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February 26, 2004
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Thank you for the honour and privilege of having me to speak with you about Bill C-6. My comments will be brief, as I hope to maximize the time for discussion.

1. Bill C-6 the *Assisted Human Reproduction Act* is a good piece of legislation. It provides a clear and sound legislative framework for assisted human reproductive technologies. I urge the Senate to pass this Bill. Canadians have already waited too long for this legislation; they must not be left in a regulatory vacuum.
2. It is important to protect the health and safety of women and children. With assisted reproduction, women are at particular risk of harm, including the twin harms of coercion and exploitation. Children born of reproductive technologies are also at risk of harm. The declaration of principles, the explicit prohibitions, and the controlled activities in Bill C-6 are responsive to the government's obligation to protect women and children.
3. The law is not a static instrument, just as moral wisdom is neither fixed nor absolute. As you well know, legislation can be changed as appropriate, on the basis of new knowledge or changing mores. Bill C-6 is good public policy for the times. Do not be swayed by false claims about legislative immutability. Indeed, the Act calls for Parliamentary review of the Act within three years after the coming into force of section 21 (See Section 70.1)
4. This legislation is not about criminalizing science. The fact that there are laws with serious penalties for drunk driving does not make all drivers into criminals. If we are serious about the principles advocated in the legislation and the specific prohibitions, it is well and good that there should be serious penalties for anyone who would choose to contravene the law.
"Scientists need to realize that society as a whole has the right and responsibility to set guidelines for profoundly consequential technologies."
5. Research involving human embryos has been explicitly permitted in Canadian research guidelines since 1987. Human embryos remaining after infertility treatment are currently used for IVF research, testing clinic procedures and developing cryopreservation technologies. All of these interventions result in the destruction of the embryo. Some argue against expanding embryo research to allow for embryonic stem cell research. The principled basis of the distinction is unclear, however, as it does not



appear to rest on a claim about moral status. Why is it wrong to destroy embryos for research to develop therapies that might benefit all Canadians, but acceptable to proceed with such research to develop infertility treatments for the 15% of Canadian couples that experience fertility problems?

6. The ban on creating embryos for research purposes by cloning and other methods is sound. Do not be persuaded by false arguments about a purported need for so-called ‘therapeutic cloning’. Somatic cell nuclear transfer (SCNT) is not necessary to harness the potential benefits of stem cell therapies.

“Scientists need to hold each other accountable for raising false hopes among vulnerable constituencies and lay publics.”

In discussion, following my comments, I would be happy to answer questions on any of these points. For now, given the recent announcement by Korean scientists that they have derived embryonic stem cells from cloned human embryos, and the fact that this may be directing some of your attention to the part of the bill that places a comprehensive ban on human cloning, I will elaborate on this last point.

Some scientists claim that there is likely to be an immune rejection problem with the transplantation of stem cells derived from other people. They claim that this problem can be circumvented effectively by autologous transplantation, where a patient is given back her own undifferentiated cells. These are false claims.

i. *There may not be an immune rejection problem* – there is no scientific proof for the claim that immune rejection is likely to be a problem with the use of embryonic stem cells.

ii. If there is an immune rejection problem – *cloning for autologous transplantation is not the best solution to the immune rejection problem for reasons of ethics, economics, and equity*. If it takes hundreds of oocytes to generate a single stem cell line, we cannot ignore the potential for the coercion/exploitation of women. Oocytes are not tissues readily available in laboratories, they come from women’s bodies and at some risk to the women. A government-funded health care system cannot responsibly suggest to 30 million Canadians that they can have access to autologous stem cell transplantation when this implies access to 100 of millions of oocytes.

iii. *Better solutions to the potential immune rejection problem include banking cell lines with defined major histocompatibility complex backgrounds or genetically manipulating ES cells to reduce or actively combat immune rejection*. In the context of a government funded health care system with a commitment to provide equal access to high quality health care to all Canadians, we ought not to embrace and promote the false promise of personalized medicine.

“Personalized” stem cell lines involve generating genetically personalized tissue for each recipient, resulting in a perfectly histocompatible tissue match.

“Matched” stem cell lines would not be individually customized, but rather would be produced to represent a wide range of “major histocompatibility protein” (MHC protein) profiles that would meet the needs of a large proportion of the population, although some individuals would receive better matches than others.

“Universalized” stem cell lines would be genetically engineered to trigger no immune response, obviating the tissue matching problem.

Canadian scientists should invest their time, energy and talent, and the government should invest its money, in research to pursue options that are effective and viable for all Canadians. This should include research to develop matched and universalized stem cell lines. In this way, Canada can make a meaningful contribution to global science in helping to develop technologies that may one day be available to the world community.

I would like to close by repeating myself... Bill C-6 the *Assisted Human Reproduction Act* is a good piece of legislation. It provides a clear and sound legislative framework for assisted human reproductive technologies. I urge the Senate to pass this Bill. Canadians have already waited too long for this legislation; they must not be left in a regulatory vacuum.

Appendix 1

Personalized stem cell lines are not a viable therapeutic option.

The odds favoring success 'are vanishingly small,' and the costs are daunting. 'The process is a nonstarter, commercially.' Thomas Okarma, chief executive of Geron Corporation.

'Where do you source that many eggs? Sourcing human eggs is a contentious issue in itself... It is not something we want to get involved in,' Alan Robins, chief scientific officer of BresaGen Ltd., a cell therapy company in Australia and Athens, Ga.

'[Therapeutic cloning] is not commercially viable... Quality control is difficult; the FDA can't regulate it, [and] no one can afford the treatment.' He said that a complete ban on human cloning would have only 'a limited impact on corporate product development.'" "Lutz Giebel, CEO of CyThera, a cell therapy company in San Diego.

Denise Gellene, "Clone Profit? Unlikely: The Technology's Commercial Viability Faces Many Hurdles," Los Angeles Times (May 10, 2002).

http://www.genetics-and-society.org/resources/items/20020510_latimes_gellene.html

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'It's too laborious and costly to employ as a routine therapeutic procedure,' Dr. Alan Colman, the research director at PPL Therapeutics, the Scottish company which helped to clone Dolly the sheep.

'They're never going to have enough women's eggs available to do it,' Dr. Alan Trounson, director of the Monash Institute of Reproduction and Development in Australia and an adviser to ES Cell International, a company based in Singapore and Australia.

Andrew Pollack, "Use of Cloning to Tailor Treatment Has Big Hurdles, Including Cost," New York Times (December 18, 2001).

http://www.genetics-and-society.org/resources/items/20011218_nytimes_pollack.html

Appendix 2

Solutions to the potential immune rejection problem

Excerpts from testimony provided by Dr. Varmus (then head of NIH), Dr. Gearhart (first scientist to isolate human stem cells from fetuses) and Dr. Thomson (first scientist to isolate human stem cells from embryos), to the subcommittee of the Committee on Appropriations of the United States Senate. Worthy of note is the fact that while they discuss the potential problem of immune rejection with stem cell transplantation, they do not identify the use of cloning technology as the likely solution to this problem.

“...before we can use these cells for transplantation, we must overcome the well-known problem of immune rejection. Because human pluripotent stem cells derived from embryos or fetal tissue would likely be genetically different from the recipient, **future research would need to focus on modifying pluripotent stem cells to minimize tissue incompatibility.**”

Statement by Harold Varmus (then head of NIH) December 2, 1998. S. Hrg 105-939. Hearings before a subcommittee of the Committee on Appropriations United States Senate, One hundred fifth congress

One of the major limitations of tissue transplantation is the issue of graft rejection. The patient's immune system must be compromised to allow for the presence of the graft. This generally involves the use of powerful drugs with side effect. In animal studies it has been found that stem cells can be genetically manipulated so as to modify graft rejection. **It may eventually be possible to produce universal donor cell lines in the laboratory through the use of hPSCs.**

Statement by John Gearhart December 2, 1998 S. Hrg 105-939. Hearings before a subcommittee of the Committee on Appropriations United States Senate, One hundred fifth congress.

Strategies to prevent immune rejection of the transplanted cells need to be developed, but could include **banking cell lines with defined major histocompatibility complex backgrounds or genetically manipulating ES cells to reduce or actively combat immune rejection.**

Statement by James Thomson December 2, 1998 S. Hrg 105-939. Hearings before a subcommittee of the Committee on Appropriations United States Senate, One hundred fifth congress.