Stem Cell Research in Canada: Business Opportunities for U.S. Companies

Cheryl Reicin and Eileen McMahon

ABSTRACT

The ban on the use of United States (U.S.) federal funds to support new embryonic stem cell research has had a chilling effect on such research in the U.S. In Canada, significant research opportunities are available for conducting stem cell research. The opportunities include using embryos that were originally produced for reproductive purposes, and using stem cells derived from adults and animals. Stem cell research in Canada is made even more attractive in view of the availability and quality of research facilities, the lower cost of conducting research in Canada than in the U.S., and the government tax credits.

INTRODUCTION

With the death of actor Christopher Reeves, stem cell research has once again come to the forefront of public attention. Mr. Reeves, a quadriplegic, was an outspoken supporter and financial backer of stem cell research as a means of developing therapies for the injury that afflicted him for over 10 years.

Stem cells are “undifferentiated” cells that are capable of maturing into any of the specialized cell types in the human body. They are found at different stages of development—embryonic, fetal and adult. Proponents of stem cell research believe that this field of inquiry holds immense potential for curing diseases such as quadriplegia and Alzheimer’s, which result from irreparable damage to tissues. There is convincing evidence that stem cells are able to self-renew and differentiate, qualities necessary for the regeneration of damaged tissues.

Despite its potential therapeutic benefits, stem cell research is not without opponents. The use of human embryos has mired the field in controversy, with strong opposition to certain forms of such research. The existence of diametrically opposed views on stem cell research has yielded a regulatory landscape in the U.S. that is highly volatile and has limited federal support for such research.

Until recently, Canada’s regulatory scheme was also in a state of uncertainty. A newly enacted law applying to assisted human reproduction and related research greatly reduces this uncertainty and makes Canada a more appealing place to conduct certain types of stem cell research. U.S.-based researchers and investors are now looking north of the border to pursue stem cell research opportunities.

Current Regulation in the United States

In the U.S., federal support for stem cell research follows the letter and spirit of the so-called Dickey Amendment, which, in summary, prohibits the use of federal funds for the creation or destruction of a human embryo for research purposes. In 2001, President Bush announced that federal funding for embryonic stem cell research would be restricted to research on the more than 60 existing stem cell lines. Currently, only about 19 of those lines are available to researchers, and difficulties have been cited in accessing that limited number of cells on the National Institutes of Health registry. Moreover, since the cell lines were prepared using mouse cells, there is concern that they may be contaminated and may pose a risk for therapeutic uses for humans.

To compensate for the ban on the use of federal funding for such research, privately funded research centers have begun to emerge in the U.S.—for example, the Harvard Stem Cell Institute. Since no federally...
government. The government has recently enacted the Assisted Human Reproduction Act\(^\text{10}\) (the AHR Act), which clarifies the scope of permitted stem cell research in Canada. The AHR Act, “establishes clear boundaries, where none existed before, as to what constitutes acceptable research and under what conditions this research can be undertaken.”\(^\text{11}\) The AHR Act also creates the Assisted Human Reproduction Agency of Canada (AHRAC) to oversee assisted human reproduction (AHR) and related research. Recognizing the necessity of acknowledging the ethical issues raised by this type of research, the AHRAC has the following objectives:

### CURRENT REGULATION IN CANADA

Regulation of health research in Canada generally falls under the supervision of the Canadian federal government. The use of stem cells derived from therapeutic cloning, a technique involving the transfer of the nucleus of a cell from an individual into an egg from which the nucleus has been removed. The object of therapeutic cloning is to produce an embryo with stem cells that are genetically compatible with the individual requiring such cells. These stem cells could then be used to provide replacement tissue to repair damage caused by degenerative diseases. Creating these cells is, however, not permitted under the AHR Act. The Act states that “no person shall knowingly create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures.”\(^\text{18}\) This means that an embryo also may not be created specifically for research purposes.

Researchers working with embryonic stem cells are required to obtain a license from AHRAC for each of their research proposals. To use human in vitro embryos to derive stem cells, researchers must demonstrate that no other source would be adequate for the purposes of their research.\(^\text{13}\) Embryos that are no longer needed for reproductive purposes may be used,\(^\text{14}\) but only with the informed consent of the donors.\(^\text{15}\) In addition, the embryo must not have been purchased, sold or advertised for sale.\(^\text{16}\)

The AHR Act does not restrict research using pre-existing embryonic stem cell lines, but such research could still be subject to oversight by funding agencies such as the Canadian Institutes of Health Research (CIHR), a Canadian federal funding agency for health research, if funding is being sought.\(^\text{17}\)

The most restrictive aspect of the AHR Act involves the use of cells derived from therapeutic cloning, a technique involving the transfer of the nucleus of a cell from an individual into an egg from which the nucleus has been removed. The object of therapeutic cloning is to produce an embryo with stem cells that are genetically compatible with the individual requiring such cells. These stem cells could then be used to provide replacement tissue to repair damage caused by degenerative diseases. Creating these cells is, however, not permitted under the AHR Act. The Act states that “no person shall knowingly create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures.”\(^\text{18}\)

This means that an embryo also may not be created specifically for research purposes.

### FURTHER PROPOSED REGULATION IN CANADA

Another set of regulations are currently being developed by the Biologics...
and Genetic Therapies Directorate, which exists under the auspices of Health Canada. These regulations will relate to the final therapeutic uses of stem cells rather than to their sources, and will deal with safety in the manufacture and use of cells for transplantation. The regulations will be based on the National Safety Standards, which were developed by the Canadian Standards Association in collaboration with experts in the field, government representatives and other stakeholders.

The regulations will be implemented in two stages. In the first stage, a registration scheme will be introduced for institutions that process and distribute cells or tissue for transplantation. Once this step is completed, all such institutions will have to register with Health Canada in order to continue with their activities. In the second stage, a comprehensive compliance and enforcement strategy will be developed. The regulations introduce some extra procedural steps to the therapeutic use of stem cells; however, they should not represent any significant obstacle to stem cell research and general use.

OPPORTUNITIES FOR RESEARCH AND INVESTMENT IN CANADA

Although the AHR Act introduces some barriers to developing cell lines from human embryos (since cell lines may not be developed by using therapeutic cloning techniques), the development of cell lines is still permitted if the cells are obtained from embryos that have not been specifically created for research purposes. There are, therefore, still significant research opportunities available for using embryos that were originally produced for reproductive purposes. Moreover, stem cells derived from adults and animals are not subject to any special regulations in Canada beyond the usual regulations governing medical research. Research involving these lines of cells can therefore be carried out with the same confidence and certainty as any other medical research, removing these cell lines from the turmoil that has surrounded stem cell research in general. For example, Toronto Western Hospital now hosts one of the only four groups in the world that are searching for a cure for paralysis by harvesting stem cells from the spinal cords of adult rats. Restrictions placed on such research by AHRAC's licensing requirements will not likely be onerous enough to make such research impractical. These requirements, for the most part, have been adopted from guidelines used by the CIHR in funding embryonic stem cell research for years prior to the passage of the AHR Act.

The existence of an Act of this nature offers researchers and investors a clear framework within which to base their research initiatives. Although the new regulations do include restrictions, general reaction to the Act suggests that it is unlikely that any further limits will be introduced. In this way, the stabilizing effect of the Act can give researchers and investors comfort that their research and clinical trials are less likely to be interrupted or adversely affected by changes in regulation and policy.

Stem cell research in Canada is made even more attractive in view of the availability and quality of research facilities, the lower cost of conducting research in Canada than in the U.S., and the government tax credits. As a result, Canada has been home to some highly prominent laboratories in the field, which have flourished from the numerous sources of funding available over the years. A Special Focus on Stem Cells by the ISI Essential Science Indicator ranked Canada second in embryonic stem cell research, on the basis of the number of papers published between 1991 and 2001 and the number of times those papers have been cited in other works. The University of Toronto ranked second in embryonic stem cell research institutions, behind only Harvard; and Mount Sinai Hospital, a research center affiliated with the University of Toronto, ranked fourth. Canada is home to the authors of classic publications, including transplantation pioneers Drs. James Till and Ernest McCulloch, and other leading researchers, including alumni of the Ontario Cancer Institute, Lou Siminovitch, Andrew Becker, Alan Wu and Ronald Worton. The Edmonton Protocol, an innovative diabetes therapy involving the insertion of insulin-producing cells into the main blood vessel of the liver, is the result of Canadian research efforts. Stem cell research in Canada is also supported by a well-organized network of stem cell researchers, including the Stem Cell Network, an association of nearly 80 leading scientists, clinicians, engineers and ethicists, and serves as the central organization bringing together the research activities of numerous centers located in hospitals and universities across Canada.

CONCLUSION

The clarity brought by Canada’s new Act and the oversight by the AHRAC offer comfort to stem cell researchers and investors by providing a stable and supportive regulatory environment (and one that is less politicized than that south of the border) in which to conduct research.
and clinical trials. Canada has taken a significant step by enacting this legislation and helping to create an environment in which the knowledge, skill and funding required for the advancement of this important area of research can be invested with confidence.

ENDNOTES

1. See, e.g., comments made in 2002 by the Canadian Institute of Health Research on the need for clear guidelines in this area at that time, www.cihr-irsc.gc.ca/e/1487.html.


8. Ibid.

9. Ibid.


13. Supra note 10, at s. 40(2).

14. Ibid. at ss. 5(1)(b) and 10(2).

15. Ibid. at s. 8. At the time of writing, s. 8 of the ACR Act had not yet come into force.

16. Ibid. at s. 7(2).


18. Supra note 10 at s. 5(1)(b).


20. Note that CIHR guidelines apply only to public institutions and are not applicable to privately funded research. For the complete text of the guidelines, see www.cihr-irsc.gc.ca/e/1487.html.

