United Nations
Educational, Scientific and
Cultural Organization

International Bioethics Committee (IBC)

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FIRST MEETING OF THE WORKING GROUP OF IBC ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE AND FIRST PUBLIC HEARINGS ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE

UNESCO Headquarters, Paris, 30 June – 2 July 2008
Room XVI (Bonvin Building)

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REPORT

Division of Ethics of Science and Technology

I. INTRODUCTION

1. Subsequent to the publication of the 2007 report *Is Human Reproductive Cloning Inevitable: Future options for UN Governance* by the Institute of Advanced Studies (UNU-IAS), United Nations University, the Director-General of UNESCO expressed his wish that the International Bioethics Committee (IBC) add the examination of this report to its agenda.

2. At its meeting in January 2008, the Bureau of IBC therefore decided to add the issue of human cloning and international governance to the work programme of IBC for 2008-2009 and to establish a working group on this topic under the chairmanship of Professor (Mr) Toivo MAIMETS (Estonia), initially composed of the following members: Dr (Mrs) Ephrat LEVY-ELAHAD (Israel), Prof. (Mr) Ching-li HU (China) and Prof. (Mr) Gamal Ibrahim ABOU SEROUR (Egypt). The specific task of the working group is to explore whether the scientific, ethical, social, political and legal developments on human cloning in recent years justify a new initiative at international level, rather than to initiate an ethical and scientific analysis of the issue of human cloning.

3. The Working Group held its first meeting at UNESCO Headquarters in Paris, from 30 June to 2 July 2008 and devoted one day to a public hearing involving a broad-based group of experts in the field. These hearings open to the participation of Member States, constituted a starting point for the deliberations of the Working Group and allowed transparency and clarity as per the mandate and the work of the Committee.

II. ONE-DAY PUBLIC HEARINGS (1 July 2008)

4. Some of the experts initially foreseen in the programme of the hearings (see Annex I) were excused from participating in the hearings due to personal or health reasons. Thus, the experts involved were: Dr (Mr) Darryl Macer (Adjunct Professor of the UNU-IAS and one of the authors of the UNU-IAS Report), Professor (Mr) Richard Gardner (University of Oxford, United Kingdom), Professor (Mr) Hans Galjaard (Erasmus MC Rotterdam) and Dr (Mrs) Marie-Charlotte Bouësseau (World Health Organization, WHO) (see list of participants in Annex II).

5. After the welcome from Mr Henk ten Have, Director of the Division of Ethics of Science and Technology, and Prof. (Mr) Adolfo Martinez Palomo, Chairperson of IBC, Professor Maimets recalled the specific mandate of the Working Group and provided an overview of past work on this topic within the United Nations system. He recalled that the speakers were provided with a set of questions to guide their presentation:

a. Considering the existing international legal framework governing the issue of human cloning, such as the legally non-binding UNESCO Universal Declaration on the Human Genome and Human Rights (1997) and the United Nations Declaration on Human Cloning (2005), have there been any recent scientific, social or political developments that would justify a new initiative at the international level?

b. The UNU-IAS report states that “international regulation is a necessity in this area…” and offers for the issue to be taken up by IBC or by the sixth committee of the General Assembly. Alternatively, the report suggests the dissemination, discussion and debate on cloning issues at the international level as a way forward. Would any of these options be realistic in terms of different cultural, religious and social backgrounds of Member States and their interests in developing medical research towards treatment of numerous incurable diseases?

c. What are the feasible options for further actions within the United Nations system that will serve the interests of Member States in the best possible way?

d. The issue of ever-evolving terminology: do the words “reproductive” and “therapeutic” cloning introduced into bioethics debate several years ago still adequately describe the technical procedures scientists use (and are potentially able to use) today?

6. The first presentation by Mr Darryl Macer, on behalf of the authors of the UNU-IAS report, concerned the report itself – the reasons behind its production, the intended audience and the reaction of the international community (see Annex III).

7. The presentation by Prof. Richard Gardner of the Mammalian Development Laboratory, Department of Zoology, University of Oxford, United Kingdom, focused on the scientific advances in cloning that raise the need for a more robust international mechanism regulating human cloning (see Annex IV). According to Prof. Gardner, since reproductive cloning is a highly intrusive application of genetics to medicine, it should not be contemplated until the many issues it raises have been properly addressed.

8. Prof. (Mr) Hans Galjaard, Emeritus Professor, Department of Clinical Genetics, Erasmus MC Rotterdam, the Netherlands, expressed his views on the subject and urged the Working Group to delink the two issues – “research cloning” and “reproductive cloning”, to focus on regulating the cloning intended for reproductive purposes, and to leave scientists to pursue progress in research cloning (see Annex V).

9. Dr (Ms) Marie-Charlotte Bouësseau, while noting that she was not in a position to provide an extensive presentation on the issue, remarked that at present WHO has no clear-cut position on the issue of human cloning and considered that the work initiated by IBC would be an opportunity for reflection. In contemplating on the potential international mechanism governing human cloning, it would be useful to look at the lessons learned in the past, and in particular the declarations that despite being adopted, have failed to work as intended.

III. EXCHANGE OF VIEWS ON THE UNU-IAS REPORT AND THE MAIN CHALLENGES CONCERNING HUMAN CLONING AND INTERNATIONAL GOVERNANCE

10. The discussion within the Working Group turned towards the preliminary issue of whether sufficiently important scientific, legal or social changes have occurred to necessitate a re-examination of international governance mechanisms for human cloning. The group also addressed the issue of terminology used and the distinction between therapeutic and reproductive cloning.

Developments in the field

11. The group agreed on the need to determine whether significant developments have occurred in the field of human cloning to call for the re-examination of its international governance. The participants agreed to maintain a sharp focus on the scientific, ethical and cultural aspects of this issue, in line with UNESCO’s mandate.

12. As a significant scientific development, the group noted the work conducted on Induced Pluripotent Stem (IPS) cells since 2006. It was agreed that the scientific progress in the possibility of transforming somatic cells into germ cells should be carefully followed. Nonetheless, the group considered this new technology to be in its nascent stage and agreed on the need to wait for further developments in this field.

13. Form the ethical point of view, the Working Group members expressed their regrets about the confusion within the ethical debate between therapeutic and reproductive cloning. This confusion stems primarily from the differences in the status attributed to the human embryo in different cultures and societies. Nonetheless, the number of countries which have ethically accepted therapeutic cloning seems to have grown from two years ago. Moreover, considerable advancement made in the field of governance constitutes an important ethical and political change.

14. While some countries have adopted specific regulations on human cloning in the last few years, many others still lack such regulations. In this respect, the Working Group considered that the IBC reflection on this issue would greatly benefit from an updated review of national legislation, and invited the Secretariat to conduct such work.

15. Furthermore, the Working Group indicated its concern about the development of both legal and illegal international exchange of stem cells lines. They noted that there is no international regulation on international exchange of stem cells and that the existing domestic rules cannot prevent their cross-border trafficking.

Terminology

16. The Working Group agreed that the use of the term “clone” is scientifically and etymologically misleading; it overlooks the differences that would appear between a person and his genetically identical “clone”. The importance of epigenetic factors in this respect has indeed to be stressed. Nonetheless, it has been recognised that the term “cloning” should not be abandoned since this term is already used in a number of national legislations and international guidelines that are currently in effect.

17. Similarly, the term “therapeutic” cloning was brought under intense scrutiny. The group agreed that while “reproductive” is a term that clearly indicates the ultimate intention of the procedure, the term “therapeutic” fails to clearly define the purpose of the procedure, considering that at present, no cloning procedure has resulted in a therapeutic use.

Focusing on the purpose of cloning

18. It has been admitted that it would be preferable to define the two types of cloning in accordance with their respective purposes rather than with the technique used. Delinking the two types of cloning would help the international community strike a balance between the need to allow for scientific progress in the field, and the imperative to safeguard human dignity in the process. Such a delinking would also help countries avoid a deadlock, such as occurred during the elaboration of the UN Declaration on Human Cloning in 2005, which resulted in a text that can be interpreted as banning both reproductive and therapeutic cloning.

19. The question was raised whether preventing reproductive human cloning was a matter of urgency. The Working Group recognized that while the technology required to give birth to a human being by cloning is not yet available, it could be developed in the near future. Therefore, the group reached the conclusion that in view of the scientific, social and political developments, the existing non-binding texts on human cloning are not sufficient to prevent human reproductive cloning.

IV. CONCLUSION

20. At the end of the meeting the Working Group agreed on the structure and the main content of its report to IBC. The document will include a progress report on the work done so far by the group including the one-day public hearings, an overview of the current scientific, social and political developments that call for a new initiatives in international governance of human reproductive cloning, and the major suggestions of the Working Group. The document will be presented and discussed at the fifteenth session of IBC in October 2008. The Committee will then decide whether it is ready to present its opinion to the Director-General, or whether it considers necessary to further pursue its work on this issue.

ANNEX I

Paris, 3 June 2008
Original: English/French

WORKING GROUP OF IBC ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE
(analysis of the UNU/IAS Report
Is Human Reproductive Cloning Inevitable: Future Options for UN Governance)

HEARINGS ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE
Paris, 1 July 2008
UNESCO Headquarters – Room XVI (Bonvin building)

PROVISIONAL PROGRAMME

9:30 a.m. – 9:40 a.m.	Words of welcome from *Mr Henk ten Have,* Director of the Division of Ethics of Science and Technology, and *Prof. (Mr) Adolfo Martinez Palomo*, Chairperson of IBC
9:40 a.m. – 10:00 a.m.	Introductory remarks by *Prof. (Mr) Toivo Maimets*, Chairperson of the IBC Working Group
10:00 a.m. – 10:40 p.m.	Presentation by *Dr (Mr) Brendan Tobin*, Fellow, United Nations University Institute of Advanced Studies (UNU/IAS), Japan *Questions / answers*
10:40 a.m. – 11:20 p.m.	Presentation by *Dr (Mrs) Chamundeeswari Kuppuswamy*, Lecturer in Law, University of Sheffield, United Kingdom *Questions / answers*
11:20 a.m. – 11:40 a.m.	*Coffee break*
11:40 a.m. – 12:20 p.m.	Presentation by *Prof. (Mr) Richard Gardner*, Mammalian Development Laboratory, Department of Zoology, University of Oxford, United Kingdom *Questions / answers*
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2:30 p.m. – 3:10 p.m.	Presentation by *Prof. (Mr) Hans Galjaard*, Emeritus Professor, Department of Clinical Genetics, Erasmus MC Rotterdam, the Netherlands *Questions / answers*
3:10 p.m. – 3:50 p.m.	Presentation by *Dr (Mrs) Sheryl Vanderpoel*, Focal point for ethics, Department of Reproductive Health Research, World Health Organization (WHO) *Questions / answers*
3:50 p.m. – 4:15 p.m.	*Coffee break*
4:15 p.m. – 5:30 p.m.	General discussion and conclusion

ANNEX II

Paris, 3 June 2008
Original: English/French

WORKING GROUP OF IBC ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE
(analysis of the UNU/IAS Report
Is Human Reproductive Cloning Inevitable: Future Options for UN Governance)

HEARINGS ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE
Paris, 1 July 2008
UNESCO Headquarters – Room XVI (Bonvin building)

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Is Human Reproductive Cloning Inevitable: Future Options for UN Governance

by Darryl Macer
Adjunct Professor, UNU-IAS
On behalf of the authors of the report:
Chamundeeswari Kuppuswamy, Darryl Macer, Mihaela Serbulea and Brendan Tobin

Human cloning has been one of the most emotive and divisive issue to face UN negotiators and the international community in recent years. The United Nations University Institute of Advanced Studies (UNU-IAS)[1] report *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance* examines how, that despite a widespread consensus amongst nations that it is desirable to ban reproductive cloning, efforts to negotiate an international convention ground to a halt due to fundamental divisions regarding so-called research or therapeutic cloning. Firm positions on both sides of the debate led to the compromise position of a non-binding UN Declaration on Cloning.

The Biodiplomacy Initiative at UNU-IAS carried out analysis of the opportunities, challenges and options for international governance of cloning. The cloning report was developed during policy analysis conducted during 2003-2007.

The report included a brief introduction to the science of cloning using the definition that Cloning is the "Process of producing cells genetically identical to the original ancestor", and that Reproductive cloning "involves the use of cloning technology to produce one or more individuals genetically identical to another individual." The report noted that over the last fifty years we have moved from being able to clone a few cells to cloning of mammals. Despite media hype, it is still reasonable to conclude, that given the amount the work ongoing in the field that advances in embryo research are set to increase during this century, providing a good reason for considering regulation. Scientists have called for allowing multiple scientific approaches to achieve beneficent goals of research. The report was written before the announcement of IPS technology.

The analysis of the ethical considerations revolved around the questions of - human dignity, what is natural, human health, social justice, freedom of research and choices. The conclusions include that the intrinsic dignity (feeling of self-worth) and extrinsic (respect for the dignity of others) dignity of the human person is not violated by human reproductive cloning. Society may have an obligation to disallow activities which might lead to commoditization of life.

The Universal Declaration on Human Genome and Human Rights (UDHGHR) of 1997 recognizes human biological diversity as part of our natural heritage. Replicating genetic characteristics via human cloning would result in shrinking of biological diversity. This will be an issue if reproductive cloning is widely practiced, but not if it was used for limited numbers.

Given the immature state of technology, the possibility of mutations and potential physical harm and general long term health risks are serious concerns that make applications of such technology ethically unacceptable. This is the point on which all parties (scientific and religious) converge and their objective of prohibiting human reproductive cloning comes together.

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1. http://www.ias.unu.edu/

Over ethical issues include the social justice issues of selection of research priorities. Prioritization of research is an issue that is being debated and progress is being made at the international level. The 2005 Bioethics Declaration developed by the UNESCO IBC seeks to establish a principle of social responsibility. Bioethics needs to rethink its agenda and part of that rethink should include an analysis on the benefit that cloning technology can bring to disadvantaged and underprivileged groups.

There is also consideration of potential discrimination against children born from cloning.

There is a call for greater research and description of diverse ethical positions from non-Western countries, and countries that were not so focal in the UN GA debates. Philosophy of science and bioethics have often ignored potential contributions from non-western philosophies, which can bring both useful insights into current issues and also aid in rethinking the agenda for bioethics in a way that is relevant to more people across the globe. An analysis of the construction of ethical positions and their application to the issue could be made. Discussion of ethics at the UN level often brings to mind the notion of deep, profound, commonly held principles to guide human actions. While general ethical principles, such as the principle of doing no harm in medical practice, are widely respected, the question of what amounts to harm is less easily defined. The debate on reproductive and research cloning has demonstrated the diversity of ethical beliefs. It is interesting, for instance, that while there is an almost complete consensus amongst countries with regard to the need to ban reproductive cloning, a number of academics and some religious groups do not necessarily believe that such cloning is unethical.

The General Assembly (UN GA) debate on the agenda item brought by France and Germany which culminated in the 2005 Cloning Declaration is instructive of a number of lessons in biodiplomacy. The choice of forum for such debate has to be carefully considered, the place of moral issues in the regulation of biotechnology has to be fully recognised, and the historical continuity with debates in assisted reproduction and reproductive technologies has to be kept in perspective.

The UN GA Cloning debate evolved from calls for a Convention to the formulation of a Declaration, as a way to bridge the division over the international governance issues. The United Nations Declaration on Human Cloning (A/RES/59/280) was thus adopted on 8 March, 2005. The Declaration was passed with 84 countries supporting it, 34 against, while 37 abstained. Comparisons are made between the reasoning of countries for and against the Declaration. Research efforts on reproductive as well as therapeutic cloning continue to be governed by national law and policy.

The Formation of Customary International Law is reviewed, and the report concludes that an analysis of existing municipal legislation on cloning indicates strong evidence of state practice and *opinio juris* supporting the prohibition of reproductive cloning. In the case of reproductive cloning, over 50 countries have legislated to ban reproductive cloning and there is no country that legislated to allow the practice. The Universal Declaration on the Human Genome and Human Rights, approved by UNESCO General Conference in 1997, was endorsed unanimously by the General Assembly, as a prohibition on reproductive cloning. There is however no consensus on use of human embryos for research cloning.

National legislation provides a framework for regulating behaviour within national jurisdictions. They do not apply beyond the boundaries of the state. However, international law is formed via national legislation, provided they are all uniform and achieving the same effect. An international Custom is supposed to have emerged. Such custom is binding on all states. International custom can be pictured as a web of rules created by the enmeshing of national legislation and other forms of official statements,

subsequently followed by action (including inaction) and provides as much coverage if not more than treaty law (Art. 38 (1) (b), Statue of the International Court of Justice). The procedure whereby a cloned embryo is implanted into the uterus has been declared a criminal offence under many national legal systems – and the same is reflected in the corresponding customary rule.

Future options for international governance of cloning could include further work by UNESCO IBC on the issue of reproductive and research cloning, in the context of resolution A/RES/59/280 and also in the context of the Universal Declaration on Bioethics and Human Rights, which was adopted by the General Conference of UNESCO on the 19th of October 2005. The UN GA Sixth committee takes up the issue of customary international law on cloning. The current status quo is one option, but the report presents discussion relevant to the different options that exist to establish temporary moratorium, total bans or to leave the decision to the national governments.

Amongst the options available for regulation of cloning only option b below has near universal consensus among governments:
a) Ban all cloning research
b) Ban reproductive cloning
c) Ban reproductive cloning but allow research cloning
d) Ban reproductive cloning and provide a time limited period for research cloning with a built in review process.
e) Place a moratorium on all cloning research.

While noting the existence of article 11 of the UDHGHR, and its endorsement by the UN GA in 1998, as the most significant international norm against human reproductive cloning, the UNU IAS report notes that is notoriously difficult to establish international custom. For that reason if it is written down in the form of a resolution, then it is recognised more easily as custom. To this end the International Community could take write the custom down into law.

The UNU-IAS report recommended that either UNESCO IBC takes up the issue of reproductive and research cloning, in the context of resolution A/RES/59/280 and also in the context of the Universal Declaration on Bioethics and Human Rights, which was adopted by the General Conference of UNESCO on 19 October 2005; and/or the UN GA Sixth committee takes up the issue of customary international law on cloning.

In discussion of governance, case studies on the ethics of human reproductive cloning research wherein a diversity of ethical positions exist on the issue could be gathered. Case studies on the ethics of healing would constitute a valuable resource for the international community to draw upon while deliberating on embryo research. Case studies on the status of the embryo in international law. Such a study will provide a sound foundation from which to consider the ethics of embryo research.

The report hopes to contribute to dissemination, discussion and debate on cloning issues at the international level, so that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology. This issue however is one that affects all of humanity, and the report is intended to provide a basis on which the international community may wish to revisit the issue of human cloning, at a time which may be not too distant. There should be dissemination, discussion and debate on cloning issues at the international level, such that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology.

HEARINGS ON HUMAN CLONING AND INTERNATIONAL GOVERNANCE
Paris, 1 July 2008

PRESENTATION BY PROF. RICHARD GARDNER

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It may be helpful to begin by briefly explaining why the technique of animal cloning through replacing the nuclear genome of eggs with that of somatic cells was initially developed. It was to ask the fundamental question of whether differential gene activity involved in the specialization or differentiation of cells entailed loss or irreversible alteration of those genes that were not required to be active.

While initial attempts to extend such studies to mammals yielded such clearly negative results as to lead Solter to assert dogmatically that cloning would not be possible in this group of animals, this proved incorrect with the birth of Dolly the sheep. That fertile adults could be produced with nuclei taken from post-natal mammals raised the spectre of the likely technical feasibility of achieving full reproductive cloning in humans.

I have long felt that simply arguing that human reproductive cloning should not be attempted because it is **an affront to human dignity** is rather vacuous.

There are, indeed, more compelling scientific reasons for not allowing it.

1. It is fraught with a high incidence of perturbed development in all mammals in which it has been achieved thus far. Even where the fetus seems to develop normally, abnormalities of placental structure and gene expression are almost ubiquitous. Cloned embryos may pose a particular risk to those carrying them in the human because our species is uniquely susceptible to a former of placental cancer called choriocarcinoma.

2. A sound case for justifying human reproductive cloning has yet to be made. The notion that it could be used to replace a child or loved-one following accidental loss betrays frighteningly naivety regarding what the outcome would be. [Beethoven preserved in the perma-frost – and the case of the Bunker twins]. Hence, expectations not fulfilled.

The second ground for doing it which has been advocated particularly by Panayiotis Zavos is to enable a biologically within couple child to be produced in cases where the male partner is completely infertile – i.e. shows complete absence of sperm production so that ICSI is of no use. The idea would be to place the nuclei of somatic cells of the male into eggs of the female partner. An obvious concern here which Zavos and his colleagues do not seem to have considered is that, on the basis of experience in other mammals, complete absence of sperm is very likely to be determined genetically – so one would be carrying the risk of producing a child that could itself reproduce only by cloning and thus be isolated reproductively from the rest of humanity. This would hardly conform to the norm of assigning primacy to the interests of the child. Zavos's real motivation for undertaken such work is perhaps betrayed by his own publicity material.

To summarize, as I have said elsewhere:

"Except for those resulting from spontaneous division of embryos to yield identical twins, we have all enjoyed a unique shuffling of our parental genes and it is this that accounts for our immeasurable diversity. Reproductive cloning entails imposing the genetic constitution of an existing individual on one or more future individuals. Since this is a much more intrusive application of genetics to medicine than has been attempted hitherto, it should not be contemplated until the many issues it raises have been properly addressed."

What about embryo splitting to produce identical twins – a form of reproductive cloning which mimics a natural process? Again, however, if the health and welfare of resulting children are paramount, this again is questionable, since such twinning carries a significantly elevated risk of morbidity and mortality, even where only one of the twins survives to birth.

Now briefly consider what has come rather prematurely to be termed 'therapeutic cloning'. The procedures it involves are initially identical to those used for full reproductive cloning except, instead of being placed in the womb, the embryos are converted in vitro into two-dimensional cultures of ES stem cells. Obviously, a concern is that any technical advances that improve the efficiency of 'therapeutic cloning' increase the feasibility of reproductive cloning. Notion is to harness technique to produce patient-specific stem cells for regenerative medicine – obviously of no value without use of genetic modification in cases where the need for stem cells is the result of genetic disease since all the patient cells will carry the same defective gene. Beset with problems of inefficiency –shortage of human eggs and doubts about the normality of the resulting stem cells. Certainly, it is most unlikely ever to be offered on the National Health Service in the UK, and thus possibly limited only to those able to afford very expensive private medical treatment. However, recent development in Japan in the production of IPS cells looks a far more promising and ethically less contentious alternative for obtaining patient-specific ES cells. Still much to be done here – while oncogene cMyc can be avoided – retroviral transfection to get pluripotency genes into somatic cells poses risk. Nevertheless, even if iPS cells provide a practical approach to regenerative medicine, this will not necessarily eliminate the case for using therapeutic cloning as an important research tool for obtaining a sufficiently detailed understanding of re-programming of the genome of adult cells so as to possibly achieve their re-specification directly rather than via an ES cell stage. This is because the egg provides only effective environment for inducing full erasure of programming, and is so much larger than all other types of cell as to offer the best chance of identifying and characterizing the molecules that are instrumental in producing such an effect.

Current UK Law proscribes human reproductive cloning as a criminal offence, but allows 'therapeutic cloning' in circumstances where it meets one or more of the specific purposes for which human embryo research is permitted, and where such a goal cannot be achieved with the use of non-human alternatives. I do not foresee the law changing so as to ban therapeutic cloning in the UK and, indeed, in a number of other countries where politicians have been persuaded of the scientific value of this procedure. Hence, I do not think achieving a global ban on all human somatic cell nuclear transfer is a realistic prospect, and believe that efforts should be confined to marshalling a broadly based case against reproductive cloning specifically.

Reflections on the UNU-IAS Report: Is Human Reproductive Cloning Inevitable?

by *Prof. (Mr) Hans Galjaard*, Emeritus Professor,
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General remarks

My response to the question is that we can prevent human reproductive cloning (HRC) but with the present technology its realization seems hardly possible and it would be unethical.

The UNU report provides a comprehensive overview of international activities of the legislation and regulation of HRC but I have not discovered any new aspects. We must be careful that one UN organization does not create unnecessary work for another.

In the preface I note a prejudice by the mention of "so-called research cloning" (RC), the reality is that some of the experimental work in research cloning is of a very high standard and is published in top scientific journals.

In the section on social justice on page 13 it is suggested that research cloning might have detrimental effects on the low income countries. In my opinion this is a non-issue compared to for instance the financial crisis, the high oil prices or the Irak war. We must not exaggerate the social and medical importance of human cloning or stem cell research because many people are so excited by the ethical aspects.

The reality is that worldwide every minute a woman dies as a result of pregnancy and a large proportion of this is related to illegal abortion (some estimated 20 million annually). It is no surprise that the maternal mortality and teenage pregnancies are high in countries where abortion is not legalized and/or the education of girls falls behind. Compared to these problems the social significance of preimplantation genetic diagnosis, research cloning and stem cell research is negligible. The number of human embryos involved in these activities is much smaller than for instance the estimated 40,000 abortions annually in India because of sex selection.

Reproductive cloning

During the ten years after the birth of the sheep Dolly there have not been relevant changes in the technology of HRC nor in the ethical or judicial positions.

- Still many dozens or several hundreds of eggs are needed to create one cloned embryo and this would be associated with discomfort, pain and possible medical complications for the women involved.
- Many dozens or more surrogate mothers would be needed to grow a baby and each of them runs a risk of spontaneous abortion, miscarriage or the (premature) birth of a child with congenital handicaps. Professor Gardner also pointed to the risk for the mother herself.
- Modification of the genetic material of germ cells may have unpredictable effects on future generations and these cannot be reversed. Also on the basis of the precautionary principle, IBC and other organizations have recommended a ban on genetic changes of human germ cells.

- Couples that have lost a child and want to replace it will be disappointed because epigenetic and intrauterine environmental factors will lead to a different child despite a similar genome.

Apart from general ethical considerations the biological uncertainties, the medical adverse effects and the transgenerational consequences justify a worldwide ban of HRC.

It is disappointing that the General Assembly of the United Nations has not been capable of issuing a bidding convention despite the fact that already in 1998 the Declaration on the Human Genome and Human Rights recommended that HRC should not be permitted. During the past decennium more than 50 countries have issued a national legal ban on HRC.

The main reason for the failure of the General Assembly to issue a convention was that some countries insisted on the coupling of a ban of HRC and RC

Therapeutic/research cloning

In the field of research cloning there have been important new developments which will be outlined below; the cultural/religious/ethical diversity, however, has remained and is not likely to change during the coming decennia. Fundamental differences in concepts of human life, human dignity and possible overriding values are at stake.

During my eight years as a member of IBC and other international ethics organizations, I have witnessed that people's views on the beginning of human life, its right of protection and the question whether destruction of embryos is a violation of human dignity determines their judgment of technologies associated with contraception, induced abortion, IVF, PGD as well as cloning and stem cell research.

The IBC reports I have been involved in underline the acceptance of pluriformity and recommend governments to act accordingly. The UNU report on page 15 states: "the UN is better not to issue declarations if it cannot adequately represent the diversity of cultures across the world when attempting to construct positions on difficult ethical issues".

The voting on the Declaration on Human Cloning in 2005 indicated the large diversity about research cloning. I agree with the more than 60 large scientific Academies, including the US National Academy of Science, to ban HRC and to permit research cloning. I do not even think permission is needed because international legislation should not interfere with the progress of research and technology. In the past we have seen so many benefits for humankind that they largely compensate some ethical complications. Even the possibility of constructing atomic bombs has not led to international legislation against research in nuclear physics.

Another disadvantage of international legislation of research are the unexpected and sometimes rapid developments especially in the area of biogenetics. Regulation takes a long time and is likely to be outdated once it is issued. An example is the publication in 2007 by Japanese and North American scientists of the possibility to create pluripotent stem cells by genetic modification of somatic cells. Both mouse and human skin cells could be reprogrammed by viral introduction of 4-5 extra genes. These stem cells are designated as iPS (induced pluripotent stem cells) and many scientists have great expectations. The group of the German-American scientist Jaenisch has recently demonstrated that iPS could correct the genetic disease sickle cell anemia in mice. Since the reprogramming requires retroviral transfection and possibly genes that have an oncogenic effect, clinical application in man is not yet justified.

These new developments are too recent to conclude that human embryonic stem cells are no longer needed. Recently the British Parliament agreed to a research project

where human and animal embryonic cells are hybridized as an alternative approach to future use of human embryonic cells. Some might consider this ethical price too high but it is unpredictable where stem cell research will take us.

Conclusions

- Ban HRC and do so by a convention in order to allow national governments to become aware and involved.
- Leave therapeutic/research cloning out of this debate; any government or scientific institute is free not to choose this area of research.

  The argument that progress in research cloning will bring human reproductive cloning closer is not valid. The aims of the two are completely different and HRC will be forbidden provided the international community dies its work better than during 2003-2005.
- IBC should start reflection on the ethical aspects if in the future somatic cells could be reprogrammed into male and female germ cells. That would mean a real new era in reproductive technology.