments have been made.

The department is now working towards changing its culture. One of the ways is through the involvement of senior managers in the departmental Management Council. A key objective is to increase openess in the decision-making process in the department. Another element is that of partnerships, collaboration and cooperation with outside groups. CIHR is an important linkage, not just for getting the work done, but for building the culture of excellence. Linkages with respect to the scientific work done within the government of Canada are also important. For example, the Winnipeg Laboratory is a world centre of excellence, and collaboration is needed, not only within the department, and with CFIA, but also with the Universities of Manitoba, Saskatchewan, Guelph and with the Manitoba Department of Health and the Winnipeg Health Authority.

The department needs to build internal capacity in the new disciplines through collaboration. The department is competing with industry and academe, especially in the high-demand disciplines. It will require creativity to deal with this, and the Board's advice would be welcome on this issue.

One of the greatest objectives is to improve the department's capacity to manage risk The Department is working towards a greater synergy between protection and promotion activities, to bring together all the evidence available across the full range of science. Improved surveillance is key to better risk management decisions. Health Canada will put more resources into this area, but progress is being made now. A Risk Management Committee that is department-wide at the ADM level has been created. The Chief Scientist, once appointed, will also have a role on the committee.

Discussion included the following comments

- Concerns were expressed that Health Canada research scientists need additional support, with respect to recruitment, facilities, processes to address their concerns.
- Encouraging HC scientists to compete for CIHR grants puts a focus back on doing good science.
- The fundamental question which the department needs to address is what is meant by science. Partnerships and using knowledge generated elsewhere are very important. The questions that must be asked include What is science in Health Canada? What must be done in-house? What kind of relationship does the department have with academia?
- Reviewers and research scientists are not interchangeable; the types of scientists are different and are often drawn by different reward systems.

The Chair thanked the Deputy Minister for his participation and remarks.

4. <u>Follow-Up Report on the Recommendations of the Board's Drug Review Process Report</u> - *(Dr. Robert Peterson)*

Dr. Peterson provided an overview of Health Canada's initiatives in response to the recommendations of the Report. The HIV/AIDS group came forward with 29 recommendations, while the SAB Report noted 12 recommendations, which were overarching concerns on resources, financial and human. Realignment will see TPP have a new identity in the future - there will be a new Directorate of Biologics and Genetics as well as the Therapeutic Products Directorate. The recommendations apply to both TP Directorate and to the Biologics and Genetics Directorate. TPP has largely accepted the recommendations, particularly the overarching ones. Human resources are a priority and that process has begun. As an ongoing oversight activity, an advisory panel, chaired by Dr. R. Goyer, has been formed. The first meeting is September 12-14 and the committee will continue to review progress towards the recommendations and is a first step in the transformative activity. The minutes from that committee will be shared with the board.

Therapeutic Products will either grow larger, with more people working on submissions, or work towards a collaboration and consortium with others through mutual recognition agreements. TPP will be exploring pilot projects over the next year.

Discussion included the following comments:

- Greater transparency and orphan drugs are two major issues. Health Canada is encouraging release of monographs and is working with stakeholders and industry on how to make product monograph more accessible. This is a prelude to legislative change and the consultative portion of that is underway now. Orphan drugs have a different problem, because of the difficulty in defining what an orphan drug is and the relatively small population base they serve.
- Some of the drug submissions are waiting in the queue because the "breakthrough" drugs are being dealt with on a priority basis. This situation may occur more frequently in the future because of rapid developments through biotechnology.
- Safety, efficacy and quality are the criteria.

Recommendation:

The Board was encouraged by the report of the progress toward implementing SAB's Drug Review Process recommendations, and in particular, by the increase in appropriations for the TPP. The SAB reiterates its advice that the legislative framework which results from the renewal process should have the flexibility to permit an "orphan Drugs" or similar program. The legislation must also ensure greater transparency in the drug review process in accordance

with the SAB Report.

Dr. Peterson was thanked for his presentation by the Chair.

5. <u>Strengthening Health Canada's Science Capacity -</u> *(Dr. Robin Hill)*

In the consultations that were held within the Department on Science Capacity, a main question asked was what was meant by science and science capacity within the department. The challenge is to ensure that Health Canada maintains, and strengthens, its essential science capacity during the process of departmental realignment and that there is a strong sense of cohesion and purpose within the science community.

Scientists are those who apply the scientific method: set up a hypothesis which is testable, test the hypothesis and it must be testable by others. They are often users rather than producers of scientific knowledge. Science Capacity is about building and improving an organization's human resources, facilities and equipment so that it is able to deliver the science needed both now and in the future. The department needs to enhance professional pride, recognition and job satisfaction.

There are strong messages from the consultations: the need for a clear mechanism for prioritization and good strategic planning which is flexible to address contingencies. The Public Service Survey shows that across the Federal Public Service there are great concerns about shifting priorities. Health Canada's scientific strengths and direction must be clearly defined; other elements include scientific excellence, a rejuvenation of science capacity, ensuring that science managers are scientists who know how to manage science, and a cross-departmental thrust to increase retention and recruitment to make the government a workplace of choice.

To respond to the challenges, a position paper is being prepared. Recommended is a departmental science committee and a strategic science fund, to determine priorities on a departmental level. The Departmental Science Committee was approved in principle by DEC; however, the Chief Scientist should provide input into the design of the committee. The BEST report recommendations include one that S&T advisory boards should be more involved in departmental planning. It is suggested that SAB members could either sit as members of the committee or make recommendations. SAB deals at a macro level, while the committee would deal with more on a day-to-day level. The challenge is to decide whether the Board should become more involved in the science committee.

Discussion included the following comments:

C The presentation makes it clear that scientists deserve to be recognized, but what is not

clear is that the scientists must also understand that they must also achieve excellence in order to be recognized.

- Thought must be given on how to establish priorities, given that there is not a clear definition on what science is in Health Canada.
- There is a need to develop an inclusive research agenda which reflects all the sciences in Health Canada.
- With regards to strategic planning, at some point one must stop planning and get on with doing the work.

C Are those who use the scientific method but do not produce new knowledge scientist or technicians? Not all science is about testing hypotheses - the new paradigm allows for both deduction and induction.

C Concerns were expressed about setting up a parallel bureaucracy with the concept of an "associate chief scientist".

C What is required is an integrator of science and policy, using output of research to develop policy. The department must be engaged in a debate about the type of research which it conducts -- research for the generation of knowledge or for the creation of public policy?

C Recruitment should be one of the things that is stressed.

C The composition of the committee is very important. They must be excellent scientists. The major responsibility should be to receive the peer review report and then do the follow-up and ensure that recommendations are followed.

Recommendation:

The Board appreciates the work which has been put into this paper and strongly endorses the establishment of the Science Advisory Committee. The Board also cautions the Department to clearly establish what its science role is: whether it uses scientific research for the purpose of knowledge generation or whether it uses scientific research to develop policy. Once this is established, the Department then can move forward on the capacity issue.

6. **<u>The Role of Social Science Capacity</u>** - *(Dr. Robert McMurtry, Dr. Wendy Watson-Wright, Dr. Sylvan Paradis)*

The new Population and Public Health Branch (PPH) was created to bring together social and biomedical science. PPH has nine centres; the Centres for Chronic Disease Prevention and Control, Infectious Disease Prevention and Control, Healthy Human Development and Surveillance Coordination, the Emergency Response Centre, Management Planning and Operations Directorate , Strategic Policy Directorate and the Winnipeg and Guelph Labs.

The presentation described the current social science capacity and possible avenues for a social science research program to enhance policy capacity. The challenges are to develop an analytical capacity that will provide a comparative impact assessment of the various social factors influencing on the health state of individuals and populations.

The criteria for science capacity: should be of a sufficient scale to achieve "critical mass"; policy-making bodies should be sufficiently expert that they can be "effective receptors"; managed by those who understand the work; who have the capacity to communicate effectively; are plugged into the broader research community; who can provide an entry point to the department; and be out of the fray. The ES group comprises 16.5 per cent of the Science and Technology groups, about 400 people, mostly statisticians, policy analysts and advisors. There are few social scientists per se, but they are spread out through the department and are not solely dedicated to social science research.

The questions asked of the Board were: Can Health Canada afford not to create a social science capacity. How can HC expand its social science capacity most effectively?

Discussion included the following comments:

- In April, 2000, over 100 researchers met to discuss social science capacity in the context of CIHR. The real task is not just building up social science capacity, but trying to find a way for researchers from the two solitudes to recognize the importance of both biological and social pathways to disease.
- Working together reduces the fear that each group has of the other. The strategy is to get people in teams, the vision of CIHR and HC is to work in teams. Leaders who understand science are needed
- The new vision is to bring together the two solitudes, to build social science research in the same way as basic science capacity.
- The added value of unique skills of the various social disciplines would be of great benefit; the expertise of a variety of people is needed to develop policy.
- Recognition must be given to those other perspectives. There are many ways to do science.

Recommendation:

The Board commends the presentation on social science capacity, however, it recognizes that this is a major transition that will take perseverance in order to implement over the longer term. The Board also reinforces its previous recommendation that the Department must bring clarity to the goals of the organization.

7. **<u>Therapeutic Products Programme Cost Recovery Initiative: An Evaluation</u>** - *(Dr. Robert Peterson, Dr. Judith Glennie)*

In 1994, as part of the federal government's deficit-reducing Program Review, the TPP's appropriations were reduced by 50 percent. Subsequently, in fiscal year 1994-95, the TPP implemented Phase I of a four-phase cost recovery initiative (CRI) for drug products. A similar approach was used for medical devices.
By fiscal year 1997-98, the TPP had implemented three phases of the original cost recovery plan. Total cost recovery revenue in 1998-99 was $31.9 million, representing approximately 45 per cent of total TPP funding.

At the time the TPP CRI was implemented, there was a commitment to include an evaluation of its impact as part of Phase IV of implementation (i.e., the Phase IV review). This evaluation would involve a comprehensive review of the impact of fees, intended and unintended, on both stakeholders and the TPP. The review was important not only in evaluating the TPP's CRI, but also in providing a model for similar reviews by other federal departments and agencies responsible for implementing cost recovery.

The Phase IV review examined the CRI's impact on the following groups:

- large, medium and small businesses in the therapeutic products industry, including distributors, wholesalers and retailers;
- consumers, including the Canadian public, provincial health ministries and other clients within the health care system; and
- the regulator (TPP).

The implementation of the TPP CRI has involved extensive consultation with manufacturers, provincial partners, health care associations and consumer groups. Continuing in this spirit of consultation and stakeholder involvement, the TPP's Phase IV review was aided by the following:

- a *Steering Committee*, consisting of about 30 representatives from federal and provincial governments, the pharmaceutical and medical device industries, consumers, and health care associations. The Committee was responsible for providing the TPP with feedback and advice throughout the evaluation process; and,

- a *Technical Working Group*, consisting of approximately 8 participants representing methodologic experts from many sectors of government, as well as academics. This group focused on ensuring the scientific rigour and transparency of the review.

The evaluation itself was carried out by KPMG Consulting LP (KPMG) starting in November, 1999. This independent contractor was selected based on submissions to a Request for Proposals developed with input from the Steering Committee and the Technical Working Group. The tendering and contracting processes were managed by Public Works and Government Services Canada.

The final report of the independent review of the TPP CRI was submitted June 19, 2000. A preliminary review of the final report indicates that the TPP CRI is consistent with Treasury Board policy and operational objectives relating to cost recovery.

Discussion included the following comments

- Concerns were expressed about the philosophical role of cost recovery. The view was expressed that Treasury Board should be encouraged to look at the broader philosophical issue.
- One of the major internal impacts of cost recovery is morale, the impact on the regulator.
- There is a need to look at this more closely to determine if cost recovery was worth the price paid in terms of public perception.

Recommendation:

The Board requested that two of its members, Doug Elliott and Leslie Millin, review the report to determine if the issues identified in the DRP on the effect of cost recovery on public confidence and the staff were addressed.

8. **<u>Update on Chief Scientist</u>** - *(Dr. Robert McMurtry)*

A revised job description has been developed and will be circulated as widely as possible. Applications have been received; it is hoped that interviews will commence in the next two to three weeks. There must be a clear mandate for chief scientist, including a direct report to the deputy minister, science committee, and a budget that is meaningful.

Dr. Jacobson shared with board members some of the experiences of the FDA with respect to the role of the chief scientist. In the FDA, the current role is to work as a central focus for issues and new technology which crosses the various agencies.

Recommendation:

The board recommended that the CIHR secretariat (currently in IACB) should report to the Chief Scientist.

D R A F T

Day 2 - September 13, 2000

In Attendance: Roberta Bondar, Yves Morin, Lynn McIntyre, Allan Ronald, Elizabeth Jacobson, Russ Graham, Karen Grant, Rodney Ouellette, Carol Herbert, Michel Bergeron, Gabriel Plaa, Neena Chappell, Richard Lessard, Stuart McLeod, Leslie Millin.

Ex Officio: Diane Gorman, Dann Michols, Marie Fortier, Mark Bisby

Secretariat: Kata Kitaljevich, Suzanne Bassett

9. Opening Remarks - *(Dr. Roberta Bondar)*

In response to the CIHR issue that was raised yesterday by Dr. Chappell, Mme Fortier clarified that the intent is the CIHR and SAB Secretariats will report to the Chief Scientist. The CIHR Secretariat is a small team that manages the relationship between HC and CIHR.

10. <u>The Decision-Making Framework</u> - *(Dr. William Ross, Dr. Tony Giulivi, Dr. Robert Peterson)*

In 1997, through the HPB Transition process, Health Canada began a review of decision making related to the identification, assessment and management of health risks. An overview of the resulting Health Canada Decision Making Framework was presented to the Science Advisory Board on November 23, 1999. This presentation provides a case study of the application of this framework to the management of health risks.

The example chosen to illustrate the framework is the vCJD donor deferral policy with respect to visitors to France.

Dr. Ross outlined the history of the BSE/CJD issue. Dr. Giulivi provided an overview of the Risk Assessment and the surveillance model that was developed, and discussed how the risk assessment was developed, since there are so many unknowns - the incubation period, the cause. All the cases in France appear to be related to food consumption of mechanically processed food; this is still a hypothesis, but with a lot of support in theory. With respect to the blood supply, the question is how to reduce the theoretical risk without reducing supply unduly.

Two models were developed based on information received. Model 1 predicted three cases in

France; the second model produced larger numbers. The first model currently provides more accurate projections. There may, however, be additional factors which are not yet known. For mechanical foods and processed meats, consumption patterns are not known.

Dr. Peterson addressed the development of the donor deferral policy. The authority of HC for this decision comes from the fact that TPP licences blood operators in Canada. Compliance with expectation about how products are available to Canadians is subject to HC license requirements. This is a fundamental precautionary principle issue. There is also the need to balance the risk reduction, i.e., the risk of a shortage in the blood supply.

Variant CJD is more complex because there is a long latency period. It is not a virus or bacterium, there is no therapeutic modality or intervention and there is no simple diagnostic test. With a new disease, one doesn't know how it will evolve, or the number of cases. Decisions must be consistent with the information available. As to the number of donors to be deferred, TPP asked the blood operators to survey their donors about the time spent in U.K. Six months would defer 3.5 per cent of donor population. Less than that would introduce a risk of shortage in the blood supply. The modelling showed the likelihood that cases of vCJD would appear in France.

The France deferral policy set the stage for the action Canada would likely take if cases of vCJD are found in other countries. Blood operators will survey donor pool and estimate impact on blood supply. The only problem is that Canada is not self-sufficient in blood products. Some have to be imported and there is a real risk if products are not available. IVIG must be balanced against theoretical. Risk assessment is different, heavily loaded to patient needing IVIG. Information is available to public and the health care provider. The decision is made on what the blood supply can accommodate, the uncertainties and the balance.

Discussion included the following comments:

- The board congratulated the department on its outstanding analytic work and leadership.
- Board members asked about risk communication and consultation. A sounding board of stakeholders has been developed and is consulted on these policies. This was part of the decision-making process. Communications documents have been developed and used. A technical briefing with the news media was held to allow for questions because of the complexity of the issue.
- The board also raised concerns about future pathogens for which there will not be risk assessments, and asked about Health Canada's role in encouraging the reduction in use of blood products. Health Canada's concern is with the safety, effectiveness and

quality; measures have been taken supporting standards for the handling of blood products and encouraging the appropriate use of products.

- Another question raised was who makes the decision as to what resources will be put to do the analysis? Health Canada is dependent on surveillance activities to identify concerns, international links. There is an opportunity to identify at an early level.
- The board also asked about communications out to the professionals and the public. TPP communications people are at meetings to help assess appropriate timing for release and to develop a background in the issue. The Deputy Minister chairs the DEC Risk and there is also a weekly communications meeting, looking at issues from a communications point of view on how to deal with issues.
- The issue of building public confidence was also raised. What is missing is the public's understanding of the departmental process. It needs a regular communication strategy, routine, utilizes professional organizations, to explain to the public the processes; that is the basis of OCAPI.

Recommendation:

The Board recommended that TPP should begin looking at the possibility of reducing the use of blood and blood products. It also recognized that vCJD is a food issue and the Department should begin examining how it deals with the future of food supply to lessen the risk of incidents such as this from happening.

11. <u>The Canadian Institute of Health Research</u> - *(Dr. Mark Bisby)*

The budget has more than tripled for CIHR, which was an expression of confidence in CIHR by the federal government. $340 million is in grants and awards budget; 20 per cent split between training and careers; 75 per cent is for operating costs, grants, clinical trials, collaborative research; five per cent is for tools, for equipment and maintenance, development of institutes, travel. Also, $42 million flow through for Canada research chairs and network of centre of excellence. When it is up and running, it will support major thrusts: i) investigator of initiated research proposals, open competition; ii) new strategic research initiatives chosen by institutes, requests for applications. These are two differently-oriented streams; to be determined is the balance of the funds between the two.

At the present time, affiliation with the institute and what it means has not been fully resolved. Those who have received grants from CIHR are affiliated, but what kind of affiliation other researchers who receive grants from other agencies will have is still undecided.

CIHR's emphasis is on strategic approach, linking research with health needs. The intent is to accelerate translation of research knowledge into improved health and health care. CIHR is looking at coordination through partnerships with other funders; improved networking; creative synergy between domains of health care; increased international collaboration; increased public recognition of the role of health research, more and larger grants and awards.

The current relationship between CIHR and HC is one of fruitful partnerships in specific research programs; collaboration in capacity-building. Some HC scientists are involved in CIHR funded projects; also, NHRDP has been folded into CIHR.

Next steps include improved access to funding opportunities for HC and government scientists; joint development of strategic initiatives in public health issues; the relationship of the Chief Scientist to CIHR; greater academic use of HC unique resources; partnership for translation/diffusion of research knowledge to the public and the decision makers.

Discussion included the following comments:

- One area to be looked at relates to international opportunities and how CIHR will discharge international mandate.
- Peer review processes must be appreciative of social science research.
- Health Canada scientists can get funding from CIHR only as a co-applicant, unless they have an appointment with a university, in which case, they can be the principal applicant. The problem is with the flow of money from one federal institution to another.
- It was suggested that university appointments may not be the most appropriate way of opening the process to HC scientists.
- The question was asked, whose job it is to ensure that the grants meet the objectives? This will be done through annual reports to Parliament. Each institute director will have to account for activities to government. The Governing Council will have an international review on a five-year rotating basis.
- With CIHR, there is an opportunity to increase the translation of research and to assess the impact of it on the health of Canadians. There is also a regional partnership program to help researchers in the "have-not" provinces which has arrested the slide in the proportion of the MRC budget that went to the "have-not" provinces.
- Research should be both "top down and bottom up"; experience has shown that they feed into each other.

Recommendation:

The Board agrees that the access of HC scientists to funding opportunities be increased. The Board recommends that there be a CIHR update at each meeting to allow them to monitor the developing interfaces.

12. **Food Safety: New Directions of the Food Directorate** - *(Dr. Marc Le Maguer)*

The Directorate has been integrating new elements, such as the Decision-Making Framework, policy development as applied to food, policy and standard setting process, the relationship with CFIA and research investment. The Food Rulings Committee helps set policies and standards, identifies issues and scoping. The committee scans the environment of an issue for different aspects, stakeholders who will be affected, checks out trade agreements, socio-economic and ethical factors to position the issues properly because the issue may not be scientific at all. The committee co-ordinates, communicates and offers timely and accountable decision-making. The Risk Management Committee operates at directorate, branch and department levels.

In the HC/CFIA relationship, HC establishes policies and standards, risk benefit assessment, surveillance, investigation of outbreaks. It also assesses the effectiveness of the agency. The CFIA administers and enforces acts and regulations, verifies that food products meet standards, issues emergency recalls.

The formal mechanisms of the HC/CFIA relationship includes MOUs and appendices, roles and responsibilities framework, which is a detailed grid with 69 elements. The HC/CFIA Food Safety and Nutrition Committees is an important element. The key principles of the committee: it must contribute to the protection of health, risk-based assessment, health and safety is paramount. The committee structure allows timely and accountable decision-making.

The Food Safety Assessment Program is not a shared responsibility with the agency. It offers checks and balances in the system, establishes processes for the program. In Research Investment, the main areas of work are microbiological contaminants in food, chemical, nutrition. New dimensions with functional foods requires investment to develop standards of evidence, veterinary drugs, novel foods, genetically modified foods, new processes, food components and processes.

Program priorities include microbiology, novel foods, raw foods minimally processed. The challenges due to the way they are produced, marketed, for example, unpasteurized juices, sprouts, antimicrobial resistance. This needs an integration of knowledge.

In the nutrition area, the need to measure the impact of health claims, the need to strengthen the nutrition surveillance system, chemical contaminants, review and anticipation of allergens, food irradiation funding, are all issues which must be addressed.

The directorate is recruiting, expanding, looking for expertise, competing with universities and industry. Almost 30 per cent of the workforce will be retiring over the next few years, so there are retention and recruitment issues.

Project areas with research as a priority include: genetically modified food, food-borne parasites and viruses, prions (TSEs), VTEC, campylobacter, clostridium botulinum, seafood toxins and biotoxins from foods from aquatic environments, mycobaterium paratuberculosis, antimicrobial resistance, macronutrients, non-halongenated hydrocarbons, food allergens.

Discussion included the following comments:

- In the acceptance of projects in new areas, such as GM foods, the department's intent is for critical evaluation using external reviewers before the projects are funded. Since it is publicly-funded research, there has to be a contribution to the knowledge, peer-reviewed at a similar level to universities, before approval. CIHR may be an excellent vehicle in targeted areas. There is a lot of information that could be moved into the public domain.
- Concern was expressed that because the involvement of industry in academia is significant, it is important that publicly funded genetically-modified food research is done.
- There is a concern that CFIA and Food are separate and that laboratory support is in Agriculture. However, laboratory and research are ongoing in Food Directorate to support policy and standard development, also the risk assessment part of CFIA's work. CFIA's laboratories with regard to food safety relate to compliance, not research, but verifies that products comply with standards determined by HC.

13. **<u>Departmental Science Committee</u>** - *(Dr. Robin Hill)*

Dr. Robin Hill returned to the meeting seeking guidance from members on the possibility of having external members of the Departmental Science Committee.

Discussion included the following comments

- Depending on how active it would be, this could be a burden on external members. Perhaps someone from outside the Federal Public Service could come in for a year on a sabbatical. It would be too much for an active scientist.
- SAB itself or Board representatives should not be part of the Departmental Science Committee; however, the Board should review the information from the Committee.

Recommendation:

The Science Advisory Board agrees external expertise might be invaluable to Department Science Committee, but the Committee should not include members or representatives of the Science Advisory Board.

14. **Post-Market Surveillance: Briefing and Overview of Activities** - *(Dr. Robert Peterson, Bruce Rowsell)*

The objective for the post-approval assessment is to access, promote, analyse, share and act on post-approval assessment to contribute to the safe and effective use of therapeutic products in the Canadian market. Post-market surveillance involves the move from a passive approach, relying on information being sent in from health care providers and consumers, to actively seeking data, and wanting industry to take stewardship of their products while on the market. There are opportunities for collaboration with other regulatory authorities and with other Canadian drug utilization information sources. Better regulatory tools are also required to allow for additional risk management options. Communications must be the cornerstone of post-market surveillance; additional work is required in this area.

Discussion included the following comments:

- It was suggested that not just adverse effects, but good ones, be tracked.
- Feedback to people inputting information is critical, both individual and aggregate.

15. **Office of Consumer Affairs and Public Involvement** - *(Murielle Brazeau)*

The new Director General of OCAPI briefed the Board on the progress to date of OCAPI. The proposed focus is public involvement: how to involve the public in developing priorities, developing programs, how to tell them what HC is all about. The main business of OCAPI is to provide expertise in the branch for the directorates to develop public involvement plans, and to be a centre point within the branch for public involvement activities. A public involvement

calender on the HC website will be developed. OCAPI will engage in public dialogue through consultations with Canadians. Another activity is the development of a citizen's council to advise the branch on how the branch does public involvement. Work is underway on developing options, business plans, work plans. OCAPI is located in HPFB, but links with other branches have already been established.

Discussion included the following comments:

- Concern was expressed by board members that the original direction for OCAPI has changed

Recommendation:

The Board requested that OCAPI return to the board for a comparison of the preliminary plans with the new proposal to identify changes made to the original concept and how it affects public confidence.

16. <u>Business Arising from Meeting</u> - *(Dr. Roberta Bondar)*

A) A discussion on future agenda items is required.

B) Phase IV CRI Evaluation: The Board agreed that Mr. Elliott and Mr. Millin should review KPMG report to see if the issues raised in the Drug Process Review with respect to the effect of cost recovery on public confidence and the staff were addressed, with a report back in November.

C) Chief Scientist: Concerns were reiterated that the chief scientist should not be encumbered with line responsibilities. The Board registered its concern and cautions about associate chief scientists. However, it was recognized that the Board could not limit the ways in which the department is managed

D) Social Science Capacity: The Board agrees there should be a social science capacity, but it is up to the department to determine its requirements.

E) Items for the agenda for November and future meetings were listed: OCAPI, CIHR, Chief Scientist; international health activities, definition of science in Health Canada. Other items are to be provided to the secretariat.

Meeting Adjourned.