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REPORT OF THE IBC WORKING GROUP ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE

This report has been drawn up by the IBC working group established by the Bureau of the Committee within the framework of the work programme of IBC for 2010-2011

It does not pretend to be exhaustive nor prescriptive and does not necessarily represent the views of the Member States of UNESCO.

1. INTRODUCTION

Based on the work carried out on this issue in 2008, the International Bioethics Committee (IBC) finalized its Report on Human Cloning and International Governance and transmitted it to the Director-General on 9 June 2009 (Ref. SHS/EST/CIB-16/09/CONF.503/2 Rev. of 9 June 2009).

At its sixth session on July 2009, the Intergovernmental Bioethics Committee (IGBC) examined the IBC report and formulated the following recommendations:

“IGBC

- *Acknowledges and values* the work carried out by IBC on human cloning and international governance, *congratulates* IBC for an inclusive and balanced report on the topic and *invites* the Secretariat to continue updating the annex to this document;
- *Concurs* with IBC that an international dialogue on the international governance of human cloning is needed and should be pursued, and that the dissemination, discussion and debate on cloning issues at the international level remain essential to foster public sensitivity and awareness-raising, with a special attention to developing countries;
- *Supports* the assessment of IBC that an in-depth analysis aiming at reviewing the terminology for human cloning according to the new developments in biomedical research would be highly beneficial;
- *Suggests* that in pursuing its reflections on human cloning, IBC considers reviewing the terminology for human cloning as well as a wide range of related issues such as other possible options for its regulation and the vulnerability of women.”

(Ref. SHS/EST/IGBC-6/09/CONF.202/2 of 10 July 2009)

The Report of IBC and the discussion it raised during the sixth session of IGBC showed how the issue of human cloning and international governance is still of high significance to the international community, especially in the light of recent scientific developments in this field. At its 16th session (Mexico, November 2009), IBC therefore held an extensive brainstorming on the main issues raised during the preparation and finalization of the Report, thus paving the way for the follow-up work of IBC on this issue.

Based on this previous work and the proposals put forward by the IBC working group after the sixteenth session, the Bureau of IBC decided at its meeting in March 2010 to continue the work on human cloning and international governance in 2010-2011 by confirming and expanding the working group on this topic under the chairmanship of Professor (Mr) Toivo Maimets, Vice-chairperson of IBC¹. The Working Group received mandate to focus on three main areas:

- terminology and its ethical impact (including reviewing the Report on the use of embryonic stem cells in therapeutic research, Ref. BIO-7/00/GT-1/2 (Rev. 3) of 6 April 2001);
- different options for legal regulation of human reproductive cloning (including the possibility of a moratorium); and
- proposals for dissemination activities concerning the issue of human cloning and its governance.

1. The composition of the IBC Working Group in 2010 is as follows: Professor (Mr) Toivo Maimets, as Chairperson; Prof. (Mr) Abdallah Daar, Prof. (Mr) Qingli Hu, Prof. (Mr) Fernando Lolas Stepke, Prof. (Mr) Takayuki Morisaki, Prof. (Mr) Fawaz Saleh and Prof. (Mrs) Jeanine-Anne Stiennon.

2. NEW SCIENTIFIC DEVELOPMENTS UNDERLYING THE RE-EVALUATION OF EXISTING INTERNATIONAL GOVERNANCE OF HUMAN CLONING

The recent technical breakthroughs as well as potential future advances in understanding cell reprogramming has created a great promise to control the characteristics of a cell, allowing the creation of cells that can have a wide range of therapeutic applications.

Since their first derivation from early mouse embryos about three decades ago, the embryonic stem cells (ES cells) have been central in the developmental biology experiments and in other areas of research. What make the ES cells unique are their characteristic features of unlimited proliferation and pluripotency, meaning that they can be used to derive any tissue. In 1998, a new milestone was achieved when human ES cells (hES cells) were established from the inner cell masses of human blastocysts taken from *in vitro* fertilized embryos. The hES cells also have characteristic features of unlimited proliferation and pluripotency, as seen with mouse ES cells.

The hES cells are expected to have a variety of future applications, including as a resource for any cell type needed for such procedures as transplantation, blood cells for transfusion, and neurons for cell therapy. However, the usage of hES cells has raised a difficult ethical question stemming from the fact that generating hES cells requires the use and subsequent destruction of a human embryo.

In 2006, scientist found an alternative method of creating pluripotent cells by artificially deriving them from a non-pluripotent cell, typically an adult somatic cell, by inducing a "forced" expression of specific genes. Such cells are called *induced* pluripotent stem cells (iPS cells), and are similar to natural pluripotent stem cells, such as embryonic stem cells, in many respects.

In 2007, Dr. Yamanaka and colleagues created pluripotent cells from human cells. This has been cited as an important advance in stem cell research, as it may allow researchers to obtain pluripotent stem cells without the use of embryos. Since human iPS cells can be created from non-embryonic cells such as adult fibroblasts and have characteristics similar to human ES cells, they are anticipated to be a better cell resource for *in vivo* and *in vitro* applications, including regenerative medicine, disease models, and drug screening. Indeed, according to experts, human iPS cells may provide a more accessible, less expensive, less resource-constrained cell resource for human pluripotent cells.

While this new method of producing stem cells does not involve the creation, usage and destruction of human embryos and the related ethical controversies, it introduces new dimensions of ethical debate on reproductive cloning. Recent research developments pursued in animal experiments have revealed the potential use of iPS cells for reproductive cloning. Since they could be used for human cloning and gamete production, the implications of this new technology on human cloning must be considered thoroughly.

Moreover, the derivation and usage of iPS cells invalidates some of the concerns behind objections expressed against the cloning ban, such as the concern that cloning might be the only available technique in cases of complete male sterility. However, due to the relative novelty of this technology, great uncertainty still remains whether iPS cells can definitively replace embryonic stem cells, which continue to be used for research in many countries.

Other ethical issues stemming from the use of iPS cells include:

- Donor privacy – since iPS cells contain the genetic information of the donor, including information about potential disease predispositions, privacy issues must be considered.
- Consent – although they can be created without use of an embryo, appropriate form of consent must be sought before obtaining and/or using the cells. This is

especially important since iPS cell lines may be established from cells that have been donated decades ago for various studies, prior to the opening of these new possibilities.

- Safety – various aspects of safety concerning the use of iPS cells has yet to be clarified, and an appropriate regulatory or oversight system must be put in place before clinical application of these cells.

The recently announced scientific advances in synthetic DNA comprise another area of development that has potential implications for the human cloning debate. In particular, the May 2010 issue of *Science* reported that the genome of the bacterium *Mycoplasma mycoides* had been successfully synthesized from a computer record, and transplanted into the existing cell of a *Mycoplasma capricolum* bacterium that had had its DNA removed, leading to the claim of the first viable 'synthetic' bacteria. Even though the technical significance of this discovery in respect to human cloning may be rather limited, it has generated great interest amongst the policymakers and the general public and hence may need bioethical survey.

3. THE ISSUE OF TERMINOLOGY

In its Report of 2009, IBC clearly stated that “the terminology used in the bioethical debates is misleading and does not adequately describe the technical procedures used (or potentially to be used) today. An in-depth analysis aiming at re-defining this terminology according to the new developments in human embryo research would be highly beneficial”.

In particular, the widely used terms “therapeutic” or “reproductive” cloning indicate possible applications and do not constitute neutral descriptions. And yet, behaviors and policies are shaped by the representations and perceptions formed through the usage of this terminology. Therefore, UNESCO can play an important role in promoting the clarification, standardization and adequate interpretation of scientific terminology as it pertains to various social consequences.

In the field of genomics, cloning, and reproduction almost all terms used in the media are value-laden and emotionally charged. To designate a technique as “therapeutic” or “reproductive” is not to describe it but to point out a possible application or eventual outcome derived from it. This is probably unavoidable if scientific terms migrate to the larger society and are employed by journalists and other professionals, but the scientific establishment should consider preserving the real meaning and scope of the terms used. This is important insofar as social representations associated with many scientific terms and procedures influence politicians, the public and decision makers in industry and government.

The WG has analysed the history and practice of using the terms “reproductive cloning” and “therapeutic cloning” and has reached at the following positions:

- the definition of “reproductive cloning” ,” indicating the production of identical human beings, is scientifically incorrect and raises several issues from strictly scientific perspective.
- Nonetheless, this wording has been deeply entrenched in the international discourse on human cloning, and is already used in a number of national legislations and international guidelines. It would therefore be useful to retain the term “reproductive cloning”, and formulate a universally acceptable definition for it, delinked from other types of cloning. This will keep this term in current debates on bioethics and make possible future initiatives such as proposing international moratorium on reproductive cloning.

- One possibility could be to define human “reproductive cloning” as using the linear DNA nucleotide sequence of an existing human being to create an embryo, which is implanted into womb with the purpose to produce human baby. This definition underlines the importance of intent behind cloning technique in reproductive cloning.
- In the context of obtaining pluripotent stem cells, using misleading terms “therapeutic” or “research” *cloning should be avoided*. Instead, a term that describes the process rather than the intention can be used, such as “*derivation of pluripotent cells*” (by somatic cell nuclear transfer; re-programming - e.g. iPS - or any other existing or future technology). This terminology has an advantage of being descriptive, technically accurate, simple, easily understandable, and capable of incorporating any future scientific and technological developments. It also allows more nuanced and differentiated ethical analyses, depending on which technology is under scrutiny.

There is a distinct need for an adequate understanding of the terms generated and used to describe scientific techniques and procedures related to human cloning. This is an opportunity for UNESCO to organize periodic meetings with a view towards clarifying misunderstandings, preventing abuse, and facilitating sound, well-informed political decision-making.

4. ANALYSIS OF ALTERNATIVE METHODS OF INTERNATIONAL GOVERNANCE OF HUMAN CLONING²

In order to engage in the exploration of the alternative mechanisms that can be put in place to meet the challenges of regulating and controlling the practices that can lead to human cloning, an analysis of the state of the art in international legal governance of human cloning was necessary. In its report of 2009 IBC presented an overview of the existing legal framework applicable to international governance of human cloning. The following relevant norms elaborated at the international and regional level were acknowledged in the Report:

Non-binding instruments:

- **Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997).** Article 11 states that “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.”
- **Universal Declaration on Bioethics and Human Rights (UNESCO, 2005).** Article 16 specifies that “the impact of life sciences on future generations, including on their genetic constitution, should be given due regard.” These norms give UNESCO a firm track record on the international stage in relation to regulating human cloning.
- **United Nations Declaration on Cloning (2005).** The Declaration, adopted by the General Assembly with a narrow margin (84 votes for, 34 against and 37 abstentions), states that “all forms of human cloning are prohibited inasmuch as they are incompatible with human dignity and the protection of human life.” On its

² The IBC working Group thanks Prof. Thomas Faunce, who accepted to contribute to the elaboration of this report in his capacity as an expert of international law.

face this norm is broader in scope than that of the UNESCO Declaration and could cover forms of genetic research that are treated as legal by legislation in many domestic legal systems. Moreover, the wording of the document left room for very different interpretations of the text, which reflected, in part, the lines of division between different Member States on this issue. The main point of contention was the question of linking the issues of reproductive and non-reproductive cloning, which was not agreeable to many States, who abstained or voted against the Declaration.

- **World Health Organization resolutions WHA50.37 (1997) and WHA51.10 (1998).** The resolutions, which do not create obligations under international law, call to “foster continued and informed debate and take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replicating human individuals.

Binding instruments:

- **Council of Europe: Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998).** Article 1 of the Additional Protocol enunciates that “any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited”; and that “for the purpose of this article, the term human being “genetically identical” to another human being means a human being sharing with another the same nuclear gene set.” As a convention this instrument creates binding international law obligations but only for those State parties that have signed or ratified it. This definition is ambiguous because the commonly used method of reproductive cloning (nuclear transfer) does not create genetically identical organisms, because of, amongst other reasons, the continuance of maternal mitochondrial DNA. It also misses all the epigenetic differences and those created by individual developmental processes.

In addition to these international instruments, a plethora of domestic laws and regulations that directly or indirectly prohibit practices that may lead to reproductive human cloning have been in place for many years (A detailed overview of the existing legislation is available online - www.unesco.org/shs/bioethics). Together they constitute “general principles of international law” under article 38 (3) of the Statute of the International Court of Justice. Any new instrument on cloning under international law will have to relate to the existing norms in this area.

The above-mentioned regulations can not be considered as sufficient in addressing the challenges posed by the contemporary developments related to human cloning for the following reasons:

- the norms contained in these instruments pose clear conceptual problems: they are often mutually inconsistent, vague and expressed in scientifically inaccurate terminology;
- the declarations do not constitute international legal obligations enforceable either by states or individuals;
- the existing instruments may have unintended consequences of either inhibiting socially valuable medical research or encouraging prohibited practices for profit.

Therefore, it appears appropriate to advance processes towards a more robust mechanism, such as a moratorium or a convention on prohibition on human reproductive cloning under international law.

As an international organization that has a solid track record in standard-setting and capacity-building in bioethics, UNESCO provides the best global platform to initiate the processes towards a moratorium or a prohibition on human reproductive cloning under international law. Today, due to the sufficient consensus amongst governments of Member States against human reproductive cloning, it is plausible for the international community to move towards a convention prohibiting human reproductive cloning.

A convention or a moratorium against human reproductive cloning could involve the following narrow and broad features that would add value to the international governance on this issue:

- clarify the terminology;
- clarify specific prohibition on reproductive cloning for purposes of national legislation and bioethical guidelines;
- highlight relevant moral issues including vulnerability of embryo/foetus/child;
- highlight related bioethical and human rights responsibilities of states, corporations and medical researchers;
- allow States to set the human cloning issue within the wider context of technological and moral challenges facing humanity-including overpopulation and equity of access to new technological developments in healthcare;
- permit embargo on research co-operation with states allowing human reproductive cloning;
- prohibit trade in cloned embryos but not cloned tissue or cells necessary for research;
- permit trade cross-retaliation against offending state and creates obligations on States parties to create penalties including funding restrictions on offending corporations or scientific institutions (that is those who facilitate human reproductive cloning);
- permit International Court of Justice to hear disputes between states;
- render human reproductive cloning a crime justifiable before the International Criminal Court; and
- require ratifying states to impose criminal sanctions under domestic law against human reproductive cloning.

In order to create incentives for compliance with the instrument, it may contain guidance for the sponsors of national and international research in this area concerning refusing new or terminating the existing funding to non-compliant researchers and institutions.

5. DISSEMINATION

The dissemination, discussion and debate on cloning issues at the international level remain essential to foster public sensitivity and awareness-raising, so that all countries, including the developing and least developed countries, can participate and put forward their concerns regarding the new technologies related to human cloning.

The IBC Working Group considers UNESCO well-positioned to develop specific strategies and materials to promote international discourse on this topic and more actively encourage and support national research organizations, academies and national bioethics committees to foster debate on cloning issues and disseminate the related outputs among the specific interest groups as well as general public. More specifically, two courses of action could significantly contribute to raising awareness of dissemination of information concerning human cloning issues:

- ***Building a network for data collection and organizing information into a database***

UNESCO can create an observatory that collects information and tracks important developments in regards to human cloning, such as scientific breakthroughs or legal initiatives at national, regional and international levels. One possibility is to create such an observatory within the framework of UNESCO's Global Ethics Observatory (GEObs) databases. However, a sustainable observatory can only be based on the network of individuals, organizations, professional societies and research groups in various countries, possibly involving former members of IBC, providing UNESCO with up-to-date information concerning the new developments.

In addition, UNESCO can organize educational activities targeting the scientific community in order to raise awareness concerning ethical issues among persons involved in relevant practices and translate the results of research into popular language understandable to people without specific background in science.

- ***Organizing a high profile international conference on human cloning and international governance***

To promote international debate and raise awareness, UNESCO should organize an international conference to target policy-makers, opinion leaders, national and international regulators.

In parallel, such conferences can also be organized at the regional level in six UNESCO regions. National initiatives as well as combined actions with professional societies should be encouraged.

Other possibilities for disseminating information about human cloning and raising awareness on the related issues nationally and globally include:

- publication of articles in prominent peer reviewed journals on the state of the art of international governance of human cloning;
- developing a text of a model law for the countries that would like to enact a national legislation prohibiting human cloning;
- holding educational activities targeting key actors, most importantly the scientific community, in order to raise awareness concerning ethical issues among persons directly involved in relevant practices; and

6. EXECUTIVE SUMMARY

The IBC Working Group has been able to identify the following findings concerning international governance of human cloning:

a. *New scientific developments*

New scientific developments in cloning technologies, such as the use of induced pluripotent stem cells and production of synthetic DNA create a new dimension of ethical debate and call for the re-evaluation of the existing international system for governance of human cloning.

b. *Terminology*

There is a distinct need to analyze, clarify and if necessary re-define the terminology related to human cloning according to the new developments in human embryo research. More specifically,

- Although the term “reproductive cloning,” indicating the production of identical human beings is scientifically incorrect, it should be retained since it is engrained in global discourse and already features in a number of national legislations and international guidelines. Instead, it would be advisable to formulate a universally acceptable definition for “reproductive cloning” and to conceptually delink it from other types of cloning.
- One possibility is to define human “reproductive cloning” as using the linear DNA nucleotide sequence of an existing human being to create an embryo, which is implanted into womb with the purpose to produce human baby. This definition underlines the importance of intent behind cloning technique in reproductive cloning.
- The use of the terms “therapeutic” or “research” cloning to describe the process of obtaining pluripotent stem cells should be avoided. Instead, a term that describes the process rather than the intention behind it, such as “*derivation of pluripotent cells*” (by somatic cell nuclear transfer; re-programming (e.g. iPS) or any other existing or future technology) can be used. This terminology has an advantage of being descriptive, technically accurate, simple, easily understandable, and capable of incorporating any future scientific and technological developments. It also allows more nuanced and differentiated ethical analyses, depending on which technology is under scrutiny.

c. *Options for international governance*

The existing legal framework applicable to international governance of human cloning is based on national and regional legislation and guidelines that prohibit various practices related to human cloning, as well as on non-binding instruments adopted by international organizations, such as the Declarations of UNESCO. Any moratorium on cloning under international law will have to relate to the existing norms in this area.

The current non-binding regulations can not be considered as sufficient in addressing the challenges posed by the contemporary developments related to human cloning. Therefore, it appears appropriate to advance processes towards a more robust mechanism, such as a moratorium or a convention on prohibition on human reproductive cloning.

As an international organization that has a solid track record in standard-setting and capacity-building in bioethics, UNESCO provides the best global platform to initiate the processes towards a moratorium or a prohibition on human reproductive cloning under international law. Today, due to the sufficient consensus amongst governments of Member States against human reproductive cloning, it is plausible for the international community to move towards a convention prohibiting human reproductive cloning.

d. *Dissemination*

In order to promote the dissemination of information and to raise public awareness of the issues related to human cloning and its regulation, UNESCO can pursue several actions, including:

- Creation of a database to serve as a clearinghouse of information and to monitor new developments that affect the ethical aspects of human cloning debate; and
- Organization of a major Conference under the auspices of UNESCO, dedicated to the theme of human cloning and international governance.