

# **Summary of Discussion Science Advisory Board Meeting**

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**June 1- 2, 2005**

## Participants

<b>Science Advisory Board Members</b> Arnold Naimark (Chair) Linda Lusby (Vice Chair, A/Chair) Keith Bailey Renaldo Battista Mark Goldberg Chris Loomis Renée Lyons Lorne Babiuk Kathryn O'Hara Jacques Simard Stanley Vollant	<b>Ex Officio Members</b> Morris Rosenberg Hélène Gosselin Chantale Cousineau-Mahoney Karen Dodds Pierre-Gerlier Forest Susan Fletcher Diane Gorman Mostafa Askari for Marcel Nouvet
	<b>Invited Guests</b> Karsten Liber Riina Bray Derek Daws Kathleen Cooper Donna Mergler Jim Germida
<b>Secretariat</b> André La Prairie Tammy Davies Susan Tessier	<b>Regrets</b> Dixie Snider Stanley Vollant

**Boardroom 0115 C, Brooke Claxton Building  
Tunney's Pasture, Ottawa**

**Wednesday, June 1, 2005**

**1. Welcome from Health Canada's Chief Scientist (CS)**

Pierre-Gerlier Forest welcomed members of Health Canada's Science Advisory Board (SAB). He noted that Health Canada is fortunate to have a nationally recognized science leader, Arnold Naimark, as the new SAB Chair. He brings with him a wealth of knowledge and is a very experienced Chair. Pierre-Gerlier Forest thanked Linda Lusby for her outstanding work as acting Chair since September 2004. Her efforts and improvements to the Board practices are very much appreciated.

**2. Welcome from SAB Chair**

Arnold Naimark spoke of his keen interest in matters regarding health and science and his belief that the Board has an important role to play for Health Canada in the area of policy development. He intends to encourage that the membrane between the SAB and the department be more porous and synergistic. He is delighted that Linda Lusby will continue on the Board in the role of Vice Chair and as the SAB representative on the Council of Science and Technology Advisors (CSTA).

**3. Opening Remarks to SAB**

Health Canada's Deputy Minister (DM), Morris Rosenberg, expressed his pleasure with Arnold Naimark's appointment as SAB Chair and supported his desire for greater permeability and dialogue with the department. The increasing number of challenges which involve other scientific sectors underlines the need for openness and collaboration. He endorses obtaining collective advice from experts from other advisory bodies on multi-disciplinary matters.

Health Canada is undertaking the development of a broad long-term vision for health. The Board and other players in the federal system will be engaged in the future to help shape the role of the department.

The meeting was opened up to invited expert participants from the Environment Canada SAB and the Pest Management Advisory Council as well as staff of Environment Canada.

#### **4. Opening Remarks to Health Canada SAB and Invited Expert Advisors**

Pierre-Gerlier Forest, Chief Scientist, Health Canada conveyed regrets from the department's Associate DM who was unable to attend and provide opening remarks. In her stead, he welcomed the newcomers to the joint Health and the Environment (H&E) session and conveyed her remarks. There was a roundtable of introductions.

Over the past few years, there have been some important and productive shifts in how government works; two of these shifts form the foundation of this special H&E session. One of these shifts is the extent to which departments are looking outside their own structures for advice. In the past few years, the Government of Canada's science departments have sought the advice and input of external experts to help them identify areas for attention. The second shift is the emergence of government-wide approaches to issues, with roles for all relevant departments. There is now more coherence and collaboration in areas of joint interest and importance.

This joint H&E session brings together external advisors to both Health Canada and Environment Canada for a multi-disciplinary and multi-departmental approach to common issues. The outcome of this day will provide the Ministers of Health and Environment with science advice in support of the Canadian position on H&E matters in preparation for the Health and Environment Ministers of the Americas (HEMA) meeting which both Ministers will attend in Argentina in mid-June.

#### **5. Science and Technology (S&T) Initiative**

Barry Stemshorn, Assistant DM, Environmental Protection Service, Environment Canada conveyed regrets from his DM, Samy Watson, who had a commitment overseas. Mr. Watson holds strong views regarding science and its role in government: he is an advocate for in-house science by the Government of Canada, while at the same time being a leading advocate for reform in how science is managed within the Government of Canada.

The experts were asked for their advice and views on 1) the governance and regulatory management of affairs of Health Canada and Environment Canada; and 2) the priorities and emerging issues which these two departments are dealing with.

Government of Canada budgetary decisions of recent years have largely ignored federal S&T in Canada compared with the high levels of support for research by academia. The October 2004 Speech from the Throne acknowledged the substantial investments - more than \$13 billion since 1997 - that the Government has made to build a strong foundation in basic science and technology. It also identified the need to bring about a fuller integration of the Government's in-house science and technology activity.

The notion of S&T integration is not new, but little progress has been made despite numerous attempts at collaboration. Integration - including the ability to manage budgets across departments - is critical to the success of federal S&T endeavours. A fundamental shift is needed in issue management in order to face the myriad of challenges - the need for horizontality, the pace of change, and the impacts of globalization - confronting the S&T community today. Increasingly, key issues facing the Government of Canada require S&T expertise found in various parts of the government as well as externally. The solutions to these challenges require strategic responses that cut across departmental mandates and draw on a broad range of sources of scientific and policy advice. So, the question is not whether to use a whole of government approach, but how to use it well.

Integration requires shared decision-making and accountability, and combining resources - people, facilities, equipment, and money - in a structural way towards a common purpose. S&T integration is not about integrating all S&T in the federal government. Rather, the goal is forging a *whole of government* response to significant national issues that cut across the mandates of more than one department or agency, while maintaining the essential research and other scientific activities which departments do in support of their individual mandates. For those areas where integration is needed, existing resources need to be reallocated towards common goals.

Strategic work must be undertaken with others in Canada's S&T system, such as universities and the private sector, to capitalize on the various strengths of the different players for the common purpose and to harness the full potential of the innovation system for maximum benefit to Canadians. Integration also means that there must be strong, interactive links between the integrated S&T and the policy functions for those national priorities. A fuller integration of science in the fabric of government policy development and decision-making will ensure that the science and policy are correctly aligned to deliver on government priorities. The science should both define the issue and inform a policy that will address it.

The vision for federal S&T in support of the public good contains five elements: focussed S&T programs aligned with mission critical goals; a talented and committed workforce dedicated to government science; state-of-the-art equipment and clusters of core infrastructure; commitment to partnerships and networks with others to lever resources and research capacity; and an enabling administrative and fiscal environment. Examples of work underway on several fronts to move the federal S&T community towards this vision were given.

The most critical foundation for realizing the vision and advancing integration of federal S&T is a solid understanding of the future of science and technology, including integrated S&T priorities at all levels - national, federal, and departmental. The DM's Committee on Environment and Sustainability was recently tasked with championing this effort. There is a workshop planned to engage scientists in a grassroots approach

to defining where science is going in the future. The workshop will tap into the perceptions and observations from across the federal government to identify emerging scientific directions and key priorities requiring integrated federal delivery of S&T. The results of this exercise will be a key building block in the overall management of federal S&T. It will come together with the other pieces underway - S&T in support of mission critical science addressing barriers to integration, and the ongoing work of the ADM S&T Integration Board - to lay the foundation for a federal S&T agenda. The directions identified will facilitate common planning and implementation and will define needs for collective S&T infrastructure, HR planning and shared services.

Environment Canada is now embarking on a new course, a new way of operating and a new way of working together, focussed on delivering a new national policy direction. The Department is developing, with other key stakeholders, a Competitiveness and Environmental Sustainability Framework that will help Canada respond to the growing recognition that environmental sustainability is essential to both quality of life and long-term competitiveness. Within Environment Canada, the approach to delivering on this Framework will be based on teamwork, bringing together people from all services and regions to think, plan and work together more effectively.

The Department's S&T management policies and practices have, in the past year, been reviewed by an independent expert panel. The intent was to look at ways for improving the efficiency, alignment, integration and synergy of the S&T effort. Recommendations from the panel will help Environment Canada to better position its S&T capacity to integrate across the government and externally on key horizontal issues.

Environment Canada and Health Canada are already working together in a number of key areas, such as water research and wildlife diseases. Stronger integration will be needed in the future to address the many complex linkages between human health and the environment.

### **Discussion:**

- Examples of successful integration were referenced; common factors were a shared purpose; the will to explore an issue; leadership by a champion; creativity; an enabling environment; and sharing of expertise and resources.
- It is important to close the gap between scientists and policy-makers through getting consensus on the right questions and creating an environment in which the scientists know how their work will feed into policy and decision-making.
- A new role for government, shifting from the traditional functions of basic science research and primary data generation, could be in developing the capacity to synthesize, interpret and translate science information into policy in collaboration with other sectors.
- Intersectoral work should engage Industry Canada, to consider economic development in conjunction with health and the environment and vice versa.

- Science Advisory Boards could work together on projects addressing substantive health and environment issues.
- Concern was voiced that the labour force is not funded or trained to take an integrated, interdisciplinary, ecosystem approach to health so although the theory is sound, it is not being put into practice.
- Integration requires organizational change and the challenge is reallocating resources when there are institutional and people barriers to change.
- In the absence of an institute devoted to environmental health, a Pan-Canadian Research Centre dedicated to integrated research and innovation in this area could be developed. It would serve to develop and validate new technological tools and provide training to address health and the environment issues.

## **6. Health and Environment Strategy**

**Paul Glover, Health Environments and Consumer Safety Branch (HECSB), Health Canada**

There is scientific evidence linking environmental risks to diseases and poor health, but the interactions between factors are increasingly complex and many are not well understood. There is also a shortage of scientific information to support decision-making. Together, the scientific challenges, growing public expectations with regard to disease prevention and health protection, expectation for greater access to health information, and transparency in decision-making, are increasing the need for coordinated government action, horizontality, partnerships and collaboration. A Health and Environment Strategy is being developed to address these challenges. While it will complement and support the broader government agenda through strong links with a number of other initiatives, such as the Competitiveness and Environmental Sustainability Framework, the 2005 Climate Change Plan for Canada, it will also draw on a wide range of partnerships with other governments, health organizations, academic institutions, etc., across the country to achieve better health outcomes for Canadians.

The Board was asked for input both on the scope and approach related to the Strategy, as well as on the following areas for focus in the short term:

1. Surveillance and monitoring -- integrating environmental monitoring and health surveillance data is a critical part of the broader spectrum of risks and outcomes management (risk identification, risk assessment, intervention, outcomes and evaluation). Currently, environmental health surveillance lags well behind that of other health and safety domains. Many bits and pieces of key elements of a national network or system exist and provide a foundation on which to build a coordinated system. The challenge is to coordinate the interests and activities of a wide range of partners.

2. Children's health -- there is currently a shortage of scientific information to support decision-making on issues related to vulnerable populations, such as children, and this compromises risk management interventions in Canada. There is a window of opportunity in making progress on this front by creating a Canadian component to a major study underway in the United States (US) which would allow for a cost-effective way to obtain valuable information.

3. The Government of Canada recently released its new plan *Moving Forward on Climate Change* to address Canada's commitment to the Kyoto Protocol. The plan sets out the federal investments in key areas related to transforming our economy and enabling Canada to reduce its emissions of greenhouse gases. While there are no investments directed to at Health Canada, there is a recognition that new technologies and mitigation measures could have positive or negative impacts on health. The plan suggests that there is a need to "develop a federal framework or mechanism to ensure health impacts of new technologies or other mitigation measures are assessed before they are widely deployed or commercialized".

## Discussion

- In dealing with the unexpected, it is fundamental to focus on priorities which are set in a relative fashion, using science, networks and foresight to identify issues which challenge society.
- Legislation, such as the *Hazardous Products Act*, does not always allow us to leverage what is going on in different sectors with respect to a dangerous substance (such as lead).
- A shared policy framework is envisioned as part of sustainable development approach.
- Health care professionals who collect exposure histories from patients can be sentinels for linking adverse health events to environmental exposure.
- Suggestions for priority areas which would benefit from a systematic approach include asthma and respiratory illness, neuro-developmental effects such as learning and behavioural difficulties, cancer in young adults, precocious puberty and a geographical "hotspot" which would benefit from intervention; the Canadian Institutes for Health Research (CIHR) also has generated a list of priority issues for study.
- Scientific evidence should be gathered on the financial burden of illness directly linked to health and environment interactions to make a case for funding strategic preventative work in this area; Statistics Canada could be involved in collecting appropriate measureable indicators, such as the number of people affected and increases in rates.
- Models, such as the one for tracing exposure of mercury and other pollutants, can be used to effectively do illness prevention.
- Research on health and the environment should be tracked.
- Links to physicians and databases should be made to provide baseline data; there is much information available nationally and globally.



- In addition to benefitting human health and the environment, the H&E Strategy has the potential to increase economic competitiveness as well as negatively impacting trade.

## **7. Global Earth Observation System of Systems (GEOSS)**

**Pierre Dubreuil, Environment Canada, Jack Cornett, Radiation Protection, Health Canada**

A presentation outlined the background of international GEO, an existing Canadian application of EO in environmental predictions in relation to health (radioactive detection and prediction), other examples of health related EO applications and discussion of the proposed way forward.

The experts' views were sought on how we can link earth observations to public policy on health, should we look for environmental predictions of health conditions and/or the utilization of the health care system and are there any new areas or applications where we could expand existing Health Canada - Environment Canada collaborations.

### **Discussion**

- GEOSS is viewed as a leading pillar of the H&E Strategy, working across disciplines and jurisdictions, and should be used strategically for the benefit of the health care system.
- More monitoring stations are needed to do long term monitoring (versus real-time data for emergencies).
- Other applications for GEOSS include monitoring of air quality and its relationship to temperature, airborne mercury, volatiles, organic compounds, industrial smokestack and nuclear plant emissions, sewage treatment, large river effluence into oceans and targeted screening for biomonitoring.
- Attention should be paid to risk communication and information dissemination when pollutant data is made available to stakeholders and the public at large.

## **8. Research and Monitoring to Support Regulatory Decisions: Pesticides**

**Karen Lloyd, Pest Management Regulatory Agency/Bob McLean, Environment Canada**

The federal role in pesticides is shared. The challenges faced in the regulatory system for pesticides was outlined and Board input was sought on the following questions:

1. Given the regulatory challenges, and limited resources in the federal government for research and monitoring, are current priorities the right ones?
2. How can regulatory decisions based on "sound science" better incorporate Canadians' values?

3. How can we better develop an integrated federal view on environmental protection goals so science and regulatory decisions better support those goals?

## **Discussion**

- Health Canada has a high level of confidence in the data and studies submitted by industry, although there are limitations in being able to predict effects on human health and the environment.
- A new reporting system will be put in place whereby industry will be legislated to report to Health Canada any adverse effects they become aware of.
- There is a large number of active ingredients in pesticides in Canada which need to be reevaluated using current sound science methodology.
- The risks of pesticides to life *in utero* and children was acknowledged.
- Effective signage and education regarding the use of pesticides is important.
- Pest Management Regulatory Agency (PMRA) is a small organization that relies on external advice and international agreements, rather than in-house capacity, to answer its research needs.
- Post registration monitoring of pesticides in Canada is inadequate because, although we know what is available and being sold, we don't know how the products are being used and therefore what humans and the environment are being exposed to or what the effects are over the long term.
- There is a challenge in communicating with the public about pesticide regulation and their uses, benefits and risks.

## **9. Health and Environment Ministers of the Americas (HEMA) Meeting Ray Edwards, HECSB**

The development and consolidation of the bonds between health and the environment is crucial to the creation of an agenda for public policies that may contribute to improved quality of life for Canadians.

In the Americas, the meetings of the health and environment authorities of the hemisphere - held in Washington in 1995 and in Ottawa in 2002 - have been pioneering events. The next meeting in Mar del Plata, Argentina, to be held in June 2005, will become an important step for the progress regarding the implementation of policies and concrete actions on essential issues for the health and the environment of Canada.

The 2002 HEMA meeting identified 8 priorities and 12 goals which included:

- concrete actions with support of partners in priority areas;
- collaboration and coordination across sectors and jurisdictions;
- development of new approaches to facilitate collaboration (capacity building);

- strengthened knowledge to support priority setting, policy development and decision-making; and
- actions for improving environmental health at all jurisdictional levels.

Approaching the June 2005 HEMA meeting, Canada supports the HEMA cooperative agenda, action plan and implementation strategies. This includes action at the national and regional levels, providing tools and resources for decision-makers and expanding civil society participation. Canada is developing an H&E strategy which could provide support for the action areas of integrated water resource and waste management, sound management of chemicals and children's environmental health.

The Board was asked to consider opportunities to build stronger partnerships domestically and internationally to support HEMA objectives and to position our science to support HEMA objectives.

## **Discussion**

- The goal for environmental health should go further to ultimately prevent, in addition to reducing, adverse health impacts in children.
- It is recognized that there must be collaboration across sectors (for example labour and education) to position economic development and strategic alliances.
- Canada needs a mechanism to align the bio-geo-chemical health issues alongside social and economic issues and showcase this integration internationally.
- Lead exposure has been falsely categorized as a "children's" problem with regulatory responses targeted to children's products only. Lead is a risk to the population at large, and all products that contain lead (such as costume jewelry) are a risk to infants and children.
- Health Canada should encourage discussion at science level at international meetings.
- There should be discussion of transfer of hazardous substances between countries and conduct of processes in other countries to encourage following Canadian protocol to ensure equity with respect to exposure to hazardous chemicals.
- Consideration should be given to pesticide use on produce which is imported to Canada.
- Capacity building and collaborating with other countries has worked well when knowledge processes are exported and the country does the job themselves.

## **10. Canadian Environmental Protection Act (CEPA)**

**Paul Glover, HECSB**

**John Arsenau Environment Canada**

CEPA is the Government of Canada's principal legislative tool to prevent pollution in order to protect the environment and human health. The goal of CEPA is pollution

prevention and protection of the environment and human health in order to contribute to sustainable development. Responsibilities shared between Health Canada and Environment Canada are: 1) research to detect and understand effects of substances on the environment and human health; 2) addressing the legacy of unassessed (existing substances: assess and manage any undue risk); and 3) prevention: pre-market assessment of new substances (chemical and products of biotechnology) and management of any undue risk.

The implementation of CEPA focusses on the following strategic directions: priority-setting, consistent application of the precautionary principle, effective risk communication, national standards and cooperative action with provinces and territories as well as the need to address emerging issues (such as the use of nanotechnology).

To address the 23,000 substances in use in Canada that have had no evaluation of their risk to the environment or human health, both departments used the criteria set out in CEPA to select (categorize) which ones should be evaluated first. Selection was based essentially either on health grounds or environmental grounds. While an order of priority has been established within each grouping, the departments need a way to create a single list, preferably by applying scientific criteria. Advice from the Board is requested.

Recent stakeholder engagement consistently raised the request for a return to State of Environment reporting and the initiation of State of Health reporting. Advice from the Board regarding the concepts, source of data and audience for a state of health report would be valuable.

## **Discussion**

- The definition of vulnerable populations will evolve as genetic predispositions are discovered and this will drive how risk assessment and risk management are done.
- The department has heeded previous advice from the Board and is considering not only exposure, but hazard level, in its priority-setting.
- Physicians should be involved in the priority setting exercise.
- Products, as well as substances, are becoming part of the CEPA review.
- Caution should be used when using structural modelling as chemicals in the same class may not react in the same way.
- Categorization is a tool for prioritizing, not decision-making; there are many other means to feed into prioritizing and validating chemicals to be shortlisted for assessment.
- Health Canada and Environment Canada are commended for their accomplishments in this area, which is an excellent example of organizational and functional connections between health and the environment.

## **12. Closing Remarks**

Arnold Naimark thanked Health Canada SAB, invited experts, Health Canada and Environment Canada presenters and staff for their participation and contributions. Health Canada's SAB could provide leadership in bringing these groups together on an ongoing basis. The departments are commended on their collaborative efforts and the respective Ministers are urged to support and capitalize on their joint activities.

**Thursday June 2, 2005**

### **13. Opening Remarks from SAB Chair**

Arnold Naimark shared a few comments with SAB members about his vision for this Board and his discussions with Health Canada's DM, the CS on how best the Board can serve the Department.

Mr. Naimark expressed his openness to the evolving interaction of advisory bodies. He observed that the Terms of Reference for the Board describes a broad mandate which should be fully explored. There is a role for the Board to contribute to the development of the department's science policy. He felt that advice is most useful at an early stage.

### **14. Risk Communications**

**Edison Stewart & Elaine Chatigny, Communications, Marketing and Consultation Directorate**

**Sarah Thorne & Gordon Butte, Decision Partners**

Health Canada's draft Risk Communications Framework was provided to the Board as background. Discussion among SAB members on risk communications was encouraged and advice was sought on what kind of social science capacity is required to support the Framework. A presentation outlined the elements of the project, the state of the science, strategic risk communication approach, objectives of the framework, challenges and next steps.

The Risk Communications Framework and Handbook will provide a process and a comprehensive inventory of robust methods and tools to accomplish continuous improvement. As it is being developed, some components of the approach to various issues such as the re-evaluation of 2-4 D, farmed salmon, telomers, and pandemic influenza have been applied. The Framework is being developed by Decision Partners, an international team of management professionals and scientists specializing in advanced behavioural decision research, strategy and communications, and a Steering Team made up of departmental representatives from the Deputy Minister's Office, the Health Products and Foods Branch (HPFB), HECSB, the Office of the Chief Scientist (OCS), the Corporate Services Branch (CSB), the PMRA, the Public Health Agency of Canada (PHAC) and others. The Framework and Handbook will be complete later this spring. Implementation and training will commence in the summer and fall of 2005.

## **Discussion**

- Risk communication is very important in translating risk in the area of health and the environment, as evidenced by the pesticides and CEPA discussions of the previous day.
- Risk communication enables initiatives such as timeliness, relevance, openness and transparency.
- Risk communication is a tool to address science in the implementation of policy regarding levels and perceptions of risk. Once key stakeholders are identified, research is done on how to communicate with this particular group; how the message is developed and guided by what the group knows and their tolerance for risk.
- Risk communications is more than media relations, rather it is an upstream, inclusive interaction and communication with stakeholders as a means to inform decision-makers.
- Risk management is a means to help the decision makers feed into decision-making.
- An additional fundamental challenge is to decide who you are going to provide risk communication to.
- The handbook should be taken to peer review and identify case studies and best practices.
- Knowing where and why experts and stakeholders disagree is an important component of developing a risk communication strategy.
- Communication can be tiered to communicate to different audiences using different levels of detail and complexity.

## **15. SAB Vice Chair Report**

Linda Lusby, in her role as Health Canada's representative on the Council of Science and Technology Advisors (CSTA), reported on the group's new project, a report on "Management of Science and Technology in the 21st Century". This is germane to the discussion of the previous day because the report will investigate models in other countries to do horizontal issue management. Linda also reported on her attendance at a roundtable consultation convened by the National Collaborating Centre on the environment.

## **16. Updates from the Office of Chief Scientist (OCS) Tammy Davies, Director, Policy, Planning & Partnerships, OCS**

Tammy conveyed Pierre-Gerlier Forest's regrets that he was unable to attend. For the more recent SAB members, it was pointed out that the OCS report is a routine fixture of the SAB agenda. The objective of the Board, CS and OCS are related, that is, to

ensure that the department is equipped with the people, the tools, and the means to perform and use the excellent science that it needs.

Following yesterday's discussions on integration, SAB should be aware that Health Canada is actively involved in interdepartmental initiatives in this area; both in terms of contributing to, and benefitting from, these efforts. The ADM level federal Integration Board has developed a Forward Plan which focuses on 3 elements: joint priority setting, barriers to science and integrated S&T management. Other initiatives of note over the next few months include developing a whole-of-government paper on the Barriers to S&T, and a workshop with scientists/science managers in September (Beyond the Horizon: Identifying Emerging Priorities for S&T Integration).

The Science Activity Valorization and Development Division has initiated the process of Programmatic Peer Review in consultation with David Blakey, Director, Environmental Health Science Bureau regarding the Air Programme within HECSB. A preliminary meeting has been held to define the scope of the exercise and an internal steering group has been formed.

The overarching theme of this year's forum is Science in Support of Health Policies and Regulations - a broad topic that connects with many issues of interest to the scientific community and the Canadian public. Organizers have selected four sub-themes: risk assessment methodologies; the role of civil society; building health: healthy individuals and healthy communities; and emerging issues and product developments. In addition, there will be some cross-cutting topics that cut across the full spectrum of health issues helping to strengthen the connections between science and potential policy or regulatory issues. In the context of the forum, cross-cutting topics may include Aboriginal health, women's health and ethics, as well as issues of accountability and transparency.

SAB was regretfully informed of the resignation of Dr. Dixie Snider due to pressures from his work commitments. This brings the number of vacancies on the Board to six which should be filled in the fall. The Secretariat will canvass the department, as well as SAB, for names of potential candidates. Profiles of nominees will be analyzed against the Board's current composition of expertise, the department's prospective needs and the four pillars of the CIHR.



## **17. Symposium on Openness & Transparency in Drug Regulation**

**Lori Harrop, Corporate Consultation Secretariat**

**Susan Gardner-Barclay, Acting Director General of the Office of Consumer and Public Involvement, HPFB**

The symposium fits in with departmental mandates of openness and transparency (O&T) and will dovetail with several projected Health Canada announcements on O&T initiatives concerning drug regulation and drug safety.

The symposium's purpose is to engage a diverse group of Canadian stakeholders and international experts in a balanced exploration of O&T in drug regulation, in order to identify a set of principles that could underscore future action by all parties.

The presentation outlined the proposed scope and scenario for the symposium, slated for November 2005, and requested the Board's input. In particular, suggestions are sought for specific content for the symposium, possible attendees, and stakeholders for the symposium steering committee.

### **Discussion**

- The conceptual framework for O&T should be defined to guide the overwhelming number of activities and desire to "get information out".
- It may not be realistic to "... ensure that the symposium provides an opportunity for real debate" versus "...educate the public and stakeholders about these new activities ...".
- Legislative change is required to be O&T with industry data.
- Stakeholder knowledge of the difference between what is gleaned from clinical trial Phase 3 data and post market surveillance will affect their perception of drug safety data.
- The symposium is targeting a well-informed stakeholder group rather than the general public.
- Media and journalists have a large stake and they should participate.
- How a drug is used in the real world and how patients are educated is part of drug safety.
- People need to be educated about the restrictions to O&T - legal, commercial, policy, legislative, ethical.

### **18. Closing Remarks**

The SAB Chair thanked the Board for their time and efforts. Health Canada is fortunate to have such distinguished SAB members. Arnold Naimark is looking forward to the outcome of this meeting and subsequent meetings.