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The Royal Society of Canada
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**Life Sciences and Public Policy Symposium:
Ottawa, January 11, 2001
Report to Participants**

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1. Summary of Findings and Proposed Actions

On January 9, 2001, the Institute On Governance, the Royal Society of Canada and the Policy Research Secretariat co-sponsored a symposium on the life sciences and public policy.*

The event brought together scientists, journalists, NGOs, ethicists, jurists, former politicians and public servants (a complete list is attached, see Appendix A). It was designed to be an exercise in collective thinking to foster discussion among colleagues who approach the life sciences revolution from diverse—and perhaps divergent—perspectives. Participants were asked to identify the issues raised by the life sciences and share insights on the impacts the science is likely to have on our institutions. Importantly, they were asked to develop an action agenda on steps to take to get a clearer understanding of the issues and their implications and develop a capacity to respond.

The main points of the discussion, and the suggestions offered by participants are summarised below. A more complete overview of the day's proceedings is provided in subsequent sections.†

Issues and Impacts

- The life sciences are a 'different issue'. The scientific and technological advances raise a myriad of risks and questions—ethical, legal, financial, political, institutional, etc. Policy-making in this area is complicated by the multiplicity of interests.
- Advances in science are very rapid and policy is not keeping up. In effect, there is a fear that science is driving public policy.
- There is a knowledge gap: because of the very complexity of the science, it is difficult to have a meaningful discussion on the advantages and disadvantages of new discoveries and applications. Consequently, it is difficult to discuss the risks inherent in biotechnological applications.
- These issues pose serious institutional challenges: politicians are reluctant to address the risks and questions. An issue that affects 26 government

* The symposium was held in connection with a broader initiative of the Institute On Governance, the "Insurmountable Opportunity" policy exchange programme, consisting of research and action learning on major themes (including the life sciences) relating to the development of policy and management capacity within the federal government.

† The Institute On Governance, on behalf of the symposium's co-sponsors, was responsible for its organisation and the preparation of this report.

departments and agencies challenges their capacity to react in a coherent and effective manner.

- Applications, especially medical, are likely to be persuasive drivers of biotechnology in Canada. People will demand to benefit from certain procedures if the technology is reliable. In the face of strong consumer and business pressure, risks and ethical issues could be overlooked.
- Attempts to regulate biotechnology in Canada could lead to migration of researchers (and consumers) to other countries. Hence, the life sciences are truly global policy issues that require international oversight and action.

Future Actions Proposed by Participants

- Build a knowledge base and create awareness. Acquire knowledge and understanding of the science and its implications and create a capacity to disseminate it.
- Develop a forecasting capacity and become more proactive. It is not enough to wait for scientific innovation before articulating policy positions. We must foster social and political ingenuity to match scientific ingenuity.
- Ensure that the information that is generated is broad and non-partisan. No single constituency should be allowed to play a predominant role and public debate on these issues should be as inclusive and varied as possible. Government could play a facilitative role in this debate.
- Engage in comparative analysis of how other countries have addressed the issues: have they successfully encouraged public awareness, implemented legislation and institutional mechanisms, etc.
- Determine and implement mechanisms to promote effective management of horizontal issues of this nature within government. Involve politicians in the process.
- Acquire knowledge (through public opinion research, for instance) on the public's expectations from biotechnology and where their hopes and reservations lie.
- Engage citizens in decision-making on these issues. Citizens have a right to choose; and independent assessment procedures, as well as public input should precede regulatory approval of a product or biotechnological application.

2. Objectives and process

The symposium was organised around three main objectives:

- review the nature of the issues raised by the life sciences;
- achieve a preliminary understanding of the institutional implications of the life sciences for government, governance and policy development; and
- develop an action plan to develop means to get a clearer understanding of the life sciences' implications and the best way to respond.

The meeting was designed to engage participants in discussion of an informal nature. Hence, we did not expect participants to prepare statements or papers. Instead, we approached three participants—Dr. Michael McDonald, Ms. Michèle Jean, and Dr. Paul Thomas—to provide overviews of specific dimensions of the topic. These overviews were used to launch the discussion brief summaries of which are included below.

This report is not intended to be a detailed account of the proceedings. Rather it provides an overview of the discussion and a summary of the main conclusions. Section 3 includes a synopsis of Dr. McDonald's and Ms. Jean's presentations, as well as a summary of the discussion on the different dimensions of biotechnology. Section 4 turns to the institutional impacts, with a review of Dr. Thomas's intervention and of the discussion that followed. Section 5 lists steps for future action.

3. Dimensions

Summary of presentations

Governance of Health Research on Human Subjects: Lessons for the Life Sciences

Dr. **Michael McDonald**, Professor and Director of the Centre for Applied Ethics at the University of British Columbia was involved in a cross-Canada research project examining the governance of health research on human subjects.*

Dr. McDonald identified some of the most salient qualities of the environment in which research on human subjects is conducted. First and foremost, it is characterised by extremely rapid technological and scientific change. This, in turn, creates a very competitive environment, which is truly global in scope as actors in different countries find themselves in competition with each other. A country that imposed tighter restrictions on research in the life sciences would

* The report is available from the Law Commission of Canada at:
<http://www.lcc.gc.ca/en/themes/gr/hrish/macdonald/macdonald.pdf>

probably see its laboratories move to more permissive jurisdictions. Does this mean we are in a race to the bottom?

The commercial and financial stakes are astounding. Business prospects are such that the impetus against erecting barriers to research and commercialisation will likely be strong. Xenotransplantation (the transplantation of animal organs into humans) is expected to be a \$6 billion a year industry. As it now stands, Canada's share of the world pharmaceutical industry is valued at little more than 3%. The prospect of further developments in biotechnology and the commercialisation of its applications constitute strong motivation to resist increasing restrictions.

Advances in artificial intelligence provide a useful parallel for understanding some of the impacts of biotechnology. Dr. McDonald explained how just as artificial intelligence has given us powerful models for reconceptualising what we do and how we relate to each other and to our work, the life sciences will also provide new models that change how we imagine ourselves and relate to nature. The changes are likely to be so profound that it is difficult to foresee the risks and implications the technology entails. In the case of xenotransplantation, for example, if we cannot predict or control the possibility of retroviruses*, how can we enact measures to protect consumers? What legal infrastructure is needed to govern this sector?

Through his research, Dr. McDonald has concluded that we are in many respects ill-prepared for the changes and impacts brought forth by biotechnology. The complexity and multiplicity of issues leads to confusion of responsibilities and standards. In fact, responsibility has been shifted from one government to another, and neither industry nor government has taken steps to establish guidelines or effective oversight. This is definitely the case in health research where ethical screening is done at early stages of research, but where no evaluation of the findings and results is performed. Hence, since we are not gathering data and evidence about successes and failures, there is little capacity to learn and be proactive. Finally, Dr. McDonald decried the significant lack of public involvement in these areas. While individuals participate in the research, they seldom play a role in its governance.

To address these gaps in our preparedness, Dr. McDonald suggests three "I's"—(1) greater **involvement** of major actors and increased interaction among them; (2) more **independence** for ethical oversight, monitoring and standard-setting; and (3) more **innovation** in exploring new forms of governance, gathering of evidence and creating virtuous learning loops.

* A retrovirus's genes are made of RNA, DNA's less stable cousin. On arrival in a cell, a retrovirus creates a DNA version of its genes and splices them into its host's chromosomes. The viral genes may now be read directly by the host's molecular machinery to produce new viruses, or they may be copied along with the rest of the chromosome in which they are hiding every time a cell containing them divides. Herein lies the danger: this disruption may damage the host's genes so that they no longer function properly, or it triggers the activity of other genes, such as cancer-promoting ones. (Definition from *The Economist*, "Foulpox", Nov. 27, 1997)

Life Sciences in the European Context

Ms. Michèle Jean, Advisor on programmes at Université de Montréal, spent two years at Canada's permanent mission to the European Union in Brussels as an advisor on health issues. Prior to that, she was Deputy Minister at Health Canada.

Ms. Jean noticed a greater interest in, even politicisation of, issues relating to the selection of embryos, patents, the use and production of stem cells, confidentiality, etc. As readers of the European press will notice, articles on the life sciences and similar issues are published on a daily basis. Controversies surrounding dioxins, contaminated blood and BSE have made it such that ethical and public health issues are at the forefront of public opinion.

As a result, many European countries have frameworks in place to manage these issues. Most have permanent committees on ethics. France, for instance, has had legislation in place since 1994, which is currently under revision. Other countries have flexible legislative arrangements and institutions that monitor and approve research and procedures on a case by case basis. For example, the United Kingdom has established the Human Fertilisation and Embryology Authority, granting it budgetary autonomy and the power to impose sanctions against researchers or companies who do not respect established guidelines.

As well, the European consumer sector exhibits greater concern for biotechnology than its North American counterparts, and seems to be more eager to get informed and participate in the debate. The role of civil society in the discussion surrounding the life sciences is prominent. In France, 'National Ethics Days' are organised to inform youth. In Belgium, public conferences are organised and routinely draw large audiences.

The UNESCO published a Universal Declaration on the Human Genome and Human Rights to ensure that research on the genome does not infringe on the human rights and dignity. The Declaration was subsequently adopted and endorsed by the United Nations. UNESCO has also created two committees that continue to work on these issues: the International Bioethics Committee (with 32 members from different fields such as ethics, genetics, history, law, etc.); and the Intergovernmental Committee consisting of government appointees who advise member states on related issues.

Despite the existence of these institutions and a greater level of public awareness, biotechnology is advancing too fast for ethical and legal guidelines to keep up. In her previous role as Deputy Minister of Health Canada, Ms. Jean dealt with a number of controversial issues, including the Krever Commission, tobacco legislation and the tri-council code. She finds that although there is a lot of expertise in Canada, it is scattered and lacks focus. Canadians are ill-equipped to deal with the issues the life sciences bring to bear. Will a full-blown public policy crisis be necessary in order for Canada to develop policies and guidelines or legislation? In conclusion, she urged that policy-making on these

issues be transparent and open. Political actors must overcome their reluctance to address these issues and work towards establishing effective risk management practices.

Summary of the discussion

Participants feel that the life sciences as a whole raise a qualitatively different set of policy issues than most society has faced in the past. A line is crossed when mankind can operate on the genome directly: scientific possibilities and discoveries are coupled with probing ethical, legal and economic questions. Some scientists, such as Dr. Lap-Chee Tsui from the University of Toronto, believe that the pace is so rapid that the technology is driving public policy.

Because the science involved is extremely complex, predicting outcomes is a difficult task. It is hard to transfer knowledge and discuss the issues. Moreover, this complexity makes it difficult to identify and plan for contingencies. How can we know before we get there? Even if government establishes plans, it is hard to cover all the angles. Inevitably, there will be gaps in our predictions and policies.

The difficulty of making predictions is especially evident when trying to manage the risks associated with an application and commercialisation of biotechnology. Medical applications are expected to galvanise public opinion and drive the issue. Whereas agricultural biotechnology did not provoke wide-scale debate in Canada, the potential medical benefits of biotechnology will likely be powerful promoters. For instance, if xenotransplantation becomes a fairly reliable technique, people are likely to demand it.

In the face of public pressure to benefit from biotech, an ethical or political discussion after the fact becomes academic. The push for benefits might effectively silence the risk issue. In face of commercial promotion of the benefits of xenotransplantation, for instance, it will be difficult to explain the downsides and risks associated with the procedure. What is more, we are at a loss to determine who would assume this role. Would industry, government, citizens speak to the risks? Would they be trusted, let alone listened to?

This points to another aspect of the life sciences— its transnational scope. If Canada's regulatory regime is too restrictive, research and consumers will likely migrate to other countries. This proposition has three corollaries. First, arguing that regulations can't control biotechnology leads to a prisoner's dilemma: if Canadians do not benefit from the technology but someone else does, in the end everyone bears its risks. In such a case, Canadians will have little incentive to regulate their use of the technology; the very case for regulatory oversight is thus significantly diluted. Second, it points to a need for international oversight to ensure that research conducted around the world is responsible and ethical. Third, it poses serious questions in terms of global equity. The ability to move companies or consumers to other, more permissive jurisdictions, is a function of resources. Inability to go to where the technology is available severely restricts the number of potential beneficiaries.

One preliminary conclusion that emerges from this discussion is that it will be difficult to control the commercialisation and application of biotechnology. Once applications are commercialised and have been shown to be fairly safe, people are likely to demand them. A pertinent example is cellular telephony. Although there are risks involved with the use of such devices, more people are using them, and for extended periods. The ethics of the cell phone are a function of people accepting risks. Hence, as one participant urged, maybe we should stop talking of 'risk benefits', but look at 'benefit risks'. The drivers of biotechnology are likely to be similarly persuasive. Profitability and a promise of a healthier life could silence a discussion on downsides and risks. Emphasis on the 'positives' might obfuscate the larger discussion on sustainability and equity, not to mention on consequences for society and families.

Biotechnology poses some interesting social questions: is it a matter of individual choice and consumption, or should collective choices govern how technology is used? It is doubtful that Canada currently has the appropriate institutions to undertake a debate on these issues. Participants were unanimous in their judgement that politicians would be extremely reluctant to tackle these issues, nor do they seem ready to play a role in a debate on the life sciences. Canada has been unable to pass legislation on reproductive technology— something that, at this point, is minor compared to what may be laying in wait. Participants believe we are ill-prepared to deal with the policy issues the life sciences are bringing to bear.

4. Institutional Impacts

Summary of the Presentation

The Life Sciences and their Effects on Public Institutions

Dr. Paul Thomas, Professor of Government in the Department of Political Studies at the University of Manitoba, believes it will be difficult to predict how advances in the life sciences will affect public and private institutions. While we might yearn for certainty and predictability, the nature of the changes instigated by biotechnology make it exceedingly difficult to control their implications. Scientific and technical innovations are quicker than the social and political ingenuity required to manage these advances. Dr. Thomas believes the immediate challenge resides in fostering such ingenuity.

The idea of 'governance' has attracted considerable interest in recent years, but it remains a under-developed concept. Modern uses of the term associate governance with institutions, or mechanical fixes. In an era where there is increasing discontent—even cynicism and apathy—with government and its institutions, it will be difficult to identify an institutional mechanism that will be seen as legitimate.

Looking to the Ancient Greeks, who defined governance as steering, what levers can we now pull to make effective public policy? By changing our understanding

of governance to focus more on steering and less on mechanisms, we may be able to develop the ingenuity required to understand and manage change. When seen as an ongoing process, in which individuals and institutions set goals and mobilise to achieve them, governance itself becomes a dynamic and uncertain process. This could enable an open-ended policy process, where sovereignty and authority are shared, and where it may be easier to cope with the rapid change technology is imposing. It might become more difficult to predict and control policy outcomes, but through such processes society may be better able to address issues and find common solutions.

To ensure good governance and good policy outcomes, legitimacy is key. Citizens must trust the people and institutions engaged in the process. Dialogue—formal and informal—is the motor of policy-making. Government should not abdicate its role in the dialogue. While it may not want or be able to lead or control the debate, it must work to facilitate it.

The life sciences present a challenge. The range and breadth of issues involved make it exceedingly difficult to foster consensus among divergent voices. In fact, with the parliamentary process almost exclusively predicated on commanding and controlling an issue, the very configuration of our institutions is a hurdle to coming to grips with biotechnology and its many corollaries. Dr. Thomas believes this underlines a need to revitalise our institutions with the aim of re-establishing their legitimacy and accountability. He also suggests that Canada reflect on the role of political parties and the role of opposition. Finally, the difficulties posed by biotechnology point to a need for knowledge: politicians and citizens alike need sufficient information to understand the changes that are occurring and to contribute to finding ingenious solutions to these changes.

Summary of the discussion

The nature of the challenges associated with the life sciences makes it extremely difficult to envision a set policy response. Since commercial interests and individual benefits are expected to be powerful drivers, participants noted the need for collaborative approaches to decision-making that balance individual and industry desires with collective choices and social responsibility.

Developing the institutions and processes that would underpin such collaborative decision-making promises to be challenging. The very nature of the issues ensures that a large number of stakeholders will be interested in the process; each advocating a different position. Hence, with a large number of positions, oftentimes in opposition, the ability to identify—and move toward—a middle ground is limited.

Participants believe the difficulty in brokering agreements between various actors creates the disincentive for politicians. It is difficult to articulate a policy response that will satisfy all stakeholders and citizens. Thus political risk management takes hold with paralysing results. Even if government and elected officials do not lead the debate, they could still work to facilitate dialogue between interested

parties. In order to accomplish this, government must be seen as a legitimate and credible facilitator. It should not appear biased, nor should it attempt to endorse a particular position or group. Engage the public, not just the stakeholder groups.

To engage the public, participants feel that awareness must be created. Increased public awareness could be fostered through the creation of learning organisations that generate and disseminate knowledge that is complete, neutral and dispassionate, thereby enabling citizens to weigh the pros and cons. International comparative analysis would give Canadians an idea of best practices and illustrate that there is indeed much thinking that needs to be done. Knowledge and understanding of the issues and an assessment of the potential benefits and risks are prerequisites to a meaningful *national* dialogue on the issues. It would be extremely difficult to engage citizens who are not aware of the possibilities and risks involved in decision-making.

Participants felt that an ability to predict and understand what scientific developments were on the way could help citizens and policy-makers be proactive on the policy front and work to devise adequate and responsible policy responses. A forecasting capability would be useful to generate information and awareness. While “stopping biotech” is not an effective reaction to scientific innovation, an ability to point to what citizens will or will not tolerate is a valid response. Overall, it is important to avoid dichotomising the issue between economics and ethics, or private versus public choice. The life sciences are so multifaceted that a debate that polarises the issues is likely to lead to policy paralysis.

This is equally applicable to government, as the horizontal nature of biotechnology as a policy issue poses special challenges: 26 federal government departments and agencies are directly affected. Such a large number of players makes it extremely difficult to articulate a government-wide approach. The fact that government must address consumer issues, social and ethical questions, financial and regulatory questions reduces the chance that it will even be able to present a common face.

In the event government is unable to provide frameworks, participants felt that citizens would have to rely on the codes of conduct of researchers and scientists, not to mention policy-makers and other professionals. Where there is a weak accountability regime, can we be confident that professionals working in laboratories, marketing the products, or setting policy are trustworthy and adhere to common standards?

5. Future Actions

To conclude, participants were asked to reflect on their interventions during the symposium, on the different dimensions and the gaps in our thinking and institutions they identified. Participants were in agreement that many gaps exist

in Canadians' knowledge of the life sciences and their capacity to respond to the challenges posed. They were asked to suggest practical steps that should be taken to build capacity for sound policy responses. Following are their recommendations:

- Build a knowledge base and create awareness. Make the information available and accessible.
- Develop a forecasting capability and become more proactive on the policy front. We cannot afford to wait for scientific innovation before developing positions and policy.
- Ensure that the information is broad and non-partisan. All perspectives on the issue—including ecological and ecumenical among others—should be included.
- Ensure that all participants have equal access to debate and decision-making on the issues—no one constituency should be allowed to get an upper hand.
- Engage in comparative analysis of what is being done in Europe and elsewhere.
- Determine which institutional mechanisms would promote better management of horizontal issues.
- Involve politicians in the discussion.
- Acquire knowledge (through public opinion research, etc.) on the public's expectations from biotechnology and where their reservations and objections lie.
- Engage citizens, not just stakeholders.
- Citizens have a right to know, and a right to choose. Independent assessments and public input should precede regulatory approval.

Appendix A: List of Participants and Contact Information

Roy Atkinson, Executive Director, Canadian Biotechnology Secretariat

Sushma Barewal, Policy Research Secretariat

Hon. Benoît Bouchard, Chairman, Transportation Safety Board of Canada

Laura Chapman, Executive Director, Policy Research Secretariat

Nathalie Des Rosiers, President, Law Commission of Canada

Dr. Peter A. Hackett, Vice-President, Research and Technology Development, National Research Council

Michèle Jean, Conseillère en programmes, Université de Montréal

William Leiss, FRSC, President, Royal Society of Canada

Peter Levesque, Programs Policy Officer, Social Sciences and Humanities Research Council of Canada

Claire E. Marshall, Director, Institute On Governance

Elizabeth May, Executive Director, Sierra Club of Canada

Dr. Michael McDonald, Professor, Director, Centre for Applied Ethics, University of British Columbia

Dr. Terry McIntyre, Head, Biotechnology Applications, Environment Canada

Anne Mitchell, Executive Director, Canadian Institute for Environmental Law and Policy

Brian Paddock, Director General, Policy Analysis, Agriculture and Agrifood Canada

Tim Plumptre, Managing Director, Institute On Governance

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Dr. Robert W. Slater, Senior Assistant Deputy Minister, Environment Canada

Stephen Strauss, Editorial Board, *Globe and Mail*

Dr. Paul Thomas, Duff Roblin Professor of Government, Department of Political Studies, University of Manitoba