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**International Bioethics
Committee (IBC)**

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**FIFTEENTH SESSION OF THE
INTERNATIONAL BIOETHICS COMMITTEE (IBC)**

UNESCO Headquarters, Paris, 27-29 October 2008

REPORT

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I. Introduction

1. The Fifteenth Session of the International Bioethics Committee (IBC) was held at UNESCO Headquarters in Paris from 27 to 29 of October 2008, bringing together more than 200 participants from 89 countries.

2. In accordance with its agenda (see Annex I) and the work programme of IBC for 2008-2009, this fifteenth session was devoted to further consideration of two main topics: the principle of social responsibility and health as elaborated in Article 14 of the Universal Declaration on Bioethics and Human Rights (2005) (hereafter “the Declaration”) and the issue of human cloning and international governance. IBC also held a preliminary reflection on the principle of respect for human vulnerability and personal integrity, as set forth in Article 8 of the Declaration.

II. Opening of the Fifteenth Session of IBC

3. Mr Koïchiro Matsuura, Director-General of UNESCO, presided over the opening of the fifteenth session of IBC. In his address (see Annex II), Mr Matsuura welcomed the newly appointed Committee members and the members of the new Bureau elected during the fourteenth session of IBC in 2007. He highlighted the unique and indispensable role of IBC in the promotion of the principles set forth in the Declaration as well as in shedding light on the major challenges facing the international community. Thus, he welcomed the inclusion of the issue of human cloning and international governance in the programme, a topic that continues to challenge the global community with rapid technical advances that result in new ethical questions for which there are no readily available answers. Only through the multidimensional, multidisciplinary and multicultural reflection facilitated by IBC can sustainable solutions be devised for the complex ethical issues concerning cloning of human beings.

4. In his address, Prof. (Mr) Adolfo Martinez Palomo, Chairperson of IBC, presented an overview of the work undertaken by IBC since the last session in Kenya, namely the elaboration of the Report of IBC on Consent, finalized in 2007, the on-going reflection on the principle of social responsibility and health, and the issue of human cloning and international governance. He insisted particularly on the importance for IBC to engage in extensive, deep and open exchange of ideas on these topics with representatives of Member States, intergovernmental and non-governmental organizations and the public in general. Finally, Mr Martinez Palomo thanked the Director-General for his unwavering support and keen interest in the work of IBC and announced the offer of the Mexican government to host the sixteenth session of IBC in May 2009.

III. Principle of respect for human vulnerability and personal integrity: Preliminary reflection

5. The thematic session on “Principle of respect for human vulnerability and personal integrity: Preliminary reflection” was organized with the aim of providing IBC with an overview of the existing debate and reflection and with some orientations on how the principle set out in Article 8 of the Declaration can be angled by the Committee.

6. Prof. (Mrs) Maria do Céu Patrão Neves, Professor of Ethics, Department of History, Philosophy and Social Sciences, University of Açores, Portugal, organized her presentation in two parts. The first part focused on the historical and theoretical overview of the concept of human vulnerability and its inclusion in the Declaration, whilst in the second part Prof. Neves shifted focus to the practical achievements made to date on determining the specific applications of the concept. As a safeguard of human dignity, the principle has been applied at three levels where bioethics operates today - human experimentation, medical practice, healthcare and biomedical research policies.

Discussion

7. Participants were united in expressing appreciation for the presentation, and expressed a wide range of opinions and attitudes in regards to this topic.

8. Several speakers recognized that the principle of respect for human vulnerability and personal integrity states the obligation of taking into consideration the vulnerability inherent to all human beings: it therefore recognizes the fact that a person is vulnerable, is exposed to being “wounded” by the other, subject to diverse and often subtle forms of exploitation or abuse, irrespective of his level of autonomy. In this respect, it was noted that there is a need to combine rights-based and duty-based approaches in a complementary way. While the western post-war moral discourse has predominantly focused on liberty and freedom, today there is a shift towards paying attention to duties and responsibilities towards others. The principle of respect for human vulnerability, together with other principles set out in the Declaration, plays an important role in reaching a right balance between rights and duties.

9. Several interventions focused on the priority given in Article 8 of the Declaration to individuals and groups classified as vulnerable, for whom it demands not only protection but also respect for their integrity. They referred to specific groups of vulnerable persons, such as children and women, especially in regards to clinical and/or pharmaceutical trials and other medical experimentation, who need extra safeguards and rules for protection. Few speakers referred specifically to embryos as a vulnerable group. It was noted that while some vulnerable groups are clearly defined, based on physical, political, social and various other contexts, others are harder to define in specific terms.

10. In conclusion, the participants agreed that the principle of vulnerability should not be considered in isolation from other principles. Rather, in order to maximize its potency and impact on policy, this important principle should be viewed in the light of all the other principles set forth in the Declaration, for instance the principle of solidarity.

IV. Draft report on social responsibility and health: Progress report of the IBC Working Group

11. Prof. (Mr) Fawaz Saleh, Vice-Chairperson of IBC, Professor of Private Law, University of Damascus, Syrian Arab Republic, chaired the working session devoted to the discussion of the preliminary draft report on social responsibility and health, drawn up by the IBC Working Group set up for this purpose. Prof. Saleh reminded the audience that IBC decided to focus on this principle (Art. 14 of the Declaration) at its twelfth session in Tokyo, Japan in 2005, shortly after the adoption of the Declaration, and decided to continue its work on this principle in 2008-2009.

12. Prof. (Mr) Adolfo Martínez Palomo, in his capacity as Chairperson of the IBC Working Group, introduced the draft report (Ref. SHS/EST/CIB-15/08/CONF.502/3 of 16 October 2008) and insisted on the fact that the introduction of social responsibility as a founding principle of bioethics constitutes a major contribution of the Declaration. This new principle reflects the need to make bioethics part of open-ended social and political debate by taking a holistic approach to health. He insisted on the fact that whilst the previous version of the draft report included mainly descriptive information and empirical health data, in the new version of the draft report the Working Group attempted to concentrate on the ethical and legal dimensions of the principle. Finally, Professor Martínez Palomo insisted on the still preliminary character of the document and the need for further improvements.

13. Then, upon the invitation of the Chairperson of the Working Group, Prof. (Mr) Donald Evans, in his capacity as Rapporteur of IBC, elaborated on the deliberations of the working group on this topic. Prof. Evans, underlying that moral obligations are rooted in social relationships and as such are integral to society, raised the question of the scope of the principle of social responsibility and the stakeholders concerned. He insisted on the close relationship between Article 14 and other articles of the Declaration, such as Article 13 on

solidarity and international cooperation, Article 21 on transnational practices, Article 15 on benefit sharing and Article 24 on international cooperation. The presentation made a strong case for not limiting the moral responsibility of governments to their citizens only, or the responsibilities of corporations to their shareholders, but rather for focusing on both the national and international moral responsibilities held by various societal actors to extend a helping hand to fellow human beings who are vulnerable to poverty, hunger, disease and other disparities.

Discussion

14. Generally, the meeting participants recognized the complexity and depth of the issue at hand, and the difficulty of the Committee's task to examine this principle. Whilst acknowledging the efforts made by the IBC Working Group to develop the philosophical and ethical dimensions of the document, several speakers noted that the report would be most effective if it strikes a proper balance between this philosophical reflection and the legal and practical approach to the promotion of the principle.

15. There was an explicit call to define the intended audience of the report, and cater for it accordingly. Most contributors stressed that the primary target for the report should be governments, as they bear a responsibility for leadership in national efforts to promote access to healthcare for citizens. However, it was noted that the responsibility is shared among many stakeholders, including various industries, civil society and individuals.

16. The connection between the principle of social responsibility and health and the other principles of the Declaration was stressed once again. It was mentioned that since the lack of health care directly infringes on the right to life, what is at stake is the issue of equality. It was also noted that contrary to some views, there is no inherent tension between the idea of autonomy and the concept of social responsibility; in fact, social responsibility should be regarded as an extension of autonomy — the recognition of duties that all societal actors share in regards to corresponding rights.

17. Some speakers stressed the plight of the poor in rich industrialized countries as they face growing health care related expenditures, and noted that the principle of social responsibility and health is relevant at equal measure to the developed as well as the developing regions of the world.

18. In the field of research, it was noted that in order to make sure that on-going scientific progress results in a fair share of benefits accrued for developing countries, the agenda of research for health should be set with a robust participation of the representatives of these countries, with the assistance of the international community.

19. In concluding the debate, Mr Palomo thanked the participants for their rich contribution, and noted that the intensity of the discussions was an indicator that UNESCO represents an appropriate forum to formulate a potent, meaningful report on this principle, and to this end, the responsibilities of all the major stakeholders in human health should be clearly defined in the report.

V. Human cloning and international governance: Progress report of the IBC working group and public hearings

20. The working session on human cloning and international governance was divided into two parts, chaired respectively by Prof. (Mr) Toivo Maimets (Estonia), Vice-Chairperson of IBC and Professor of Cell Biology and Director of the Institute of Molecular and Cell Biology, University of Tartu, Estonia, and by Prof. (Mr) Takayuki Morisaki, Member of IBC and Director of the Department of Bioscience, National Cardiovascular Center Research Institute, Japan. The first part was devoted to public hearings with representatives of national bioethics committees and international scientific organizations whilst the second part focused specifically on the work of the IBC Working Group on this issue.

21. Professor Maimets introduced the hearings by illustrating the context of the reflection of IBC on the issue. Subsequent to the publication of the 2007 report *Is Human Reproductive Cloning Inevitable: Future options for UN Governance* by the United Nations University Institute of Advanced Studies (UNU-IAS), the Director-General of UNESCO expressed his wish that IBC add the examination of this report to its agenda. The issue of human cloning and international governance was therefore added to the work programme of IBC for 2008-2009 and a working group established under Mr Maimets' chairmanship. The specific task of the Working Group was to explore whether the scientific, ethical, social, political and legal developments on human cloning in recent years justify a new initiative at international level. By focusing on this specific aspect, the IBC Working Group avoided initiating a highly divisive ethical debate on the issue of human cloning.

22. Representatives of national bioethics committees from Brazil, Indonesia and Madagascar took part in the hearings as well as the representative of the International Society for Stem Cell Research (ISSCR).

23. The presentation by Dr (Mr) Dirceu Bartolomeu Greco from the National Commission of Ethics in Research (CONEP) of Brazil, focused on the existing laws and regulations governing human cloning in Brazil, and the role played by CONEP. While Brazilian law strictly forbids human cloning, stem cell use for research and therapeutic purposes is allowed by a specific law. All projects involving stem cell use must be submitted to CONEP, which is accountable to the National Health Council. Dr Greco focused on various core considerations that should guide future reflection on regulating human cloning, such as prudence, social justice, demystification (clearly informed data), visibility/clarity (including but not limited to an international database of norms), an international database of research proposals and up-to-date results open to all for access, and civil society participation.

24. Dr (Mr) Rajaona Andriamananjara, Chairperson of Madagascar's Committee for Ethics of Science and Technology (CMEST), presented the newly created Committee and its recent deliberations concerning the issue of human cloning and international governance. He singled out five central questions that need to be examined in regards to international regulation of this practice: purpose (what is the objective of human cloning?); integrity (is the human clone the same biologically as the human born through natural process?); identity (the clone's identity as a member of society); decision-making (who has the authority to make the decisions regarding cloning time, place, person, finance and other related matters?); and freedom of research (does the scientist have freedom and/or right to pursue research in a given direction?). At the present stage of its examination of the subject, CMEST is of the opinion that human cloning for therapeutic purposes may be acceptable, under certain conditions and with appropriate safeguards, whereas human cloning for reproductive purposes still leaves many questions unanswered and therefore its present ban should be maintained.

25. The presentation by Dr (Mr) Carolus B. Kusmaryanto, Member of the National Committee of Health Research Ethics (KNEPK) of Indonesia and Chair of the KNEPK Working Group for developing guidelines on stem cells, focused on the Indonesian perspective on the governance of human cloning. While Indonesia does not have legislation on either reproductive or therapeutic cloning, there is ethical guidance based on religious and cultural traditions. It is a dominant understanding in Indonesian society that cloning, regardless of the intended ends, is a transgression of God's law in which God is the sole creator of the universe and humankind. Dr Kusmaryanto suggested that since the right to life is the basic right of humanity with an intrinsic value, respect for this human life needs to be firm. Therefore, a total ban on all human cloning would be the best approach to protecting human rights and human dignity from the various threats posed by the cloning procedures.

26. The presentation by Prof. (Mr) Lars Ährlund-Richter, Professor of Molecular Embryology, Karolinska Institutet, Sweden, elaborated the position of ISSCR, of which he is a member, and highlighted the most recent advances in human pluripotent stem cell research. Founded 6 years ago, ISSCR is an independent, non-profit organization

established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem-cell research and application. The ISSCR guidelines on the conduct of human embryonic stem cell research define human reproductive cloning as the act of seeking to establish either a pregnancy or the birth of a child by gestating or transferring into a uterus human embryos that have been derived in vitro by nuclear transfer or nuclear reprogramming. Given current scientific and medical safety concerns, ISSCR considers that attempts at human reproductive cloning should be prohibited. However, the Organization is of the position that research on stem cells of all types should be pursued with the goals of reducing human suffering and better understanding human physiology.

27. The presentation Ährlund-Richter also focused on new studies demonstrating that human skin cells can be transformed into embryonic stem cell-like cells. The technology used to create these cells, induced pluripotent stem cells or iPS cells, holds great promise for creating patient- and disease-specific pluripotent stem cells for both research purposes and longer-term possible clinical use. While it is premature to suggest that the use of iPS cells could replace the derivation of embryonic stem cells from embryos or by nuclear transfer, Dr Ährlund-Richter believed that research on human embryonic stem cells, somatic cell nuclear transfer and "adult" or tissue-specific stem cells needs to continue in parallel as part of a research effort that seeks to expand our knowledge of how cells function, what fails in the disease process, and how the first stages of human development occur. This general knowledge holds great promise to ultimately generate safe and effective therapies.

28. After the hearings, Prof. Maimets presented the work done so far by the IBC Working Group and its main preliminary conclusions (document ref. SHS/EST/CIB-15/08/CONF.502/2 of 19 September 2008). He gave a brief account of the new developments that raise questions about the need for a new international initiative. These concerned the scientific advances mentioned by the preceding presentations, but also societal and political developments such as increased public awareness and sensitivity, updates of legal regulations in several Member States, and increased national and international financing of and multinational commercial private interest in traffic of embryos, eggs and stem cells.

29. According to Prof. Maimets, the Working Group formulated its position that the issues surrounding human reproductive cloning can not be ignored and therefore a focused international dialogue considering a binding instrument against reproductive cloning is needed. Although the ban of human reproductive cloning is already a part of international instruments such as the UNESCO Universal Declaration on the Human Genome and Human Rights (1997), the Working Group believes that the final aim of the developments in international governance of human reproductive cloning should be a ban of this practice at the level of a legally binding convention. In addition, Prof. Maimets expressed the belief of the Working Group that guidelines for regulating human embryo and stem cell research in the countries where it is legal should be developed at international level, possibly based on several already existing guidelines formulated by different professional societies.

Discussion

30. During the discussion, some speakers considered that IBC should focus on those aspects of human cloning and international governance where a consensus does seem to be emerging, for example on banning human cloning that is carried out with a sole purpose of human reproduction, and to reflect on the possibilities of strengthening the international regime that governs this practice.

31. Nevertheless, several participants considered it very important to remember the political debate at the United Nations General Assembly in 2005 when, due to the drastically different positions of member States, the non-binding UN Declaration on Human Cloning was adopted by a vote. Most speakers remarked that since countries' positions remain relatively unaltered since 2005, it would be counterproductive for UNESCO to reopen the debate without a reasonable guarantee to reach a consensual position.

32. Regarding recent scientific developments, the core question tackled by the participants in the debate was whether there have been sufficient changes to justify new international governance initiatives: while some speakers argued that no significant changes have occurred, others pointed out that the new advances in the production of iPS cells and hybrid cells are among the emerging factors that raise the need for strengthening the existing mechanisms of governing the issue of human cloning.

33. Several participants echoed the IBC working group in underlying how the terms and definitions traditionally used in this field have themselves led to discussions and have created boundaries: the words “reproductive cloning” and “therapeutic cloning” introduced into bioethical debates several years ago do not adequately describe the technical procedures used (or potentially to be used) today. A call for a reflection on this subject was therefore expressed.

VII. Conclusions and closure of the fifteenth session of IBC

34. At the end of the fifteenth session of IBC, Mr Henk ten Have, Secretary-General of IBC, on behalf of the Director-General, thanked all the participants for their contributions during the debate. Underlying the importance for IBC to benefit from the broad-based input from scientists, ethicists, civil society representatives and other interested actors, he insisted on the crucial role of IBC on the one hand in elaborating from a global perspective the principles set forth in the Declaration, and on the other in promoting an anticipatory approach to identify sensitive ethical issues for the future.

35. Professor Martinez Palomo closed the fifteenth session of IBC by expressing gratitude to all the participants. He insisted on the preliminary character of the reflection on the principle of human vulnerability, the challenge of the work on the principle of social responsibility and health, and the sensitiveness of the debate on human cloning and the difficulty for IBC to incorporate the diversity of views and opinions in the deliberations.

36. On the basis of the discussions at its fifteenth session and the exchange with the Intergovernmental Bioethics Committee (IGBC) at the joint session that immediately followed (Paris, 30 and 31 October 2008), IBC decided to pursue its work on the issue of social responsibility and health as well as on the issue of human cloning and international governance, with a view to approval by the Committee of its final reports at the sixteenth session of IBC in 2009.

**FIFTEENTH SESSION OF THE
INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)**
UNESCO Headquarters, Paris, 28-29 October 2008

Agenda

1. Opening of the fifteenth session of IBC;
2. Presentation of the new members of IBC^(*);
3. Presentation of the work of the Committee since its fourteenth Session (Nairobi, Kenya, 17-19 May 2007);
4. Human cloning and international governance: Progress report of the IBC working group and public hearings;
5. Draft report on social responsibility and health: Progress report of the IBC working group;
6. Principle of respect for human vulnerability and personal integrity: Preliminary reflection;
7. Conclusions and closure of the fifteenth session of IBC.

* Item 2 will be dealt with during meetings reserved for the members of IBC.

**Address by Mr Koïchiro Matsuura, Director-General of UNESCO,
on the occasion of the opening ceremony of the
fifteenth ordinary session of the
International Bioethics Committee (IBC)**

UNESCO, 28 October 2008

Mr Chairperson of the International Bioethics Committee,
Distinguished Members of the International Bioethics Committee,
Excellencies,
Ladies and Gentlemen,

It is with great pleasure that I open the fifteenth ordinary session of the International Bioethics Committee (IBC) at UNESCO today.

As you know, this meeting is very important to the Organization, as it is an opportunity for an open and multidisciplinary appraisal of current thinking and new challenges in bioethics. We shall thus be informed of the outcome of your reflection on such complex subjects as human vulnerability and personal integrity, social responsibility and health, human cloning and international governance.

Gradually over the years, as you know, we have been joined by new members, who raise the quality of our discussions all the more. At the beginning of this year, in accordance with the IBC Statutes, I renewed half of the membership of the Committee. It is therefore a great privilege for me to welcome the new members here as a group and to thank them for agreeing to use their knowledge, experience and expertise to serve the international community.

Ladies and Gentlemen,

I am pleased to see that various meetings at this session will focus on debating points that are central to the Universal Declaration on Bioethics and Human Rights, adopted by UNESCO in 2005.

I am most gratified by this, for we must continue to nurture international reflection on the principles recognized in the Declaration and to suggest new lines of action and enquiry for the future.

These principles are not merely only theoretical or abstract principles. They also concern real life and have important implications for our values, statements, practices and individual and collective representations.

This is particularly true of the principle of "social responsibility and health", on which a progress report will be made by one of your working groups, which has worked under the stewardship of the Chairperson of IBC himself, Mr Adolfo Martinez Palomo.

This principle, which has been discussed by the IBC since its twelfth session in Tokyo in 2005, is indeed one of the most innovative in the Declaration, raising highly sensitive issues with concomitantly political, economic and social features.

Aware of these implications, the Committee has decided to concentrate quite appropriately on the ethical and legal aspects of the principle, in an endeavour to link together the principles of international solidarity, those of bioethics and policies currently implemented in the fields of health and science.

I therefore hope that the IBC will continue to discuss this important subject with a view to adopting a final report next year.

Ladies and Gentlemen,

As you know, the IBC also discharges an analytical and intellectual watch function at UNESCO, thus shedding light on the major challenges facing the international community.

This session will thus be required also to organize public hearings on the question of interrelations between international governance and human cloning.

The debate is not new. It will be recalled that in 2005, after discussing the matter for four years, the United Nations General Assembly adopted a Declaration on Human Cloning prohibiting all forms of cloning, by 84 votes in favour, 34 votes against and 37 abstentions, having failed to reach a consensus. The link between the prohibition of reproductive cloning and that of therapeutic cloning was then the issue that caused dissension among the States.

The matter was also discussed here within these very walls at UNESCO more than ten years ago, when the draft of the Universal Declaration on the Human Genome and Human Rights was being finalized for adoption in 1997. At the time, the first cloned sheep had been born, and the Member States had then adopted a consensus position on human reproductive cloning, as reflected in Article 11 of the Declaration, which clearly stipulates that practices which are "contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted".

The publication in 2007 of the important Report of the United Nations University Institute of Advanced Studies, entitled "*Is Human Reproductive Cloning Inevitable: Future Options for United Nations Governance*", again raised questions within the international community as to whether our approaches to human cloning should be reconsidered.

As that report refers repeatedly to UNESCO and the IBC, while mentioning the Organization's pioneering standard-setting work, I have requested the IBC to examine the report and inform me of its findings.

I am thus very grateful that the IBC and its Chairperson have acceded to my request and have scheduled many public hearings, in a transparent and participative manner, with experts, the national bioethics committees and scientific organizations. Of course, I await with great interest the outcome of those discussions and exchanges.

Ladies and Gentlemen,

As usual, I am very pleased that this IBC session will be followed immediately by a joint session with the Intergovernmental Bioethics Committee (IGBC), so that discussion on the various issues may be pursued.

These two bodies can and must continue to play together a pivotal role in international reflection, each contributing analyses and complementary points of view. Unfortunately, I shall not be able to open the joint session, but I know that Mr Pierre Sané, who will represent me on that occasion, will convey to the members of both committees my wish to see them pursue an ongoing constructive dialogue.

It now remains for me to stress how particularly useful and necessary this opportunity for reflection is. It enables us to take an objective view and to improve performance in carrying out the many practical activities currently planned by UNESCO, such as the Global Ethics Observatory (GEObs), projects for the provision of assistance in establishing national bioethics committees, especially in Africa, and the Ethics Education Programme.

I am indeed most gratified to note that a new database of the Observatory on resources in bioethics and a new "bioethics core curriculum" will be launched simultaneously at Headquarters during this session of the IBC.

By elucidating the link between analysis, research, education, capacity-building and information sharing, we shall, I believe, show the extent to which the IBC's work fits into a coherent chain of interlinked action and activities, all conducive to a holistic view of the issues at stake in bioethics.

I must stress that the report of the Working Group on human cloning and international governance identifies new fields of thought and action which, in the light of recent far-reaching scientific developments, should be given full attention. Here, I refer in particular to induced pluripotent stem cells (IPS), which effectively raise hopes for therapeutic treatment without recourse to embryos but which could also be used for reproductive purposes, thus posing unprecedented ethical problems.

As it is possible to create germ-line cells from somatic cells through "IPS" cells, we must re-examine the dividing lines between the various constituent stages of human development and of reproduction.

UNESCO, and the IBC, will certainly be required in the future to address these new issues that are revolutionizing our knowledge of living beings.

Ladies and Gentlemen,

The last ordinary session of the IBC was held in Nairobi, Kenya, in May 2007, to take account of Africa's concerns. The next one will take place in May 2009 in Mexico City, at the generous invitation of the Mexican authorities, to whom I extend my warmest thanks, and will allow us to turn our attention to Latin America.

Although it is convened at Headquarters, this session will, I dare say, also afford a unique opportunity for work and debate, open to the universality of ideas and cultures. I hope your discussion will be most fruitful and I thank you for your attention.