

EXECUTIVE SUMMARY

INTRODUCTION

- 1 In December 2000, the Bioethics Advisory Committee ('BAC') was appointed by Cabinet to examine the ethical, legal and social issues arising from biomedical research and development in Singapore, and to recommend policies to the Ministerial Committee for Life Sciences on those issues.
- 2 In particular, the Human Stem Cell Research ('HSR') Sub-Committee was formed under the BAC in February 2001 to specifically deal with the ethical, legal and social issues arising from human stem cell research, and to consider the related issues of reproductive and therapeutic cloning.
- 3 Since then, the BAC has examined and deliberated on the relevant scientific, ethical, legal and social issues in this area, and undergone an extensive consultation process, culminating in this Report. In addressing these issues, the BAC's fundamental approach is to balance the two ethical commitments: to protect human life and the rights and welfare of the individual, and to advance human life by curing disease.

SCIENTIFIC ISSUES

- 4 Chapter 2 of the Report deals with the science surrounding human stem cell research and identifies three widely recognised categories of stem cells, namely, embryonic stem cells ('ES cells'), embryonic germ cells ('EG cells') and adult stem cells ('AS cells').
- 5 ES cells originate from early human embryos and may be obtained from human embryos created by *in vitro* fertilisation ('IVF'), by cloning technique, or from existing ES cell lines. EG cells originate from primordial reproductive cells of developing foetuses, and can be derived from cadaveric foetal tissues. AS cells are derived from certain adult tissues such as the bone marrow, brain, skin, intestine and blood cells of the umbilical cord at time of birth.

- 6 The three types of stem cells appear to differ in their ability to specialise into other cell types. At present, ES cells appear to have the greatest potential to develop into nearly any cell type, followed by EG cells and to a much lesser extent, AS cells.
- 7 The BAC acknowledges the promise of tremendous benefits to mankind held by ES cells, in particular, for research in areas of treatment and therapy, and in the study of human developmental biology.
- 8 Chapter 3 of the Report discusses the science of cloning, and how cloning technology is linked with human stem cell research. A distinction between reproductive cloning and therapeutic cloning is drawn. Reproductive cloning refers to the application of cloning technology to animal or human cells that result in the creation of a complete animal or human being. Therapeutic cloning describes the use of cloning technology on such cells for therapeutic or research purposes that do not result in the creation of a complete animal or human being. The Report also discusses the potential which therapeutic cloning holds for furthering the understanding and treatment of human diseases.

ETHICAL, LEGAL AND SOCIAL ISSUES

- 9 Chapter 4 of the Report examines the ethical issues, social norms, theological and philosophical perspectives that arise and impact on human stem cell research. It focuses on the ethical issues of whether human stem cell research, reproductive and therapeutic cloning should be allowed, and if so, the extent thereof. It is acknowledged that there are detailed legal and regulatory issues that arise from positions adopted on the ethical issues, but such legal and regulatory issues will not be covered exhaustively in the Report.
- 10 The Report identifies the crux of the matter as arising from the ethics of deriving ES cells from human embryos for research purposes. This is closely linked to the on-going debate on the beginning of life, status of life and respect

for life. The spectrum of views held as regards this issue is also presented in this chapter.

11 Chapter 5 describes the extensive consultation process undertaken in an effort to understand all aspects of this issue, the concerns and sentiments of local interest groups as well as the views of the general public. A consultation paper was released on 9 November 2001 to 39 religious and professional organisations for their views. Written responses were received and dialogue sessions were held. Papers were also commissioned from a panel of seven local experts, and inputs obtained from the BAC constituted International Panel of Experts.

INTERNATIONAL PERSPECTIVES

12 Chapter 6 charts a comprehensive survey of perspectives and positions adopted by countries worldwide on the issues of human stem cell research, reproductive and therapeutic cloning. These views were extracted from various sources, including legislation and guidelines commissioned by ethics committees, as well as news reports. The study revealed that different countries adopted diverse and often conflicting positions, and that ethical positions adopted in one society may not be accepted in another.

DELIBERATIONS, CONCLUSIONS AND RECOMMENDATIONS

13 Chapter 7 of the Report begins by presenting an overview of the areas of concern that arise from human stem cell research, reproductive and therapeutic cloning. It acknowledges that there are serious ethical issues that have to be addressed and understands that social norms, theological perspectives and philosophical persuasions all shape the answers given by each society in response to these difficult questions.

14 As a starting point, two broad ethical guiding principles accepted by most responsible societies in discussing the exploitation of science and technology, namely that the results must be just and sustainable, were adopted by the BAC

as a conceptual framework in formulating its recommendations. The BAC views human stem cell research as having much potential benefits to offer to mankind, and that such research is important in the major areas, namely treatment and therapy, and in the study of human developmental biology.

- 15 Concerning the derivation and use of stem cells from adult tissues, the BAC views the process as analogous to the collection of specimens of biological materials from biopsies, and is ethically well accepted. Thus, there are no reservations as regards the derivation and use of AS cells, provided there is no adverse impact on and subject to the informed consent of the donor.
- 16 The derivation of EG cells from cadaveric foetal tissue however, encroaches upon the contentious issue of abortion. As abortion is permitted by the Termination of Pregnancies Act (Cap 324), the BAC would not revisit this issue. Hence the BAC is of the view that the derivation and use of EG cells is permissible, subject to informed consent of the donor. The decision to donate the cadaveric foetal tissue must be made independently from the decision to abort.
- 17 The use of ES cells has by far raised the most ethical debates. Diverse views have been proffered regarding the status of a human embryo, ranging from the absolute view that human life with full personhood begins at conception, to the view that the early embryo is only a clump of cells and research using the embryo is ethical in the light of the potential benefits to mankind.
- 18 Taking into account the diversity of views, the BAC adopts the intermediate position that a human embryo has a special status as a potential human being, but is not of the same status as a living child or adult. However, such respect is not absolute and may be weighed against the benefits arising from the proposed research.
- 19 Therefore, the BAC supports ES cell research subject to strict regulation of the means and methods of derivation of ES cells. The BAC takes the view that as a measure of respect and protection for the human embryo, ES cell research

should take place only when there is very strong scientific merit in and potential medical benefit from such research. Further, only embryos less than 14 days old should be used for the derivation of ES cells.

20 Currently, existing ES cell lines form a ready source for ES cells without requiring further sacrifice of embryos. In addition, ES cells can be derived from surplus embryos not created for the purpose of research but for fertility treatment, which are no longer required. Rather than allow them to perish, their use in research which would serve a greater good is not lacking in respect for these embryos.

21 ES cells can also be derived from embryos created by IVF or by cloning¹ technology. While there are concerns about creating an embryo solely for research purposes, in the final analysis, the essential task for the BAC is still to weigh the need to respect and protect the human embryo against the potential benefits to be reaped from research. The creation of embryos through therapeutic cloning offers an opportunity to derive stem cells which are immunologically compatible with the person being treated, thereby avoiding the problems of rejection. Therapeutic cloning also enables scientists to learn about the mechanisms of reprogramming adult cells to behave like embryonic stem cells again. In the future, adult cells may be able to be reprogrammed to behave like embryonic stem cells, potentially making it unnecessary to resort to using embryos to derive ES cells. Further, ES cell research today is developing at a fast pace, and the scientific evidence on the need for the use of research embryos is emerging day by day. There is a need to be able to respond effectively to such advances.

22 The BAC is of the view that research can adequately be carried out using the existing ES cell lines, and if necessary, surplus embryos. The creation of human embryos specifically for research can only be justified where there is

¹ The use of the word “embryo” in this case is a further extension of the use of the word which now encompasses post-fertilisation products prior to differentiation of placental from foetal products: later products of development where the early foetal structures are already visible, and this new class of cells derived from cloning technology which are not products of gametic fusion.

strong scientific merit in, and potential medical benefit from, such research, no acceptable alternative exists, and on a highly selective, case-by-case basis, with specific approval from the proposed statutory body.

23 As for reproductive cloning, the BAC is of the view that the creation of a human being by any cell nuclear replacement techniques or in any other method should be prohibited as the public policy reasons against this are overwhelming.

24 The BAC recognises that it is crucial to set up a comprehensive legislative and regulatory framework to control human stem cell research, and proposes the setting up of a regulatory body to license, control and monitor human stem cell research in Singapore. The constitution, powers and functions of the legislative and regulatory framework as proposed are set out in Chapter 7. Other features would include provisions for informed consent, protection of donors against inducements, coercion or undue influence, control of commerce and sale of donated materials, and conscientious objection to such research or manner of research.

SUMMARY OF RECOMMENDATIONS

25 The BAC believes that the recommendations would lead to ‘just’ and ‘sustainable’ results. The results would be ‘just’, in that research with tremendous potential therapeutic benefits to mankind will proceed. The results would be ‘sustainable’ as such research has little biological or genetic impact on future generations, especially with the ban on the reproductive cloning.

Recommendation 1: Research involving the derivation and use of stem cells from adult tissues is permissible, subject to the informed consent of the tissue donor.

Recommendation 2: Research involving the derivation and use of stem cells from cadaveric foetal tissues is permissible, subject to the informed consent of the tissue donor. The decision to donate the cadaveric foetal tissue must be made independently from the decision to abort.

Recommendation 3: Research involving the derivation and use of ES cells is permissible only where there is strong scientific merit in, and potential medical benefit from, such research.

Recommendation 4: Where permitted, ES cells should be drawn from sources in the following order: (1) existing ES cell lines, originating from ES cells derived from embryos less than 14 days old; and (2) surplus human embryos created for fertility treatment less than 14 days old.

Recommendation 5: The creation of human embryos specifically for research can only be justified where (1) there is strong scientific merit in, and potential medical benefit from, such research; (2) no acceptable alternative exists, and (3) on a highly selective, case-by-case basis, with specific approval from the proposed statutory body.

Recommendation 6: For the derivation and use of ES cells, there must be informed consent from the donors of surplus human embryos, gametes or cells.

Recommendation 7: There should be a complete ban on the implantation of a human embryo created by the application of cloning technology into a womb, or any treatment of such a human embryo intended to result in its development into a viable infant.

Recommendation 8: There should be a statutory body to license, control and monitor all human stem cell research conducted in Singapore, together with a comprehensive legislative framework and guidelines.

Recommendation 9: In obtaining consent from donors of cells, gametes, tissues, foetal materials and embryos, the information provided to the donors must be comprehensive, and there must not be any inducements, coercion or undue influence.

Recommendation 10: The legislative and regulatory framework should prohibit the commerce and sale of donated materials, especially surplus embryos. Researchers should not be prohibited from gaining commercially from the products of research, as well as treatments and therapies developed from the donated materials.

Recommendation 11: The legislative framework should provide that no one shall be under a duty to participate in any manner of research on human stem cells, which would be authorised or permitted by the law, to which he has a conscientious objection.