Report from
the Planning Workshop :

PUBLIC INVOLVEMENT
on XENOTRANSPLANTATION

Government Conference Centre
April 10 - 11, 2000
Ottawa, Ontario
A. PURPOSE, PEOPLE, PROCESS

Welcome, Context and Purpose of the Workshop

Moderator’s Welcome
John Benesh, Consultant

The moderator welcomed participants and told them that the planning workshop is an opportunity to bring together scientific and policy knowledge about xenotransplantation. A participant stated that it was important to stress that the purpose of the planning workshop is to consult stakeholders on a process for public consultation on xenotransplantation, and that workshop participants should not be seen to have endorsed any political process or substantive decisions beyond the focus of the meeting.

The moderator described three types of participants at the workshop: those who will be actively involved in discussions; those who are resource people or subject matter experts; and other interested observers. The moderator emphasized that the resource and interested people were considered observers in the workshop, and that they would be expected to participate only insofar as their expertise was requested by participants.

Introductions

Participants and observers introduced themselves stating their name, organization, role and title, either their participation in xenotransplantation or public involvement, and the perspective they were invited to represent. Information on participants and perspectives was provided in the workshop materials (see Appendix 1).
Therapeutic Products Programme’s Welcome

Robert Peterson, M.D., Associate Director General
Therapeutic Products Program, Health Canada

Dr. Peterson, introduced the context for the planning workshop. The role of Health Canada in the Canadian health care system, as well as the mandate of Therapeutic Products Programme (TPP) were outlined. Health Canada has a close proximity to the Canadian public, and that proximity is a means of maintaining close links between government policy and health care needs. The introduction of new therapeutic products into the health care system, requires careful consultation with Canadians.

The TPP’s mandate is two-fold:
• to ensure that new therapeutic products reach the health care system in a timely manner, and
• to regulate the sponsors of new therapeutic products.

As part of its regulatory mandate, TPP ensures that sponsors provide reasonable evidence to demonstrate that the therapeutic product they propose to introduce to Canadians is safe and effective. Evidence is furnished in terms of statistics, which must also translate into clinical evidence. The TPP frequently seeks external expert advice.

Dr. Peterson informed participants that additional perspectives on how — and whether — Health Canada should move ahead with exploring xenotransplantation are required. The planning workshop discussions would guide Health Canada on how to move consultation forward on the xenotransplantation issue. To illustrate this point, Dr. Peterson posed several questions, underlining that it was not Health Canada’s intention to determine the agenda of discussions:

• What should the timing of public involvement be?
• What degree of transparency will meet public expectations?
• How should the proprietary expectations of the sponsors be managed — specifically, how can Health Canada maintain the confidence of proprietary information and still share information with the Canadian public?
• How can the issue of transparency be redefined?

According to Dr. Peterson, Health Canada needs help managing two key issues:
• the fact that the population in Canada needs organ transplantation materials, and
• how the public will feel about a xenotransplantation clinical trial.

Dr. Peterson underscored the need for participants to recognize that, in Canada, there is a demand for organ transplant material that is not being met by human source material (i.e., tissue, cells, organs). This fact should be considered during workshop discussions.
Dr. Peterson then discussed the issue of a xenotransplantation clinical trial. International use of xenotransplant material should be studied before engaging in a clinical trial in Canada. There has been no submission of a formal application for a xenotransplantation clinical trial in Canada, nor is one pending. However, the issue of such a clinical trial needs to be discussed so that Health Canada will have guidance when an application is made.

Health Canada faces a number of scientific (medical) challenges in relation to xenotransplantation, such as:

- The use of animal source materials in the form of living cells.
- The fact that some genetic modifications of animal source materials will have to be made.
- The issue of the threat of infection carried by the living tissue that would be used in xenotransplantation. In the case of live tissue, it is not possible to process animal source material to ensure that infectious agents are not present.

In conclusion, Dr. Peterson stated that consultation with Canadians must take place now because the xenotransplantation challenge is pending. It is necessary to develop educational materials and a framework for consulting the public. Health Canada is relying on the workshop participants to provide guidance on how to move consultations forward.

Questions and Answers

Q? What impact will consultations have on the decision-making process at Health Canada?
A The federal government rules necessitate public consultation. When recommendations are discussed with the Minister, Health Canada officials must illustrate how public input shaped the outcomes.

Q? What lessons can be learned from abroad and international collaboration?
A There is a lot that can be learned from the international community about xenotransplantation science and how this area of clinical investigation has been presented to the public. It would be interesting to obtain information about how the public in other countries understand the reasons why xenotransplantation is important.

Q? A comment was made that the presentation seemed to imply that there would be clinical trials. The question was raised if consultation moves forward, will clinical trials also move forward?
A Health Canada expects to receive submissions for clinical trials. Health Canada cannot refuse applications for clinical trials however there may be scientific and safety reasons for not approving a submission. The public debate is also important to have and if a clinical trial submission is received it might be that the science and/or the public that may influence that the trial be delayed; not occur; or describe how (conditions) it would take place.
Q? Will safety and effectiveness (regulator’s screen) be in the issues for public consultation?
A Because xenotransplantation is cutting-edge science with tremendous risks, all public input is important. Health Canada is seeking information about values in addition to the scientific barometers of safety and effectiveness.

Q? What is Health Canada’s interpretation of “reasonable doubt” and the precautionary principle?
A Since the precautionary was developed in international environmental law, it requires adaptation in the medical field. In medical terms, it is important to evaluate the risk of doing nothing versus the potential benefits. In medicine, it is necessary to balance theoretical risks with known risks. The result is a “balanced risk reduction” approach that is extrapolated from the environmental example. Examples of application of the precautionary principle to theoretical risks include blood products and new variant Creutzfeldt Jacob Disease.

Q? How does Canada’s consultation exercise compare to that of the United States?
A There is no comparative data available at this time.

Q? Is there a special access mechanism for physicians to obtain xenotransplants outside of a clinical trial?
A A special access mechanism exists in general for therapeutic products. Under this special for xenotransplantation exists, individual consideration can be given to permit a doctor to treat a single patient with a therapeutic product in a life-or-death situation. Despite this exception to clinical trial submission process, Health Canada is not interested, at this time, in allowing access to xenotransplants through this mechanism.

Q? What about Canadians that travel to other countries for xenotransplantation?
A Members of the Canadian population may travel to another country to obtain xenotransplant material and then return to Canada. This possibility should be an issue for consideration during the planning workshop.
Review of the Agenda

During review of the agenda, the moderator asked participants to turn their attention away from their personal feelings about xenotransplantation and to focus instead on how the public consultation process should be framed and structured. The main tasks include:

- Identifying and prioritizing questions and issues that will be important to the Canadian public — but not solving them.
- Creating a model for involving the Canadian public in discussing these issues.
- Identifying the roles and responsibilities. Specifically, identifying what relationships will be established between stakeholders, the public and Health Canada.

Participants’ Expectations

Participants expressed the following expectations for the two-day planning workshop:

- To obtain an operational definition of how Health Canada will make decisions.
- To receive the results of the workshop in a timely manner and before a report is released to the public.
- That the report generated from the workshop be accurate and not extend beyond the public consultation focus. The reports should not be presented as an endorsement of anything beyond the focus of the meeting.
- That participants come away with an understanding of the impact of public consultations on government decision making, specifically in terms of clinical trials and how they will balance with other competing interests.
- To have an opportunity for continuous dialogue.
- To establish a definition of “public” — is it generic or does it consist of special populations? What is an informed consumer compared to an uninformed consumer?
- To establish a definition of “interest groups” that shape the public. To obtain greater clarity about which groups are being discussed, to establish which groups need to be consulted and to agree to consult with all identified groups.
• To obtain a commitment to diversity and to not making assumptions about what will or will not happen. The public’s input should have meaningful impact on the decision of whether to proceed with clinical trials.

• To understand the role of health care deliverers and the impact that public consultations will have on them.

• To discuss a plan to deliver scientific information to Canadians. That science will be defined broadly to include research and the animal welfare dimension.

• That participants will leave with a clear understanding of next steps.

• To ensure that the view of the broad Canadian public (not narrow interests) is incorporated in the consultation process.

• To understand what is meant by public involvement and to use international examples.

• To develop a strategy to communicate the consultation plan to provincial and territorial governments.

• That the multicultural nature of Canada be considered.

Steps to Success!

Participants were asked for feedback on what the participants themselves, the moderator and Health Canada could do to make the planning workshop a success.

• the moderator should “exercise enlightened control,” since participants “need to talk, listen, and avoid domination.”

• participants “need to keep the range of questions wide open”

• participants should “start thinking now how we’re going to translate this material to the constituents we represent.”

• “At some time, somebody should bring us up to date on where Health Canada is,” If they’re on the fourteenth draft (proposed Standard for Xenotransplantation), this didn’t start yesterday.”
B. ISSUE IDENTIFICATION

What are all the questions/issues raised by xenotransplantation that you would like addressed?

Participants were invited to identify questions or issues surrounding xenotransplantation that the public would want to have addressed, in whatever manner (eg. through research, public involvement, decisions...). Seventy questions/issues were recorded. (see Appendix 2)

What questions should be addressed through public participation?

Participants were each given nine sticky dots and asked to vote for any of those 70 questions/issues identified they felt were the highest priority items requiring public participation. The moderator indicated that the results of the dot vote exercise would be used later on Day 1, when three breakout groups would each be assigned three different questions to develop details for a public involvement plan.

A participant expressed concern about the process, noting that the questions participants would expect from the public might be dramatically different from the questions people should be asking, or from the questions participants would want to ask the public. A concern was expressed that readers of the planning workshop report might not understand the context and limitations of the dot vote exercise, which could lead to a misinterpretation that the group or Health Canada was concerned only with those questions/issues. For example, seventy questions were listed on flipchart papers on the walls, similar questions were not grouped (or counted together for votes) and each participant had only nine dot votes, which could result in a perceived downgrading of priority of some of the questions/issues. Health Canada agreed that the dot vote process has limitations and is only used to get a very quick ‘snapshot’ from a very long list, of the kinds of questions/issues that might be important to Canadians, which will then assist Health Canada to better prepare for public involvement (eg. awareness, information, consultation) and to continue with addressing the objectives of the planning workshop. The key questions/issues identified through the dot vote exercise included (see Appendix 2):

1. Will xenotransplantation have an impact on the financial sustainability of the health care system? Will the cost of this technology create a financial burden that pushes other options out of the picture? (15 dots)
2. What are the risks and benefits for the individual and community? (14 dots)
3. What is the relationship between corporations and the development of this technology? Many questions around business ethics: transparency; accountability; degree to which product under development drives the process versus medical need; what is a conflict of interest? (14 dots)
4. What is being done to prevent conditions for the need for xenotransplantation? (12 dots)

5. Will Canada allow experimentation in transgenics? How will it be regulated, monitored and controlled? What will be done with the results? Will this issue be included as a topic for public consultation, and how will the public be notified that transgenics is a part of this process? (12 dots)

6. Is there a framework for obtaining consent for third party involvement? (11 dots)

7. What plans would Health Canada have for educating and involving the media (act as a conduit for larger community)? (10 dots)

8. By whom and how will decisions be made on xenotransplantation? And in what other countries will decisions be made for us? (To the regulators) (8 dots)

9. What is xenotransplantation? Why do we need it? What are the alternatives? How long till xeno happens? What would it mean to patients, their families and care givers? (9 dots)

C. PRESENTATIONS

Decision-Making Framework for Xenotransplantation

Ms. Julia Hill, Director
Bureau of Policy and Coordination
TPP, Health Canada

Dr. Peter Ganz, Manager
Bureau of Biologics and Radiopharmaceuticals
TPP, Health Canada

Ms. Hill presented the decision-making framework from the policy development perspective (see slides, Appendix 3a) and Dr. Ganz presented the perspective of scientific evaluation of clinical trial submissions (see slides in Appendix 3b). Both presenters addressed questions raised by participants.
Questions and Answers

Q? What is the current state for approval of clinical trial submissions? Is there a present regime to review submissions?
A TPP does not have legal authority to not receive a submission for a clinical trial. Until there is a regulatory framework completed, TPP is obliged to receive submissions.

Q? Why is the review time for clinical trial submissions sixty days?
A International competitiveness to conduct timely research in humans with new therapeutic products influences the review time.

Q? How is the best way to do risk communication at the different stages of decision-making?
A There are several levels of decision-making. The technical level conducted by TPP, the broader safety level of the Minister of Health and the level of Canadian parliament. The TPP will advise the Minister of Health on all aspects, through policy-making framework and not only on the technical and scientific (medical) aspects and has to make it very clear to the Minister what we hear from the public consultation. The second arena to public consultation is lobbying Ministers of Parliament.

Comment Suggestion to add to Dr. Ganz’s slide presentation an additional mandate to find out other concerns of stakeholders.

Q? Regarding the risk assessment process, please clarify: During the technical assessment, where does the burden of proof lie, with respect to third party risk? Are any other factors included? During the review of a clinical trial, what is the minister of Health informed of and when?
A The Minister has legal authority to prohibit the use of xenotransplants if it is in the interest of public health to do so.

Comment There is an ambiguity around risk assessment. There is a presumption of certainty of science. There is a need to clarify where the burden of proof lies for risk to third parties. Health should be considered as greater than just physical health.

Q? Is information on an adverse event non-proprietary information?
A Unfortunately the response was not captured in any of the session records.
Health Canada’s Public Involvement Plan

Ms. Kim Hannah, Policy Analyst
Bureau of Policy and Coordination, TPP

Ms. Hannah presented an overview of the objectives of Health Canada’s public involvement plan (see Appendix 4). The plan was developed by a Health Canada team, has undergone extensive consultation with Health Canada and has the support of Health Canada to move forward. The planning workshop is the intended final stage of planning where advice, from an invited public representative of diverse perspectives, is being sought to finalize details of the plan and to determine whether the public is comfortable in moving forward with the plan.

Questions and Answers

Participants’ questions were addressed by Ms. Hill. It was explained that it is difficult to predict how scientific findings and the results of public involvement on xenotransplantation would come together. “If there’s unanimity around the notion that xenografts should go forward, and that the process as we’ve (TPP) described it is perfect, I don’t suppose we’ll really see much impact, because there won’t be any kind of polemic or discussion around it”. “If, on the other hand, the results of the public consultation show that the public is very opposed, or wants to set particular parameters around how xenotransplantation happens, then you will probably see that impact in the way the regulatory framework is structured.” It would be unreasonable to expect every viewpoint to be reflected in the regulations, “because there are going to be contradictions, so it’s a difficult line to balance”.

Ms. Hill cited a survey of 2,500 Canadians (workshop materials, also see website: www.hc-sc.gc.ca/hpb-dgps/therapeut/blood tissues organs xenografts) had revealed some public desire to proceed with xenotransplantation, but stressed that public consultation would be needed to help determine “the parameters that should be put around that” (1see footnote). In response to a participant, who said he had never heard the survey described as a measure of public support for xenotransplantation, she agreed to distribute full details. Another group member conveyed her respect for Health Canada’s effort to consult, but expressed concern that public involvement might be pressured by the fear that an application for clinical trials might be right around the corner.

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1The Health Canada Survey indicated that Canadians are somewhat aware of xenotransplantation and the potential benefits and risks, and have indicated a preference to be involved in the dialogue. The design of the survey and the resulting statistics were not intended to provide any basis for conclusions as to whether Canadians do or do not support xenotransplantation.
A. DEVELOPMENT OF A PUBLIC’S MODEL FOR INVOLVEMENT ON XENOTRANSPLANTATION

This portion of the workshop was intended to address one of the main objectives of the planning workshop, which was for Health Canada to obtain advice from participants on:

- What extent should activities be undertaken, in the areas of awareness, education/information and dialogue on xenotransplantation;
- Who the target populations are for each of these activities; and
- What kinds of activities would be most effective to reach and involve those target populations.

The moderator introduced the discussion process for the afternoon. Three breakout groups (see Appendix 5) would be assigned three of the nine topics identified in the dot vote exercise. For each of the questions assigned, the breakout groups would be asked to address the following questions:

- What is the goal of public involvement in relation to this question? What level of awareness, education and dialogue do we hope to achieve, and why?
- Who do we need to reach and engage? What is the target?
- What types of activities might we use to reach and engage the target audience(s)?
- Based on the foregoing, how much importance should Health Canada attach to awareness, education, dialogue and public involvement on this question?
- Is there a general model emerging for awareness/education/dialogue from the three questions/issues discussed?

Each of the breakout groups would summarize the discussion in plenary at the end of Day 1 and one or two volunteers from each breakout group would be tasked to come up with a general model or summary, from discussions of all three breakout groups, and report to the workshop at the beginning of Day 2.
Breakout Group Reports (see Appendix 6)

Breakout Group One

The group had found itself “raising questions more than providing answers” in relation to its three assigned topics.

Question #1  Will xenotransplantation have an impact on the financial sustainability of the health care system? Will the cost of this technology create a financial burden that pushes other options out of the picture? (15 dots)

The group expressed interest in better health care at lower cost, but also explored what the notion of better health care means, and to whom. Group members stressed the importance of equitable access to health care, and expressed interest in the social context and social location of medical technologies. They looked at how resources are allocated and how health care priorities are set, acknowledging that the question should be of interest to health economists, industry, governments, medical associations, hospital associations, and patients. It was concluded that communication objectives on this topic can be met through regional and annual meetings of interested organizations, Internet communications, and Health Canada-financed research, but concern was expressed about the ethics of collecting data in countries that can’t afford to do the research themselves.

Question #7  What plans would Health Canada have for educating and involving the media (act as a conduit for larger community)? (10 dots)

The purpose of reaching out should be to explain the risk-benefit ratios associated with xenotransplantation, present the players involved with the issues in relation to their respective interests, demystify the jargon surrounding the technology in the hope that media will do the same for the public, and adopt a proactive, totally transparent philosophy related to information-sharing. The group agreed that a consistent — but targeted — message could be delivered to mass and scientific media via the Internet, news releases and media kits, focus groups, and meetings of media associations through a process that is driven by Health Canada in consultation with interested third parties.

Question #4  What is being done to prevent conditions for the need for xenotransplantation? (12 dots)

The group agreed on the need to inform the public of the option of organ donation, adopt preventive measures that would reduce demand for all medical interventions, including xenotransplantation, and inform the public of potential alternatives like gene therapy. Participants listed the same target audiences and communication mechanisms they had identified for previous questions.
**Breakout Group Two**

**Question #2**  What are the risks and benefits for the individual and community? (14 dots)

**Question #5**  Will Canada allow experimentation in transgenics?  How will it be regulated, monitored and controlled?  What will be done with the results?  Will this issue be included as a topic for public consultation, and how will the public be notified that transgenics is a part of this process? (12 dots)

**Question #8**  By whom and how will decisions be made on xenotransplantation?  And in what other countries will decisions be made for us? (To the regulators) (8 dots)

The group ended up brainstorming lengthy lists to answer each of the discussion questions. From a public participation standpoint, it was recognized that this type of consultation on a topic such as xenotransplantation introduces new processes for Health Canada in terms of determining policy from a participatory perspective. But the topic under consideration adds a layer of complexity to the whole exercise, because the knowledge and the science will be shifting, there will have to be a continuous dialogue, whatever mechanism is put in place. The rapidly evolving character of the issue, combined with the large number of unknowns, will make it that much more important to put the right structure in place so that dialogue can shift to incorporate new information as it becomes available.

The group identified a series of target audiences for public engagement, including specific communities of interest, medical, scientific and voluntary health organizations, media, and groups that are not well represented by advisory groups such as older adults, poor people, and communities in which neither English or French is the first language. Politicians should be targeted at all levels, and educational efforts should combine formal and informal strategies. Participants echoed other groups in stressing the importance of honesty and transparency in all communications.

Newsletters, Web sites and evening news features emerged as key communication tools. The group agreed that education, awareness and dialogue should be a high priority for Health Canada, and recommended putting a structure in place now, even though there is only a limited amount of information available to be disseminated.
**Breakout Group Three**

The group had been unable to reach sufficient consensus to come up with a synopsis of any of its assigned topics. Through the confusion of our comments, group members realized that they needed more clarity themselves, and concluded that the process would be no easier for the public.

**Question #9**  What is xenotransplantation? Why do we need it? What are the alternatives? How long till xeno happens? What would it mean to patients, their families and care givers? (9 dots)

Participants concluded that it would be important for members of the public to see that they were being asked for an opinion on whether clinical trials should proceed, and to have confidence that their opinions would make a difference. However, the group identified basic education as a requirement for answering the question, and called for an outreach effort aimed at reaching the broadest possible segment of the population with easily understood information on the issue. For this purpose, group members agreed that communication should flow in one direction only — since the goal is to provide the public with enough information to form an opinion in order to take part in consultation.

**Question #6**  Is there a framework for obtaining consent for third party involvement? (11 dots)

Group members agreed on the need for better understanding of what is meant by third parties. Depending on circumstances, they concluded that the definition could be as narrow as individuals close to the patient or as broad as the public at large. Without clarity on this issue, group members felt they couldn’t answer the question.

**Question #3**  What is the relationship between corporations and the development of this technology? Many questions around business ethics: transparency; accountability; degree to which product under development drives the process versus medical need; what is a conflict of interest? (14 dots)

The group was unable to address the question of business ethics in the time available.

In conclusion, it was stated that this is a confusing, far-reaching subject. The group came away with as many impressions of what was being asked as there were people in the room, leading participants to agree that public consultation would depend on an ability to present the issues to the public in a far more succinct way.
**General Discussion**

In general discussion, a participant underscored the importance of focus groups as a means of determining which part of an information campaign is reaching different target audiences. However, another participant expressed concern about a “fundamental ambiguity” in the motivations behind education and awareness activities, noting that the discussion was supposed to be about how Health Canada should seek public input, not about an educational effort outside that context. While acknowledging the need to raise awareness in order to consult, the participant said it was “imperative” that the government be able to report on the beliefs people hold in relation to xenotransplantation.

Health Canada’s Ms. Hill, acknowledged the frustration that had been expressed in the course of the day, stating that the discussion was helping Departmental officials to describe the feedback they were looking for. She stressed that the purpose of the workshop was to deal with public involvement and engagement strategies, but added that people will need information in order to take part in any participatory process. The other “big piece” of the picture is the legal framework that is already administered by Health Canada. “We can squeeze xenografts into those laws,” Ms. Hill said, “but we don’t think they’re finely tuned enough” to deal with a technology that represents a “whole new domain”. This means that a new regulatory framework will be needed, regardless of the outcome of a public involvement process: If Canadians want xenotransplants, a set of laws will be needed to establish the conditions, limitations and nuances. If not, a law will have to be put in place to prohibit the practice. Against this backdrop, it is important to get information out to the public in a “very objective fashion”, so that people can debate the issue and come back to Health Canada with a set of parameters.

A participant thanked Ms. Hill for her explanation, but asked how it would translate into a question to the public. Ms. Hill said she would be inclined to ask whether Canadians want xenotransplantation within their society, and, if so, what limits they would set on the practice. But another participant expressed concern at the possibility that a broad public awareness campaign would be followed by an effort to gather opinions from a select group of contacts. He added that a media blitz would be insufficient to ensure that there was an informed public in advance of a wider consultative effort. The next speaker clarified that media outreach would be one of a cluster of strategies, including focus groups and town hall meetings.

One participant said the day’s discussion had helped him understand that there are different types of xenotransplantation, multiple stakeholders and many different types of communication that may be appropriate to the effort that is required. “So when you add these three complexities to an already muddy question, it may be that there’s no one model,” he said. On the contrary, there may be 25 or 30 different elements of a wider strategy. Another participant noted that the group had prioritized the media as a target audience that will have to be dealt with responsibly to ensure that the public debate over xenotransplantation is not derailed.
E. EVALUATION OF DAY 1

- What Went Well?
  - facilitators

- What Could Be Better?
  - more time for group discussion
  - better clarity
  - separate what the public needs to know from how to educate the public
  - process confusing
  - ask what Health Canada wants to know
  - facilitators should help focus better
  - unclear objectives
Day 2 - April 11, 2000

A. PURPOSE, PROCESS

Welcome and Agenda

The moderator opened Day 2 of the workshop by recapping the previous evening’s dinner speech by Ms. Maureen McTeer (see Appendix 7), former member of the Royal Commission on Reproductive Technologies and wife of the former Prime Minister, Rt. Hon. Joe Clark. “It was a very tough process they went through, and she said her knowledge and experience had been moderated by being out of the process for about five years and then coming back”. He recalled that Ms. McTeer had recounted “a shift in government, and a shift in the way people react to government,” leading to greater emphasis on public involvement at every stage of the decision-making process.

Following a review of the process issues participants had raised at the end of Day 1, the moderator opened the floor for discussion. A participant took note of Ms. McTeer’s comment that the old tradition of command and control and paid advisory groups had been replaced by a new paradigm, driven by globalization and the emergence of the Internet. He said Health Canada was trying to reach out to this new future, while recognizing that everyone involved is constrained by their past. The participant recalled that one of Ottawa’s first successful consultations, dealing with the 416 Highway, had taken place about 20 years ago. By the end, the process had identified and summarized the views of 16,000 registered stakeholders. “So while this is a new mode of operation,” he said, “there are nearby examples” of what works.

“It was almost as if she’d been here yesterday,” another group member said of Ms. McTeer’s talk. “She underscored something that we revisited at the end of the day yesterday, and that was the differences between consultation, meaningful dialogue, and influencing the decision.”

The public decision-making processes are not set in stone. They require some updating, and new ways to involve more Canadians in informed discussion are always welcome. They will need to take account of the ever-moving and changing targets that are at the heart of the massive technological and scientific revolution now under way to ensure that our public policy is sensible and strong. In this process, each of us must accept a role and responsibility. It is up to all of us to ensure that, in the tough choices that lie ahead, we achieve the benefits science and medicine promise and still protect our societal interests and human rights. (page 132, Tough Choices: Living and Dying in the 21st Century. Maureen A. McTeer. Published by Irwin Law, Toronto ON, 1999)
Ms. Hill quoted the closing paragraph of Ms. McTeer’s recent book to illustrate that “this is a risky business for us, as well. We’re in the midst of a significant change process, in terms of how we make policy. We know the traditional way doesn’t work, and we know that somewhere out there is a solution,” but “the path is going to be in the walking.” In seeking solutions that build confidence and trust with people from across the country, the risk is that departmental staff might look like they don’t know what they’re doing. She said she was also sensitive to the possibility that participants might feel they were being used by the consultative process.

At the same time, Ms. Hill emphasized that “the multiplier effect of this group is extraordinary,” noting that she’d been pleased to learn from participants about the Calgary process and the Highway 416 consultation. “It’s from people like you that we’re going to learn about that,” she said. “You’re a tremendous asset, and we really need to make sure we treat you carefully and responsibly...because we need you.”

B. PUBLIC’S MODEL FOR INVOLVEMENT ON XENOTRANSPLANTATION

Report of the Working Group

The working group that had met to draw common themes from the previous day’s breakout sessions reported to plenary. While the sessions were fascinating, the working group could not arrive at a single, coherent message that represented the full range of opinions expressed. But while the group concluded that ambiguity and irreconcilability cannot be eradicated from these proceedings, it did come up with an overall goal for the conference: “to engage the Canadian public in an informed dialogue on xenotransplantation, with the objective of creating a regulatory framework that reflects the hopes, values and concerns of Canadians.”

In support of this goal, the working group agreed that:

• The workshop should look at ways of creating an informed public, to ensure broad-based understanding of the benefits, risks and ethics of xenotransplantation. It was suggested that there were two distinct target audiences for this effort: stakeholders with a specific vested interest in the discussion, including patient groups, transplant physicians, clinicians, hospital, volunteer groups, educators, researchers and industry; and related interest groups, including animal advocates, labor groups, ethicists, and the interested general public.
• Public outreach on this issues should be guided by the principle of absolute transparency. Information must be updated as new knowledge is generated, and a “concerted effort” will be needed to demystify the jargon of xenotransplantation.

• Key communication channels include a website, conventional media, focus groups to measure the effectiveness of the overall effort, and public advisory groups modeled on the consensus groups that have been convened in Europe. The working group agreed that theologians should also be involved in the discussion.

The working group concluded that content for the website should be generated by Health Canada, in conjunction with its consultation partners, and should include as many links as possible to “virtually every known, credible website that touches on xenotransplantation”. The site could include an interactive discussion forum to gather and measure public input. Media can be reached through background kits, and through news conferences or briefings designed to convey basic background on the issue. The importance of effective media management, was stressed, in order to counter tendencies toward sensationalism.

**Participant Discussion**

**Definition of Stakeholders**

A participant asked why the working group had differentiated between stakeholders and other interest groups, suggesting that people who speak for animals have a primary interest in the discussion.

**Urgency for Discussion**

A couple of participants underscored the urgency of the discussion, noting that Health Canada could receive an application for a clinical trial at any time. “This process is incredibly important before any such thing does proceed,” one of them noted. The other stated that “the potential biggest harm that we’re worried about in terms of third party involvement and release of infectious agents is likely to happen in trials,” before xenotransplantation becomes a proven, routine practice. Canada can have an impact on discussions and decisions in other countries, by taking a thoughtful position on xenotransplant regulation. Globalization will raise other complications as well, if xenotransplantation eventually releases a virus comparable to HIV: “It’s people in Third World countries who are least able to deal with and contain that kind of epidemic.”

**Internet**

A participant agreed that Web sites are useful communication tools, but warned that extensive hyperlinking can open the door to sites that are inaccurate or irresponsible. Other participants raised similar concerns about online discussion groups. A website editor or manager should be assigned to ensure the validity of all links, and note that discussion groups tend to correct their own problems. It was noted that fewer than 50% of Canadians have access to the Internet, stressing that xenotransplantation information must be accessible and understandable.
A participant said the background materials prepared for the workshop had been a great model for the way discussion should proceed. The discussion papers should be posted on the Internet, possibly with revisions to reflect comments onsite. Another commented that “people want to talk about this with other people,” and stressed the value of creating “communities of discussion” across the country.

**Faith Communities**

A participant agreed that faith communities will want to come to their own conclusions on xenotransplantation, but said religious groups have a broader contribution to make, based on 30 years of advocacy around corporate social responsibility, business ethics, and investor input on corporate decisions.

**Media**

Participants were urged to hit the delete key very, very quickly” before recommending any effort to “manage” media coverage of this issue. “It’s called ‘working with’. You’re never going to be a partner (with media), but you can certainly work with them and treat them as equal, intelligent human beings.” Reporters won’t always write what different communities of interest want to read, “but the better journalists will always be open to the dialogue,” as long as information is presented in an honest, transparent way. It was also recommended against trying to retaliate against unfavorable coverage. “The moment you try to punish someone for writing something you don’t like, you’re in deep trouble,” suggesting that a more pragmatic approach would be write a letter to the editor. “Eventually, it will take care of itself. A bad reporter gets weeded out by his or her own bad reporting.” It should also be considered that a media strategy may vary with each phase of the xenotransplantation project. A Web site should not be created until Phase I of the project is completed because as soon as the Web site is launched the media will pick up on the issue.

A participant endorsed the idea of informal media briefings or seminars to provide background on xenotransplantation, and strongly recommended inviting reporters from weekly newspapers and weekly television shows, where new reporters get their start. It was also recommend to make contact with the Entertainment Industry Council in the United States, which provides background content for television scriptwriters and producers.

**Risk Communication**

A participant commented that the assessment of risk communication presented was both correct and comprehensive. Issue specific communication and dialogue is beneficial because it allows the decision maker to have clear choices. It was specified, however, that the information provided by Health Canada must be “bullet proof” before it goes out to stakeholders, who would then perform a check-and-balance function. Finally, a mechanism for collecting and synthesizing information should be established. This mechanism would also be responsible for matching communication efforts with those issues deemed important to the public.
Communities of Discussion

The idea of creating a space for discussion for communities of discussion is an intriguing one. Establishing these communities would provide an opportunity to engage in consultation approaches that involve talking directly to Canadians. The approach used at the Calgary Consensus Conference was suggested as a model for public consultations. The Calgary approach helped interested people learn about a particular subject matter and then engage in discussions with experts about issues they considered important. The idea behind communities of discussion is to complement the use of traditional models of consultation (e.g., stakeholder consultations) and to engage the public at large. Health Canada must work to enhance their trust of citizens in this process, as difficult as doing so may be; this is necessary in order to Health Canada to relinquish control of the consultation process. Health Canada seems to be willing to take the risks associated with giving up control and there are several approaches that can be used for honest, transparent interaction with the public. A town-hall approach was raised as another possible consultation approach.

Scope of Consultations

The concern was raised that the scope of consultations on xenotransplantation could expand to the Health Care system as a whole. As such, Health Canada was cautioned to be careful to keep the scope of consultations narrow (i.e., dealing specifically with xenotransplantation). Maintaining a tight focus will be a challenge, said the participant. Despite the fact that there are new issues emerging (e.g., allotransplantation), it will be necessary to focus on the issues relating directly to xenotransplantation.

This position was challenged by a participant who said that the call to keep the consultations about xenotransplantation narrow should be resisted. Whereas it is recognized that it is always difficult to obtain answers if consultation on a subject is broad, if consultations are artificially narrow, there is the risk of not obtaining all the relevant information.

Role of Religious Groups

A participant said that a recent survey completed by a religious group based in the United States asked 20,000 members of the public who they would believe most on xenotransplantation issues; most identified their religious leader. Religious leaders often work from the perspective of the common good and have been involved in other areas such as business ethics. Their role should be one of animation and not direction.
Comments from Health Canada

Health Canada representatives told participants that the target for getting groups convened and information out is 15 months. However, since the resources for this initiative are reserved, Health Canada would be prepared to act sooner if participants thought that this was appropriate. The commitment of resources should be proportionate however, to the importance of the issues.

Canada is in a leadership role in terms of the moral position it holds in the developing world. Whereas Canada is not a leader in xenotransplantation in the scientific realm, it does have strong ethics leadership potential.

In relation to creating communities of discussion, Health Canada wants more information about how organizations might see their role in comparison to Health Canada’s role. Is there a desire to establish something non-governmental?

Responding to the Health Canada representatives’ comments, participants said that Canada needs to act quickly because xenotransplantation is happening now. There was concern that if Canada does act soon it may fall even further behind.

Health Canada’s Proposal for a Public Advisory Group (PAG)

Participants were asked to think about their vision for a Public Advisory Group (PAG) for xenotransplantation. Specifically, they were asked to reflect on PAG’s mandate, the nature of the group’s membership, how to select that membership and the group’s method of operation.

Remarks

Mary Hegan
Office of Consumer Affairs and Public Involvement
Health Canada

Mrs. Hegan informed participants that the work being done by the Office is ground-breaking. The creation of the Office stemmed from Health Canada’s realization that it needed to change its culture relative to public involvement. She stated that although the workshop was principally about xenotransplantation, the discussions have taught her a great deal about consultation on a range of health issues.

Participants were referred to the draft framework for the PAG in their workshop binders. Mrs. Hegan stated that, when developing the PAG framework, Health Canada envisioned a group representing a cross section of the public and acting at arms length from the Department. From Health Canada’s perspective, the PAG’s main function will be to play a lead role in analysing and synthesizing what Canadians have to say, and contributing that information to the decision-making
process. It was emphasized that Health Canada was seeking leadership from workshop participants on process questions, specifically in terms of design, implementation and evaluation. Health Canada representatives addressed questions raised by participants.

**Questions and Answers**

**Q:** What are the expected time commitments of PAG members?
**A:** The issue of time should be kept in mind when the role of members is discussed. It is important to be realistic about members’ roles and about what Health Canada will require to meet their needs.

**Q:** Will Health Canada provide a Secretariat for PAG?
**A:** Resources are available to do so. However, the issue of a Secretariat is up for discussion. It is possible that, in the interest of keeping an arms-length relationship with PAG, a third party may be hired to provide Secretariat services. The ultimate budget for PAG depends on how the group is defined.

**Q:** Is it possible that there will be overlap with other government consultations?
**A:** Links are already established to prevent duplication of efforts.

**Q:** Where will the PAG get its scientific information and to whom it would report.
**A:** These types of questions were subject to the discussions and recommendations of workshop participants.

**Participants’ feedback on Health Canada’s PAG proposal:**

**Likes, Concerns and Suggestions**

**LIKES:**
- includes early involvement of public
- PAG takes the lead in interpreting results
- important that Health Canada is recognized for this undertaking
- that the PAG is an advisory group–adds value, credibility

**CONCERNS & SUGGESTIONS:**
- PAG mandate seems “back-end”. Is there a front-end role? PAG should also act as a steering committee. Need clarification on advice (“about what”?)
- concern about out-sourcing Secretariat responsibilities. Health Canada would be better able to respond to the advisory group’s needs
- regulator has to be regulator–Health Canada must be the one receiving advice as they will be the ones using it
- PAG should report to Health Canada at a senior level. It is important for PAG’s sense of worth that its advice be seen as influencing Health Canada’s decision-making.

- PAG needs to be given, by Health Canada, the clear focus statement and clear questions, so that the PAG’s recommendations can relate to the focus statements is clear about what advice is being sought. The kind of information that is being+ asked for will have implications for consultations.

- would the PAG would be a one-shot grouping or would it have an ongoing role?

- if PAG reports to Health Canada alone, the arms-length relationship between the two organizations might be reduced. It was recommended that PAG also report to the public.

- given the range of tasks to be completed by PAG, some clarity about the group’s ability to appoint sub-groups and to farm-out tasks should be established. As the regulator, Health Canada must be involved in PAG’s activities because, even if PAG can provide independent advice, Health Canada must ultimately make the decisions. Perhaps Health Canada should have a parallel set of tasks.

- it is necessary for PAG to be at arms-length from Health Canada, but that it must have strong links to the Department. Furthermore, it would be redundant to have duplicate skill sets.

- the line of accountability between Health Canada and PAG is a crucial question. Regardless of how Health Canada chooses to proceed, transparency is essential.

- PAG act as an independent group that will respond to specific questions. As such, how the group is selected is a very important consideration. The Royal Society procedure was recommended as a model that could be used to establish a PAG.

- A debate ensued about the value of using the Royal Society model. Concerns were raised because the Royal Society model relies on an expert-based approach when PAG is intended to be citizen-based. The PAG approach should be focused on a public- engagement approach, said a participant. Another participant raised concerns that PAG would actually overlap with Royal Society initiatives.

- concern about the need for PAG members to be “credible to the regulator” (Health Canada’s proposal). The meaning of “credible” was questioned.

- PAG must have a continuous link to the public and, therefore, a mechanism for the PAG to obtain public’s views.
• The issue of xenotransplantation is very important to the public. As a result, the nomination process should be open so that various members of the public can be nominated. Public may wish to elect/select/nominate members for PAG

• PAG should include public and expert skills, and it should be as diverse as possible.

• there should be a cross representation of skills between PAG and the expert committee. Minutes of meetings and subject-matter documentation should be shared between the parties.

• concern about PAG’s purpose: Is it an advisory group about xenotransplantation or is it an advisory group about public consultation? Perhaps a change in title would be appropriate to reflect that its relevant expertise is in the area of public consultation and that it is not influenced by narrow interests. Perhaps the group should be called the “Public Involvement Advisory Group”

• both process and nomination of members need to be independent—must start with the terms of reference, then select members

• PAG members need to be comfortable with delivering specifics from a “sea” of uncertainty

• concern that very specific details about what PAG should do was being discussed when no clear idea about PAG’s mandate has been established. Need clear policy questions for the PAG to commence.

• PAG’s mandate seems clear. PAG will provide recommendations and advice requested by Health Canada, and the group may supplement the information requested with issues they consider to be important based on public consultations.

• to what extent will PAG interact with the Minister of Health? A Health Canada representative stated that PAG would not be prohibited from communicating with the Minister; however, the standard procedure is for the Minister to be briefed on relevant issues by the Department at regular intervals.

• the PAG needs to clarify the state of the question about xenotransplantation in the public’s mind. To this end, it must have a public education role that is shaped so as to not unduly influence the process. A key question is how to make resources available to fulfil the education role. The PAG has to determine the public’s perspective about certain questions. To this end, an understanding of popular views as well as expert/strategic stakeholder views is needed. In addition, PAG needs a feedback loop. It is not enough for the group to report, it must make its reports accessible to a variety of publics — both general and expert. If Health Canada
chooses to consult publically on xenotransplantation, there could be political implications that should be considered. There may be a political role for those groups who argue that PAG should have an arms-length relationship with Health Canada.

• it is essential that there be an openness to changing the questions forwarded to PAG. Further, it is vital that PAG have a role in prioritizing issues and facilitating effective change for public feedback.

• the PAG’s task is not only to educate the public but also to empower the public. It is necessary to move away from the perspective that the public is ignorant and to recognize that they have legitimate concerns. PAG should provide an avenue for bottom-up information gathering and should contain the expertise necessary to respond to the public’s concerns.

• need clarity on educating the public versus empowering the public

• PAG members should be credible to both experts and the public at large. Educational conceptualization must not be condescending.

• PAG membership must be merit based, where merit is broadly defined. Appointment of the Chair must be transparent and lines of accountability clarified.

• proposed PAG mandate: “To engage the Canadian public in an informed dialogue on xenotransplantation with the objective of creating a regulatory framework that reflects the hopes, values and concerns of Canadians.”
PAG Membership and Selection

Participants broke into small table groups to discuss PAG membership selection. A report was made from each table on membership and how the selection process should occur.

Table One

Membership

They recommended that membership should come from a broad range of representatives and that it should be balanced. It should encompass individuals from the educational and scientific communities as well from a range of NGOs (non-government organizations) and public advocacy groups. Membership should be demographically diverse (i.e., age, economics, education) and include representation from the First Nations.

Selection Criteria

There should be some grouping and some random selection. For example, there are a number of organizations representing youth, and while there should be youth members there is no need to include every group. There is a great need to determine the principles regarding the educational requirements of members, as the information to be synthesized is both varied and technical. Time, availability and a willingness to serve are also critical components given the urgent need to move forward.

Table Two

Membership

The table group emphasized many of the same requirements as table one, with a caveat that cultural diversity is critical to making the process work. There needs to be a range of diversity — without polarization — as well as a range of backgrounds. A faith and spiritual perspective is also important to have in the group. It would be valuable to have people naive to the process as group members, noting that those with no background in, or no knowledge of, xenotransplantation would bring “fresh eyes” to the group and would be a microcosm of the general public. There also should be representatives from the animal perspective (e.g., the Canadian Council on Animal Care). The Canadian Nurses Association and the Canadian Medical Association should also have representatives in the group. It would be helpful to have an expert in market research and communications as well.
Selection Criteria

There would ideally be an open nomination for membership to the PAG. Individuals would, in all likelihood, be connected to an organization but would not necessarily represent the views of that organization. Nominations would be approved by the Minister of Health.

Table Three

Membership

This table group recommended that the PAG should be diverse and include membership from the many facets of the xenotransplantation issue. There should be an expert in xenotransplantation as well as a representative from the patient perspective (e.g. from the Kidney Foundation) and an organ donation committee. The animal protection movement should be included and there is a need for an ethicist as well as a faith perspective in the group. The general public should be included and multi-cultural representation is necessary. Communications experts and the media would be valuable to include as well.

Selection Criteria

Two possible methods of selection were discussed:

- A Nomination Committee could be struck comprised of five people, one from Health Canada. The others could come from this workshop. The Nomination Committee would report back to workshop participants, or
- This workshop could provide criteria to Health Canada, which will then nominate individuals.

Table Four

Membership

This table group reported that it found itself discussing whether a stakeholder representation versus ‘perspectives approach’ should be used, and that it decided that the latter was preferable. They identified eight perspectives that should be included along with Health Canada as ex officio:

- patient
- health care providers
- animals
- public at large
- ethics
- gender, age, regional representation and ethno-cultural concerns

- theological
- social issues
- economics

All need to be taken into consideration.
Selection Criteria

None were discussed.

Table Five

Membership

The table group noted that much of what they decided is a repetition of earlier table reports. They broke membership down into three distinct areas:

- stakeholders, including patients, animal rights groups, pharmacists, etc.;
- experts, including those in xenotransplantation, clinicians, bio-ethics, public communications; and
- intelligent, but disinterested public, or those with no stake in the issue

The PAG should have its major deliverables to Health Canada within four to six months.

Selection Criterion

The process should be merit-based, not equity-based. People could be nominated from the public at large or self-nominated, although the final say would be up to Health Canada. The selection of the chair would also be at Health Canada’s discretion. They questioned whether or not the PAG should have a sunset mechanism and self-destruct at the birth of the new regulatory framework or after making recommendations for follow-up.

Participant Discussion

It was noted by one participant that any PAG would be a small group with a big mandate working in a short time frame and that merit, knowledge and ability are much more important considerations in the selection of members than is race and gender. Another participant voiced objection to this, stating that the two points are not antithetic and that the PAG should not be exclusive. Another participant expressed a concern about the time frame and said that the process falls in the area of political cynicism. He urged Health Canada to build confidence in the process by giving it adequate space and time to work and proposed that an announcement be made to that end. Another participant suggested that Health Canada designate one person as a contact for information. Another participant noted that in risk-management terms there is a lot of uncertainty and unknowns. “It is impossible to cover 100% of the waterfront all the time, or 100% of the issue with the people in the room.” However, he suggested that there are ways to mitigate this situation and urged everyone to make sure that the workshop proceedings are reviewed and discussed.

A participant expressed thanks for the direction this program is taking, and said that it was different from any others she had been involved in. She noted that if discussions are open to the public there is a degree of vulnerability, and that the results are not always what the organization or the
Minister might want. Another participant echoed the previous speaker’s comments and expressed personal appreciation for the process. “I have sat through a lot of things and get cynical and skeptical about the process. Congratulations to Health Canada for taking the risk.”

Decision-Making Framework Revisited

Dr. Peterson returned to the workshop to continue discussions started earlier on the decision-making framework. He explained that the TPP wants to initiate the process of transparency and to push the envelope for input and guidance from the public. This has not been done before, and it must an integral part of Health Canada and its decision-making process. It is necessary to have it at arm’s length so as not to influence proceedings, but TPP does not want it cut free either; they want to be there to answer questions and use the output in decision-making, but not to direct.

Dr. Peterson explained that TPP knows they will hear from the public before clinical trials take place and they want to come up with a public consultation venue before clinical trials take place. He stressed that he believes there is adequate time for consultation, but there is a regulatory process that must follow the law. It will be easier to tell a company, requesting permission for xenotransplantation trials, that nothing is possible until the conclusion of public consultations if these consultations are underway with a specific time frame in mind. “We do not wish to push something through behind closed doors for something this controversial.”

It was noted that there are already people on the Expert Panel, and their voices are heard. Health Canada has experience in target consumer groups such as the one for HIV. He said that these have been brought to a satisfactory conclusion focusing on how clinical trials will take place. Xenotransplantation is more complicated though because of the third-party risks. “There will have to be a cautious, judicious move forward should trials go ahead.”

Questions and Answers

Q? If a company come forward to request permission to undertake xenotransplantation trials, would they be told that it wasn’t possible while the public consultations phase was underway?
A Under the law Health Canada cannot decline a request to submit a clinical trial, and that sponsor would most probably meet with Health Canada before submitting a clinical trial. At this point they would be informed of the consultation exercise. The current level of science does not demonstrate the level of safety required by TPP. Even if a clinical trial is approved in the United states, this doesn’t mean TPP would approve them. The TPP has no regulatory authority to refuse authorization for a clinical trial, based on the fact that public consultation is ongoing. That authority rests with the Minister of Health. Should a decision be made to go ahead, the Minister has that responsibility. The Minister wants this public consultation phase to take place first.
Q? The issue of timing of public consultation and clinical trials is a paradox, and the public consultation phase is meaningless if trials were allowed to go through in the interim. The third-party risks makes this scenario different; who says no, to whom and for how long? What level of input would the PAG/public really have? To have clinical trials approved while the public input phase was ongoing would trivialize the process.

Comment The public understands imperfect laws and would understand a law that allows for a trial to take place during the public consultation process. He suggested that there is a track record in place as in the example of Parkinsons patients.

Response Having a trial take place during public consultation process is highly problematic because of the safety and risk factors to third parties. The trial would have to be a very carefully sculpted application for it to move forward. Under Canadian law, Health Canada has to review any application that does come forward. There are studies in other countries in which safety issues have been addressed, but just because something is passed in the United States does not necessarily mean it will be passed here. If something were to be licensed it could not be denied here, but we are nowhere near that.

Q? Would be a news release this week regarding the PAG?
A This announcement will not happen this week but that it definitely will happen. The TPP wants to see this through. Other groups will be involved and the business plan needs to mature. The fact that this meeting took place is in the public domain, and that it will move forward; however, this will not happen by the end of this week.

Comment A caution against a single report on a topic that is so diverse. It is anticipated that the first request for xenotransplantation trials will come from extra-corporeal transplants and will be from someone dying of liver failure. This is not elective surgery and a request would have to be carefully considered. It no longer becomes an academic problem and is not a wait-and-see scenario. In this instance, it would be difficult to wait for the work of a PAG. There is a need to start disseminating information immediately and to have a graduated approach rather than an all-or-nothing answer.

Response These types of preliminary studies (eg. extra-corporeal) must take place within the regulations; they are related to safety issues. Clinical trials have to meet certain standards set by local research ethics boards. What was described by the participant has happened, but it does not fall under the regulatory framework of laws in Canada. In the United States, State Congress sets the laws for medical experiments, but in Canada it falls under the Food and Drug Act, which comes under the criminal law power.

Comment It may come down to a critical choice for families between two countries and that there could be close scrutiny of these choices. Canada will want to offer xenotransplantation within its regulatory framework and that third-party risks are already know in instances such as HIV and Hepatitis C. You cannot anticipate
knowing all risks. It is imperative to start disseminating information, but not in a Royal Commission approach. However, it will take a Royal Commission to ban treatments if they are available elsewhere.

Q? Patients will travel to the United States for procedures and then return to Canada with no follow-up if treatment is banned here. Did a xenotransplant procedure already did take place recently in Montreal?
A Yes, a procedure did take place, but not recently. There is no one walking around at the moment with a xenotransplant. Cells are a different matter; the medical community is not yet ready to deal with organs. It will be several years before animal organs are being transplanted into humans in Canada. There is the possibility that people will go to other jurisdictions, and third-party risks are also a reality, but these will not be a result of an investigative protocol that took place in Canada.

Partnerships

Health Canada’s Ms. Hill said that the process today was one of outreach, of making connections and working with groups outside of government. She stated that it is a good experience for Health Canada and helps to build on the notion of partnerships. One participant said that “partnership” is a buzzword that needs to be clarified. Ms. Hill responded that Health Canada assumes partnership is a two-way street and asked the group to consider what it means to be in a partnership and what they might need from Health Canada.

Over the course of the workshop, participants had been encouraged to post on a ‘partnership wall’, names of those individuals/organizations with whom they would like to partner with and names of those individuals/organizations that would consider some form of partnership with Health Canada to promote the xenotransplantation debate within Canada. The participants suggestions were shared with the group (see Appendix 8).

D. EVALUATION OF DAY 2

Did We Have the Right People?

Participants were asked to identify who was missing from this meeting. The following groups were identified:

- Diabetes Association (It was pointed out that the representative from The Islet Foundation could speak on their behalf.)
- First Nations
- social scientists
• cultural anthropologists
• other professional associations
• the Quebec transplant organization
• Canadian Health Care Association
• AIDS organizations
• Women’s Health Network
• seniors organizations

Key Messages and Recommendations

Health Canada’s Ms. Hill summarized the workshop proceedings. She said that in going back to review the notes posted around the room, it becomes obvious that there is not consensus, and that this is a huge issue, in addition to the biomedical issues. There seems to be agreement that the public needs to be involved and a Public Advisory Group, but the notion of how this will work requires careful consideration. The discussion on xenotransplantation needs to occur in many fora and in many walks of life.

Next Steps?

Ms. Hill told participants of Health Canada’s follow-up plans from this workshop, and said that they have made a commitment to have all documentation and reports back to the participants within a month. Health Canada will receive the workshop proceedings within the week, they will be reviewed internally, and documentation will be added before it is forwarded to participants for comments. The issue identification process will continue.

In the interim she asked if delegates would consent to acting as a sounding board and promised to maintain contact with them via e-mail. Health Canada will pull together the advice from the workshop on the PAG and send to participants for comment. She noted that a number of people have made suggestions for a nomination process for a PAG and that these would be considered. She asked if this arrangement was acceptable and there was consensus that it was.

Ms. Hill closed by thanking the participants, the facilitators and the logistics staff for their time, effort and contributions.
LIST OF APPENDICES

Appendix 1 Participants and Perspectives

Appendix 2 Questions raised by xenotransplantation that need to be addressed.

Appendix 3a Regulatory and Policy Decisions for Xenotransplantation. Julia Hill.

Appendix 3b Review Process for Possible Clinical Trials Using Xenografts. Peter Ganz.

Appendix 4a Public Involvement Plan for Xenotransplantation. Kim Hannah.


Appendix 5 List of Breakout Groups. Development of a Public’s Model for Involvement on Xenotransplantation.

Appendix 6 Flipchart Reports from Breakout Groups. Development of a Public’s Model for Involvement on Xenotransplantation.

Appendix 7 Notes for remarks provided by Maureen A. McTeer.

Appendix 8 Partnership Wall

Website:  www.hc-sc.gc.ca/hpb-dgps/therapeut/blood tissues organs xenografts
### Appendix 1: Participants and Perspectives

<table>
<thead>
<tr>
<th>Perspective: Those who may have different value sets - animal protection</th>
<th>Perspective: Les personnes ayant peut-être des échelles de valeurs différentes - protection des animaux</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jacqui Barnes</td>
<td>#101, 221 Broadview Avenue</td>
</tr>
<tr>
<td>Animal Alliance of Canada</td>
<td>Toronto, ON M4M 2G3</td>
</tr>
<tr>
<td>L’Alliance animale du Canada</td>
<td>Tel: 416-462-9541 ext. 22</td>
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<tr>
<td></td>
<td>Fax: 416-462-9647</td>
</tr>
<tr>
<td></td>
<td>Email/Courriel : <a href="mailto:jacqui@animalalliance.ca">jacqui@animalalliance.ca</a></td>
</tr>
</tbody>
</table>

**Biography:**

If xenotransplantation is to occur in Canada, the Canadian public (including patients and society at large) must be fully aware of the risks/benefits and implications of the procedures. Animal Alliance of Canada represents the animal side of the xenotransplant equation.

**Declared Conflict of Interest:** None

**Robert R. Van Tongerloo**  
Executive Director / Directeur exécutif,  
Canadian Federation of Humane Societies / La Fédération des sociétés canadiennes d’assistance aux animaux  
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**Biography:**

Member of Expert Committee on Livestock Bio-technology, representing the Canadian Federation of Humane Societies; participant in Canadian Council on Animal Care (CCAC) assessments.

**Declared Conflict of Interest:** None

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**Notice biographique:**

Si la xénotransplantation doit voir le jour au Canada, il faut que la population canadienne (y compris les malades et la société en général) connaisse bien les risques, les avantages et les conséquences des interventions. L’Alliance animale du Canada représente l’élément animal de l’équation de la xénotransplantation.

**Conflit d’intérêts déclaré: aucun**

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**Notice biographique:**

Représentant de la Fédération des sociétés canadiennes d’assistance aux animaux au sein du Comité d’experts en biotechnologie du bétail; participant aux évaluations du Conseil canadien de protection des animaux.

**Conflit d’intérêts déclaré: aucun**
**Deborah Gordon-El-Bihbety**  
**Canadian Public Health Association**  
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**Biography:**  
Xenotransplants could pose a risk to public health in that they may cause new types of infectious diseases. Public Health advocates the establishment of national registries for xenotransplantation surveillance to assure the safety and efficacy of ongoing investigations.

**Declared Conflict of Interest:**  
- none

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**Dr. Ian Gemmill**  
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**Biography:**  
Board member, CPHA, Communicable Disease Surveillance and Control Section, since October, 1998. Medical Officer of Health with a strong interest in communicable disease. Xenotransplants could pose a risk to public health in that they may cause new types of infectious diseases. Public health advocates the establishment of national registries for xenotransplantation surveillance to assure the safety and efficacy of ongoing investigations.

**Declared Conflict of Interest:**  
- none
Prudence Taylor
F/P/T/ Advisory Committee on Health Services
Alberta Health
Comité consultatif FPT des services de santé
Santé Alberta

Biography:
Government co-chair of the Advisory Committee on Health Services Working Group on organ and tissue donation and transplantation. My husband is an infectious diseases physician at the University of Alberta.

Declared Conflict of Interest:
My husband, Geoffrey Taylor, is an infectious diseases specialist. His research area is nosocomial infections.

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Notice biographique:
Prudence Taylor est coprésidente du Groupe de travail sur les dons d’organes et de tissus du Comité consultatif des services de santé. Son conjoint est médecin spécialiste des maladies infectieuses à l’université d’Alberta.

Conflit d'intérêts déclaré:
Mon conjoint, Geoffrey Taylor, est médecin spécialiste des maladies infectieuses. Son domaine de recherche porte sur les infections nosocomiales.
Perspective: Those who may have different value sets - spiritual views
Perspective: Les personnes ayant peut-être des échelles de valeurs différentes - vues spirituelle

Rev. Canon Eric B. Beresford / Le chanoine Eric B. Beresford
Canadian Council of Churches
Anglian Church of Canada /
Conseil canadien des Églises
Église anglicane du Canada

Biography:
The Rev. Canon Eric Beresford is consultant for Ethics and Relations for the Anglican Church of Canada. From 1991 – 1997 he was assistant professor of Ethics in the Faculty of Religious Studies at McGill University in Montreal where he also taught graduate courses as part of the interdisciplinary program organized by the Centre for Medicine, Ethics, and Law. His current work involves policy formation and interpretation for the Anglican Church of Canada on a range of ethical issues. He is involved in promoting inter-religious cooperation on ethical issues that are courses of common concern across a variety of religious traditions and perspectives. He is also a member of the biotechnology reference group of the Canadian Council of Churches. Xenotransplantation raises a number of issues that are of concern to the religious communities in Canada. There are issues of long-term safety, and questions about the appropriate ethical treatment of animals. These arise both because of concerns related to the commercial cloning of animals which would be part of any large scale xenotransplantation program and with regard to the appropriateness of using animals as sources of live organs for transplant. Finally, there are issues related to the acceptability of such grafts on both religious and ethical grounds. While few religious communities currently have policies in place around xenotransplantation, concern within religious communities will likely be quite high.

Declared Conflict of Interest: - none

Confut d’intérêts déclaré: - aucun

Prepared by: Therapeutic Products Programme & InfoLink Consultants Inc.
Perspective: Those who may have different value sets - cultural views

Les personnes ayant peut-être des échelles de valeurs différentes - vues culturelle

Dmytro Cipywnk
Canadian Ethnocultural Council
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Biography:
Impact of xenotransplantation in relation to ethnocultural communities.

Declared Conflict of Interest:- none

Conflit d’intérêts déclaré:- aucun

Perspective: Those who have a special interest in that they may be potential candidates

Les personnes ayant un intérêt spécial en tant que candidats éventuels

Mrs. Janet Duff
Parkinson Foundation of Canada
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Biography:
The Parkinson Foundation of Canada is interested in possible benefit for people with Parkinson’s disease, so that we may continue to provide current information about potential new treatments, risks, as well as benefits, to our constituents. I am a nurse, who speaks frequently to patient support groups, as well as to Parkinson’s Clinic nurses.

Notice biographique:
La Fondation canadienne du Parkinson s’intéresse aux bienfaits possibles pour les personnes atteintes de la maladie de Parkinson afin de pouvoir continuer à fournir de l'information à jour concernant les nouveaux traitements potentiels, les risques et les avantages à ses membres. Je suis infirmière et je parle fréquemment avec des groupes d’aide aux patients et aux infirmières travaillant dans les cliniques pour personnes atteintes de Parkinson.

Declared Conflict of Interest:
- I am currently in the employ of a Clinical Research Organization that contracts with...
pharmaceutical and biotechnology firms to conduct research studies. I have, nor has my employer (CroMedica Inc.) ever been involved in clinical trials relating to xenotransplantation.

- I was the nurse-coordinator of a Parkinson’s Clinic for seven years, involved in surgical treatments for Parkinson’s disease, but not related to transplantation.

Beryl Ferguson
National Program Director / Directeur national de programme
The Kidney Foundation of Canada La Fondation canadienne du rein

Biography:
The Kidney Foundation of Canada, is a national voluntary health organization committed to improving the health and quality of life of people living with kidney disease. As such, xenotransplantation is of interest to us as it may become a viable treatment option for people in end stage organ failure. Personally, I am the National Program Director for the Kidney Foundation with a social work background, knowledge of principles of community organization and an interest in the development of social policy.

Declared Conflict of Interest:- none

Alastair T. Gordon
The Islet Foundation

Biography:
The Islet Foundation supports researchers seeking a cure for diabetes. Xenotransplantation of pig islets is a promising technology for eradicating this disease.

Notice biographique:
La Islet Foundation appuie les chercheurs qui veulent trouver un remède au diabète. La xénotransplantation d’ilots pancréatiques de porcs est une technologie prometteuse pour l’élimination de cette maladie.
Declared Conflict of Interest:
- As a person with diabetes and a founder of the
  Islet Foundation, my goal is to assure a rational,
  science-based Xenotransplantation policy for
  Canada. If Islet xenographs become a safe and
  effective cure for diabetes, I will personally benefit.

Penny Marrett
Coalition of National Voluntary Organizations

Biography:
As some members of National Voluntary
Organizations (NVO) have an interest in
xenotransplantation, this issue is of some interest to
the organization. As stated in the conflict of interest
form, NVO receives funding from the federal
government, including Health Canada. I also sit on
the Expert Advisory Committee on Blood Regulation.

Declared Conflict of Interest:
- Member of TPP’s Expert Advisory Committee on
  Blood Regulation
- Coalition of National Voluntary Organizations
  receives funding from various departments within
  the federal government including Health Canada.

Susan McCabe
Canadian Liver Foundation
Fondation canadienne du foie

Biography:
Currently serving on Expert Working Group
drafting Standards for Organ & Tissue
Transplantation. I do not see this as a conflict,
however, there is the possibility that I may not be
perceived as at “arm’s length” from Government.

Conflit d’intérêts déclaré:
- En tant que diabétique et fondateur de la Islet
  Foundation, je vise à l’établissement d’une politique
  scientifique rationnelle en matière de
  xenotransplantation au Canada. Si les xénogreffes
  d’îlots s’avéraient un remède sûr et efficace contre
  le diabète, j’en profiterais personnellement.

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Biographie:
Étant donné que certains membres des
Organisations nationales volontaires (ONV)
s’intéressent à la xénotransplantation, cette
question suscite un certain intérêt au sein de
l’organisation. Comme le précise le formulaire
relatif aux conflits d’intérêts, les ONV reçoivent
des subventions du gouvernement fédéral, et
notamment de Santé Canada. Par ailleurs, je
siège au Comité consultatif d’experts sur la
réglementation du sang.

Conflit d’intérêts déclaré:
- Membre du Comité consultatif d’experts sur la
  réglementation du sang du PPT
- La Coalition des ONV reçoit des subventions de
divers ministères fédéraux, dont Santé Canada.
Notice biographique:
Mme McCabe est actuellement membre du Groupe d’experts qui élabore l’ébauche des normes concernant la transplantation d’organes et de tissus. Elle ne considère pas cela comme un conflit, mais il est possible qu’on la juge comme insuffisamment indépendante du gouvernement. Son rôle au sein du Groupe d’experts est de défendre les intérêts du public.

Conflit d’intérêts déclaré:
Je suis membre du Groupe d’experts de la Division des organes et tissus du Bureau des produits biologiques. Nous préparons l’ébauche des normes concernant la transplantation d’organes et de tissus au Canada. Je ne considère pas le fait de recevoir un salaire pour cette fonction comme un conflit d’intérêt sérieux malgré l’impression que certains jugent peut-être que je ne suis pas suffisamment indépendante du gouvernement. Mon rôle au sein du Groupe d’experts est de représenter le public, et je suis d’avis que cette fonction n’entre pas en conflit avec ma participation à l’atelier sur la xénotransplantation.

Declared Conflict of Interest:
I am a member of the Bureau of Biologics (tissue & organ division) Expert Working Group (EWG) which drafts the standards for organs & tissue transplantation in Canada.
Although I receive honoraria for this service, I do not see that there is a material conflict, in spite of the perception that I may be seen by some as not being enough at “arm’s length” from the Government. My role on the EWG is as a public representative and as such, it is my personal opinion that this affords no conflict with my participation in the Xenotransplantation Workshop.

Perspective: Those with knowledge in risk decision-making
Perspective: Les personnes ayant une connaissance de la prise de décisions à l’égard des risques
John Shortreed, Ph.D.
Director/Directeur,
Institute for Risk Research
University of Waterloo
Université de Waterloo
Biography:
General interest in processes for risk management that will assist decision-makers with nasty difficult decision problems such as xenotransplantation, which are wonderfully complex and full of all manner of conflicts. Looking forward to the workshop.

Notice biographique:
Intérêt général pour les méthodes de gestion de risques qui aideront les décideurs à prendre des décisions très épineuses à l’égard de questions merveilleusement complexes et extrêmement conflictuelles, comme la xénotransplantation. J’ai très hâte à l’atelier.
Declared Conflict of Interest:
- I served on the Krever “safety of the blood system today” committee which was critical of the Bureau of Biologics.
- I provided advice to the Ethics Advisory Committee funded by Bayer in 1997(?)
- I am part of a NERAM proposal to Health Canada on a framework for risk management.
- Have made many statements in favor of risk management.

Conflit d'intérêts déclaré:
- J’ai siégé au comité Krever sur la sécurité du système actuel d’approvisionnement en sang qui a critiqué le Bureau des produits biologiques.
- J’ai donné des avis au Comité consultatif d’éthique financé par Bayer en 1997(?).
- Je participe à une proposition faite par NERAM à Santé Canada concernant un cadre de gestion des risques.
- J’ai fait de nombreuses déclarations en faveur de la gestion des risques.

Perspective: Those with knowledge in consultation processes and methodologies
Perspective: Les personnes ayant une connaissance des méthodes de consultation

Edna F. Einsiedel
Graduate Program in Communications
Programme d’études supérieures en communications
University of Calgary
Université de Calgary

Biography:
I am a researcher in the area of Biotechnology and Social Issues. Research includes public involvement mechanisms on biotechnology and will be doing work on public participation on xenotransplantation issues.

Declared Conflict of Interest: - none

Jennifer Medlock
Communications Department
Département des communications
University of Calgary
Université de Calgary

Biography:
I am currently an MA student at the University of
Calgary. My thesis work is on public participation in science, and more specifically, with regards to xenotransplantation.

Declared Conflict of Interest: none

Perspective: Those with knowledge of research ethics review
Laura Purdy, Ph.D.
Joint Centre for Bioethics
University of Toronto

Biography:
As a bioethicist, I am interested in xenotransplantation. I have written (so far unpublished) paper on the topic, arguing that there should be a moratorium. I have spoken to the media, and have written a short, popular editorial for Free Inquiry.

Declared Conflict of Interest:
- I have given scholarly presentations about xenotransplantation
- I have spoken to the media about it
- I have published a short, popular piece on the subject (in Free Inquiry)

Perspective: Those with community knowledge / work at the community level
Dr. Taylor Alexander
President & CEO
Canadian Association for Community Care
Association canadienne de soins et services communautaires

Notice biographique:
Je fais présentement une maîtrise à l’université de Calgary. Mes travaux de thèse portent sur la participation du public à la science, et la xénotransplantation en particulier.

Conflit d’intérêts déclaré:
- J’ai donné des exposés scientifiques sur la xénotransplantation
- J’en ai parlé aux médias
- J’ai publié un court article de vulgarisation sur le sujet (dans Free Inquiry)
Nicholas F. Hurley
Canadian Association for Community Care
Association canadienne de soins et services communautaires

Biography:
Health Care organization advocating on behalf of community care in Canada. Member of HEAL (Health Action Lobby).

Declared Conflict of Interest: none

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Biography:
Lawyer, Master’s of Law. I work in the field of health and bioethics. I am president of an organ donation organization called Info Don d’Organes.

Conflict of interest:
- I am a volunteer with the Kidney Foundation of Canada. I am president of the Organ Donation Committee, Quebec Section, and a member of the National Organ Donation Committee.
- I am president of Info Don d’Organes.

Perspective... Those with knowledge of the role of media in public consultation

Perspective... Les personnes ayant des connaissances sur le rôle des médias dans le cadre de la consultation publique

Jim Warren
Transplant News
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Biography:
Jim Warren has been a professional communicator in the transplant field since 1976 and is president of Transplant Communications. He has been Editor & Publisher of Transplant News since he founded the publication in 1990. In 1995, he published the first International Transplant Director, which is now in its 6th year of publication. In addition, Warren is a partner in TransCom Media, an audiovisual company specializing in transplantation topics. He is currently co-producer of Transplant Video Journal, a quarterly video news magazine on transplantation. Prior to founding Transplant News, Warren was a communications consultant in the transplant field. He was editor of a bi-monthly news service - ACT Newsline - as well as co-producer of a series of national interactive teleconferences which focused on increasing organ and tissue donation. He began in the transplantation field as director of public relations for the National Kidney Foundation, a position he held for nearly 11 years. Prior to that, he served as communications officer of the American Psychological Association. Warren received a Bachelor of Science degree from Hastings College (Nebraska) in 1965 and Masters Degree in Communications from Syracuse University in 1968. He currently resides in the San Francisco area.

Declared Conflict of Interest:
Transplant Video Journal is underwritten through an educational grant from Novartis Pharmaceuticals USA, East Hanover, NJ. I am a co-owner and co-producer of the video.

Notice biographique :

Conflit d’intérêts déclaré:
Le Transplant Video Journal a été réalisé grâce à une subvention de la société Novartis Pharmaceuticals USA (Hanover Est, New Jersey), qui est destinée à la production de matériel éducatif. Je suis copropriétaire et coproducteur de ce vidéo.
Perspective: Those who may be indirectly exposed to risks of infection
Perspective: Les personnes susceptibles d’être indirectement exposées à des risques d’infection

Jean Jones
Consumers Association of Canada
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Biography:
Consumers Association of Canada brings the consumer perspective to the table with concerns and questions about risks, benefits, liability and costs.

Declared Conflict of Interest:
- none

David Pfrimmer
Interfaith Social Assistance Reform Coalition
Wilfred Laurier Seminary
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Regrets for this Section:
Marillies Rettig
Canadian Teachers Association

Ken Georgetti
Canadian Labour Congress

Carol Hunter
Canadian Cooperative Association

Ivan Hale
One Voice: The Canadian Seniors Network
Perspective: Those who could derive an income or profit - industry/institutions
Les personnes susceptibles de retirer un revenu ou un profit
- industrie/institutions

Dr. Barbara Fagg
Novartis/Imutran

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Biography:
Imutran is focused in developing xenotransplantation as a potential solution to the organ donor shortage.

Declared Conflict of Interest:
- Director of External Affairs for Imutran Ltd. (A Novartis Company), responsible for communications/public relations for xenotransplantation program.

Notice biographique:
Imutran s’emploie à développer la xénotransplantation comme solution possible à la pénurie de dons d’organes.

Conflit d’intérêts déclaré:
- Directrice des Affaires extérieures à Imutran Ltd. (une compagnie Novartis), chargée des communications et des relations publiques concernant le programme de xénotransplantation.

Guy Rousseau
Novartis Pharma Canada Inc.

Biography:
Novartis is actively involved in the development of xenotransplantation.

Declared Conflict of Interest:
- Employed by company actively involved in the development on xenotransplantation.
- Have access to confidential information (on xenotransplantation).

Notice biographique:
Novartis s’intéresse activement au développement de la xénotransplantation.

Conflit d’intérêts déclaré:
- À l’emploi d’une compagnie qui s’intéresse activement au développement de la xénotransplantation.
- Accès à des renseignements confidentiels (sur la xénotransplantation).

Regrets for this Section:

Robert Giroux
Association of Universities & Colleges of Canada
Perspective: Those who could derive professional advantage
Perspective: Les personnes susceptibles de retirer des avantages sur le plan professionnel

Keith G. Campbell, M.D.
Canadian Veterinary Medical Association
Association canadienne des médecins vétérinaires

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Biography:
Dr. Campbell is a veterinarian who practices Small Animal Medicine and surgery in Winnipeg. He serves on the Animal Welfare Committee of the Canadian Veterinary Medical Association (CVMA). CVMA is concerned with the animal welfare issues and safety issues (zoonotic diseases) of xenotransplantation.

Declared Conflict of Interest:
- none.

Vivian McAlister
Canadian Society of Transplantation
Société canadienne de transplantation

Biography:
I am a transplant surgeon in Halifax. I research the immunological barriers to xenotransplantation. I am the President of the Canadian Society of Transplantation for the year 2000.

Declared Conflict of Interest:
- President, Canadian Society of Transplantation 2000
- Transplant surgeon
- Researcher in xenotransplantation/xenotransfusion

Patricia Rodney
Canadian Nurses Association
Biography:
Dr. Patricia (Paddy) Rodney is an Assistant Professor with the University of Victoria School of Nursing. She is also a Faculty Associate with the University of British Columbia Centre for Applied Ethics and a Research Associate with Providence Health Care Ethics Services.

Dr. Rodney’s clinical background is in critical care nursing. Over the past ten years she has developed an academic and practice focus in health care ethics. She is a member of the St. Paul’s Hospital ethics committee and Co-Chair of the BC Women’s ethics committee. She also consults for other ethics committees in the BC Lower Mainland, and is a regular speaker at local and national ethics conferences/workshops.

Dr. Rodney’s research and writing focus on end of life decision making and the “culture” of health care delivery. In a recent cross-cultural ethics text, Dr. Rodney contributed to and edited a section on health policy and public participation.

Declared Conflict of Interest:
- none.

Biographie :
Patricia (Paddy) Rodney est professeure adjointe à l’école des sciences infirmières de l’Université de Victoria. Elle est également professeure agrégée au Centre for Applied Ethics de l’Université de la Colombie-Britannique et agrégée de recherche pour les Providence Health Care Ethics Services.

Même Rodney possède une expérience clinique dans le domaine des soins infirmiers en phase critique. Ces dix dernières années, elle s’est spécialisée dans l’éthique des soins de santé, tant sur le plan théorique que dans la pratique. Elle est membre du comité sur l’éthique du St. Paul’s Hospital et coprésidente du comité sur l’éthique de l’organisation BC Women. Elle est également consultante auprès d’autres comités sur l’éthique de la vallée du bas Fraser, et fait régulièrement des présentations lors de conférences et d’ateliers nationaux et locaux.

Les recherches et les publications de Patricia Rodney portent sur la prise de décisions en fin de vie et sur la « culture » de la prestation des soins de santé. Dans un texte publié récemment qui portait sur plusieurs domaines, elle a révisé une section consacrée à la politique en matière de santé et à la participation du public, et fait office de consultante.

Conflit d’intérêts déclaré:
- aucun
Dr. Karim Qayumi
British Columbia Transplant Society
Biography: I am an M.D., Ph.D. with an interest in xenotransplantation and am representing the British Columbia Transplant Society.
Declared Conflict of Interest: -None

Dr. Claude Renaud
College of Family Physicians of Canada

Perspective: Those with knowledge of Health Economics
Perspective: Les personnes ayant une connaissance des sciences économiques de santé

Michael Yeo
Canadian Medical Association
Biography: I am a philosopher, with specialty in ethics. Interest here is ethics of public participation, plus ethics and economics. I am here as an individual, not presenting any association.
Declared Conflict of Interest: -None

Notice biographique:
Regrets for this Section:

Michael Gross Co-Chair of the National Forum on Xenotransplantation, November 1997

Margaret Sommerville Co-Chair of the National Forum on Xenotransplantation, November 1997

Presenters & Planning Team:

Robert Peterson Associate Director General, TPP, Health Canada
Julia Hill Director, Bureau of Policy & Coordination, TPP, Health Canada
Peter Ganz Bureau of Biologics & Radiopharmaceuticals, TPP, Health Canada
Kim Hannah Bureau of Policy & Coordination, TPP, Health Canada
Andre La Prairie Bureau of Policy & Coordination, TPP, Health Canada
Mary Hegan Office of Consumer Affairs & Public Involvement, Health Canada
Marie Hirtle Bioethics Advisory to TPP, Health Canada

Observers:

Claire Farid Legal Services, Health Canada
Etienne Ouimette Bureau of Compliance & Enforcement, TPP, Health Canada
Sue-Anne Blakely Bureau of Policy & Coordination, TPP, Health Canada
Eileen Tackaberry Bureau of Biologics & Radiopharmaceuticals, TPP, Health Canada
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Dasha Pelka Women’s Health Bureau, Health Canada
Peter Crooks Industry Canada
Nasreen Bughio Canadian Food Inspection Agency
Francois Auger Expert Advisory Committee to TPP: Xenograft Regulation
Lyne Letourneau Expert Advisory Committee to TPP: Xenograft Regulation
Henry Dinsdale Expert Advisory Committee to TPP: Xenograft Regulation
Peter Portluck Expert Advisory Committee to TPP: Xenograft Regulation
Clement Gauthier  Canadian Council on Animal Care
Arlene Klotzko  Consultant

LOGISTICS:

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Mat Bondy  Bureau of Policy & Coordination, TPP, Health Canada

FACILITATION TEAM

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Nathalie Perron  Office of Strategic Planning, Communication & Quality, TPP, Health Canada
Patricia Russell  Bureau of Policy & Coordination, TPP, Health Canada
Peter Uhthoff  Medical Devices Bureau, TPP, Health Canada
Tara Bower  Bureau of Biologics & Radiopharmaceuticals, TPP, Health Canada
Appendix 2: Questions/issues raised by xenotransplantation that need to be addressed

1. Has Health Canada budgeted both the dollars/funds and the time to conduct an exhaustive public consultation and to analyse the findings? (3 dots)
2. Is there a deadline? What is the urgency in undertaking clinical trials in Canada?
3. How will we deal with the segment of the public whose religious/ethical values rule out xenotransplantation, regardless of any debate? (4 dots)
4. What will be the process for disseminating educational information and details of any plans for xenotransplantation to the Canadian public in a way that allows for dialogue with the public and minimizes media interpretation or manipulation of the facts?
5. In what countries are clinical trials being undertaken? (1 dot)
6. In countries where clinical trials are being undertaken, what public consultation process was involved?
7. Is the public in those countries even aware that xenotransplantation is taking place? (1 dot)
8. How is Canada consulting and working with OECD (Organisation for Economic Cooperation and Development) countries and others to ensure appropriate and ethical conduct? (2 dots)
9. Has there been an evaluation of the impact of xenotransplantation on human organ and tissue donation, and is the financial impact taking away from the human organ donor program? Interest in this area is said to be driven by a shortage of organs for donation, but has every effort been made to strengthen organ donor programs? Are both options receiving the funds they need, or are private sector dollars flowing predominantly to xenotransplantation? Is the financial and political will within the private sector as intense for organ donation as it is for xenotransplantation, or is the financial commitment to xenotransplantation taking resources away from organ donor programs? (6 dots)
10. Will hospitals’ capacity to deliver and administer organ donor programs be impaired as xenotransplantation receives greater emphasis?
11. Will xenotransplantation programs have an impact on the financial sustainability of the health care system? Will the cost of this technology create a financial burden that pushes other options out of the picture? (15 dots)
12. What are the core religious, ethical and spiritual values that should inform the decision to proceed with xenotransplantation? What are the mid-level axioms that will be used to interpret core values as they apply to the actual policy decisions facing Health Canada? (4 dots)
13. Should the xenotransplantation debate be opened up to the ethical issues that are already accepted by society at large? For example, if people eat pigs, is there an animal rights concern that presents society from using pig genes to save lives? We recognize the right to refuse treatment but not to deny treatment to others. (7 dots)
14. Will Canada allow experimentation in transgenics? How will it be regulated, monitored and controlled? What will be done with the results? Will this issue be included as a topic for public consultation, and how will the public be notified that transgenics is a part of this process? (12 dots)
15. Given the global dimensions of this issue, what will be the impact on Canadians of complications that may arise if xenotransplantation is performed in uncontrolled environments in developing countries? (2 dots)
16. How will legal and effective monitoring be implemented; given our constitutional guarantees, for example, of privacy and freedom of movement? Once an individual has received a xenotransplant, how should routine assessment be enforced? How likely is it that third parties will willingly accept the restrictions applied to transplant recipients? Is there an effective framework for obtaining third-party consent? Is there a way of obtaining consent during the experimental stage, when the potential risks of xenotransplantation are expected to be the most serious.
17. How will the Canadian government deal with “transplant tourism”?
18. Would we accept the privacy and freedom costs of effective monitoring? (4 dots)
19. Is it possible to determine whether a symptom or disease (eg. third party/public disease) is related to xenotransplantation?
20. Who would monitor the public for symptoms or disease?
21. How would monitoring be conducted, and who would cover any medical care costs?
22. How should ongoing assessment be monitored (enforced)? What to do? (Recipient) (4 dots)
23. Is there a framework for obtaining consent for third party involvement? (11 dots)
24. How do we ensure adequate consent at the experimental stage?
25. What are the limitations of our science in providing information for consent?
26. If we don't have the science, how can we have informed consent? (5 dots)
27. What relevant contributions can social sciences make to the assessment of risks and benefits and to the establishment of informed consent? If people must engage in blood and body fluid precautions for the rest of their lives, what are the impacts related to isolation from family and stigmatization by the wider community?
28. Religious beliefs need to be taken into consideration for informed consent (1 dot)
29. What does informed consent mean in the xenotransplantation context? (5 dots)
30. What are the risks and benefits for the individual and community? (14 dots)
31. What are the known risks of not proceeding with clinical trials? Who stays sick, who dies? (2 dots)
32. What are the psychological impacts from the patient perspective, given the link between donor and receiver, given it’s an animal? (3 dots)
33. By whom and how will decisions be made on xenotransplantation? And in what other countries will the decision be made for us? (To the regulators) (8 dots)
34. Who provides data on which decisions are made (to go or not to go ahead)? (1 dot)
35. What does xenotransplantation mean for identity as a human? (2 dots)
36. What are the ethics of using animals for xenotransplantation? What are the problems inherent in creating familiarity with animals as in the example of transgenic animals? (8 dots)
37. What is the risk-benefit to species and individual animals?
38. Is any animal or species exempt?
39. What is a conflict of interest?
40. How will Health Canada relate to communities as well as individuals (ie. social ethics versus personal ethics)?
41. What is the estimated number of lives saved or extended using xeno transplantation? (4 dots)
42. What is the quality of life (of the extended life)?
43. What is being done to prevent conditions for the need for xeno transplantation? (12 dots)
44. During the development of populations of source animals for xenotransplantation, what will be the disposition of rejected animals?
45. How can we be sure that the social and behavioral needs of those animal populations will be met? (1 dot)
46. How will we disseminate the facts? (1 dot)
47. How do we avoid media bias? (2 dots)
48. What is the urgency of conducting clinical trials for xenotransplantation in Canada?
49. How are/will clinical trials in Canada be approved, evaluated, monitored and reported? (7 dots)
50. Is this just more GMO (genetically modified organisms episode) (if so , it’s a bad idea) (2 dots)
51. Re: Page 10, 13 and 14 Ethical Issues (March 30/00 draft). Given links between socio-economic and health status, how will we avoid the danger of a two-tiered system, one in which some people have access to either xenotransplants or human-derived organs/tissues, but others only have access to xeno-derived
transplants? To the extent that the suitability of organ recipients is often based on compliance issues, which then translate into questions of worthiness, a two-tiered system becomes a very real risk.

(3 dots)

52. Given the underlying issues of values, choice, economics, what is the role of enabling policy and regulation, versus compulsory provisions? Where enabling regulations would allow access to xenotransplantation for wealthier individuals, mandatory access might apply in situations where the state has to step in and ensure that a procedure is available to someone in need. (2 dots)

53. What constitutes meaningful and effective public consultation and involvement with xenotransplantation? What are the essential components that ensure transparency and full public participation in this process? (5 dots)

54. How much scientific background can or should be provided to the public? Who will decide what information should be included? (4 dots)

55. What decision-making principles are appropriate for new technologies like xenotransplantation? In particular, what are the advantages and disadvantages of the precautionary principle and of any alternate approaches? (6 dots)

56. What is the range of alternatives to xenotransplantation?

57. What universally accepted practices and freedoms pose a known risk to third parties? The examples given were AIDS treatment in hospital and the risk posed to health care workers, and travel to countries known to have the Ebola virus. We do not propose draconian measures of follow up for people with AIDS, so why would we do that for xenotransplant recipients? (1 dot)

58. What is xenotransplantation? Why do we need it? What are the alternatives? How long till it happens? What would it mean to patients, their families and care givers? (9 dots)

59. What are the potential benefits of xenotransplantation?

60. When wouldn’t xenotransplantation be used?

61. Is the need for xenotransplantation temporary, in light of developing technologies for producing human organs? If the need is temporary, how long? Is the risk justified is this a temporary need? What artificial technologies (in development) could substitute the need for xenotransplants? (7 dots)

62. Does medical interest or medical need justify any risk or any cost to others? What are the appropriate moral boundaries?

63. What impact will any regulation have on current available therapies?

64. What plans would Health Canada have for educating and involving the media (act as a conduit for the larger community)? (10 dots)

65. Will there be plans to communicate with the public immediately, should something go wrong with xenotransplantation? This is not meant as a cover-up, but rather as a mechanism for educating the public. (7 dots)

66. What is the relationship between corporations and the development of this technology? Many questions around business ethics: transparency, accountability, degree to which product development drives the process versus medical need; what is a conflict of interest. (14 dots)

67. What terms should be avoided so as not to create a bias? It would be useful if the group could generate a list of words or terms to avoid. An example given was that of the Novartis pig, which is also referred to as a “humanized pig” because of its added human protein. However, by calling it a “humanized pig” it takes on a totally different meaning. (4 dots)

68. Is there an economic benefit to doing xenotransplantation nationally or will it be offshore? (1 dot)

69. How many animal lives will it cost?

70. Is xenotransplantation safe? (2 dots)
Appendix 3a Regulatory and Policy Decisions for Xenotransplantation. Julia Hill

Appendix 3b Review Process for Possible Clinical Trials Using Xenografts. Peter Ganz

Appendix 4a Public Involvement Plan for Xenotransplantation. Kim Hannah.

### Appendix 5: Development of a Public’s Model for Involvement on Xenotransplantation: List of Breakout Groups

<table>
<thead>
<tr>
<th>GROUP 1-Sussex Room</th>
<th>GROUP 2-Room 303</th>
<th>GROUP 3-Room 304</th>
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<tbody>
<tr>
<td><strong>Facilitator:</strong></td>
<td><strong>Facilitator:</strong></td>
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<tr>
<td>NATHALIE PERRON</td>
<td>TARA BOWER</td>
<td>PETER UHTHOFF</td>
</tr>
<tr>
<td>PATRICIA RUSSELL</td>
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<tr>
<td><strong>Participants:</strong></td>
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<tr>
<td>Taylor Alexander</td>
<td>Keith Campbell</td>
<td>Dmytro Cipywnk</td>
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<tr>
<td>Jacqui Barnes</td>
<td>Janet Duff</td>
<td>Beryl Ferguson</td>
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<tr>
<td>Eric Beresford</td>
<td>Nicholas Hurley</td>
<td>Deborah Gordon-El-Bihbety</td>
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<td>Edna Einsiedel</td>
<td>Penny Marret</td>
<td>Barbara Fagg</td>
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<tr>
<td>Ian Gemmill</td>
<td>Vivian McAlister</td>
<td>Susan McCabe</td>
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<tr>
<td>Alistair Gordon</td>
<td>Jennifer Medlock</td>
<td>Laura Purdy</td>
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<td>Jean Jones</td>
<td>David Pfrimmer</td>
<td>Karim Qayumi</td>
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<tr>
<td>Guy Rousseau</td>
<td>Patricia Rodney</td>
<td>Prudence Taylor</td>
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<tr>
<td>Denise Tremblay</td>
<td>John Shortreed</td>
<td>Robert Van Tongerloo</td>
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<td>Jim Warren</td>
<td>Michael Yeo</td>
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<td><strong>Resource:</strong></td>
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<tr>
<td>Kim Hannah</td>
<td>Mary Hegan</td>
<td>Andre La Prairie</td>
</tr>
</tbody>
</table>

| **Observers:**      | **Observers:**   | **Observers:**   |
| Francois Auger      | Gloria Bishop    | Sue-Ann Blakely  |
| Clement Gauthier    | Peter Crooks     | Nasreen Bughio   |
| Arlene Klotzko      | Claire Farid     | Henry Dinsdale   |
| Lyne Letourneau     | Peter Portluck   | Eilleen Tackaberry |
| Etienne Ouimette    |                  |                  |
Appendix 6: Development of a Public’s Involvement Plan for Xenotransplantation

Breakout Group 1

Question #1 Will xenotransplantation have an impact on the financial sustainability of the health care system? Will the cost of this technology create a financial burden that pushes other options out of the picture? (15 dots)

Question #4 What is being done to prevent conditions for the need for xenotransplantation? (12 dots)

Question #7 What plans would Health Canada have for educating and involving the media (act as a conduit for larger community)? (10 dots)

Question #7 What plans would Health Canada have for educating and involving the media

1. **Objective:** What are we trying to achieve?
   - Present risk/benefit and non science-based issues to the public
   - Valid, credible to public
   - Provide balanced info
   - May want information not only about the issue but about the players
   - Disseminate scientific jargon for general public
   - Everyone being proposed is also targeted to the public
   - You want to be proactive get timely information
   - By keeping them briefed about CTs
   - To temper the sensationalism
   - Colloques, symposium, etc...Don’t wait before something bad happens give info to them
   - Give some level of exclusivity and withdraw the favors if they are not responsible
   - Spread the good news
   - Internet: Accurate, timely – get info out before others do
   - Using the media to educate the public may not be OK
   - “Managing” the media may be a better approach - Get the issue out
   - Educate media on regulatory process and science writer as target
   - Transparency – if there is a lack – the media will get you -> Be transparent
   - No adverse effect should be confidential!
   - “Media” should include community newspaper - closer to the people

**HOW**

- Internet
- Press releases, press kits
  - Focus groups in already established networks: National assn., churches, synagogues
- Educate the media to get through to public
- Annual meetings of media associations
- Players: need to be involved in press communication
- Process and production of information: Transparency, credibility
- **Means:** Public Advisory groups

**WHO**

Prepared by: Therapeutic Products Programme & InfoLink Consultants Inc.
• Depends on nature of issue
• HC with PAGs & other associations
• “Tailor” the message to the audience
• Widely available
• Cooperation with departments where there is overlap

Questions #1 and #4
• #1 and #4 could be linked and could be separate -> separate views
• Better health at lower costs?
• What is “better” health/could be different things for different people
• Xeno for one person could mean “less care” for another
• Sustaining equitable for health care
• “Social location” of the medical technology could have an impact (e.g. reproducible tech)
• This question should not be different for this technology than for others (e.g. vaccines)
• Is this the road we go down or not? What are people needs?
• Repartition des resources va-t-elle changer? Va-t-elle être équitable.
• Pas de campagne de dons d’organes
• Peu coûteux – moins compliqué que les dons d’organes
• Perception that this could help reduce costs
• Quality of the “consent” from the patient
• Patient may not have a choice in the future to have xeno or not (compared to human organ donors)

WHO (sources)
• Health economist
• Industry
• “Keepers” of patents
• Governments (single buyer concept – e.g. U.S.)
• Medical associations
• Health care providers
• Patients
• Hospital associations
• Regional Health Authorities

HOW
• Regional conferences
• Internet
• Press releases
• Annual meetings
• Surveys
• Finance reports & information gatherings, university research
• Focus groups – to gather info on economic priorities
• International papers
• Caution: ethical issue when using 3rd World countries to get info

COMMENTS
1. Consult consumer on relative costs and implications
2. If put list of priorities – there are other things that can be put in other order of priorities
3. Put in wider context in health care

**Question #4: What is being done to prevent the need for xeno?**

- Prevention in general/application should be related
- Prevention is not only related to xeno: should apply to everything
- Difference between tissue and whole organs
- Prevention can be...has everything been done to increase organ donation? Not everything has been done – should be part of communication
- Kidney transplant problems for diabetes › should we not look at better treatment for diabetes?
- Focus should be to other alternative therapies e.g. gene therapy

**Breakout Group 2**

**Question #2** What are the risks and benefits for the individual and community? (14 dots)

**Question #5** Will Canada allow experimentation in transgenics? How will it be regulated, monitored and controlled? What will be done with the results? Will this issue be included as a topic for public consultation, and how will the public be notified that transgenics is a part of this process? (12 dots)

**Question #8** By whom and how will decisions be made on xenotransplantation? And in what other countries will decisions be made for us? (To the regulators) (8 dots)

**HIGH PRIORITY**

- If Question #2 is answered you will have provided ‘enough’ information to make informed decisions on other questions asked.
- Must have the acceptance and commitment of public before scope of issue can be projected.
- Timeliness – pressure to act quickly.

**Question #2** What are the risks and benefits for the individual and community?

**WHAT**

1. Greatest amount of accurate information to the greatest number of Canadians.
2. Good quality public education.
3. Obtain public’s perception/opinions of risks and benefits of xeno from community and individual perspectives
4. Actual meaningful dialogue within the publics at all levels
5. Transmit and receive information
7. Hear issues from public (apart from risks/benefits) i.e. social, economic, religious
8. All stakeholders feel satisfied that they have sufficient information to form an opinion
9. They (stakeholders) have a means to make that opinion known (i.e. 3-level documents)
10. Do not want to alarm public or generate false expectations
11. Discussion focused on exact examples.
12. Obtain balance in information provided to public
13. Full disclosure: embedded procedure/implications of decision
14. Clear understanding of the use of information from consultation
15. Develop a new kind of participatory process from public (not total opinion survey)
16. Education should be continuous
17. Consider risk communication approach – explore more fully
18. Allocate the ‘right’ amount of (scarce) resources
19. Timeliness – need for quick action with max. of ‘useful’ information
20. Address misperceptions

WHO
1. Specific interest groups (medical, scientific, voluntary health organizations who may benefit or not etc.) (NAPO)
2. Media (very broad!) – group to be educated on its own. If not, misinterpretation & alarm may result
3. General public who don’t fit in other groups
4. Politicians – at all levels. Municipal -> national
5. Decision-makers, budget-makers, regional board members, hospital administrators, health care workers/deliverers/providers
6. Imp. to identify those not well captured in strong advocacy groups i.e. elderly, poor, english as 2nd language
7. Researchers & scientists
8. Actual pts, families & community
9. Educators (at various levels) not only formal education system

HOW
1. Surveys, stratified sampling
2. Respond to those interested
3. Website
4. Targeted groups -> doctors; different communication vehicles for all groups
5. Information intermediaries i.e. libraries
6. Newsletters
7. Town hall meetings, focus groups targeting wider range of population/match vehicle with group
8. Series of press briefings/seminars with press -> emphasize honesty, transparency
9. Media -> 6 o’clock news fillers/HC to issue x no./year
10. Citizens jury – gather group of citizens – educate them then meet with expert advisory committee – developed in Europe (precautionary issue)
11. Forming partnerships i.e. National Anti-Poverty Organization (NAPO)
12. Ad campaign
13. Info package to magazine editors, tabloids to reach broad public
14. Childrens’ stories, narrative stories
**Breakout Group 3**

**Question #3** What is the relationship between corporations and the development of this technology? Many questions around business ethics: transparency; accountability; degree to which product under development drives the process versus medical need; what is a conflict of interest? (14 dots)

**Question #6** Is there a framework for obtaining consent for third party involvement? (11 dots)

**Question #9** What is xenotransplantation? Why do we need it? What are the alternatives? How long till xeno happens? What would it mean to patients, their families and care givers? (9 dots)

**WHAT**
- Education & information/i.e. the information given. Add pictures & examples/illustration. Need basic literacy. Purpose will determine content.
- Need clarity & balance
- Uniformity of message across language & cultures
- Avoid bias
- Define the scope which will determine the content
- One way education
- Public awareness? High
- Education: High in amount & not complexity
- Dialogue? Low but moving to a higher
- Plain language & limit the amount (not overbad)
- With references

**WHO**
- General public
- Children (not valuable for immediate input?)
- Consumer
- ccint be left out

**HOW**
- TV: Documentary, information package/public service, paid delivery
- Town hall
- Internet
- Newspaper – paid delivery
- Press release

**WHAT**
- Third party = public
- Third party = close patient contacts, H.C. providers
- 1st defined
- then education, dialogue
- implementation
Appendix 7: Notes for remarks kindly provided by Maureen A. McTeer
to the Health Canada Planning Workshop on Public Involvement for
Xenotransplantation, Ramada Hotel, Ottawa, Ontario
Monday, April 10, 2000, 8:00 p.m.

I am pleased to be included in this exercise. I feel I owe it to Andre La Prairie, who was a super help to me on this subject when I was completing the chapter on this subject in my most recent book. Now I am sure you are speechless and I have found over the years that after a day of intense discussions like you have had today, that most people look forward to an after dinner speaker with as much anticipation as a trip to the dentist. So, for both of our sakes, I will be brief.

By way of context, my interest in these issues is both substantive and procedural. I have spent most of my life in a kind of limbo-close enough to the centre of the public stage to know how decisions are made, yet far enough removed to be able to look at the process and the people with an appraising and sometimes critical eye.

During the past decade, at least three major and simultaneous changes have affected how the governed and their government interact. All three will continue to have a huge impact on public policy and political action.

The first is perhaps the most troubling if you are a political scientist and that is the assumption by Canadians that we have a system of representative government, when in fact we have a system of responsible government. That mistake has led us down all kinds of roads that the current structures can not hope to rectify in the short term. Instead, the public continues to turn away in cynicism, resignation or even disgust from the political process upon which our very democracy depends for its strength, vitality and legitimacy.

The second major change is a technical one. As the Internet puts the possibility of direct communication at everyone’s fingertips, it has made existing and traditional systems of government control and “consultation” almost irrelevant. The legitimacy of government and its bureaucracies are challenged as people opt out of the system, and seek to influence public policy in other ways. In this kind of system, those with the most money have a privileged access to both the legislator and the media, making the discussion of controversial and current issue, such as GMOs (genetically modified organisms) or xenotransplantation, for instance, into grist for the entertainment mill.

The good news of this sea-change is that thanks to the Internet, more people with a large cross-section of interests are now able to participate and influence public decision-making. The bad news is that it comes at a time when, at least in most of English Canada, governments have lost their historic legitimacy and credibility as protector of the public interest and guarantor of the public’s health and safety.

The final change involves the very stuff that raises the issues in the first place—and that is science. The most crucial issues of this decade are raised by science. Science will continue to forge ahead regardless of whether we are present or absent from the debate. What science can do, science will try.

Our challenge will be to balance the mandate of science with the interests of the community and the rights of both the individual and the collective. But unfortunately, science is also the subject most of us know the least about. We are scientifically illiterate at a time when we need to understand more, not less, about what science offers—for good and for bad. These new realities will shape and dictate how we respond to the current and controversial issues science raises for society.
The larger questions you and I have to answer now are “How do we prepare Canadians for the ongoing, rapid and interrelated revolution of science? And, having accomplished this, how do we ensure that what they say and recommend forms the basis of public policy and Canadian law? That is what you are charged with in these 2 days of fake Spring in the Nation’s Capital.

Speaking personally, I believe that if governments really want to involve Canadians in these incredibly exciting issues, that they will have need to be a great deal more creative and take a much more radical approach that in the past. Governments are criticized as being out of touch with the people. Many even go so far as to deny ANY role for government.

How, then, might we make the process of community participation more relevant and meaningful? How can we prevent Canadians feeling used and others feeling excluded? How can we make public policy setting more meaningful to Canadians and ensure that governments and bureaucracies are on the right track?

I believe that one of the reasons people feel distanced from decision-making is that, even if they do become involved—it comes too late in the decision-making process. If we really want broader and more representative involvement by Canadians, we will have to accept that most of these consultative processes and so-called public discussions are rigged from the beginning.

To counter the power of government and the bureaucracy, we need some fundamental rethinking of how we are governed and determine public policy. We cannot build the country we want and need in this new century by just relying on the frameworks that were designed for a much earlier time and set of circumstances. Canadians know this.

It is always good for the ego to be among the select group that get the trip to Ottawa or are solicited for their views. But if you have done this before, you know that real power remains elsewhere. How do we ensure that all Canadians—no matter their background or point of view on controversial issues are included in these kinds of groups? And how do we ensure that Canadians who participate in these exercises are not reduced to the crossers of Ts and the dotters Is? How do we involve Canadians in real power—the power to set the rules, determine which questions are asked and which priorities chosen for funding and fast-tracking?

The current traditional process brings together SOME people and asks them to ADVISE and CONSULT. Can we ever move beyond this narrow base to where ALL Canadians with an interest and some knowledge DETERMINE the issues to be considered? I believe that we must and there are some indications that we can.

I am amazed at how corroded our trust in government has become and worry about its impact on our democracy. I have thought a lot about what we might want to do to improve the situation; and urge a framework for action that is more independent of government control and more community-based.

How might this be achieved?

Since so much of life is serendipitous, I am sure that many in Health Canada were pleasantly surprised by the success of a recent exercise in “consultation” about food biotechnology—a hot and controversial topic if there ever was one. Part of the success of that exercise was directly attributable to the real control that the participants exercised in the definition of the agenda and the determination of the issues to be discussed. Normally I would balk at a title as pretentious as The Citizens’ conference on Food Biotechnology, but in this case, that is exactly what it was. Health Canada officials are to be commended on this effort. Since my own dismal experiences of intrigue and controls as a member of the Royal Commission on New Reproductive
Technologies a decade ago, I have avoided involvement in these kinds of “consultation” processes. I don’t like to be used or manipulated.

But the Citizens’ conference held in March of last year broke new ground and endorsed a different approach. The Calgary exercise moved beyond a mere “consultation” to one where people from the community exercised leadership and control on the agenda and the results.

Are there lessons we can learn from the Calgary community process, and if so, are they applicable to the task you are facing here on xenotransplantation? I believe that the answer is “yes” on both counts.

**LESSONS WE CAN LEARN**

There are several lessons we can learn from the Calgary experience. I will mention only a few here.

Perhaps the most important lesson we learned is what community representatives are able to accomplish when given authority and a measure of control over their work. The Calgary group avoided taking the easy road and they seemed just stubborn enough to refuse to be controlled or dictated to, especially as it related to time frames for their work and reporting. Independence is essential to attract the best minds to these exercises and to build credibility for their findings.

Second, there is a need for maturity among the participants, especially those who are designated to take on additional leadership responsibilities within the group. This is not about personal power, but group power. Leaders of these groups must know that, and be held accountable by their group of peers, if there is to be real discussion and consensus-especially on these controversial issues.

Third, building on this, the group must adopt a consensual and inclusive approach to its work. This is essential on issues as controversial as GMOs and xenotransplantation, for instance, where there is no firm consensus at present on whether we should proceed with this research; and what are the most important issues to be addressed and given priority. People must be able to disagree on fundamentals and not be ostracized.

Fourth, the members of the Calgary group assumed a representative role. In my experience, governments and bureaucracies assume their job is to shape the outcomes as part of the setting of the agenda. That hands-on attitude allows them to keep control, as does the fact that they have control of the selection of who is invited and the budget. Keeping control is what we must change if we are to re-engage the public and earn their trust. Yet this is foreign to most bureaucracies and bureaucrats who have always exercised control. I remember the Summits and how the Sherpas (even the name speaks volumes) would have everything in place before the Ministers even met. And why not if that’s your ob? It is much less messy to have the final report and press release drafted and at the translators before the group has even met. In the Calgary exercise, the participants saw their role in a much more idealistic way. They believed that they had a special role to play and were committed to contributing, in their sense, as part of their civic duty.

Fifth, for whatever reason (and it would be worth looking at to find out what these actually were), the Calgary group was able to feel and articulate the pulse of the community on genetically modified foods. That is a rare talent and they did it very well indeed. They quite clearly identified the whole area of GMF’s as one whose acceptance depended on public trust. They were clear that food was about more than research. It affected each and every Canadian in a direct and personal way. Mothers concerned about what was in the food they were feeding their children’ people with allergies worried about an unexpected reaction; vegetarians or religious observers refusing to eat foods altered with human or animal genes. Food is at the heart of how we live and even define our cultures and communities.
Health is also one such issue, I believe, and to the extent that xenotransplantation touches our lives in many ways, you will want to be sure that you hear and reflect all the messages that Canadians will offer you in your work.

Finally, while the team in Calgary addressed specific regulatory or legislative initiatives, such as labeling, for instance, they also captured the bigger picture and understood that when all is said and done, genetic engineering of food is only partly about science and a whole lot about society. Knowing that makes it possible to face criticism and meet concerns that are much about individual perception as reality. It will also color how we craft ways to deal with these matters in the future.

In concluding, I want to say that it is essential to bring these matters to the public for discussion and resolution. I mentioned earlier the book I have recently written on some of the questions science and medicine raise for society and the law. From the beginning I had a clear purpose—to provide succinct and accessible information to Canadians so that they can join in the public debate and decision-making about some of the issues that will revolutionize our living and dying and touch each of us and those we love in the years ahead.

Xenotransplantation is one of those issues. In its resolution, there are so many factors at play—animal rights, public health and safety; access to organs for transplant; legal issues of consent; the sheer curiosity of science to know if it can be done. There is no large consensus on this yet. Your work will be most helpful to all of us in both its content and its context. Good luck.
Appendix 8: Partnership Wall

“I volunteer myself or my organization”:

- Jan Duff, Parkinson Foundation of Canada
  jduff@cromedica.com
  - to utilize resources of organization to help in dissemination of information (web-site, newsletters, national magazine, meetings, etc)
  - (personally) to participate on Public Advisory Group

- Beryl Ferguson, The Kidney Foundation of Canada
  - would be able to facilitate distribution of information & dialogue with renal patients across Canada
  - other involvement as required

- Canadian Veterinary Medical Association
  339 booth St., Ottawa
  dthiel@cuma-acmv.org

- Jennifer Medlock, University of Calgary
  jennifer-medlock@hotmail.com
  (403) 282-6638
  - will be running a ‘citizen’s jury’ in Alberta
  - I would love any help from any interested group (including Health Canada) in terms of expert advising of the process, the best way to run the jury, etc.

- Robert Van Tongerloo, Executive Director, Canadian Federation of Humane Societies
  613-224-8072
  cfhs@storm.ca
  - volunteer in PAG or other advisory capacity
  - now member of CCAC, expert ctte on livestock biotechnology

- The Canadian Association for Community Care
  1 Nicholas St, Ottawa
  613-242-7510
  - Taylor Alexander (CEO), Nicholas Hurley (Chair)
  - to assist in the consultation process

- Canadian Council on Animal Care, Clement Gauthier
  - offer a network of 224 community representative of animal care committees for input, feedback

- The Canadian Liver Foundation, Susan McCabe
  - has past experience partnering with HC to disseminate public information to the medical community & the general public.
  - we would be able to assist with information dissemination
Animal Alliance of Canada, Jacqui Barnes  
jacqui@animalalliance.ca  
-help disseminate information

Rx&D, Guy Rousseau  
-activities not specified, preferably Novartis (to be determined)

The Islet Foundation, Alastair Gordon  
A.t.gordon@attglobal.net  
416-486-8784  
-“will consider all proposals for enslavement”

Edna Einsiedel, University of Calgary  
-I continue to do work (research) in public involvement on biotechnology applications (eg. Jennifer Medlock, my student, is doing thesis on public participation in xeno). We would love to continue this work in partnership with HC

Consumer Association of Canada, Jean Jones  
“I should be reporting to the Health Network at CAC about collaborating in dissemination & in developing focus groups”

“People/Organizations I suggest”:

Eric Beresford, Canadian Council of Churches –by David Pfrimmer, Biotechnology Reference Group

Professional Associations: medical, nurses, social work

Dr. Anthony E. Lang  
Neurology Clinician & Research, Professor, U of T, Dept of Medicine  
399 Bathurst St–MP11  
Toronto Western Hospital  
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-expert advisory

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Regulatory and Policy Decisions for Xenotransplantation

Julia Hill,
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Planning Workshop
Public Involvement on Xenotransplantation
April 10, 2000
What is the Therapeutic Products Programme?

- National authority which
  - regulates, evaluates and monitors
    - the safety, efficacy, and quality
    - of therapeutic and diagnostic products and vaccines available to Canadians.
What products does the TPP regulate?

- Products regulated include:
  - drugs,
  - medical devices,
  - blood, tissues, organs,
  - disinfectants and sanitizers with disinfectant claims.
Where does the TPP derive its mandate?

- The Food and Drugs Act defines the scope of regulated products.
  - Food and Drug Regulations
  - Medical Devices Regulations
- Regulations carry the purpose and provisions of the Act into effect.
How are therapeutic products regulated?

- The Regulations control the sale of therapeutic products throughout the life cycle of the product.

- **Life cycle begins with clinical research:**
  - experiments on humans;
  - Sponsors file a submission; if TPP raises no objections with 60 days (changing to 30), trial can proceed;

- **Pre-clinical research is not regulated by the TPP:**
  - laboratory research, pig to non-human primate transplants, creating transgenic pigs;
How are therapeutic products regulated? (Pre-Market)

- Sponsors file a submission, with information and data:
  - the product's safety, effectiveness and quality;
  - results of preclinical and clinical studies.

- The TPP reviews submission, sometimes using external consultants and expert advisory committees;

- if conclusion is that the benefits (effectiveness) outweigh the risks (safety), then

- a licence is issued, a product can be sold in Canada.
How are therapeutic products regulated? (Post-market)

Once a product is on the market, the TPP:

- collects reports of adverse events;
- investigates complaints and problem reports;
- conducts inspections of facilities.

The TPP can seize products not in compliance or order the removal of the product from the market.
How are regulations made?

- Regulations are made by the Governor in Council (in practice a Committee of Cabinet).

- Subject to the Federal Regulatory Policy and the Regulatory Process Management Standards.

- Federal Regulatory Policy requires that:

  - **Canadians are consulted, and that they have an opportunity to participate in developing or modifying regulations and regulatory programs.**
What is TPP policy development process?

The policy development process consists of six steps:

1. Identify the problem or issue;
2. Analyze the issue;
3. Generate solutions;
4. Select and plan solution;
5. Implement solution;
6. Evaluate.

Depending on the nature of the issue, the TPP may consult with stakeholders and the public at every step.
Consultation and Xenos, activities to date:

- In preparation for consultations, the TPP has issued:
  - Notice of Intent to develop a regulatory framework for Xenografts (Feb. 6, '99);
  - Notice to Hospitals advising that all clinical trials for xenografts must be approved by the TPP (Mar. 29, '99).
  - Fact Sheet on Xenotransplantation issued in July '99.
  - A draft standard for the transplantation of xenografts in humans posted to TPP Website for comment in Sept '99. Mailouts to over 900 stakeholders.
Current status of Clinical Trials for Xenografts

- *Preclinical* studies on Xenotransplantation are being conducted in Canada;

- The TPP has not yet received a submission for approval to conduct *clinical* trials in Canada;

- One sponsor has provided notice that a submission will be filed sometime in 2000;

- The TPP has had preliminary discussions with this sponsor to discuss the technical and scientific aspects of a submission.
What happens if a submission is received before public consultations are completed?

► If sponsor's data and information are scientifically acceptable, the TPP currently has no authority to prevent a clinical trial from proceeding.

► The Minister has the authority to prohibit the use of xenografts in clinical trials if it is in the interest of public health to do so.

► The Minister may also request that sponsors agree not to file submissions until public consultations are completed. The request does not have the force of law; compliance would be voluntary.
How will this workshop make a difference in the development of policy?

- We are committed to ensuring that the views of the public are heard before decisions are made;

- We want to design this exercise so that Government views do not influence the public discussion.

- We need your help to develop a plan that will help achieve these objectives.

- We need your advice before making recommendations to our Minister on the announcement of a Public Involvement Plan.
How will the views of the public make a difference in the development of policy?

- Government's business is to make sound public policy;

- Policy *for* public versus policy *with* public;

- **Implementable decision = logic x acceptance.**

- Views of public will be given serious consideration; along with those of other stakeholders;

- Democratically elected representatives also speak on behalf of public.

Parliament will have final say.
Health Canada Commitments:

- To give Canadians an opportunity to express their views before policy decisions are made;
- To provide Canadians with access to the information they need to participate in an informed manner, while protecting confidential information;
- To inform the Minister about the results of the consultations and how the views expressed influenced the advice and recommendations given; and
- To inform Canadians about how the views of those who participated have been taken into account when decisions are made.
Review Process For Possible Clinical Trials Using Xenografts

Dr. Peter R. Ganz,
BBR
April 10, 2000
Clinical Trials Using Xenografts?

A balance between the requirement for knowledge and the principle of precaution.

One should develop areas where there is great potential for addressing major health related needs but this needs to be balanced by the need to minimize harm by influencing the design if the system of rules and other elements to ensure the existence of various protective measures and other precautions.
The Review Process...

A manufacturer who seeks approval for a drug product must submit data to support the safety and effectiveness of the product, in compliance with the requirements of the Food and Drug Regulations.

The data submitted by the manufacturer (e.g. IND or a New Drug Submission) is screened for completeness and acceptable format and is then subject to an extensive review process.
The submission is reviewed by a team including:

- a principal clinical reviewer
- a principal chemistry and manufacturing reviewer
- a team leader: the Division Manager or a designated person who assumes the overall responsibility for the review.
...The Review Process...

The team review process may also involve:

- other reviewers from the same Division or Bureau
- other reviewers from other Bureaux
- other experts from the Therapeutic Products Directorate (e.g. clinicians, immunologists, virologists, toxicologists, statisticians)
- consultation with external experts (EAC-Xeno, EWG-Xeno)
- formal discussions with reviewers from other regulatory agencies (e.g. FDA)
- joint review (e.g. FDA)
The data for review is detailed and extensive. The review involves the examination of a large number of volumes (several in the case of INDs to sometimes exceeding one hundred for a NDS), in addition to:

- relevant publications not submitted by manufacturer (bibliography search)
- international approval status, foreign evaluation reports and post-marketing experience, when available
- evidence of product consistency from lot to lot
- report of on-site evaluation
The Review Process

Review Criteria:

- Safety
- Efficacy
- Quality
- Benefit/Risk Evaluation
The Review Process...

Review Tools:

- Review Templates
  - Preclinical and Clinical Evaluation Report Template
  - C&M Review Template (Quality Evaluation Report Template)
- Canadian and International Guidelines and Regulatory documents (ICH, EC, FDA, TGA...)
- Draft Canadian Safety Standard for Xenografts and Xenotransplantation
Status of Pre-Clinical and Clinical Trials Using Xenografts-Canada

- Preclinical studies on xenotransplantation are being conducted in Canada.
- The TPP has not yet received a submission for approval to conduct clinical trials in Canada.
- Several sponsors have provided notice that submissions to conduct xenograft clinical trials will be filed sometime in 2000 or early 2001.
- The TPP has had preliminary discussions with several sponsors to discuss the technical and scientific aspects of submissions.
What information is submitted to the TPP for clinical trial approval?

- Examples of the kind of information submitted, includes:
  - data respecting the safety, quality of the xenograft
  - data respecting the manufacturing process
  - results of relevant laboratory and preclinical testing;
  - results of any clinical testing;
  - details on the proposed design and conduct of the clinical trial;
  - details of any activities that may negatively influence the safety or quality of the therapeutic product to be tested in humans during the trial.
What information is submitted to the TPP for clinical trial approval?

Sponsors are aware of the publication by TPP of the draft Proposed Canadian Safety Standard on Xenotransplantation.

This document specifies the kinds of issues that should be addressed, if a clinical trial were to proceed.

It is anticipated that data required as set out in the PCSX will dictate the nature of the sponsor's submission.
How will the TPP decide whether to approve a clinical trial for xenografts?

- The decision whether to approve a clinical trial will take into consideration:
  - safety, quality and effectiveness if the xenograft
  - risk to the recipient;
  - benefit to the recipient;
  - risk to third parties; and

- any other factors that concerning the health and safety of trial participants and third parties.
What happens if that information is not complete or unacceptable?

- If the information in a clinical trial submission is not complete or unacceptable, the sponsor will receive a notice that they cannot proceed with the proposed clinical trial in Canada.

- The sponsor may choose to resubmit the clinical trial proposal with new information or data to address the deficiencies.
Summary of the Current Review Process

- Team approach
- Uniform approach and focus on benefit and risk evaluation
  - Product-specific templates, PCSX
  - On site evaluations
- Internal and external consultations
- Global considerations
PROPOSAL FOR A

PUBLIC INVOLVEMENT PLAN for
XENOTRANSPLANTATION

Health Canada

March 2000
I BACKGROUND

II OBJECTIVES OF THE PUBLIC INVOLVEMENT PLAN

III PROJECT PHASES

Phase 1 Information and Initial Outreach
Phase 2 Planning Workshop: Public Involvement on Xenotransplantation
Phase 3 Public Education, Awareness and Dialogue
Phase 4 Regional Consultation
Phase 5 Synthesis of Public Input for Policy Development
Phase 6 Continuation of Public Involvement

APPENDIX 1: Formation of a Public Advisory Group
I BACKGROUND

Who is the Public and What is Public Involvement?

The purpose of this document is to describe a plan, developed by Health Canada, for involvement of Canadians in issues raised by xenotransplantation and the development of policy. In this document, public refers to the general public and includes individual Canadians and groups with diverse background and interests such as: health, animal welfare, cultural, religious, legal, medical research and industry. An important principle of the plan is that there be as broad a representation of public perspectives as possible to develop policy on xenotransplantation. Public involvement refers to participation of the public, through various activities, at all stages of the policy development process.

Why Consult?

A fundamental rationale for public involvement is to produce high quality policy and promote a transparent and open decision-making process. The importance of this basic rationale is emphasized in Treasury Board’s guidelines for development of regulatory policy. As well, given the scientific uncertainty concerning unknown, unrecognized or emerging risks, a risk management approach to the issues is required. The nature of the research and possible technological developments in xenotransplantation warrant a broad decision-making base arising from consultation and involvement of the public. Issues raised by xenotransplantation occur at several levels of society: the individual level (patient in need of care), community (patient groups), Canada society in general and the international community. It is the very breadth and profoundness of the issues raised that necessitate informed public debate to promote credible policy development.

Public Involvement Principles

It is important that the consultation process be based on a sound, rational, value-driven process. Therefore, the overall exercise of the public involvement plan should include a statement of principles that will guide the process and can then be helpful to assess successful outcomes. The public involvement plan will strive to respect the following principles:

- visible/transparent process
- credible (includes honesty and willingness to discuss hard issues)
- equal opportunity for all to participate
- each participant will be considered as contributing valuable input
- willingness of Health Canada to seriously consider all the input from the public involvement process
II OBJECTIVES OF THE PUBLIC INVOLVEMENT PLAN

The specific objectives of the public involvement plan include:

1. To increase the public’s knowledge and understanding of the benefits and risks of xenotransplantation so that Canadians may participate in the development of policy and make more informed choices regarding policy options.

2. To educate Health Canada about the public’s perceptions, opinions, concerns and knowledge regarding xenotransplantation so that policies and programs are responsive, timely, and of high quality.

3. To inform Canadians, on an ongoing basis, about the process for managing the risks and benefits of xenotransplantation. This includes information on regulations, programs, research, decisions, and opportunities for public involvement.

4. To clarify the roles and responsibilities of all interested and affected parties.

5. To provide opportunities for the public to: a) participate in the development and implementation of policies and programs on xenotransplantation; b) participate in evaluating the impacts of these policies and programs on the health of Canadians.

Sub-Objectives:
(i) To obtain public input on a proposed standard on xenotransplantation;
(ii) To discuss and further develop the issues identified at the National Forum on Xenotransplantation, November 1997;
(iii) To clarify and validate the public’s opinion of the issues surrounding the regulation of xenotransplantation in Canada;
(iv) To obtain public input on the criteria and methods used to assess proposed clinical trials for xenotransplantation; and
(v) To discuss the use and mandate of a Public Advisory Group as a method of continuous public involvement on issues concerning xenotransplantation.
III PROJECT PHASES

PHASE 1 INFORMATION AND INITIAL OUTREACH

Objectives: • To gauge the level of public awareness of, and receptivity to, xenotransplantation.

• To define a representative cross-section of public necessary for a credible process.

• To identify critical public issues and concerns and assess the public’s preferences on the awareness, education and consultation processes.

• To determine the focus and intensity of pre-consultative educational efforts needed to ensure informed involvement and also serve as a benchmark against which to assess the relative success of outreach efforts.

• To determine communication priorities, including effective communication vehicles and trusted information sources.

Activities:

1. Develop initial work plan and receive management support:

   Objectives: • To determine whether there is consensus within Health Canada on the role and responsibility of the regulator, TPP.

   • To develop and implement a public involvement plan on xenotransplantation.

2. Environmental Scan:

   a) Identify interested and affected public sectors

   Objectives: • To define a representative cross-section of the public necessary for a credible process.

   • To identify those interested in participating in consultations and/or obtaining educational material.

   b) Conduct public opinion research

   Objectives: • To define the present public dialogue, debate, points of view.

   • To identify critical public issues and concerns, preferences on consultation processes, communication priorities, effective communication methods and credible information sources and to establish benchmarks.

   c) Develop information kits

   Objective: • To provide information to the public on xenotransplantation and public involvement activities.
d) Enhance TPP website for xenotransplantation

**Objectives:**

• To enhance transparency of the process, to inform the public in a timely manner on current activities.

• To obtain public comment, provide feedback and linkages to other website initiatives.

e) Conduct media analysis and develop key media contact lists.

**Objective:**

• To determine the media perspective and to engage the media in a role for public education on xenotransplantation and public involvement activities.

**PHASE 2  PLANNING WORKSHOP**

1. Planning Workshop: Public Involvement on Xenotransplantation

**Objectives:**

• To obtain guidance on elements of the *Public Involvement Plan*, including:

  - identification of key issues raised by xenotransplantation which may require further awareness, information or education, and dialogue;

  - identification of criteria for the process to broaden awareness, information or education, and dialogue on xenotransplantation; and

  - formation of a Public Advisory Group (see Appendix 1)

• To define the roles and relationships, in public involvement and decision-making on xenotransplantation, of all interested and affected parties.

**PHASE 3  PUBLIC AWARENESS, EDUCATION AND DIALOGUE**

**Objectives:**

• To provide the public an opportunity to understand the issues, benefits and risks of xenotransplantation, and equally important, to understand their own individual attitudes or values on xenotransplantation issues.

• To identify as broad a range of public as possible to participate in consultations on policy for xenotransplantation.

**Considerations:**

• The development of policy on xenotransplantation requires the engagement of individual Canadians, the public, in a discussion of the many issues raised by this new technology.

• The broad scope and sensitivity of issues concerning xenotransplantation makes it important to solicit the widest possible range of public views.
• Xenotransplantation has not yet been elevated to a sufficient level of debate among Canadians. Therefore, one can’t expect to find in the general public, at this time, a sufficient basis of informed judgement for conducting a meaningful dialogue by a broad segment of the public.

Activities:

1. **Develop an awareness and education strategy**

   **Objective:** •To provide educational materials to promote awareness of issues concerning xenotransplantation and facilitate informed dialogue.

2. **Elevate the profile of the issue**

   **Objectives:** •To create interest in the issue and to assist in ensuring a broader representation of public perspectives in public activities.

   • To determine any educational component for further consultations.

   • To promote transparency of the process.

**PHASE 4 REGIONAL CONSULTATION PHASE**

**Objectives:** •To identify effective methodologies to promote public dialogue, education and debate.

• To obtain feedback on issues raised by xenotransplantation.

**Considerations:** There are an endless variety of means through which the public can contribute to the development of a Canadian xenotransplantation policy. Examples of possible methodologies include the citizen panel, town hall meetings, partnered consultations undertaken by community advocacy groups and a printed workbook for completion by individuals/groups in a manner consistent with their particular organizational or cultural preferences (e.g. discussion circles).

**PHASE 5 SYNTHESIS OF PUBLIC INPUT FOR POLICY DECISION MAKING**

**Objectives:** •To obtain a synthesis and analysis of public input on issues concerning xenotransplantation.

• To obtain recommendations from an independent PAG derived from the analysis of public input.

• To promote transparency and credibility of the process.
PHASE 6  CONTINUATION OF PUBLIC INVOLVEMENT

Objectives:
• To evaluate the outcomes of the various phases.
  • To advise the regulator on the need for ongoing public involvement and appropriate mechanism(s).

Considerations:
• The process of developing policy is at least as important as the content of the policy itself. In fact, the two cannot be separated and the inclusiveness of the policy development process will determine the quality of the policies produced.

• Evaluating the process of the public involvement plan is critical to using resources wisely, to improving our understanding of how to structure the plan for maximum impact and to demonstrating the credibility of the process. All steps of the public involvement plan must be evaluated.

• The public should be involved wherever possible in the evaluation processes.
Formation of a Public Advisory Group for Xenotransplantation

**Objective:**
- To form an Public Advisory Group (PAG) that would serve as an affordable, conduit for informed, objective and timely advice to Health Canada on issues raised by xenotransplantation.

**Considerations:**

a) Health Canada retains the ultimate decision making authority and accountability.

b) The PAG’s decision-making processes must be open and transparent and it must take the lead in interpreting the results of the public involvement process, both of which are crucial to its credibility.

**Suggested functions of the PAG:**

- to assist in the identification and prioritization of key issues for public dialogue;
- to assist in the design of the format and content of the consultation; methodologies; such as study groups, town hall meetings, study circles or other mechanisms, and also advise on who should participate and how they are chosen;
- to assist in the implementation of the public involvement plan;
- to evaluate public involvement as it unfolds, including oversight and recommendations on pilot consultation;
- to participate in the general consultation processes (e.g. Chairs, moderators, guest speakers, observers);
- to synthesize input from the public;
- to prepare a report containing recommendations based on public’s views;
- to provide policy advice to Health Canada, from the perspective of the PAG; and
- to advise on the need and mechanism for continuation of public involvement.

**Suggested Conditions of Operation:**

- The PAG should operate at arms length from Health Canada and its membership comprise a representative cross-section of key public interests.
- The public, and not Health Canada, should identify specific groups or expertise to be included in the PAG. However, some general considerations
are recommended by the regulator:

♦ perceived as legitimate representatives of public sectors (known, nominated, or endorsed by public bodies);
♦ perceived by the public as balanced in membership (all sectors represented);
♦ capable of exercising open and transparent decision-making processes;
♦ trusted and credible to the regulator; well-informed as to the issues and consequences;
♦ able to deal with information appropriately, have good communication and negotiation skills, as well as group processing and decision-making skills;
♦ available to participate in PAG meetings, analyze data, draft documents and participate in consultations;
♦ able to work effectively to accomplish the mandate, with a non-restricting number of core members (e.g. 8-12);
♦ sensitive to the members needs. Care should be taken to ensure that subject matter experts, if included as members, do not overwhelm the lay public representatives. It is preferable that the PAG have access to subject matter experts as required;
♦ linked to key groups; such as *ex officio* members from Health Canada and TPP’s Expert Advisory Committee on Xenograft Regulation; and
♦ in agreement to declare any conflict of interest. Any declarations must be acceptable to all.

• The PAG should have some flexibility in membership to consider including representatives of interested public sectors that may be identified in subsequent consultations.
Public Involvement Plan for Xenotransplantation

Planning Workshop
April 10-11, 2000
K. Hannah
Public Involvement is ...

Communication + Participation in Decision-Making

"public involvement" refers to a continuum of activities & relationships between the government and public in decision-making.

"Public" refers primarily to the general public, consumers, & special interest groups such as health & consumer groups, industry, scientific and professional associations.

Level Involvement

- joint decision-making
- partnership projects
- consultation/dialogue
- advisory committees
- public/government education
- two-way communication
- information out
Public Involvement and Policy Development
Why Public Involvement for Xenotransplantation?

- science does not have all the answers on issues of health and safety for potential recipients & public

- broad issues with potential ethical, social, cultural, legal, economic impact

- issues occur at many levels of society: individual (patients in need of care), community (patient groups), Canadian society in general, international community

- development of policies & regulations

- key messages:
  - National Forum on Xenotransplantation (Nov '97)
  - Standing Committee on Health (April '99)
  - International Agencies
Objectives of a Public Involvement Plan

- To increase knowledge & understanding of the potential benefits & risks so Canadians may participate in the development of policy.
- To educate HC about the public's views & concerns so that policies are responsive, timely & of high quality.
- To inform Canadians, on an ongoing basis, about the process for managing the risks & benefits.
- To clarify the roles & responsibilities of all interested & affected parties.
- To provide opportunities for the public to participate in the development/implementation of policies & in evaluating the impacts of these policies on the health of Canadians.
Phase 1: Information & Outreach

Phase 2: Planning Workshop & Issue Identification

Phase 3: Public Awareness, Education, Dialogue

Phase 4: Consultations

Phase 5: Report-Public's Recommendations

Phase 6: Evaluation-Continuation of Public Involvement

Public Advisory Group
PHASE 1: Information & Outreach

**Objectives:**

- determine level of public awareness, interest
- develop public profile: identify interested /affected public; range of opinions
- determine the focus/intensity of pre-consultative educational efforts needed
- provide benchmarks to assess relative success of outreach
PHASE 2: Planning Workshop

• Objectives:

  • to obtain guidance on elements of the Public Involvement Plan, including:
    - identification of key issues
    - identification of process to broaden awareness, education and dialogue
    - formation of a Public Advisory Group

  • to define roles & relationships, in public involvement & decision-making
Proposed Functions of a PAG

- assist in:
  - implementation of a Public Involvement Plan
  - identification issues for public dialogue
  - design of consultation methodologies

- participate in consultations
- evaluate public involvement as it unfolds
- report on recommendations of Canadian public
- advise on implementation of recommendations
- advise on the need for or mechanism of continuation of public involvement
Phase 3: Public Awareness, Education & Dialogue

Objectives:

- to identify broad range of public to participate in consultations
- to provide opportunity for the public to understand the issues, potential benefits & risks & individual attitudes on xenotransplantation
Phase 4: Regional Consultations

- **Objectives:**
  - to identify effective methodologies to promote public dialogue & debate
  - to obtain views, from broad public, on issues raised by xenotransplantation
Phase 5: Synthesis of Public Input

- Objectives:
  - to obtain an analysis of public input on issues raised by xenotransplantation
  - to obtain recommendations from an independent PAG
  - to promote openness & credibility of the processes for analysing public input & decision-making
Phase 6: Continuation of Public Involvement

Objectives:

- to evaluate the outcomes of all Phases
- to determine the need for ongoing public involvement & appropriate mechanisms
Planning Workshop Challenge

✓ To what extent should Health Canada undertake activities for enhancing awareness, education, dialogue on issues raised by xenotransplantation?

✓ What is the role for the Public Advisory Group?