IN BRIEF

Parliamentary Information and Research Service
Library of Parliament

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Revised 11 July 2005

Human Embryonic Stem Cell Research

INTRODUCTION

Embryos, as well as fetal tissues, have been used for medical research since its beginning. Historically these tissues were obtained through therapeutic, and sometimes spontaneous, abortions. Now, however, with the dawn of artificial conception, embryos can be created in the lab and used in their very early stages of development for research.

In recent years, a considerable amount of controversy has surrounded the use of human embryos for research now that the possibility of creating embryos solely for the purpose of research has become a reality. This controversy has been most apparent in the United Kingdom and the United States, and has been related to the use of embryonic stem cells for research. For the purposes of this paper, "embryo" refers to those manufactured in the lab and only in their very early stage of development, less than 14 days.

STEM CELLS

Stem cells are undifferentiated cells that theoretically have the potential to become any type of cell (pluripotent), for example, nerve cell, blood cell, liver cell. Stem cells removed from embryos are known to be pluripotent, whereas stem cells from adults have been considered to have only the potential to become certain cell types. However, recent advances have suggested that adult stem cells may also be successfully "reprogrammed" to grow into any tissue type. The allure of stem cell research is the potential to manipulate these cells to grow into any transplantable tissue or organ.

EMBRYOS USED FOR RESEARCH

Discussions of human embryonic research usually refer to the use of "spare" embryos, those that were destined only to be discarded after no longer being required for *in vitro* fertilization or other reproductive techniques. Many scientists claim that embryos are never produced specifically for research purposes. This distinction, however, is suggested by some to be quite artificial. They point out that it is a simple thing to "overproduce" embryos for assisted fertility with the intention of having many remain for stem cell research.

THE EXPERIENCE IN THE UNITED KINGDOM

In addition to licensing and inspecting all fertility clinics in the United Kingdom, the Human Fertilisation and Embryology Authority (HFEA) also licenses and monitors all embryonic research. The HFEA was set up following the enactment of the *Human Fertilisation Act* in 1990. Each research project involving human embryos must be licensed, must meet the criteria for an acceptable purpose of research, and must absolutely require the use of embryos.

The Act does not prohibit the creation of embryos specifically for research. Embryonic research that is prohibited by law includes:

- research on embryos older than 14 days;
- the placement of human embryos in non-human animals;
- one type of cloning which is not common (embryonic nuclear transfer); and
- genetic alteration.

The HFEA will license the use of embryos for research into:

- infertility;
- congenital disease;
- miscarriages;
- contraception;
- the development of pre-implantation genetic diagnoses;
- embryo development;
- serious disease; and
- treatments for serious disease.

The *Human Fertilisation Act* makes no specific mention of stem cell research using embryos, and there is no other legislation in force in the United Kingdom to regulate it. The HFEA amended its code of practice in 2001 to permit embryonic research into serious disease and to develop treatments for such disease; embryonic stem cell research now proceeds under these

categories. Licences for embryonic stem cell research have been issued in the United Kingdom since 2002.

THE U.S. EXPERIENCE

Federal legislative initiatives tend to focus on issues driven by the abortion debate, and involve voluntary moratoriums and refusal to fund certain research activities. Embryonic research is one such issue. Current federal law forbids the use of federal funds to harm a human embryo. The ethical concerns are primarily related to the moral status of the embryo.

In August 2000, President Bush announced the release of new National Institutes of Health guidelines allowing, for the first time, federal funds to be used for human embryonic research. The guidelines allow research on embryonic cells originating from frozen embryos destined to be discarded. The destruction of these embryos will not be permitted to proceed under federally funded research protocols. Instead, the stem cells would have to be extracted from embryos by privately funded researchers who would then pass the cells on to federally supported scientists. In addition, several states have passed laws permitting the use of state funds for embryonic stem cell research; others have legislated against it.

EUROPEAN EXPERIENCE

In many member states of the Council of Europe, all embryonic research is prohibited; in others, it is severely restricted. The European Group on Ethics in Science and New Technologies, established by the European Commission, issued its opinion on the matter in November 2000. The Group believed that a centralized authority should exercise strict public control in those countries that permit embryonic research. The Group also indicated that creation of embryos for the purpose of stem cell research is ethically unacceptable.

The Group further declared that therapeutic cloning is unacceptable. It indicated that, although creation of an embryo by nuclear transfer to supply pluripotent stem cells genetically identical to a patient who requires a transplanted organ or tissue may be an effective technique, other sources of stem cells – from the patients themselves – are also promising and not ethically volatile.

THE AUSTRALIAN POSITION

Australia passed federal legislation in December 2002 to permit research involving human embryos. Australia's states have subsequently passed similar legislation to complement the Act. Research involving human embryos, including stem cell research, is strictly regulated; it is permitted only on surplus embryos and requires a licence.

CANADIAN LEGISLATION

In March 2004, Bill C-6, *An Act respecting assisted human reproduction and related research*, was passed into law. This legislation prohibits a number of activities, such as cloning and genetic alteration, while also providing for the regulation of a variety of controlled activities, including research on human embryos. Other prohibitions set out in the Act that must be respected by those who carry out embryonic research include a prohibition on creating embryos for any purpose other than reproductive, and a prohibition on allowing an embryo to develop outside the womb past day 14.

The Act established the Assisted Human Reproduction Agency of Canada, which is responsible for establishing regulations, issuing licences, maintaining personal and public databases, advising the Health Minister, etc. The Agency is responsible for issuing licences for controlled activities, including research involving human embryos. A licence authorizing the use of an embryo for the purpose of research may be issued only if the Agency is satisfied that the use is necessary for the purpose of the proposed research. Specific types of embryonic research are not listed in the legislation. Regulations set out by the Agency will determine the types of research that can qualify for licensing. The Agency's work is now in its infancy. It is not yet issuing licences, and regulations have not yet been set for embryonic research. In addition, the *Assisted Human Reproduction Act* contains a transitional provision that permits individuals to continue to carry out controlled activities, such as embryonic research, without a licence until such time as the Agency dictates.

CONCLUSION

The use of embryos as a source of pluripotent stem cells has been a contentious issue in many countries. It is an emotional issue for those who condemn it as being inextricably linked to the abortion debate. Those who see the therapeutic potential in embryonic stem cells defend the research just as passionately. Ultimately, however, the debate over the use of embryos as a source of stem cells may prove unnecessary, as researchers have shown significant success in demonstrating pluripotency in stem cells originating from adult muscle, brain and blood.