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Policy Design for Human Embryo Research in Canada

Francoise Baylis
Dalhousie University, francoise.baylis@dal.ca

Matthew Herder
Dalhousie University, matthew.herder@dal.ca

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Françoise Baylis
Professor and Canada Research Chair
Dalhousie University,
5248 Morris Street
Halifax, Nova Scotia, Canada B3H 4R2

Matthew Herder
Assistant Professor
Dalhousie University,
5849 University Avenue
Halifax, Nova Scotia, Canada B3H 4R2

Abstract: In Canada, research involving human embryos is circumscribed by law and research guidelines. This chapter describes the development of these policy instruments over the past 20 years and analyses this history using a typology of modes of public consultation developed by Eric Montpetit. (2003) Over time, the degree to which the views of Canadian residents and citizens on human embryo research have been solicited as part of the policy-making process has diminished significantly. We expect this trend to continue given the presence of powerful interest groups and policy communities "speaking for" Canadians.

Competing Interests: Françoise Baylis was a member of the CIHR *ad hoc* Working Group on Stem Cell Research from November 2000 to December 2001 and a member of the CIHR Governing Council from January 2002 to December 2004. She was a Principal Investigator funded by the Stem Cell Network from January 2002 to December 2005. In 2006 she prepared an Expert Opinion for the federal government in *Attorney General of Québec v. Attorney General of Canada*. From 2006-2010 she was a member of the Board of Directors of Assisted Human Reproduction Canada. The views expressed herein are her own.

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Policy design for human embryo research in Canada

Introduction

In Canada, research involving human embryos is circumscribed by law promulgated by the federal Parliament and research guidelines issued by the Tri-Agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). To be precise, the use of human in vitro embryos is governed by the Assisted Human Reproduction Act, S.C. 2004, c.2 (hereafter *AHR Act*), which prohibits some types of human embryo research under threat of criminal sanction (maximum penalties are a fine of $500,000, or ten years imprisonment, or both). As well, human embryo research is governed by the 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (hereafter, *TCPS2*), (CIHR 2010) in addition to which research involving the derivation and study of human embryonic stem cells, is governed by the *Updated Guidelines for Human Pluripotent Stem Cell Research* (hereafter, "*Guidelines for Stem Cell Research*" or "*Guidelines*"). (CIHR 2010)

Unlike the *AHR Act*, which covers both publicly- and privately-funded embryo research, the *TCPS2* and the *Guidelines for Stem Cell Research* only govern federally-funded research —that is, research conducted by individuals or in institutions that receive funding from one or more of the federal research Agencies. Individuals are required to certify compliance with the *TCPS2* (and, if applicable, the *Guidelines for Stem Cell Research*) in their grant applications. And institutions that receive Agency funding must sign a formal "Memorandum of Understanding" with the Tri-Agencies certifying compliance with the *TCPS2* and the *Guidelines for Stem Cell Research*. (Hadskis 2011, 443; Tri-Agencies MOU 2008) Where the research guidelines and the *AHR Act* overlap, the *AHR Act* takes precedence; where the *AHR Act* is silent, the research guidelines set the standard for federally-funded research.

There are two parts to this chapter. The first part provides a chronological description of policy developments related to human embryo research in Canada over the past twenty years, with particular attention to efforts at public consultation. We begin with a review of the policy processes leading up to, and following on from, the promulgation of the *AHR Act*. We then turn to review the development, introduction and subsequent modification of the *Guidelines for Stem Cell Research*. We do not review the history of the *TCPS2* given the broad scope of these research guidelines. We do, however, include information on the substance of these guidelines where relevant. The second part of the chapter critically examines the history of policy design for human embryo research in Canada, applying a typology of modes of public consultation developed by Eric Montpetit (2003). Our effort to better understand the various episodes of policy design and their corresponding outcomes reveals a depreciating linkage between policy development related to human embryo research and the input of Canadians through public consultation.

Policy Design for Human Embryo Research in Canada: A Brief Chronology
(See Figure 1 for a summary)

From the Royal Commission to the AHR Act

On October 25, 1989, following a couple of years of intense lobbying, Canada's Royal Commission on New Reproductive Technologies (hereafter the "Royal Commission" or the "Commission") was announced. (Roberts 1999) The Commissioners represented the fields of medicine, law, religion and sociology and the Commission's explicit mandate was to,

> inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied. (RCNRT 1993, 3)

The Royal Commission on New Reproductive Technologies had two overarching tasks: to provide an opportunity for public involvement in policy design; and to assess the relevant medical and scientific developments. (Massey 1993) In planning for public participation, the Royal Commission "set up an extensive Public Consultation Program to give Canadians from all walks of life and from all regions of the country the opportunity to contribute to the works, as it studies the origins, effects and impacts of the technologies." (RCNRT 1990)

The final report spanned two volumes and contained 293 policy recommendations. Although the financial cost was significant (according to Montpetit $28 million (2003)), the Royal Commission's efforts to raise awareness of its work and the issues, to stimulate conversation and debate at the community level, and to receive input from Canadians were unprecedented. In total, over 40,000 Canadians "participated in clinical studies and national surveys, attended Public Hearings and Private Sessions, sent letters of opinion and written submissions, or left their thoughts on our toll-free telephone lines." (RCNRT 1992, 1) (See Table 1) On the basis of this public consultation effort, the Royal Commission reported a "consistent and widespread demand for national leadership and action in relation to [new reproductive technologies]." (RCNRT 1993, 11)

INSERT TABLE 1

In its final report, *Proceed with Care*, the Royal Commission recommended that the Canadian government develop a comprehensive legislative response to new reproductive technologies, including human embryo research. At the time, the Medical Research Council's *Guidelines on Research Involving Human Subjects* provided three basic parameters around when, why, and what types of human embryos could be used in research. (MRC 1987, 35) In contrast, the Commission specifically recommended that research on embryos be "restricted to the first 14 days of development"; that embryo research related to "ectogenesis, cloning, animal/human hybrids, and the transfer of

zygotes to another species be prohibited, under threat of criminal sanction"; that "clinics and researchers be permitted to use human zygotes for research only with the fully informed consent of the persons who have donated the gametes used to create the zygote"; and that a "woman's or couple's consent to donate zygotes generated but not used during infertility treatment for research never be a condition, explicit or implicit, of fertility treatment." (RCNRT 1993, 636-37, 639, and 640, Recommendations 184, 184, 186, and 187, respectively) The Commission also recommended that embryo research be subject to licensing requirements. (RCNRT 1993, 645, Recommendation 193)

In the spring of 1994, the Health Policy Division, Policy and Consultation Branch of Health Canada initiated a consultation on the findings of the Royal Commission with over 50 stakeholders from groups as diverse as the disabled community and anti-abortionists. (Health Canada 1996b, 14). The predominant views in Canada at that time reflected competing beliefs about the moral status of the developing human embryo. For some, the human embryo had near-person status. For others, the human embryo was a mass of tissue that did not deserve special protections.

In April 1995, Health Canada established a nine-member multidisciplinary Discussion Group on Embryo Research (hereafter Discussion Group) "to propose logically, ethically and socially justifiable policy in this area" (Discussion Group 1995, 36), and more specifically to address the following question: "Should experimentation on human embryos, including pre-implantation diagnosis, be permitted in Canada?"

In July 1995, while the work of the Discussion Group was in midstream, then-Minister of Health Diane Marleau announced a voluntary interim moratorium on nine new reproductive and genetic technologies, many of which (directly or indirectly) concerned embryo research. Practices governed by the interim voluntary moratorium included: sex-selection for non-medical purposes; commercial pre-conception or "surrogacy" arrangements; buying and selling of eggs, sperm and embryos; egg donation in exchange for in vitro fertilization (IVF) services; germ-line genetic alteration; ectogenesis (creation of an artificial womb); the cloning of human embryos; formation of animal-human hybrids by combining animal and human gametes; and the retrieval of eggs from cadavers and foetuses for donation, fertilization or research. (Health Canada 1995; Health Canada 1996a) At the same time the voluntary interim moratorium was announced, the federal government outlined its plan to develop regulations for sperm donation (for artificial insemination and *in vitro* fertilization), and to develop (in consultation with the provinces and territories) a comprehensive legislative framework for new reproductive and genetic technologies.

The Discussion Group submitted its final report in November 1995. It concluded that embryo research should be permitted in Canada and issued twenty policy recommendations (see Table 2), all of which assumed that a National Regulatory Body would be created to approve and oversee human embryo research. (Discussion Group 1995, 2)

INSERT TABLE 2

In January 1996, amidst concerns about the degree to which researchers and clinicians were conforming to the voluntary interim moratorium, an Advisory Committee on the Interim Moratorium on Reproductive and Genetic Technologies (soon after renamed the Advisory Committee on Reproductive and Genetic Technologies) was created to monitor compliance and advise the federal government. Later that same year, in June 1996, the prohibitions bill was introduced into the House of Commons by then-Minister of Health David Dingwall. Bill C-47 the *Human Reproductive and Genetic Technologies Act* aimed to reflect "the views of Canadians that certain practices are unacceptable and violate the principles of human dignity." (Health Canada 1996b, 6) The Bill prohibited, under threat of criminal sanction, 13 discrete practices, including all of the practices listed in the voluntary interim moratorium. At the same time the Bill was tabled, Health Canada published *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (hereafter *Setting Boundaries, Enhancing Health*). This document outlined the government's two-part legislative plan: "outright prohibition of unacceptable technologies through legislation; and development of a legislated regulatory regime to manage acceptable technologies." (Health Canada 1996b, 5) This document was to inform the next consultation phase.

Before the legislative process for Bill C-47 was completed a federal election was called, and the bill died on the order paper. After Parliament reconvened in the fall of 1997, Health Canada was instructed to undertake new public consultations on the basis of which new legislation could be drafted.

In May 2001 then-Minister of Health Alan Rock presented the House of Commons Standing Committee on Health with *Proposals for Legislation Governing Assisted Human Reproduction.* (Health Canada 2001) A year later, in May 2002, comprehensive legislation on new reproductive technologies, Bill C-56, *An Act respecting assisted human reproduction* was introduced in the House of Commons. Notably, parts of this Bill overlapped with the *Guidelines for Stem Cell Research* introduced in March 2002 by CIHR. (Baylis 2002) This Bill, which aimed to establish a legislative and regulatory framework for assisted human reproduction and embryo research, also died on the order paper when Parliament was prorogued in September 2002. When Parliament resumed in October 2002, Bill C-56 was reinstated as Bill C-13 at the same stage in the legislative process as prior to prorogation—this had not happened with the previous bill (Bill C-47). On March 11, 2004, Bill C-6 (formerly Bill C-13) completed all legislative stages. On March 29, 2004 the *AHR Act* received Royal Assent bringing to an end 15 years of policy development. (Health Canada 2008)

In 2006, however, the Government of Québec filed a reference with the Québec Court of Appeal challenging the constitutionality of several sections of the AHR Act. (Attorney General of Québec 2006)[1] The Québec government argued that health was a provincial responsibility. The federal government insisted that the *AHR Act* was a valid exercise of its authority to act to safeguard morality, safety and public health. In June 2008 the Québec Court of Appeal opined that the federal government did not have the constitutional authority to legislate this (and other) provisions under its criminal law

power. In August 2008 the Attorney General of Canada filed an appeal to the Supreme Court of Canada (SCC). On April 29, 2009 the SCC heard the appeal and on December 22, 2010 released its decision.[2] The SCC held that some of the contested sections, including section 10, which governs the use of in vitro embryos, were indeed unconstitutional. (Baylis 2011) Because the case was initiated by a reference from the Québec government, the SCC's decision is considered advisory rather than legally binding. However, no provincial or federal government in Canadian history has ignored a Court's advisory decision in a reference case, thus it would seem to be only a matter of time before the SCC's decision is implemented.

Meanwhile, the constitutional challenge did not affect the prohibited activities: human cloning; creating an embryo for research (except for the limited purpose of improving or providing instruction in assisted human reproduction procedures); creating an embryo from an embryo or a fetus; maintaining an embryo *in vitro* for more than 14 days; purchasing gametes, embryos; creating or transplanting a chimera made from a human embryo; creating a hybrid for the purpose of reproduction; using reproductive material without consent; and obtaining gametes from a donor under the age of 18 except for the purpose of preserving the sperm or ovum or for the purpose of creating a child to be raised by the donor(s) are all legally prohibited in Canada (See Table 3).

INSERT TABLE 3

Meanwhile, human embryo research that is not prohibited in legislation can proceed in accordance with current research guidelines (the *TCPS2* and, as applicable, the *Guidelines for Stem Cell Research*). The *TCPS2* stipulates that:

> Research involving embryos that have been created for reproductive or other purposes permitted under the Assisted Human Reproduction Act, but are no longer required for these purposes, may be ethically acceptable if:
>
> (a) the ova and sperm from which they are formed were obtained in accordance with Article 12.7;
> (b) consent was provided by the gamete donors;
> (c) embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and
> (d) research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended. (CIHR 2010, 178)

Guidelines for Stem Cell Research: Take One, Take Two (Take Three, Take Four…)

The first edition of the *TCPS* came into effect in 1998 before James Thomson and John Gearhart announced their respective successes in deriving human pluripotent stem cells (Thomson et al 1998; Shamblott et al 1998). In the absence of explicit Canadian policy or law on human embryonic stem (hES) cell research, the CIHR struck an *ad hoc* Working Group on Stem Cell Research in late 2000 (hereafter Working Group). This

nine member group included six scientists/clinicians (one of whom was Chair), two philosophers (one of whom was FB), and one lawyer. (CIHR WG 2001) Amidst a slew of governmental and quasi-governmental reports trumpeting the promise of embryonic stem cell research but tempered, to varying degrees, by the attendant ethical concerns (AAS 1999; Chapman, Frankel and Garfinkle 1999; NBAC 1999; United Kingdom 2000; Vogel 2000), the Working Group was mandated to evaluate whether CIHR should fund research to derive and study pluripotent stem cells and, if so, under what conditions.

March 29, 2001, CIHR initiated a three-month public consultation on a Discussion Paper prepared by the Working Group, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives*. (CIHR WG 2001) There was a national press conference announcing the electronic publication of this document on the CIHR website and the document was disseminated electronically to all CIHR-funded institutions (which essentially includes every academic research institution in Canada). There were 116 responses to the Discussion Paper: 89 from individuals and 27 from "special interest groups, professional groups, health charities, [and] governmental agencies." (CIHR WG 2002) "Many" of these responses highlighted concerns about the moral status of the human embryo, the need to utilize adult stem cells instead of embryonic or foetal stem cells, the potential coercion of couples involved in fertility treatment or women undergoing therapeutic abortion, the slippery slope to cloning and eugenics, and the lack of governance for private sector research. "Some" of these responses expressed concern about likely research delays resulting from the introduction of an oversight mechanism, the skewed composition of the Working Group (too many scientists and no lay representation), and the ambiguity of the term "moratorium" in the Discussion Paper. Finally, a "few" respondents noted that CIHR's chosen medium of consultation—the web —precluded certain segments of society from participating in the process. (CIHR WG 2002)

On March 4, 2002, with the legislative process for the *AHR Act* underway, the CIHR released its guidelines *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research.* (CIHR 2002) The guidelines stipulated that research to derive and study human pluripotent stem cell lines from embryos, fetal tissue, amniotic fluid, the umbilical cord, placenta, and other body tissues (either from persons or cadavers) was eligible for funding, but that research involving the creation of human embryos for research purposes, the use of somatic cell nuclear transfer to develop stem cell lines, the mixing of human or non-human stem cells with a human embryo or fetus, and the mixing of human stem cells with a non-human embryo or fetus was not eligible for funding.

Until June 2005 there were no revisions to these *Guidelines*. At that time, and again in June 2006 and 2007, annual revisions were recommended by the CIHR Stem Cell Oversight Committee (SCOC) and approved by the CIHR Governing Council. Unfortunately, the initial (albeit limited) effort at public consultation in drafting the original 2002 *Guidelines for Stem Cell Research* did not have a precedent setting effect. The successive revisions made in 2005, 2006, and 2007 were all made without public consultation. Breaking with that tradition, in October 2007 the CIHR SCOC initiated a 4-month web-based consultation on whether all human pluripotent stem cell lines derived

under the auspices of an Institution that receives Agency funding must be listed with the registry, or whether the inclusion rule only applied to lines created using CIHR funds (October 19, 2007 to February 15, 2008).

In June 2010, the *Guidelines for Stem Cell Research* were updated for a fourth time.[3] Two major changes were introduced. The SCOC's purview was extended to include oversight of research involving induced pluripotent stem cells ("iPS cells"). (CIHR 2010a) Experimental work demonstrating the successful reprogramming of human somatic nuclei to create iPS cells was first published in November 2007. (Takahashi et al. 2007; Yu et al. 2007). The *Guidelines* now specify what types of research involving iPS cells would and would not conform with the *Guidelines*. As well, following on the public consultation, the scope of the national stem cell registry was clarified. The *Guidelines* now specify that human iPS cell lines will not be listed in the registry, but that all other "human pluripotent stem cell lines derived directly from embryos under the auspices of an Institution that receives any Agency funds must be listed with the registry and made available by the researcher to other researchers, subject to reasonable cost-recovery charges." (CIHR 2010a) Of note, this change does not mirror the majority opinion of the web-based consultation.

Of the revisions made to date, several are consistent with the public interest insofar as they (i) clarify areas of uncertainty, (ii) exclude problematic areas of research from being eligible for funding, and (iii) extend the purview of the SCOC[4]. For example, over the years, there has been some uncertainty regarding the scope of the *Guidelines for Stem Cell Research*. The 2005 revisions clearly stipulated that these guidelines, though originally issued by CIHR, applied to all "research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an Institution that receives any Agency funding."

Other changes to the *Guidelines for Stem Cell Research*, however, appear to have served the interests of the stem cell research community more so than Canadian publics. Particularly noteworthy in this regard are changes made in 2005 to the timing of consent for hES cell research—a change rescinded in 2006—and to the sources of embryos eligible for hES cell research (Baylis and McInnes 2007). To expand briefly on this last point, in Canada, only embryos "no longer required for reproductive purposes" can be used for research. Prior to the 2005 Update, it was generally understood (consistent with practice in IVF clinics) that "embryos no longer required for reproductive purposes" included (1) poor quality embryos unsuitable for embryo transfer or freezing and (2) frozen embryos not intended for thawing and embryo transfer. (See, Rivard and Hunter 2005, 135–136; Baylis and McInnes 2007, 64 and 66). This changed with the 2005 *Guidelines* which allowed fresh embryos to be considered in excess of clinical need regardless of whether they were suitable for transfer or freezing. This policy change was made despite the fact that asking women infertility patients to give their fresh embryos to hES cell research is: (1) contrary to the CMA Code of Ethics and the physician's primary obligation to promote patient interests (Nisker and White 2005); (2) contrary to women's reproductive interests, (Baylis and McInnes 2007; McLeod and Baylis 2007); (3) challenges the process of informed consent (Nelson et al. 2008); and (4) unnecessary—a

majority of hES cell lines have been derived from frozen embryos "in excess of clinical need", and poor quality embryos that have reached the blastocyst stage are a robust source of normal hES cells (Lerou et al. 2008).

As we detail in the second part of this chapter, this series of problematic updates to the *Guidelines for Stem Cell Research* dovetails with a troubling trend in policy design for human embryo research – diminishing participation in policy development by Canadian residents and citizens. As best we can discern, of late, Canadians who are not members of special interest groups or policy communities have been spoken for, rather than spoken with, in matters relating to the oversight of human embryo research. We show this by reinterpreting the foregoing history of embryo research policy development through a typology of modes of public consultation developed by Montpetit (2003).

Policy Design for Human Embryo Research in Canada: A Brief Analysis

Legitimacy in policy design depends, in large measure, on achieving the right balance between output-oriented legitimacy and input-oriented legitimacy. In very general terms, output-oriented legitimacy is usually expertise-based, while input-oriented legitimacy is always citizen-centered. Or, following Montpetit, "[o]utput-oriented legitimacy is conferred onto public policies to the extent that they are viewed as enhancing the public good, independently of who has conceived them. To obtain such policies, policymakers have traditionally relied on experts." (Montpetit 2003, 97) Conversely, "[i]nput-oriented legitimacy … depends on the extensiveness and intensiveness of public participation in the making of policy. Legitimacy here is conferred upon policies when a large public feels it has been consulted and heard." (Montpetit 2003, 97)

In a helpful analysis of policy design for assisted human reproduction in Canada, Montpetit looks beyond the variety of instruments available for public consultation (e.g., advisory committees, focus groups, sequential consultations, consensus conferences, information-technology-supported dialogues or surveys, citizen juries, and toll-free numbers), to critically examine the institutional and cultural contexts in which these instruments are used in pursuit of input-oriented legitimacy for public policies. (Montpetit 2003) From an input-oriented legitimacy perspective, "[p]olitical choices are legitimate if and because they reflect the 'will of the people' – that is, if they can be derived from the authentic preferences of the members of a community." (Scharpf 1999, 6)

Because input-oriented design processes require public involvement, they have a higher potential than output-oriented design processes to reduce the legitimacy deficit. (Montpetit 2008) But this potential comes at a price. Public policy consultation can be difficult – cumbersome, confusing, time-consuming and expensive – particularly if there is a genuine commitment to diversity, where the goal is not only to hear from 'more people' (i.e., a wider array of actors), but also to hear from 'more standpoints' (i.e., a wider array of ideas).

Montpetit defines three triangulated modes of public policy consultation – consultation conducted in a mode of communicative action, strategic consultation, and rule-guided consultation. In turn, he explains how each of these modes of consultation characterizes a particular style of political interaction between those who are responsible for public policy consultation and those who are consulted.

With communicative action as the mode of public policy consultation, genuine dialogue and deliberation are the hoped-for modes of interaction. Those responsible for public consultation and those consulted may have preconceived ideas and preferences about what policies should be generated, but they are willing to set them aside and to learn from each other, as a means to the end of better policy development. According to Montpetit, "[p]ublic consultations here are neither strategic instruments nor mere obligations in the policy design process, but rather, opportunities to argue in pursuit of unforeseen ideas to resolve policy problems." (Montpetit 2003, 101) As Montpetit, Scharpf and others concede, however, a problem-solving orientation to policy design is a most rare occurrence because it requires of policy designers that they accept challenges to their preferences and give up control over the outcome of the public consultation process. In short, it requires a commitment to genuine discourse and this may not always be feasible or desirable.

With strategic consultation, those who are responsible for policy design and who initiate the public consultation have clear policy preferences for which they are seeking input-oriented legitimacy. In this instance, the goal of public dialogue is not to generate policy options, but rather to effectively communicate policy preferences and persuade those who are consulted to support the preferred policy option.

With rule-guided consultation the principal aim is to satisfy political obligations, as when politicians demand public consultation in an effort to increase the input-oriented legitimacy of the policies they intend to promulgate. This mode of public consultation may or may not have an impact on the original policy intent and orientation, depending upon the fit between the preferences of the civil servants directed to undertake the consultation and the public that is consulted.

Here we re-canvass the various policy-making exercises on human embryo research undertaken by the federal government and the CIHR over the last 20 years using Montpetit's framework.

Communicative action and the law on embryo research

The legislative process that ends with the introduction of the *AHR Act* in 2004 begins with the Royal Commission in 1989. The Royal Commission's mandate, as outlined in the Order in Council did not explicitly name 'identifying the views and values of Canadians' among its objects. It is nonetheless clear that the Commission regarded this as integral to its investigative methodology, ethical analysis, and final output. This, in part, owes to the nature of Royal Commissions established under the federal *Inquiries*

Act, R.S.C. 1985, c. I-11, and the function that Royal Commissions have historically performed in Canada. (Massey 1993)

According to Montpetit, the Royal Commission was an opportunity ripe for communicative action. Indeed, some 40,000 Canadians contributed to the Commission's work. While some complain that this number is misleading insofar as it includes some 15,000 survey respondents in the rate of public participation (Massey 1993, 245), current lore and government policy-makers certainly have it that the Commission succeeded in articulating "Canadian values".

Critics insist, however, that the Commission failed to achieve communicative action owing, in part, to the inherent limitations of public hearings as a technique of public participation, and the nature of the deliberations among Commissioners.

First, the centerpiece of the public consultation effort undertaken by the Royal Commission was the public hearing. According to Christine Massey, there are a number of serious weaknesses with this technique relative to the goal of public engagement:

> Some of the most common drawbacks are: procedural rules which make it difficult to initiate two-way communication; intervenors who are not representative of the total population; and the lack of impact on the final decision. Abuses to which the public hearing lends itself are: a habit of inadequate notification; the selective or elite involvement in the hearings; and an overemphasis on providing information rather than receiving it. (Massey 1993, 238)

Of particular concern among this list of weaknesses is the fact that royal commissions typically privilege the powerful:

> … commonly, royal commissions give voice and legitimacy to those groups in our society who already have it. While all intervenors may officially be equals in the hearings process, those with financial and/or legal interest in the issue tend to be given greater status. Advocacy groups, especially those with more diffuse memberships, suffer most. (Massey 1993, 239)

With specific reference to the Royal Commission the record shows that professional organizations, especially those representing the scientific and medical communities, were able to engage more effectively in the public hearing process than women's advocacy groups. In part, this is because no collective voice emerged to represent the full diversity of women's views.

Second, with regard to the nature of the deliberations among Commissioners, Janet Hatcher Roberts (past-Deputy Director of Research and Evaluation for the Royal Commission on New Reproductive Technologies) reports that there was considerable mistrust among the Commissioners along the axis of medical bias:

> Concepts such as "weight of evidence," relative effectiveness, and meta-analysis were considered suspect because some Commissioners felt they were driven by medical models of evaluation. … while to a certain degree their questioning was relevant, significant effort was given to social, feminist analysis of these issues and to integrate this analysis with the other medical, social, and economic analyses. Yet, the polarization remained and in fact became more pronounced as the Commission did its work. (Roberts 1999, 20)

Part way through the Commission's deliberations four Commissioners filed a lawsuit against the Commission and the Canadian government alleging a flawed public engagement process and an unclear research agenda. (Roberts 1999) These Commissioners were fired, as a result of which they lost their standing before the court, and the lawsuit was dropped. Two new Commissioners were appointed and the reconstituted Commission went on to publish a comprehensive set of recommendations.

Now, according to Montpetit, truth-seeking is a feature of public consultation in the mode of communicative action, and so the question arises: were the Commissioners genuinely "prepared to put their preferences on the back burner for the sake of truth-seeking ... [in an effort to identify] the best possible policy solution for the problem at issue?" (Montpetit 2003, 101). Arguably, this question cannot be answered authoritatively except by individual Commissioners who can speak to their willingness (or not) to entertain challenges to their ideas and preferences. However, the Commission's troubled history suggests that the answer to this question may be "no".

Strategic consultation and the law on embryo research

Between the publication of the Royal Commission's final report *Proceed with Care* (1993) and the publication of Health Canada's paper *Setting Boundaries, Enhancing Health* (1996) outlining the planned federal legislation, a strategic public consultation was undertaken by the federal government to validate the Royal Commission's recommendations. With this second wave of consultations, unlike the previous one undertaken by the Commission, there were clear and somewhat fixed policy preferences, namely the policies recommended by the Commission. As Montpetit explains,

> Several officials of the Health Policy Division responsible for ART policy design after 1993 were either close to the Royal Commission, or actual former employees of the commission. It was therefore difficult for the Health Policy Division to accept challenges to the … recommendations for limited prohibitions of ART practices and for the establishment of a regulatory commission to oversee standing practice – when so much effort and money had been invested in them (Montpetit 2003, 105)

While the strategic public consultation undertaken at this time revealed considerable disagreement between various interest groups (researchers and the medical profession, consumers, women's groups, pro-life groups and the provinces), Health Canada concluded that the Commission's findings were valid. It acknowledged,

however, a need for additional consultation on embryo research and a need for further consultation with the provinces and territories. A Discussion Group on Embryo Research was established in April 1995 and its final report was issued in November 1995 (Discussion Group 1995). Subsequently, Health Canada published *Setting Boundaries, Enhancing Health* and Canadians were invited to provide written comments on the proposed legislated regulatory regime. However, as reported by Montpetit, at this point in the process at least some Health Canada officials were not keen on further public consultation:

> It was basically the government's position paper. That was the government thing: we looked at all the stuff, we talked to all these people, this is now what we're going to do. Some people within government would refer to it as a discussion paper, and I'd say, "no, we've discussed, we're finished discussing. This is what we're going to do, we're going to pass legislation, and it's going to look like this." And so it was [Bill C-47]. (Montpetit 2003, 106)

Rule-guided consultation and the law on embryo research

After Bill C-47 died on the order paper and Parliament was reconvened in the fall of 1997, staff at Health Canada were instructed to consult with the Canadian people on the matter of assisted human reproduction so that their views could inform the drafting of a new bill. Staff in the Health Policy Division of Health Canada, however, considered further public consultation unnecessary as evidenced by the limited consultation that followed in 1999. What little public consultation took place had a limited objective: to satisfy a government directive. No doubt, for some, a certain amount of policy design fatigue had set in and there was little (or no) desire to hear from, or even persuade Canadians. Meanwhile, many Canadians expressed increasing frustration with the ongoing delays in acting on the recommendations of the Royal Commission.

For reasons that are not clear, the public consultation task was moved from the Health Policy Division of Health Canada to a special project division. Eventually this task was moved to the House of Commons Standing Committee on Health when then-Minister of Health Alan Rock presented the Standing Committee with *Proposals for legislation governing assisted human reproduction*. (Health Canada 2001) In the months that followed, a number of interested "experts" (including FB) appeared before the Standing Committee.

In 2004 the *AHR Act* received Royal Assent, at which time work began on the development of regulations pursuant to the legislation. Public involvement activities for this rule-guided consultation included a number of topic-specific workshops with different constituencies. For example, medical fertility clinics and laboratories of assisted reproduction services were consulted on the licensing and regulation of controlled activities and the obligations of licensees regarding health reporting information. Before this, patients/consumers of assisted reproduction services were consulted on the development of regulations under the *AHR Act* with respect to: aggregate outcomes of AHR procedures; health reporting information; counseling; and

information to be made available to the public by Assisted Human Reproduction Canada. Nothing came of these public consultations, however, ostensibly because of the pending constitutional challenge.

Communicative action and research guidelines for embryo (stem cell) research

The mandate of the CIHR Working Group on Stem Cell Research was very modest compared with that of the Royal Commission. The Working Group was not expected to develop an ethical framework for stem cell research, but rather to work within existing frameworks as found in the final report of the Commission (1993) and in the 1st Edition of the *TCPS* (MRC 2003). This meant, for example, that the permissibility of *ex utero* human embryo research up to day 14 was not subject to debate and discussion. Within this limit the Working Group was to advise CIHR on the research use of human embryos (and other human tissues) to derive and study pluripotent stem cells. As well, the Working Group's mandate did not include public consultation; this was undertaken at the initiative of (some) members of the Working Group.

Consistent with the goals and objectives of communicative action, and in an effort to simulate some form of dialogue, all comments received from the Canadian public were summarized and distributed to members of the Working Group for consideration. Some of these comments informed the Working Group's discussions and influenced the drafting of the final report. Other comments (especially bulk form letters that addressed issues beyond the limited mandate of the Working Group) had little impact. All comments from the public received a formal reply in aggregate in an Appendix to the Working Group's final report. Here there was an attempt to explain whether and how the public input had been included in the final policy recommendations. As appropriate, links were drawn between expressed concerns and measures taken by the Working Group to address those concerns in its final report.

There were, for example, concerns about the composition of the Working Group and about use of the web to solicit feedback from Canadians. With respect to the first concern, the Working Group was in the awkward position of having to generate an explanation for a decision into which it had no input. For good or ill, the Working Group defended its membership stressing the need for scientific expertise and noting that some members (presumably, the two philosophers and the sole lawyer) had no personal commitment to the pursuit of stem cell research. With regard to the second concern, about whether the consultation mechanism (posting a Discussion Paper on the CIHR website and inviting written comments) was an effective means of soliciting public input, the Working Group offered the following comment acknowledging the possibility of bias:

> The original mandate of the Working Group did not include a public consultation phase and it was initially anticipated that the Working Group would report back to the Governing Council of CIHR by June 2001. The consultation was done at the initiative of the Working Group and an extension of the reporting deadline was sought. The Working Group and CIHR also made sure that the document received

> wide media coverage to ensure that its existence became known to interested parties. The goal was never to do a full survey of Canadians' views on this topic- that would have required a different mandate, budget and time frame. Although the Group's survey of public opinion was limited and possibly biased, it did identify many issues that informed the final report. (CIHR WG 2002)

In this reply (as in others) there is evidence of a willingness to be challenged, a key feature of communicative action. Is there also evidence of a willingness to set aside preferences "for the sake of truth-seeking … [to identify] the best possible policy solution for the problem at issue?" (Montpetit 2003, 101) This is much less clear and arguably this is where the issue of membership bias in favour of the research community is most germane. It is not clear (indeed it is doubtful) that a majority of the members of the Working Group were able or willing to adopt a true problem-solving orientation to policy design regarding stem cell research in Canada. The Working Group was advisory to CIHR, a federal granting agency with a clear preference to fund at least some pluripotent stem cell research (albeit within a clear ethical framework).

Strategic consultation and research guidelines for embryo (stem cell) research

In October 2007 the CIHR SCOC initiated a four month strategic public consultation on a discrete business issue of critical important to the future of hES cell research in Canada (CIHR 2007a). This consultation is here described as 'strategic' because, in our view, those conducting the consultation had a clear policy preference for which they were seeking input-oriented legitimacy; namely, to exempt certain hES cell lines from the requirement that they be available to other researchers on a cost-recovery basis. The goal of the consultation was not to generate policy options (as would be the case with consultations conducted in the mode of communicative action), but rather to persuade those who were consulted to support the preferred policy option. Below we explain the strategic nature of this public consultation.

At the time the CIHR SCOC consultation was initiated, the *Guidelines for Stem Cell Research* required that all hES cell lines established through research funded by one or more of the federal research granting agencies or conducted in Agency funded institutions be (1) included in an hES cell registry and (2) available to other researchers on a cost-recovery basis. The preferred policy would amend this requirement so that only those hES cell lines established with Agency funding would be available to other researchers on a cost recovery basis, while hES cell lines established within Agency funded institutions, but without Agency funding, would be exempt from this requirement.

The online survey included the following statements followed by a simple request for agreement (i.e., endorsement of the preferred policy options) (CIHR 2007a):

> SCOC suggests that the registry include the following [hES cell] lines to be subdivided into two distinct lists:

> i) lines established through research approved by SCOC and with funding from any of the Agencies (not just CIHR). These lines would be listed in the registry and made available by the researcher to other researchers on a cost-recovery basis. *Do you agree with this application of the registry?*
>
> ii) lines established through research approved by SCOC and carried out in an institution that receives Agency funding, but whose derivation was not directly funded by an Agency. These lines would be listed in the registry but there would be no requirement for the researchers to make the cell lines available to other researchers on a cost-recovery basis. *Do you agree with this application of the registry?*

The information provided to prospective survey participants in support of the first policy choice explains the need to expand the registry in the following terms:

> The planned incorporation of the Guidelines into the *Tri-Council Policy Statement* (TCPS) is an argument in favor of expanding the scope of the registry. Such incorporation would, *per force*, expand the registry's scope because compliance with the TCPS is required for all research conducted in institutions receiving funds from the Agencies. It is also felt that the registry would be less useful if it did not include all hES cell lines derived under the auspices of an institution receiving Agency funds.

The reference to "expanding the scope of the registry" is inaccurate, however, as is the suggestion that this would happen, *per force*, with the planned incorporation of the *Guidelines* into the *TCPS*. In point of fact, the first policy choice is merely a statement of the status quo. As explained above, the *Guidelines* (as stipulated therein) already apply in their entirety to "all research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an Institution that receives *any* Agency funding" (CIHR 2007, s. 7.0, emphasis added), specific references to CIHR notwithstanding. This is because "NSERC and SSHRC [have] joined CIHR in agreeing to a Tri-Agency approach requiring adherence to the *Guidelines* as a condition for Agency funding of research" (CIHR 2007, s. 3.0). Further, the "Guidelines for Human Pluripotent Stem Cell Research: Policy Highlights" (CIHR 2008a) explain that:

> New or ongoing human stem cell research that is:
>
> i. funded by the Agencies; or
> ii. conducted under the auspices of an institution that receives any Agency funding, whether on site or off site; or
> iii. conducted elsewhere with any source of funding, by faculty, staff or students from an institution that receives Agency funding,
>
> must be in conformity with the Guidelines.

It follows that *all* hES cell lines established with Agency funding or conducted under the auspices of an institution that receives any Agency funding must be included in the Canadian stem cell registry and must be made available to other researchers on a cost-recovery basis. This fact suggests that the SCOC strategic public consultation may also have been strategic in the pejorative sense, viz. "calculated to take advantage of" those consulted. To be clear, there was no need for the SCOC to recommend statement (i); this was already required in the *Guidelines*. But if the SCOC consultation had only been about statement (ii), it would not have been possible for the SCOC to present the recommendation to exempt certain hES cell lines from the requirement that they be "made available to other researchers, subject to reasonable cost-recovery charges" (CIHR 2007, Section 6.0), as a reasonable limit on an effort to otherwise expand the Canadian hES cell registry—the impression created with statement (i). Indeed, a public consultation limited to statement (ii) would have made transparent the intention to limit (not expand) the hES cell registry and this could have undermined public support.

The results of the strategic public consultation on the hES cell registry were made public June 2009, more than a year after the survey was conducted and the results were discussed by the SCOC (CIHR 2009a). In response to the second question about hES cell lines at an institution that receives Agency funding, but whose derivation was not directly funded by an Agency, a majority of respondents (19) agreed that these hES cell lines need not be made available on a cost-recovery basis. A lower, but nonetheless relatively significant, number of respondents (12) disagreed with the proposed policy change, with "[s]everal respondents [noting] that the lines should be made available on a cost-recovery basis, regardless of the funding source." (CIHR 2009a)

At the same time the survey results were made public, a national electronically accessible registry of hES cell lines was created (CIHR 2009b). Initially, despite the fact that at least four hES cell lines had been derived in Canada and approved by the SCOC for research use, there were no hES cell lines listed in the registry. This was at odds with the stipulation by CIHR that all publicly funded pluripotent stem cell lines "must be made available to other researchers, subject to reasonable cost-recovery charges." (CIHR 2010a). Confusingly, though, CIHR characterized listing lines with the registry as a voluntary decision: "[i]nvestigators with lines derived under the auspices of an institution that receives Agency funding *will be asked if they wish to voluntarily list their cell lines*." (CIHR 2009b) In June 2010, CIHR clarified its policy by making participation in the registry for all lines derived under the auspices of an institution that receives Agency funding mandatory, and as of July 2010 four hES lines are listed in the registry.

Policy Design for Human Embryo Research in Canada: What Might the Future Hold?

As we look to the future, we note an important shift in the landscape of policy design for human embryo research in Canada – aside from very limited efforts at polling, there appears to be no concerted effort to dialogue with Canadians about embryo research. Meanwhile, there is reason to think that the views of Canadian citizens and

residents on the scope of acceptable hES cell research may have changed, or be in a state of flux.

It is widely understood that the science and practice of human embryo research is fast outpacing the policy-making process. In addition to the fast pace of science, there are the frequent media reports of national and international political controversies (especially in the United States), hoped-for-cures, and human tragedies. Against this ever changing, scientific, political and social backdrop, it is possible that available information about the views of Canadians is outdated. This suggests the need for additional policy consultation, but there appears to be little appetite for this. Moreover, from the perspective of some, it would be preferable to access the contributions of interest groups and policy communities (i.e., tightly interconnected groups closed to a limited number of influential state actors (Montpetit 2004, 72)) as these might more easily contribute to cohesive public policy. In Canada, one of the more powerful, knowledgeable, well-organized, well-connected, and well-funded policy communities with an interest in stem cell research is the Stem Cell Network (SCN).

The Stem Cell Network

The SCN is a non-profit organization created in April 2001 through the federal Network of Centres of Excellence program to serve as an interdisciplinary hub for researchers and clinicians across Canada engaged in the field of stem cell research. As currently described, the SCN mission is "to be a catalyst for enabling translation of stem cell research into clinical applications, commercial products or public policy." (SCN 2008a) From the beginning, the SCN has had a clear interest in embryo policy in Canada.

The SCN research program began in earnest in January 2002 when individual projects received funding.[5] At this time, the House Standing Committee on Health was reporting back to government on the draft legislation on assisted human reproduction, and the CIHR Governing Council was considering the final report of the *ad hoc* Working Group on Stem Cell Research. To this point in the policy process, individual members of the SCN may have had an impact on the legislation via presentations to the House Standing Committee on Health (see, for example, Baylis 2001) and on the *Guidelines for Stem Cell Research* via membership on the Working Group. The SCN as a discrete organization did not participate in policy design. However, in the 2 years between the adoption of the *Guidelines* (2002) and the passing of the *AHR Act* (2004), this changed. While the legislation was being debated in Parliament, SCN members testified before House and Senate committees and lobbied members of Parliament. Some SCN members spoke on behalf of the Network, others spoke on their own behalf. Some spoke in support of the legislation; some spoke against.

With the introduction of the *AHR Act* much of the overt advocacy activity quietened, but the SCN remains invested in policy issues and is now committed to ensuring a united front on matters of public policy. It has adopted a number of different

strategies to enhance its influence and further the objectives of those with vested interests in stem cell science.

First, in November 2005 the SCN created a multidisciplinary Policy Development Committee with a mandate "to consider issues of public policy relevant to stem cell research and to develop draft position papers for approval by the SCN Board as representing the official views of the Stem Cell Network" (SCN 2009c).[6] To date, the SCN Policy Development Committee has issued two policy papers – "Use of human embryos for stem cell research"; and "The need for public umbilical cord blood collection" – each aimed at advancing the SCN's interests. Consider, for example, the first of these policy papers, which advocates the research use of fresh embryos. With this paper, the SCN sought to legitimize (after the fact) research by an SCN researcher that resulted in the derivation of Canada's first hES cell lines. The policy paper also aimed to shore up the *Guidelines for Stem Cell Research*, as amended in 2005 "to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research."[7] (CIHR 2005)

Second, SCN policy objectives are also pursued through collaborative research and academic publications. Consider, for example, the recent collaboration involving SCN researchers and CIHR SCOC members who together published an article defending the use of fresh embryos in hES cell research. (Cohen et al. 2008)[8] This joint publication is significant insofar as it represents a potential, apparent or actual conflict of interest because of the different roles and interests that the different authors are expected to serve and protect. The CIHR SCOC is the national oversight committee mandated to provide CIHR Governing Council with policy advice on ethical and scientific issues (including updates to the *Guidelines for Stem Cell Research*), and to provide ethics review of stem cell funding applications (many of which would be submitted by SCN researchers). To avoid potential, apparent and actual conflict of interest, CIHR SCOC members should not be collaborating with SCN researchers on policy matters that directly impact research subject to SCOC review.[9] CIHR SCOC members and SCN researchers should be working at arms-length. The fact that they are not, speaks to the skill of the SCN in advancing its policy objectives.

Third, the SCN has also been successful in collaborating with various health charities that are well-positioned to support SCN policy objectives. It is generally understood that in some domains, not-for-profit organizations such as health charities have been co-opted by private interests (Batt 2005). The pharmaceutical industry, for example, has been quite successful in utilizing health charities as a means to "inform" patient populations about drugs "of questionable benefit." (Angell 2004; Herxheimer 2003) In the realm of stem cell research, the risk of capture does not appear to be an issue—not because health charities interested in hES cell research have a unique immunity to capture, but rather because their interests appear to be broadly aligned with those who promote hES cell research, including the SCN. At the time of writing, the SCN counts 43 health charities/not-for-profit organizations among its partners. In addition to joint investment in research, partners collaborate with the SCN "on education and public

awareness initiatives in order to encourage public dialogue on the potential of stem cell research in the context of a realistic understanding of where we are today." (SCN 2009b)

The 'official' positions of individual charities on stem cell research are not uniform. Nonetheless, to the extent that the SCN is able to coordinate a common front between the research community and the health charities/not-for-profit sector,[10] it will succeed in creating an impression of enthusiastic 'public' support for the research efforts of stem cell scientists and the efforts to create a more permissive research environment.

Fourth and finally, the SCN is able to advance its policy interests through its research portfolio, which includes a Strategic Program on Public Policy & Ethical, Legal & Social Issues. Currently this research is "focused on projects that are of interest to policymakers and to an ELSI core facility.…Guided by the SCN's Clinical Trials committee, the facility prioritizes *where the Network can have the most impact in easing the ethics/regulatory/policy pathways* and undertakes or co-ordinates work to address the hurdles." (SCN 2008b)[11] Some of the SCN's strategic research includes empirical research on the views and values of Canadians. For example, one SCN-funded project aims to examine popular representations of stem cell research in the media to better understand the impact of such representations on public perceptions of the science and policymaking. Over the next few years, the SCN likely will be in the unique position of being the only group able to provide the federal government with information about what Canadians "believe" about embryo research (and more specifically hES cell research), as no other research team has ready access to the requisite funds to generate this type of data. But as the SCN—an "interested" expert group with a clear policy preference for "*easing the ethics/regulatory/policy pathways*" (SCN 2008b) —will control the research questions and be responsible for the research interpretations, there will be good reason to consider the research findings with caution.

Consider, for example, the claim by SCN researchers that the current criminal prohibition on cloning for research is inconsistent with the majority of public opinion in Canada and therefore should be amended (Caulfield et al. 2002; Caulfield et al. 2005). This claim is surprising insofar as the researchers are aware of the serious limitations of public opinion data and well understand that the public's opinion is often rooted in "hype" emanating from the scientific community as reported by the media (Caulfield 2004; Caulfield et al. 2005). This knowledge ought to preclude advocating a policy change on the basis of polling data. Instead, as the data supports a desired policy position it is presented as authoritative and weighty.

In summary, the SCN is well placed to effectively participate in future public consultations on human embryo research through its Policy Development Committee, its diverse collaborations with CIHR and various health charities, and its own research agenda.

<u>Future policy design consultations</u>

For many and varied reasons, the SCN is well positioned to influence future policy consultations on human embryo research in Canada. First, as a Network of Centres of Excellence in stem cell research, the SCN carries with it the traditional authority of science. Second, that it can list world class researchers amongst its members is additional source of power and authority, as is its leadership role in creating the International Consortium of Stem Cell Networks (ICSCN). (ICSCN 2005) The mandate of the ICSCN is to facilitate international cooperation and to pursue collaborative research in areas of mutual interest including "stem cells and public policy". Third, the SCN readily assumes an air of reasonableness owing to its efforts at internal self-regulation (i.e., SCN policy documents) and its acceptance of external oversight (e.g., research review by the CIHR SCOC). Fourth, as noted above, there are structures and partnerships in place to produce and promote highly cohesive policy positions on human embryo research. Fifth, there is the weight of the SCN's financial interest in human embryo research. The SCN's current budget from the Networks of Centres of Excellence program is $6.4 million for the years ending March 2009 to March 2012 (SCN 2008a). A portion of this research budget directly funds hES cell research and is also used to leverage additional research funds. Sixth, through its partnerships with industry and specific initiatives like the creation of Aggregate Therapeutics Inc., the SCN's full embrace of commercialization is in keeping with the federal government's core science and technology policy objectives. (Herder and Dyck Brian 2008; Government of Canada 2007)

For all of the above reasons, the SCN's participation in policy design is likely to command significant attention and constitute a considerable counterweight to the contributions of concerned residents and citizens. The consequences of this could be damaging to future public consultation efforts (and the legitimacy of any policy decisions that might flow from such efforts) in at least two ways. First, public consultations may be more apt to be undertaken by interested experts (not the government) for strategic purposes and may intentionally privilege participation by the medical and research communities. Second, insofar as future public consultations are primarily strategic in nature (and driven by the research community), these consultations may mask important differences in what come to be identified as "Canadians values" and what those values actually are.

In either of these instances, input-oriented legitimacy would be seriously compromised. In the first instance, the information generated through the public consultation would come largely from a discrete "interested" constituency but be (mis)described as "public" input. In the second instance, the issue would not be biased participation so much as biased interpretation.

Conclusion

The public consultations that have contributed to the formulation of current embryo research policy in Canada (legislation and research guidelines) have not been free from controversy. But at least conflicting views and interests of Canadians have been relatively transparent which, in our view, is essential for informed and respectful debate, not to mention strengthening the input-oriented legitimacy of any resulting policy.

However, Canadian residents and citizens have been less and less involved recently in policy design for embryo research. One plausible reason for the decline in citizen engagement is the sheer cost of meaningful public consultation. This requires a significant investment (in both time and resources) in public education, data collection, and analysis. Another equally plausible reason for the decline is the belief among some civil servants and politicians that the time for public consultation has passed.

We are less convinced. As noted above, legitimacy in policy design depends, in large measure, on achieving an appropriate balance between output- and input-oriented legitimacy. What is "appropriate" will depend on: i) what policies are already in place; ii) what consultation efforts preceded the introduction of these policies (and, more precisely, whether relevant and diverse constituencies were consulted and heard); iii) what power dynamics currently exist between various interest groups and policy communities; and iv) the nature of the policy choice under consideration. In our view, the best way to ensure that no one particular set of interests dominates the agenda in this ever-shifting area of public policy is to regularly assess (and as needs be adjust) the balance between output- and input-oriented legitimacy.

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[1] FB prepared an expert opinion for the federal government in relation to the Québec reference (See, Baylis 2006).
[2] Reference re *Assisted Human Reproduction Act*, 2010 SCC 61.
[3] June 27, 2008 and June 30, 2009 CIHR announced "There are no updates to the *Guidelines for Stem Cell Research*" effective June 29, 2007. l
[4] For a helpful discussion of the public interest see Pal and Maxwell 2004.
[5] This is a reference to the time at which individual research groups received monies through the SCN to begin their research.
[6] At the time of writing, Janet Rossant, previously the Chair of the CIHR *ad hoc* Working Group, and Bartha Knoppers, previously a Commissioner with the Royal Commission on New Reproductive Technologies, co-chair this committee.
[7] Whereas typically practice is made to conform to guidelines, in this instance guidelines were made to conform with practice. The 2002 Guidelines did not discuss the use of fresh versus frozen embryos for hES cell research. Once it became clear that researchers were using fresh embryos for hES cell research, the 2005 Guidelines were amended to legitimize this research. For a detailed discussion of this see Baylis and McInnes (2007).
[8] Note, the information on consent to hES cell research included in this article is both incomplete and inaccurate insofar as it fails to discuss the relevant legislation and explain that the legislation takes precedence over the directives in the *Guidelines for Stem Cell Research*.
[9] At the time this article was published (May 2008), three of the authors (Knoppers, Isasi, and Nagy) were SCN-funded researchers, Cohen and Dickens were former SCOC members, and Brandhorst, Leader, and Evans were current SCOC members. In our view, it is possible (likely) that the former SCOC members were current SCOC members at the time the original manuscript was prepared. In the body of the article the authors acknowledge that five of the authors "are current or former members of the SCOC" (Cohen et al. 2008, 417). In the acknowledgements, three of the authors "thank the Canadian Stem Cell Network for funding support" (Cohen et al. 2008, 420). Nowhere in the article is there a statement about conflict of interest.
[10] This could occur in one of three ways: (i) by the SCN (perhaps through its newly formed Public Policy Committee) actively persuading health charities of its policy preferences; (ii) by health charities acquiescing in whatever policy positions the SCN advocates for; or (iii) some combination of these two options. Because of the SCN's apparent scientific expertise, health charities may simply not feel as though they have the capacity to question the SCN's policy preferences in pursuit of their common goal.
[11] This wording was eliminated from the SCN website following the publication of Baylis and Herder (2009). The text cited can be retrieved through www.archive.org by: (i) inserting http://www.stemcellnetwork.ca/ (ii) selecting the date May 26, 2008 and (iii) following the 'Research' link. Text also on file with the author