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VERS UNE DECLARATION RELATIVE
A DES NORMES UNIVERSELLES EN MATIERE DE BIOETHIQUE
Session extraordinaire du CIB
Paris, 27-29 avril 2004

TOWARDS A DECLARATION
ON UNIVERSAL NORMS ON BIOETHICS
Extraordinary Session of IBC
Paris, 27-29 April 2004

Contributions écrites / Written Contributions

Division de l'éthique des sciences et des technologies /
Division of the Ethics of Science and Technology

ORGANISATIONS INTERGOUVERNEMENTALES

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INTERGOVERNMENTAL ORGANIZATIONS

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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1. INTRODUCTION

In recent years, increasing attention has been paid by national authorities in many countries, by civil society and the general public, and by intergovernmental organizations, to ethical questions of relevance to food and agriculture. Major recent changes in the fields of food and agriculture—including accelerating technological development, changes in the resource base, and economic and market developments—have also brought to the fore a variety of ethical questions of relevance to food security and sustainable rural development.

The Director-General has established a Panel of Eminent Experts on Ethics in Food and Agriculture, to advise specifically on ethics in food and agriculture, in order to better meet country demands for policy advice, and to further global debates on questions related to ethics in food and agriculture. Its reports are publicly available, including on the internet at http://www.fao.org/ethics/exp_en.htm.

Ethics is by its nature crosscutting and multidimensional, and FAO has therefore designated "Ethics in Food and Agriculture" as a Priority Area for Interdisciplinary Action within its Programme of Work, and established an internal Committee on Ethics in Food and Agriculture to guide its actions in this regard. Within this framework, a number of studies of key topics have been prepared and published, within the *FAO Ethics Series*. Another publications series, *FAO Readings in Ethics*, brings together the results of the increasing number of interdisciplinary activities related to ethics that are being undertaken as an integral part of FAO's regular programme of work. The internet website of the Priority Area for Interdisciplinary Action on Ethics in Food and Agriculture is at http://www.fao.org/ethics/index_en.htm. The publications of the *FAO Ethics Series* are at http://www.fao.org/ethics/ser_en.htm and the *FAO Readings in Ethics* are at http://www.fao.org/ethics/readings_en.htm.

FAO is the international apex organization dealing with all aspects of food and agriculture, including forestry and fisheries. The technical questions that arise within these fields are frequently very specific to these crucial and complex fields of human endeavour, upon which world food security now and in the future depend. It is therefore clear that ethical reflection upon questions of food and agriculture must be grounded on a clear appreciation of the specificities of these sectors. For this reason, should it be decided that the aims and scope of a *Declaration on Universal Norms on Bioethics* will cover matters of relevance to food and agriculture, the concerns and opinions of the sector will need to be fully taken into account.

2. PANEL OF EMINENT EXPERTS ON ETHICS IN FOOD AND AGRICULTURE

Establishment and Terms and Reference

The Panel of Eminent Experts on Ethics in Food and Agriculture was established by the Director-General as of 1 January 2000, for a period of four years, under the terms of Article VI.4 of the FAO Constitution and Rule XXXV of the General Rules of the Organization, and the guidance provided by the Conference, to advise the Director-General on ethical issues in food and agriculture, including forestry and fisheries. The Panel is composed of eight Eminent Experts designated in their personal capacity by the Director-General, in accordance with established procedures and practices.

The members of the Panel for the first four years were Mr Francisco J. Ayala, a philosopher and geneticist from the United States of America, Ms Chen Chumming, a nutritionist from China, Mr Asbjørn Eide (Chair), a human rights specialist from Norway, Ms Noëlle Lenoir, a constitutional lawyer from France, Mr M.N. Salleh, a forest scientist from Malaysia, Mr Mohammed Rami, a fisheries expert from Morocco, Ms Lydia Margarita Tablada Romero, a microbiologist from Cuba and Mr Melaku Worede, a geneticist from Ethiopia. Their biographies are at http://www.fao.org/news/2001/010407-e.htm.

The Panel is currently being renewed, for a further period of four years.

The Terms of Reference of the Panel of Eminent Experts on Ethics in Food and Agriculture are as follows:

1. The Panel of Eminent Experts shall reflect and promote reflection upon ethical issues arising out of food production and consumption as well as agriculture development, including forestry and fisheries, in the context of food security and sustainable rural development against an environment of rapid global change;
2. The Panel shall in particular consider ethical issues relating to the interests of present and future generations regarding the sustainable use of natural resources, the safeguarding of biodiversity and the balanced mix of traditional and modern technologies to increase food security and sustainable agriculture.
3. Based on the above considerations the Panel shall:

a. Promote an overall sense of international responsibility with regard to the development of necessary policies and instruments aimed at maximizing global benefits, while minimizing risks arising from the application of modern technologies to food and agriculture;

b. Seek to increase the awareness of States, intergovernmental organizations, non-governmental organizations, civil society and public opinion worldwide, with regard to ethical issues in food and agriculture in order to promote international understanding and appropriate action on such issues, bearing in mind that different communities have different cultural values;

c. Advise on possible international, regional or national action or the preparation of instruments, as appropriate, to best respond to ethical issues arising out of food and agriculture, with due regard to interdependence among generations, among countries and between food security and other community needs;

d. Encourage exchange of information on all issues of an ethical nature arising out of food and agriculture;

4. The Panel may consider any other issue related to the above;

5. In its consideration of the above, the Panel shall advise the Director-General on the possible role and policies of FAO.

Panel sessions

The panel held its first session in Rome from 26-28 September 2000. The Panel discussed general questions identifying ethical issues in food and agriculture, and specifically questions related to biotechnology, including genetically modified organisms. The Panel decided that the ethical foundations of its work should be the Universal Declaration of Human Rights and sustainable use and conservation of natural resources. The most urgent ethical task was to assess activities relating to food and agriculture in the light of their actual and potential impact on the reduction of poverty, hunger and malnutrition. Its report is at http://www.fao.org/DOCREP/003/X9600E/X9600E00.HTM.

The Panel held its second session in Rome from 18-20 March 2002, at which it discussed six main themes: i) ethical aspects of the global emergency of hunger, i) ethical limits and challenges in the intensification of agriculture, iii) ethics and economic globalization in food and agriculture, iv) sharing the benefits of biotechnologies as part of the advancement of science, v) TRIPS, UPOV and Farmers" Rights, and vi) GMOs and ethics in decision-making: Participation and transparency. Its report is at http://www.fao.org/DOCREP/005/Y8265E/Y8265E00.HTM.

The following are matters that the panel has considered:

Ethical issues in food and agriculture

The ethical concerns related to food and agriculture identified by the Panel are essentially twofold: to promote conditions by which sufficient food is produced and where everyone has access to adequate food; and to promote policies and measures ensuring the ecological sustainability of food production, including fisheries, and to ensure similar sustainability in the practice of forestry.

The Panel identified a number of ethical challenges, including loss of biodiversity; the widening gap between rich and poor; and the lack of global governance instruments through which to promote the positive effects of economic globalization and address its negative effects. The Panel recommended the adoption of comprehensive ecosystem management at all levels, whereby natural resources may be managed for multiple objectives—including economic, social, ecological and dietary objectives—taking both long-term and shorter-term interests into account. Buffering the negative consequences of agricultural intensification—including monoculture and overuse of chemicals—was also seen as a very important task, as was counteracting the negative consequences for agricultural research of the concentration of economic power. The Panel also expressed concerns about the concentration of proprietary rights and the overextension of intellectual property rights.

The Panel also recommended greater promotion and protection of all human rights, especially those of the poorest and most disadvantaged, including the right to food, education and information, as well as political rights, and more participatory and empowering approaches to development.

The Panel endorsed the following guidelines and measures, directed at the national and the international level, for implementing its recommendations:

- Creating the mechanisms necessary to balance interests and resolve conflicts;
- Supporting and encouraging broad stakeholder participation in policies, programmes and projects;
- Designing incentives that will encourage individuals, communities and nations to engage in dialogue and, ultimately, to do what is ethical;
- Ensuring the transparency of information and decision-making;

- Fostering the use of integrated and empirical science and technology in the service of a more just and equitable food and agricultural system;
- Encouraging cooperation and solidarity among institutions engaged in research and development, making it possible to take appropriate action more quickly;
- Ensuring the incorporation of ethical considerations in all programmes, policies, standards and decisions, thereby contributing to improved human health and well-being and environmental protection;
- Developing codes of ethical conduct where they do not currently exist;
- Periodically reviewing ethical commitments and determining whether or not they are appropriate on the basis of new knowledge and changes in circumstances.

Biotechnologies, including genetically modified organisms

The Panel agreed that science and technology have provided great benefits in the past and are likely to do so in the future, as long as they are properly managed and applied. It noted, in this connection, that international human rights stipulate that everyone has the right to share in the benefits of scientific progress and its applications (Universal Declaration of Human Rights, Article 27).

The accelerating rate of development within the modern biotechnologies, including genetic engineering, has led to intense public debate, especially about its risks and potential benefits. The Panel considered that biotechnologies in its wide sense provide many alternatives to the production of GMOs, and that such alternatives should be preferred where there are significant risks or uncertainties at present concerning the use of GMOs, particularly when the expected benefits of the latter are few. Preference should be given to the most appropriate technologies. The Panel considered that ethical challenges were posed not only by technologies themselves, but also by the ways in which they was marketed, utilized and controlled. The Panel was concerned that these technologies might lead to over-concentration of economic power and that poor farmers would be excluded from benefits. The Panel was also gravely concerned with Gene Utilisation Restriction Technologies (GURTs), which it felt might unduly infringe on Farmers' Rights.

The Panel explored ways in which the potential of modern biotechnologies could be realized and the risks avoided. It thought it was misleading to lump together the various biotechnologies under the word "biotechnology". There are, it felt, many different biotechnologies, some modern, others old and tested, some controversial, others not tested at all.

The Panel considered that a key issue was how access to beneficial technologies was facilitated and how benefits from science and technology were shared. It noted that most research was undertaken and most technologies were produced in the North, while the genetic resources were mainly found in the South. Equitable benefit-sharing between North and South was therefore crucial, in a system that recognized not only the rights of the researchers but also the rights of all humankind to enjoy the benefits.

The Panel also discussed the impact of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organisation, the system of plant variety protection provided by the International Union for the Protection of New Varieties of Plants (UPOV), and Farmers' Rights. Concerns were raised concerning: (1) the increasing transfer of important knowledge from the common domain (public goods) to the private domain; (2) possible negative impacts of TRIPS on the livelihood of poor farmers; (3) its uncertain impact on sustainable access to affordable, safe, nutritious food for consumers with limited income; and (4) its environmental impact, including its effect on biodiversity.

The Panel pointed to a number of important principles that could guide ethical decision-making regarding GMOs: public participation in decision-making through stakeholder consultations and public debates; access to information, including labelling and traceability standards; and monitoring and oversight processes to ensure public accountability. The Panel considered that a more holistic approach to decision-making, including socio-economic considerations, may result in a more accurate consideration of costs and benefits in the regulatory decision-making process.

Intensification of agriculture

The Panel noted that agricultural intensification—while a necessary condition to produce more food— does not by itself ensure access for all to sufficient and adequate food. In this regard, the Panel recommended that the concept of sustainable development might be broadened to cover ethically sound development, embracing social and ecological sustainability. Intensification should be pursued in ways that are socially responsible and respect the interests of future generations, and pay more attention to the needs of those who are marginal or weak. It considered that the main priority at the present stage was not a global increase in food production, but to ensure broader access, including by those who do not now have adequate food because they cannot afford to buy it and cannot produce it themselves. Intensification which could increase the income of those farmers who are presently marginal and poor would serve that purpose and should be welcome.

Ecologically sustainable intensification would require greater productivity without dependency on non-renewable resources. There was a serious risk that—without more effective management of land and water resources, and of forest and fishery resources—we may be nearing carrying capacities at local, regional and even at world level, sometimes as a result of capital-intensive exploitation that undermines the livelihood of local populations. The Panel also pointed out that, in many cases, smaller scale farmers play the role of farmer-curators, who pursue more traditional farming practices in ways that assist in maintaining biodiversity, local knowledge and technologies, and sustain the traditional cultures of the societies where they live. There may be a need for both, but the farmer-curator may need financial and other support in order to avoid or get out of poverty.

Economic globalization in food and agriculture.

In its discussion on globalization, the focus of attention for the Panel was on processes of economic globalization in food and agriculture. The main features were the expansion of foreign private investment in agriculture, food processing and marketing, to a large extent but not only through transnational corporations, and increasing international trade in food, facilitated by the reduction of trade barriers. The consequences of these processes for the environment and for the livelihood of those who suffer from hunger and malnutrition needed to be examined.

The Panel observed that economic power is becoming more concentrated: the world's 200 largest transnational corporations now accounted for a quarter of the world's economic activity, and were often beyond the control of the governments in the territories in which they operated.

One prominent aspect of contemporary processes of globalization was the transition from public services and regulation to privatisation and deregulation. Another was a reduction in the space for national, democratic governance. The Panel considered that the market should not be the sole governor of social and economic processes. It felt that there should be movement towards a global society which gives equal opportunities for all, rather than focussing on economic globalization which gives the prime benefit to those who are already

the strongest actors in the global economic system. Global governance was required in order to advance the benefits, particularly for those who are presently disadvantaged, and to offset the risks and negative consequences.

The Panel considered that it might be advisable to develop a code of conduct for economic globalization to avoid some of the negative consequences and to ensure a better and more equitable sharing of benefits for all.

3. THE FAO ETHICS SERIES

The *FAO Ethics Series* was launched in 2000 and aims at publishing one paper per year. Its main purposes are to promote ethical reflection and constructive dialogue, and clarify the issues underlying current public debates in ways which help both policy makers and the public at large to form their own opinions.

Ethical Issues in Food and Agriculture

"Ethical Issues in Food and Agriculture" (2000) aims to identify the main ethical issues and challenges, which include achieving the global goals of food security for all; achieving sustainable rural development; ensuring equitable participation and balancing the interests of the wealthy and the poor; and guaranteeing viable options for future generations (ftp://ftp.fao.org/docrep/fao/003/X9601e/X9601e00.pdf). The paper provided an assessment of current trends, identifies the main issues and stresses the need to balance interests, resolve conflicts and build a more equitable and ethical food and agriculture system.

The stubborn persistence of hunger and poverty raises what are among the most burning ethical questions of the age. Freeing humanity from hunger and malnutrition is a moral obligation that weighs more and more heavily as our capabilities and technologies advance. The technological advances and organizational changes affecting food and agriculture systems over the past years have been both radical and rapid, will have repercussions for a long time to come, and have sometimes had irreversible consequences.

Genetically Modified Organisms, Consumers, Food Safety and the Environment

The "Genetically Modified Organisms, Consumers, Food Safety and the Environment" discusses many aspects of the global debate on genetically modified organisms (GMOs), in the light of relevant current knowledge about food safety and environmental conservation (ftp://ftp.fao.org/docrep/fao/003/X9602e/X9602e00.pdf). It seeks to unravel and explore the claims and counterclaims being made in the GMO debate from an ethical perspective, considering the proprietary nature of the tools used to produce GMOs, the potential consequences of their use in intensifying food production, and the unintended and undesirable effects that their application could have, both now and in the future.

Both the potential contributions of genetically modified products to world food production and the possible risks with regard to food safety and unpredictable environmental hazards—the most commonly cited being the feared transfer of toxins or allergens and unintended negative effects on non-target species—need to be taken into account, as well as possible long term consequences, such as diminished biodiversity through the loss of traditional crops. Finally, like all the new technologies, GMOs are merely technical instruments that can be used for good and for bad. How they are used will determine whether they benefit the neediest, or privilege specific groups that hold political, economic and technological power. The main beneficiaries to date have been the private sector technology developers and large-scale agricultural producers, mostly in developed countries. To ensure that benefits are shared more fairly with developing countries and resource-poor farmers, intellectual property rights should not impede the use of technologies by those who most need

them, and research must be directed towards their needs and the needs of disadvantaged farmers, and ways must be found to guarantee that increased production benefits accrue to the poor and food-insecure.

The Ethics of Sustainable Agricultural Intensification

"The Ethics of Sustainable Agricultural Intensification" (to be published in early 2004) will review ethical issues that arose the history of agricultural intensification, and propose a framework for analysing the ethical issues surrounding modern agricultural intensification, in particular how sustainability can be ensured. It will focus on informing decision-making including ethical decision-making, using a variety of approaches, including utilitarian, rights-based and virtue-based ethics.

Ethics and Globalization of Food and Agriculture

"Ethics and Globalization of Food and Agriculture" (to be published in 2004) will seek to explore the term, "globalization" and to distinguish which major current changes are attributable to "globalization" and which to other factors. It will discuss ethical issues relating to effects of globalization on hunger, poverty, diversity and equality.

Global Public Goods in Food and Agriculture

"Global Public Goods in Food and Agriculture" (to be published in the 2004-2005 biennium) will address ethical issues relating to the sustainable management of global public goods in the modern world. Among trends discussed will be the progressive privatisation and ownership of natural and intellectual resources. The paper will consider the ethical dimensions of the management of Global Public Goods, as a common responsibility of mankind, and in order to safeguard inter- and intra-generational equity.

Ethical Issues in Fisheries

"Ethical Issues in Fisheries" (to be published the 2004-2005 biennium) will focus on selected issues in fisheries, including the major ethical issues and challenges posed by multiple use of, and multiple access to, marine resources, including over-fishing, bye-catch, discards, degradation and pollution of the aquatic environment, industrialisation of fisheries and aquaculture, new technologies and the information revolution, and the conflicts between global and local fishers, traditional and modern.

4. FAO READINGS IN ETHICS

This new series is intended to draw together relevant publications resulting from the regular work programme of the Organization. The first publication in the series is the Report of the FAO Expert Consultation on Food Safety: Science and Ethics", which was held in Rome, 3-5 September 2002. ftp://ftp.fao.org/docrep/fao/006/j0776e/j0776e00.pdf.

5. CHALLENGES AHEAD AND FUTURE PERSPECTIVES

The experience of the first years of the FAO Ethics Programme has led to significant increased awareness and articulation of ethical consideration, within the Organization and generally. New methodologies for analysis and discussion are being internalised and are influencing other FAO activities. Questions of ethics in food and agriculture are increasingly being addressed within the Organization's Regular work programme, and ethical considerations are informing policy formulation.

UNITED NATIONS UNIVERSITY (UNU)

1. UNU Interest in Bioethics

The United Nations University (UNU) is an intergovernmental organization, and has great interest in bioethics discussion, and in the work of UNESCO in this area. In article 1 of the UNU charter a special relationship with UNESCO is outlined, "The United Nations University shall be an international community of scholars, engaged in research, post-graduate training and dissemination of knowledge in furtherance of the purposes and principles of the Charter of the United Nations. In achieving its stated objectives, it shall function under the joint sponsorship of the United Nations and the United Nations Educational, Scientific and Cultural Organization (hereinafter referred to as UNESCO)…" <http://www.unu.edu/hq/rector_office/charter.htm>

Article 2 and 3 of the UNU charter outline our mandate to work in bioethics areas:

"2. The University shall devote its work to research into the pressing global problems of human survival, development and welfare that are the concern of the United Nations and its agencies, with due attention to the social sciences and the humanities as well as natural sciences, pure and applied."

"3. The research programmes of the institutions of the University shall include, among other subjects, coexistence between peoples having different cultures, languages and social systems; peaceful relations between States and the maintenance of peace and security; human rights; economic and social change and development; the environment and the proper use of resources; basic scientific research and the application of the results of science and technology in the interests of development; and universal human values related to the improvement of the quality of life."

Recently our comments and support for the two UNESCO Declarations from the work of the IBC was sent from Rector Hans Van Ginkel to Director-General Matsuura (see appendix).

2. Comments on Aims and Scope of a Declaration on Universal Norms on Bioethics

1) The existence of a Declaration would highlight attention upon ethical implications of scientific progress, and it could be a tool used by persons at all levels suggested. It is unclear whether it would help better "assess" the ethical issues because of a diverse way of viewing ethics, and because we have found a wide range of ethical codes and norms in different professions and in different member countries. We note that one of the ethical norms may be to recognize diversity of decisions that individuals and societies can take about these bioethical issues, which in itself, is a worthy Declaration.

2) The Declaration on Universal Norms on Bioethics should not be limited to human beings. Human beings are one of the members of a wide biodiversity, and many applications of life technology touch other living organisms besides human beings. There are some general principles such as respect for life, and to minimize harm to living organisms that could be included. For some peoples and countries the measure of an ethical society includes the way animals are treated and the way the environment is protected. There are many relevant United Nations Documents in these spheres as well, that can be included in a Declaration on Bioethics.

3) Some examples of issues that we would raise for consideration to this process include:

   a) the treatment of animals in research and therapy/clinical trials;

b) the use of genetically modified organisms;

c) the extent of tolerating human chimeras with other organisms, as cell fusion hybrids, and including gene and/or chromosomal transfer;

d) the transfer of human genes, including genes that convey "human properties" to other organisms with the intent to study or modify animal behaviour;

e) agreements to protect the common environment, reducing pollution, minimizing impact upon the environment, protecting biodiversity. This could include recollections from a range of existing international treaties relating to this area, as well as any new work to highlight and explore ethical norms.

In all these areas the approach of UNU is to try to further clarify the diversity of views expressed in different communities on these issues around the world, considering the possible benefits to living organisms themselves as individuals, and the benefits to the environment and humankind. Against this the risks to the individuals themselves and to the broader environment and humankind should be balanced.

3. Comments on Structure and Content of a Declaration on Universal Norms on Bioethics

1) The structure of the Declaration should include a preamble with following sections, and an explanatory document attached to the declaration to explain the process. There is room for both descriptive statements that represent the reality of global thinking, and some prescriptive recommendations on what are norms. A wide range of topics should be included, but in some areas where agreement and consensus is not expected, then a description of diversity of views would still be useful. We do not think the name of any country should be in the Declaration, however, in one of the explanatory documents it may be useful to review positions of different countries.

The documents need to be prepared in multiple languages in order to generate discussion on bioethics. The Declaration should not preclude the future evolution of different views, nor tell a culture that their accepted views on an issue is bioethically "wrong". We see the primary function of a Declaration as educational.

2) We would support the inclusion of the following principles (this is not an exclusive list). UNU also notes that the principles proposed by different persons vary in their number, names, and organization, yet sufficient convergence exists to allow us to endorse the ethical values of:

a) respect for persons, families, groups and communities,

b) doing good (beneficence),

c) doing no harm (non-maleficence),

d) justice,

e) freedom of moral decision-making.

The definition of bioethics is important and suggest the following words (from the Eubios Declaration on International Bioethics <http://www.biol.tsukuba.ac.jp/~macer/eeidec.htm>):

"Bioethics is an interdisciplinary field that needs to be nourished by debate among all disciplines and people, not limited to any academic specialty or professionals. There are a

variety of definitions of bioethics, and this variety is part of the intrinsic value of the field of bioethics. We consider bioethics to be the process of reflection over ethical issues raised in our relationships with other ***living*** *organisms; the consideration of the ethical issues in spheres including environmental ethics, health care ethics, social ethics, and in the use of technologies that affect life; and the love of life."*

"There are different ways to view bioethics and in discussions of bioethics we should be clear which approach we are addressing. These include:

> ***Descriptive bioethics*** *– understanding the way people view life, their ethical interactions and responsibilities with living organisms in their life.*
>
> ***Prescriptive bioethics*** *or normative bioethics examines what is ethically good or bad, or what principles are most important in making such decisions. It may also be to inquire into when to say something or someone has rights, and others have duties to them. When one person tells another what is ethically good or bad they are prescribing bioethics. If prescriptive bioethics leads to paternalistic elitism, then we reject it."*

There are at least two essential approaches to bioethics: **Interactive bioethics** is discussion and debate between people, groups within society, and communities about descriptive and prescriptive bioethics. **Practical bioethics** is action to make the world more bioethical, for example, health projects for medically deprived populations, and environmental activism."

Also the virtues of the moral agent and his/her relationship to others and the environment are emphasized. The examination of these principles is part of bioethics, so the precise application of these principles for different societies for different applications of science and technology is an essential part of the living process of bioethics. There does not need to be a dogmatic definition of these principles but rather general recognition, and encouragement for study to examine these and other principles that may be useful for decision-making.

There are also principles for children's rights, refugee rights, and vulnerable groups within society that could be adopted from other international treaties. The ideal of solidarity is often promoted in UN declarations, but sadly there are many deficiencies in practice. However, a declaration of ethics should be a goal for individuals and societies to achieve, but balancing needs of individuals and society might never be accomplished perfectly.

3) If there exists international consensus than the most detailed possible consensus should be written. Please refer to point 3(1) above, on the role of an explanatory document. There are areas where there is agreement, and the previous Declarations of the IBC provide some examples where details may be possible.

4) Subject areas that we would suggest considering to include are:

   a) Respect for and dependence upon living organisms and the environment.

   b) General principles of ethics

   c) Human rights

   d) Beginning of human life, but note that reproductive control, abortion, contraception have blocked many well intentioned UN agreements. It may be difficult to include issues upon which passionate opposed views are expressed, and have always been expressed through a written human history of several millennia, but tolerance and harmony are important for the UN.

   e) Access to assisted reproductive technologies, including sex selection

f) Prenatal Diagnosis

g) Genetic Testing

h) Gene and Stem Cell Therapy

i) Genetic enhancement

j) Population genetics and group discrimination

k) Reproductive Cloning

l) Intellectual property rights

m) Access to personal health-related information by individuals (e.g. truth-telling, right not to know) and others

n) Euthanasia and Palliative care

o) Definition of Human Death

p) Organ Donation and Transplantation

q) Access to drugs and alternative medical therapies

r) Allocation of health care resources and balancing public and private sectors

s) Public health ethics and group consent

t) Community engagement and consultation

u) Human research

v) Use of non-human animals

w) Transgenic and modified living organisms

x) Cyborgs and human chimeras

y) Education

z) Ethics committees

We also note that there may be other areas of bioethics that could be sought if we consult more communities about their views. It is important to see life in its whole, not only focusing on humankind. Every person has a lifelong responsibility to develop his or her own bioethical maturityand values. We could define bioethical maturity as the ability to balance the benefits and risks of ethical choices, considering the parties involved and the consequences. At the societal level, public policy and law need to be developed, which requires a social mechanism for balancing conflicting ethical principles.

4) Expected Future UNU work that may be relevant to the evolution of a Declaration on Universal Norms on Bioethics

UNU-IAS has developed a program of work on bioethics, within the framework of the Institutes' Biodiplomacy Initiative. The Program has a particular focus on issues of human cloning and on the relationship between traditional knowledge and access to health. At present a collaborative project with Eubios Ethics Institute is seeking opinions from many individuals around the world on priority areas for global bioethics. We expect this to identify some different issues of bioethics that face different regions, ethnic groups and communities. The results of this project will allow further input into the UNESCO IBC project later in 2004.

Should such a Declaration be developed it is important to circulate calls for input in more than just the major United Nations languages, otherwise the English and French speakers will dominate the discussion, and the diversity of views will be smaller. It may be important to circulate the call for input more widely, although we appreciate the efforts that UNESCO IBC secretariat has made towards having this extraordinary session. We hope that all scholars and community representatives will take what they learn from others back to each community and provide further input into this process.

Research on the thinking and reasoning of all people should be more emphasized in order to understand the diversity of people's thinking. This is necessary for determining the degree of universality that is possible, and should be used to complement other research approaches in bioethics. We conclude with some quotes from the Eubios Declaration on International Bioethics:

"There is no inherent reason to believe a priori that the views of one person are intrinsically more valuable than another, based on gender, age, educational background, physical, mental, or psychological condition or life experience. Such ethical understanding is necessary to develop international cross-cultural bioethics, and no one culture should claim to be the dominant source of the concept of bioethics.

To work towards a social consensus requires participation of informed citizens, which requires education about issues of bioethical importance. We applaud the public discussion on bioethics that has started to emerge in a number of countries, but these efforts need further support.

In order to achieve the above goals, greater effort is required to educate all members of society about the scientific and clinical background, and the ethical principles and social and legal problems involved, in the life and medical sciences. This will enable the active collaboration of all individual members of society, many academic disciplines, and the international community.

Education of bioethics is to empower people to face ethical dilemmas. Ethical challenges come to everyone. The process of debate and discussion is important for developing good minds to face bioethical dilemmas. It also develops tolerance and respect of others. In these troubled international times, it is very important to develop tolerance of others, and to learn that everyone as a human being is the same regardless of race, sex or religion. Same in this sense means equally diverse, it does not mean identical."

5. **<u>Contact Information</u>** for UNU and the IBC plans for a Declaration on Universal Norms on Bioethics:

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Further website information can be obtained through this link to the Bioethics homepage at UNU which is being established.

6. Appendix 1: Endorsement of UNESCO Bioethics Declarations by UNU

Your note on the unanimous adoption by the General Conference of UNESCO on 16 October 2003 of the International Declaration on Human Genetic Data was received with great satisfaction and I congratulate UNESCO for this very important initiative.

The ethical guidelines set out in the Declaration are of particular importance, especially in the light of the rapid progress in science and technology, and the need for ethical application of genetic technology for humankind. Extensive coverage of issues through the provisions of the Declaration clearly indicates the depth of study and thought that was put in developing the Declaration. The United Nations University strongly endorses this excellent Declaration as we endorse the 1997 Universal Declaration on the Human Genome and Human Rights and will assist UNESCO in any possible way with the implementation of these Declarations.

Research and human capacity development in Bioethics have been one of the areas of our activity for several years. Currently the UNU Institute of Advanced Studies is actively engaged in policy research on ethical implications of human therapeutic cloning and access to essential medicines. We are preparing a report to contribute to the ongoing debate on whether to develop a UN treaty on Human Cloning. We shall also remain committed to facilitate the implementation of the International Declaration on Human Genetic Data through research and human capacity building. In particular, by providing policy briefs and training government negotiators, and others who might be concerned.

ORGANISATION ARABE POUR
L'EDUCATION, LA CULTURE ET LES SCIENCES (ALECSO)[1]

Contribution arabe concernant l'élaboration d'une déclaration relative à des normes universelles en matière de bioéthique

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INTRODUCTION

Les progrès scientifiques soulèvent actuellement un certain nombre d'interrogations pressantes particulièrement dans le domaine de la génétique et tout ce qui touche à l'Homme et son environnement. Actuellement, les techniques du génie génétique posent des défis importants en bioéthique.

L'UNESCO a toujours été, sur le plan international, l'un des promoteurs de la réflexion sur le vivant particulièrement en développant un programme de bioéthique par la mise en place du Comité International de Bioéthique (CIB) en 1993.

Le programme a connu un premier grand succès avec l'adoption par la conférence générale en 1997 de la « Déclaration universelle sur le génome humain et les droits de l'Homme », ainsi que la déclaration internationale sur les données génétiques humaines.

L'UNESCO doit être félicitée pour ses efforts visant à élaborer des lignes directrices, des normes universelles en Bioéthique.

La nécessité de déterminer des valeurs communes et des repères et de promouvoir des principes universels s'impose aujourd'hui pour guider le progrès scientifique et technologique et tout ce qui concerne l'Homme.

Bien sûr, nous voulons que la recherche avance ; nous voulons qu'elle progresse, car c'est la source d'espoir pour l'humanité ; mais nous voulons aussi que des normes universelles soient établies.

L'Ethique des sciences et des technologies s'avère alors une priorité principale pour notre Organisation Arabe (ALECSO) qui a constitué son comité d'éthique en 2003. Ce comité s'est réuni en Août 2003 à Beyrouth sur le thème « Procréation médicalement assistée (PMA) » et les problèmes éthiques qu'elle soulève.

Le débat a porté sur :

* Les progrès de la PMA sont justifiés pour redonner espoir à de nombreux couples souhaitant un enfant. Les risques et les dérives qui en découlent ont été présentés.

Je cite par exemple le choix du sexe sans raison médicale.

Les recherches sur l'embryon humain et les cellules souches (ES) : Faut il interdire ces recherches ?

Bien sûr que non, mais avec des limites.

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La conception in vitro d'embryons humains à des fins de recherche ou d'expérimentation doit être interdite. Mais les embryons surnuméraires, destinés de toute façon à être détruits pourraient être utilisés à des fins thérapeutiques.

Donc, une réflexion éthique commune à nos Etats arabes s'impose, réflexion prenant racine de notre héritage culturel, juridique et philosophique.

Une deuxième réunion de notre comité d'éthique aura lieu en Juin à Tripoli sur le thème « les Banques de gènes »

I. OBJECTIFS ET PORTEE D'UNE DECLARATION RELATIVE A DES NORMES UNIVERSELLES EN MATIERE DE BIOETHIQUE

1 - La question qui se pose est la suivante : comment apprécier sur le plan éthique, des découvertes scientifiques qui peuvent soulager les souffrances mais qui peuvent peut être, transformer la vie ou l'espèce humaine ?

La réflexion éthique doit dépasser les frontières nationales, doit être menée sur le plan international en faisant participer toutes les communautés et les régions du monde.

On ne peut ignorer l'impact des progrès scientifiques sur les droits et les libertés de la personne humaine.

Cette déclaration relative à des normes universelles en bioéthique et le suivi qui en découle, constitue l'une des réalisations les plus marquantes de l'UNESCO.

La déclaration pourrait contribuer à une meilleure prise de conscience des progrès scientifiques et leurs applications à plusieurs niveaux :

- les scientifiques d'abord : la prise de conscience par les communautés scientifiques de leurs responsabilités sociales vis-à-vis de l'humanité, d'expliquer au public les résultats des découvertes et leurs applications dans la transparence totale. Le partage des connaissances entre les scientifiques des différents pays permet de mesurer mieux les risques ;
- les organisations nationales, régionales, intergouvernementales et à la tête l'organisation internationale ;
- la réflexion intéresse aussi les sociologues et les juristes ;
- les décideurs, le pouvoir politique : pour mettre l'application de lois relatives à ces propositions et tracer les limites qui s'imposent.

2 – La déclaration devrait elle se limiter à l'être humain ? notre réponse est non.

On ne peut pas dissocier l'être humain de son environnement : plantes, animaux, tous les écosystèmes.

Par conséquent, la déclaration devrait traiter en premier lieu les questions éthiques relatives à la personne humaine, mais aussi des questions éthiques concernant la relation de l'être humain avec les autres organismes vivants.

En recherche fondamentale comme en recherche appliquée et médicale, le modèle est toujours l'animal.

a - En recherche fondamentale

La découverte de la structure des gènes et de leurs produits les protéines, ainsi que l'identification du code génétique ont été à l'origine d'une compréhension sans précédent de ce que sont et comment fonctionnent les organismes vivants depuis la bactérie jusqu'à l'Homme.

Les mécanismes du Développement embryonnaire peuvent être élucidés grâce à la génétique du développement découverte chez la Drosophile (Insecte), gènes qui ont leurs équivalents chez les animaux supérieurs jusqu'à l'Homme.

b - En recherches appliquées et médicales

Ensuite, ces découvertes ont fourni à l'Homme des moyens nouveaux pour observer et exploiter certaines espèces vivantes dans plusieurs domaines.

1- Production d'hormones et de médicaments

Et ceci grâce aux techniques du génie génétique (clonage, transgenèse, fabrication de chimères…).

Par exemple : l'accès aux gènes a permis de préparer certains médicaments (protéines déficientes chez certains patients) par des bactéries et d'autres animaux.

La quasi-totalité de l'insuline est préparée par des bactéries recombinantes (qui portent le gène humain codant pour l'insuline).

L'hormone de croissance provient également des bactéries recombinantes.

On peut aussi produire des protéines médicaments à partir de divers fluides biologiques d'animaux, transgéniques (le lait de brebis ou de chèvre).

Plusieurs protéines médicaments ont été ainsi fabriquées : des facteurs sanguins, des anticorps monoclonaux, des hormones, des vaccins.

L'utilisation des animaux comme source de protéines humaines (protéines médicaments) est justifiée.

2- Les animaux transgéniques utilisés comme source d'organes pour l'humain = les xénogreffes. C'est un projet ambitieux qui devra beaucoup à la transgenèse et à la connaissance des gènes.

Je rappelle que le manque croissant d'organes d'origine humaine pour des greffes à des patients a fait envisager depuis longtemps l'utilisation d'organes d'origine animale et le porc a été retenu par les scientifiques comme donneur potentiel.

Notre point de vue :

- D'abord la xénogreffe pose des problèmes éthiques spécifiques graves. Comment recevoir dans son organisme du matériel vivant (un organe) d'origine animale ?
- Ces réticences sont compréhensibles d'autant plus qu le donneur potentiel d'organe serait le porc dont l'image est très contestée dans la plupart des communautés humaines.
- Ajoutons que le porc même pour la consommation est interdit dans certaines religions.

3- Les organismes génétiquement modifiés (OGM) et l'environnement

On sait que le milieu environnant influence profondément l'évolution des êtres vivants.

Les êtres vivants mutent spontanément au hasard et le milieu se charge de ne conserver que ceux qui sont les mieux adaptés et aptes aux conditions du moment.

Seules, les conditions particulières actuelles de la terre permettent aux organismes vivants, de se maintenir, de proliférer et d'évoluer.

Donc nous vivons dans un environnement à préserver. L'écosystème risque d'être bouleversé par des OGM non contrôlés, disséminés dans la nature.

C'est une forme de pollution plus grave que la pollution chimique, car l'ADN (le gène) se reproduit ⟶ risque de pollution biologique par les OGM.

Je cite le cas des poissons transgéniques ayant une croissance accélérée grâce à l'utilisation de l'hormone de croissance humaine.

⟶ Le danger : on ne sait pas encore l'effet d'un transgène disséminé dans l'environnement.

La présence de ces animaux dans la nature perturbe dangereusement la vie de leurs homologues sauvages (normaux) car ils peuvent s'accoupler entre eux et l'ADN se reproduit…

Notre position :

Une biosécurité s'impose pour la non dissémination des transgènes dans l'environnement. Les animaux transgéniques doivent vivre dans des espaces, des parcs surveillés et ne pas s'échapper dans la nature.

4- OGM et consommateurs

Il est à priori très peu probable que le transgène dont on connaît bien les propriétés apporte des éléments négatifs pour le consommateur. A priori, il n'y a aucun danger, mais, cela ne peut être exclu.

→ il convient donc de procéder à un examen des animaux transgéniques pour évaluer les risques éventuels : toxicité, allergénicité…

II – STRUCTURE ET CONTENU D'UNE DECLARATION RELATIVE A DES NORMES UNIVERSELLES EN MATIERE DE BIOETHIQUE.

1) La déclaration devrait nécessairement comporter un préambule, tenant compte de tous les avis (voir notre introduction).

Elle devrait être structurée en sections. Je cite particulièrement :

a- la recherche fondamentale scientifique pour comprendre les mécanismes de la vie, doit être encouragée, doit avancer. C'est la base de tout progrès scientifique. Le partage des connaissances entre les scientifiques des différents pays permettra de mieux mesurer les risques et les limites.

b- Les applications médicales particulièrement du génie génétique.

On sait actuellement remplacer un gène défectueux par un gène normal. On sait introduire un gène humain chez un animal et recréer chez celui-ci des modèles de maladies humaines en vue d'apporter des remèdes adéquats.

La thérapie génique humaine est en application. La thérapie génique (avec la thérapie cellulaire) est considérée comme étant la thérapie de l'avenir. Cependant, on distingue deux sortes de thérapies géniques :

- La thérapie génique somatique

Dans ce cas le matériel génétique, pour corriger une maladie est transféré directement dans les cellules de l'organe déficient du patient.

Cette thérapie parait prometteuse dans le futur dans le traitement de certaines maladies comme le sida. Cette thérapie somatique ne présente aucun danger. Elle revient à faire une prothèse avec un gène qui apporte à des cellules une protéine déficiente chez les patients et corriger la maladie.

C'est un cas couronné de succès qui doit être encouragé. On peut citer l'utilisation pour certaines maladies dégénératives, certains cancers…

- La thérapie génique germinale

Le gène est inséré dans les cellules germinales (gamètes). Cette thérapie génique dans les cellules germinales humaines ne peut être pratiquée en raison de considérations éthiques. Les modifications génétiques des cellules germinales pourraient avoir des conséquences graves sur les individus qui pourraient hériter d'altérations potentielles à travers des générations. En plus, les risques de dérapage dans ce domaine sont immenses…

Certes, ce progrès comporte d'immenses espoirs thérapeutiques, mais soulève aussi des inquiétudes.

2) Quels principes fondamentaux devraient être réaffirmés dans la déclaration ?

On peut citer plusieurs principes :

- Le respect de la dignité humaine en premier lieu.
- Le principe de justice
- Le respect de la vie privée
- La solidarité, entraînant l'accès universel à l'information et son utilisation. Internet permet actuellement un meilleur partage des connaissances.
- La confidentialité peut parfois s'imposer
- Le consentement libre et éclairé.

Je cite par exemple le recours à l'analyse génétique dans plusieurs cas :

- Dans la recherche scientifique
- Dans l'utilisation médicale → prévention et traitement de maladies
- A des fins d'identification des personnes en code civil : filiation en cas de contestation
- En droit criminel pour identifier le coupable
- Ou encore à des fins socialement bénéfiques ;

Ce recours à l'analyse génétique ne peut se faire sans l'avis de la personne ou plutôt de toute la famille (parents, enfants, frères et sœurs) car l'analyse génétique concerne la famille.

On peut ajouter certains principes :

- respecter le droit de « ne pas savoir » sur son identité génétique particulièrement pour les personnes prédisposées pour une maladie génétique incurable dans l'état actuel de la science.
- L'analyse génétique des maladies incurables et qui peuvent concerner des familles soulève des problèmes éthiques très sérieux : doit on alerter ces familles susceptibles de développer une maladie génétique que nous savons incurable du moins dans l'état actuel des recherches scientifiques.

→ Notre réponse est non. Pourquoi alerter un patient porteur d'un gène d'une maladie incurable et générer chez lui une angoisse permanente ? Bien sûr, dans le cas de certaines maladies actuellement curables, le patient doit être prévenu.

- L'information génétique recueillie à une fin donnée, ne doit pas servir à une autre fin, sans le consentement de l'intéressé.
- La protection des gens contre la discrimination particulièrement sur la base de leur information génétique.
- L'analyse génétique peut donc être utilisée mais avec des limites et des lois qui s'imposent (protection de la vie privée de la personne).

Elle ne doit jamais être utilisée dans l'emploi par exemple ou l'assurance, ce qui entraîne une discrimination à l'égard des personnes en raison de leur état de santé ou de leur origine.

3) <u>Le principe général du consentement dans la recherche</u>

Le consentement doit être libre et éclairé. La personne à qui sont prélevés des échantillons biologiques doit savoir d'avance que l'échantillon est destiné à telle ou telle manipulation et donner librement son consentement. Elle doit être prévenue des finalités du prélèvement.

4) <u>Le partage des bienfaits</u>

Les biotechnologies posent des problèmes nouveaux et complexes de propriétés intellectuelle et industrielle.

Par exemple, le ***brevetage des gènes*** est l'objet de vives controverses soulevées en particulier par le séquençage complet de plusieurs génomes, en particulier le génome humain.

→ notre point de vue : il ne s'agit nullement d'invention nécessitant un brevetage, mais seulement d'une maîtrise d'un aspect scientifique et technique auquel toute la communauté scientifique a participé progressivement.

Donc, nous disons non au brevetage.

Le partage des bienfaits de la science appartient à toute l'humanité.

5) Quelle que soient la structure et la portée de la déclaration, quand cela s'avère possible, elle devra proposer des orientations sur des sujets spécifiques. On peut citer par exemple :

- le statut de l'embryon (personne potentielle…)
- les technologies de la Reproduction
- L'utilisation des cellules souches ES (Thérapie cellulaire) → prometteuse pour l'avenir
- Génétique et biologie moléculaire.
- Clonage et la transgenèse
- Les xénogreffes
- Données génétiques et autres données personnelles relatives aux soins de santé.
- Recherche sur l'embryon.

WORLD HEALTH ORGANIZATION **ORGANISATION MONDIALE DE LA SANTE**

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In reply please refer to:

Your reference: SHS/EST/04/093

Professor Henk ten Have
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FRANCE

30 March 2004

Dear Professor ten Have,

The World Health Organization (WHO) is grateful for the opportunity, conveyed on 3 March 2004 by Mr. Pierre Sané to our Director-General, Dr LEE Jong-Wook, to comment on the plans of UNESCO's International Bioethics Committee (IBC) to begin elaborating a "declaration on universal norms on bioethics." This is an ambitious undertaking, given the potential scope of the declaration as outlined in attachment to Mr Sané's letter.

Many of the subject areas set forth as possible topics for the declaration are familiar to WHO because they are areas in which we work. The beginning of life, end of life, genetics and molecular biology, health care systems, human genetic data and other personal healthcare data, organ and tissue transplantation, public health, and research are matters where the funding and oversight of research at a national level often lie with health ministries and biomedical research institutions and the regulation of the application of research findings rests with healthcare professionals and the bodies that license them.

Consensus amongst WHO Member States in many of these areas usually is achieved in the context of practical analysis germane to a particular subject. We will be pleased to provide you with relevant WHO documents that deal with the particular topics that the IBC decides to address in the proposed declaration. We have already begun doing this through the UN Interagency Committee on Bioethics, such as the recent WHO documents on organ and tissue transplantation, and on intellectual property, innovation and health, which were distributed to the Committee a few months ago.

We thus look forward to learning the views of your Member States on the scope and purposes of the declaration, so as to know which of our reports would be relevant to the IBC's work. Meanwhile, we extend best wishes for the IBC's extraordinary session on 27-29 April.

Sincerely yours,

Alexander M. Capron
Director
Ethics, Trade, Human Rights and
Health Law

WORLD TRADE ORGANIZATION

Contribution to the Extraordinary Session of the International Bioethics Committee of UNESCO (IBC)

Paris, 27-29 April 2004

This note aims to set out briefly the way in which the principal provisions of the multilateral trade agreements established under the WTO relate to issues of bioethics. The note focuses primarily on the main agreement relating to trade in goods, namely the General Agreement on Tariffs and Trade 1994 (GATT 1994), and two other agreements on trade in goods, those on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS), together with the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Core WTO principles and objectives include non-discrimination and the liberalization of obstacles to international trade. For example under the GATT, WTO Members cannot discriminate between their trading partners and, in regard to their internal measures, between imported and locally produced goods. As regards border measures, only tariffs are permitted and these are subject to negotiated reduction and binding. But there are exceptions. For example, since the inception of the GATT more than 50 years ago, Article XX of the GATT guarantees q Member's right to take measures to restrict imports and exports of goods when those measures are necessary to protect public morality (Article XX (a)) or the health of humans, animals and plants (Article XX (b)). Similar provisions can be found in the GATS (Article XIV). These provisions recognize that there are cases where Members may wish to subordinate trade-related considerations to other policy objectives and constraints, such as public morality and health.

The TBT and SPS Agreements recognize that countries should not be prevented from applying technical regulations and standards to fulfil a legitimate public policy objective even if they restrict trade, as long as they should be no more trade restrictive than necessary to meet their purpose. WTO jurisprudence in relation to public health has established that WTO Members have the right to determine the level of the protection to be given to the public policy objective in question. Similar principles can be found in the GATS provisions relating to domestic regulation (Article VI).

The TRIPS Agreement, being focused on the protection of intellectual property rights, does not affect the right of governments to regulate research or the way in which the results of research can be used. In regard to patent protection, the Agreement requires that in principle protection shall be available for inventions for a term of 20 years counted from the date of application. However, there is special flexibility in regard to biotechnological inventions. The Agreement allow Members to exclude from patentability plants and animals (other than micro-organisms) and essentially biological process for the production of plants and animals (other than non-biological and microbiological process) (Article 27.3(b)). If a Member excludes plant varieties from patent protection, it should provide an effective *sui generis* system for their protection. The provisions of Article 27.3 (b) are presently under review in

the WTO. A range of proposals have been made. For example, while the TRIPS Agreement does not prevent countries from applying the provision of the Convention on Biological Diversity in regard to prior informed consent and benefit sharing, some proposals have been made in this review for reinforcing the operation of these principles by requiring patent applicants to disclose such information as a condition of patentability.

The Agreement also recognizes the right of Members to exclude inventions from patentability where it is necessary to prevent the commercial exploitation of such inventions in order to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment (Article 27.2).

With a view to finding a proper balance between the public policy objectives of providing incentives for new inventions and of ensuring affordable access to ones that have already been made, the Agreement provides for a number of exceptions to patent rights, for example the granting of compulsory licences and parallel importation. In regard to public health, this flexibility was reaffirmed and clarified by the WTO Members at the 2001 WTO Doha Ministerial Conference and has subsequently been expanded in regard to the important of generic drugs by a decision of WTO Members of August 2003.

PAN AMERICA HEALTH ORGANIZATION (PAHO)

TOWARD A *CODEX BIOETHICUS*
A position paper by the PAHO Bioethics Unit

Prepared by Fernando Lolas, MD, Unit Director

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Established in 1994 under an agreement between the Pan American health Organization (PAHO, Regional Office of the World Health Organization), tha University of Chile and the Chilean Government, the **Regional Program on Bioethics** (now **Bioethics Unit,** BU) has worked in the Region of the Americas and the Caribbean in three main areas: *human resources development* through courses and training, *surveys and research on bioethical practices and standards*, and *support of public and private institutions* in the development of approaches to the formulation, justification, and application of bioethical principles in legislation, health care and health research. It has also interacted with other UN agencies in the development of appropriate frameworks for collaborative efforts and has contributed to the drafting of international guidelines for research on human subjects, most notably those prepared by CIOMS (Council of International Organizations for Medical Sciences).

The environment in which BU-PAHO has developed its activities is a highly diverse one in terms of cultures, political organization, legislation, socioeconomic development, literacy and equity. Addressing the most pressing problems in the social and institutional spheres, aspects of practitioner/client relations as well as macrobioethical dimensions involved in public health decisions, BU has explored the suitability and applicability of numerous international documents aimed at improving health care delivery and health research. Appraisals of their impact on actual practices indicate that many of them are largely unknown by the professionals and the population.

This experience is useful when evaluating the need and usefulness of a declaration on universal norms on bioethics, as proposed in the extraordinary meeting of UNESCO IBC convened in Paris.

In agreement with the Report prepared by Berlinguer and De Castro, we feel that the format of a *declaration* is better suited to the current purpose. Also, that the term "universal" applied to such a declaration would be at this time too ambitious to be taken seriously for many stakeholders and parties concerned. It would be better to work towards a "*codex*

bioethicus" in several stages involving the opinion of different members of society and exploring the opinion of many different users. The experience of drafting and approving the last version of the CIOMS Guidelines demonstrated, however, that this process should not be an endless one and at some point in time decision should be taken as to the final wording of a document.

Aims and scope of a *codex bioethicus*

A document of such generality should not ignore already existing ones and **should not be restricted to work with and on human beings**. It should encompass vast number of issues, such as ecological ethics, genetically modified organisms, biotechnology, intellectual property rights, trade agreements, and, in short, all those aspects of human interaction influenced by science and technology which can be examined or applied taking into consideration bioethical principles.

The first aim of such a document should be **pedagogical**. It should help professionals and lay people alike to identify those issues which merit attention and teach how to formulate conflicts in the context of differing cultures, legislations, and socioeconomic conditions.

To maintain **respect for cultural diversity** without falling prey to single-minded relativism and reaffirming universal values is certainly a challenge and a declaration needs a preamble contextualizing the intentions and objectives.

Another aim of a declaration which attempts to be considered by all parties concerned is to delineate ways in which **dialog** between disciplines, groups, and social interests could be established. Legitimate concerns arise whenever general principles pretending to be universal are formulated without due consideration to the different rationalities which influence social life. A declaration should indicate how conflicts are to be formulated and solved if they arise. In this regard, the objective is not to have a canonical text but a set of general principles which may probably need a **permanent group devoted to its interpretation and application** according to context.

Structure and content of a *codex bioethicus*

A preamble is essential in a general text which has the potential of being used or consulted in a variety of circumstances and contexts. It should include a brief history of "universal" declarations and covenants and also some explanation about the scope and intentions of previous documents.

Following ***sections*** seem important: a) general considerations (what is a text of this kind, what its audiences are); b) health care; c) biological and health research; d) epidemiological and social research; e) institutional ethics; f) ecological issues; g) communication and dissemination of information.

A basic problem with the declaration of "universal" principles is that many of these principles have different meanings in different cultures, or may possess different forms of expression. Insofar as autonomy, solidarity, respect for dignity, reciprocity, beneficence, non-maleficence and others are "formal" principles they need to be filled with significance in the context of particular cultures.

A broad formulation is to be preferred to any detailed explanation of moral principles. Experience with international texts shows that exact interpretation is difficult and that even translation problems militate against proper understanding of even those "canonical" texts which appear unquestionable.

The idea of establishing **a permanent body of experts and scholars** in charge of appropriate interpretation in difficult cases is a sound one, and has been entertained before in the case of CIOMS Guidelines. Perhaps it is appropriate to suggest that IBC-UNESCO, or a commission thereof, could have this responsibility. In a document supposedly useful in many different languages and cultural contexts, this body of interpreters is very important and could help improve the text as time goes by.

A framework for a universal text

The aspiration to have a universal, univocal, and meaningful text in all languages and situations is utopian. Moreover, an aspirational text, indicating what "ought to be" and not only "what is the case" is subjected to many interpretations depending upon framework and intentions of the users. This is the reason why the text should be considered only as a transient consolidation of expectations and desires in need of permanent revision and interpretation.

This is one reason for **not listing** exhaustively areas of application or guidance of the text to be prepared. More important is to stress the general orientation of an ethical text, in keeping with the two major traditions in Western thought: teleological or consequentialist and deontological or duty-based. A separation should be made between those rules of conduct which are based on **duties** (professionals and experts) from those which are based on **rights** (experimental subjects, patients) and stressing that in both cases the **aims** and **motivations** of social and individual behaviour should be spelled out.

A *codex bioethicus* should be short, simple, and amenable of translation by avoiding specialized jargon or idiosyncratic expressions. A thorough revision and appropriate content analysis should be carried out. ***Stress should be placed on procedures for reaching agreement rather than on apodictic formulations***.

The experience of PAHO Bioethics Unit

Throughout the years, our Unit has dealt with different international or "universal" texts studying their reception, comprehension, and use in different contexts. The experience has been mixed and has indicated the need for thorough training of those involved in the preparation and dissemination of such texts. In case a declaration is drafted, it should be placed on the Internet for several months and amended in accordance with suggestions received. The preparation of the CIOMS Guidelines for research involving human subjects indicated that there are, in moral matters, irreducible positions honestly maintained which make the very idea of a universal consensus a fiction. What can and should be expected is an agreement regarding procedures for reaching agreement.

Some publications for use in Spanish :

CIOMS *Pautas éticas internacionales para la investigación biomédica en seres humanos.* Traducción Unidad de Bioética PAHO (OPS-OMS), 2003

Lolas, F. & Quezada, A. *Pautas éticas de investigación en sujetos humanos: Nuevas perspectivas*. Unidad de Bioética, OPS-OMS, Santiago de Chile, 2003.

ACTA BIOETHICA (Bilingual journal) ISSN 0717-5906, peer-reviewed publication from the PAHO Bioethics Unit with articles and book revies relevant to the subject.

Further information at the following websites
http://www.bioetica.ops-oms.org
http://www.paho.org
http//www.uchile.cl/bioetica

ORGANISATIONS NON GOUVERNEMENTALES

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NON-GOVERNMENTAL ORGANIZATIONS

THE WORLD MEDICAL ASSOCIATION

Comments on the UNESCO Project of a Declaration on Universal Norms on Bioethics

The World Medical Association (WMA) is an international non-governmental federation of National Medical Associations representing the millions of physicians worldwide. Acting on behalf of patients and physicians, the WMA endeavours to achieve the highest possible standards of medical care, ethics and education and health-related human rights for all people.

The WMA is pleased to have this opportunity to address the UNESCO International Bioethics Committee (IBC) on the subject of its proposed Declaration on Universal Norms of Bioethics. Since its formation in 1947, the WMA has never ceased to be a major force in medical ethics and bioethics (cf., its *Declaration of Geneva*, adopted in 1948, *International Code of Medical Ethics*, 1949, *Declaration of Helsinki*, 1964, and more than 50 other statements on ethical issues). The formation and staffing of a dedicated Ethics Unit in 2003 is further evidence that the WMA is continuing to play a major role in international bioethics.

This submission will follow the order set out in the outline provided by the IBC Secretariat. It will reference, where appropriate, the 13 June 2003 *Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics* (SHS/EST/02/CIB-9/5 [Rev.3]) and the 22 September 2003 *Report by the Director-General on the Possibility of Elaborating Universal Norms on Bioethics* (32 C/59).

I. Aims and Scope of a Declaration on Universal Norms on Bioethics

Perhaps the biggest challenge that this project faces is the one described in para. 47 of the Director-General's Report: "If the framework is too general, it may be less useful in terms of its application to specific practices. Conversely, if it is very detailed, it may be rendered obsolete by rapid advances in practices and techniques." Bioethics is a very large field and covers many specific topics, as can be seen in the list at the end of the Secretariat outline. It would not be feasible to deal with all of the topics in one declaration.

Bioethics has three major divisions: clinical ethics (dealing with the relationship of health care professionals and the individuals they care for), research ethics (dealing with issues in scientific experimentation), and public ethics (dealing with laws, regulations and policies on issues in biology, medicine and health care). The IBC would be wise to focus the declaration on public ethics, since many other organizations are dealing with clinical ethics and research ethics. Nevertheless, any declaration on public ethics needs to take account of both the resolved and the unresolved issues in the other fields so that it is supportive where appropriate and does not interfere where that would be inappropriate.

In formulating a declaration dealing with issues in public bioethics, the IBC must be clear about the relation of law and ethics. While it may be appropriate to have legislation and regulations on some bioethical issues, ethics and law must never be conflated. Ethics often calls for higher standards of behaviour than the law requires and in some cases ethics requires

disobedience to (unjust) laws. As the IBC Report states (para. 40), "At any level, laws accompanied by effective control should be adopted in order to facilitate personal choices, and only a few substantial issues should be regulated through international rules. In other words, the aim should be to maximize moral evolution and to minimize the need for legislation." On the other hand, the Director-General reported (para. 27) that the Intergovernmental Bioethics Committee sees the declaration "as a tool to help States wishing to enact laws in that field." The IBC will have to decide whether the declaration is primarily an ethical document, in which case it should be educational in nature, or primarily a legal one, in which case it probably should not include the word 'bioethics' in its title.

Another challenge for the project is to find consensus among different cultural, religious and philosophical traditions on a wide range of bioethical issues. On each of the topics listed, there is considerable diversity about how humans should behave and the role of the state in regulating their behaviour. The Director-General might have been overly optimistic when he stated (para. 36): "…an instrument on bioethics can provide unity, while recognizing the special challenges posed by the unique histories, cultures, politics, judicial systems and economic situations of the countries involved worldwide."

One way of achieving unity in the face of diversity is to leave key words undefined. 'Dignity' is a prime example. It is cited by both opponents and proponents of abortion, euthanasia, and therapeutic cloning, but obviously to support entirely different positions. Another example is 'norms'. The declaration should define its key terms, even if this makes it more difficult to achieve consensus.

For all these reasons, the IBC needs to determine very carefully the aims and scope of the declaration. The aim should be either an ethical, primarily educational, document or a legal one, but not both. The scope should be the public policy dimension of bioethics, not clinical or research bioethics.

It should be noted that two of the aims of the declaration, as stated by the Director-General (para. 44), namely, "to encourage Member States to set up national and regional bodies designed to encourage the population to take part in informed debate in various fields, including those related to the most recent developments in biotechnology," and "to encourage States to strengthen the dialogue with their scientific community, universities and other academic centres, the media and non-governmental organizations and to promote the active participation of all interested parties," can be accomplished whether or not there is a declaration.

For practical reasons, the declaration should probably be limited to human beings. It will be difficult enough to achieve consensus at this level without involving the relationship of humans to animals, the environment, etc. A subsequent declaration could deal with these broader issues.

II. Structure and Content of a Declaration on Universal Norms on Bioethics

Discussion of the structure of the declaration is premature. The nature and scope of the document must be decided before any determination of the appropriate structure ("form follows function").

It will be especially important to establish the basic principles for judging whether particular scientific or health-related activities should be obligatory, encouraged, merely tolerated, or

forbidden. The declaration should not simply state conclusions without providing the reasons for them. In a pluralistic world where the meanings of autonomy, dignity, benefit sharing, justice, etc. are all contested, the surest foundation for international bioethics are the major human rights principles. The declaration should use these principles to ground and support whatever norms on bioethics it sets forth.

Whatever topics it treats, the declaration should distinguish carefully between those on which a general consensus has been achieved (e.g., on informed consent) and those where there is no such consensus. For the latter, the role of the declaration should be to identify relevant ethical considerations and present the arguments for the different positions on the issue. It should not attempt to foreclose debate prematurely.

The list of topics in the Director-General's report and the Secretariat outline is clearly far too extensive for adequate treatment in a declaration. Moreover, if the aim of the declaration is to identify universal norms on bioethics, there is no need to discuss all the specific issues in bioethics. Some of them can be cited as examples of how the norms apply.

3. Conclusion

We hope that these remarks will help to focus the aims and scope of the IBC project. The WMA, with its long experience in developing and reviewing policies on bioethical issues, is very willing to work with the IBC to bring the project to a timely and fruitful conclusion.

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THE HUMAN GENOME ORGANIZATION (HUGO)

Bartha Maria Knoppers, O.C.
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Chair: HUGO Ethics Committee (Human Genome Organization)

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I. Aims and Scope of a Declaration on Universal Norms on Bioethics

1.1 The Declaration (if any) should be more modest in its title. Universal is presumptuous. "Norms" could be misunderstood as meaning "standards". Some would argue that there can be no universal bioethics. If this initiative proceeds perhaps: "International Declaration on Bioethics"?

1.2 HUGO's mandate is the "human" genome. Recognizing however the need for an approach that appreciates the fact that we need to respect our role in the ecosystem, animals, plants and the environment should be included. Many cultures have an appreciation of respecting nature and other life forms with an understanding of our co-evolution and co-adaptation with other species and the environment.

1.3 Declarations are by their nature very general thus leaving it to countries to interpret and apply the principles according to differing worldviews and values.

II. Structure and Content:

11.1 The preamble should be short and tie in with the 1948 Universal Declaration on Human Rights as an example of the role that UNESCO's bioethics principles of 2005 could play in reinforcing human rights around the world.

HUGO's Ethics Committee has used as its guiding principles for all of its Statements the following:

1. Recognition that the human genome is part of the common heritage of humanity;
2. Adherence to international norms of human rights;
3. Respect for the values, traditions, culture, and integrity of participants; and
4. Acceptance and upholding of human dignity and freedom.

11.2 We also suggest discussion on including the following:

1. Access to a decent minimum of health care and public health-clean water, sanitation, a diet adequate for the lives lived in that community, and access to effective and affordable health care.

2. Compassionate and humane care, especially for those suffering from chronic illness and pain and for those at the end of life.
3. Respect for participants in research, including a prohibition on exploitation, attention to informed consent, and a review process to insure that research projects meet both international and local standards for ethical research.
4. Justice: attention to the demands of justice within each nation and across national boundaries; justice in the allocation of benefits and burdens in health, health care, research, and the development of new technologies including biotechnologies.

11.3 General principles of broad application are best so as to avoid ethical imperialism. If plants, animals and the environment are included, there will be a lot of subject matter. In addition, emphasis should be on specific procedural and infrastructure mechanisms and support (e.g. education, open-access, technology transfer, international collaboration etc…) so as to make the principles viable. As concerns implementation and respect for the Declaration. Perhaps a national reporting system every 5 years on national progress? Difficult to do with a Declaration(!).

11.4 My Committee may add more (or think differently) during our April 4th meeting but I suggest avoiding specific subject areas except for research involving humans, public health, IP, health care systems and education (presuming that the Declaration covers humans, the environment, plants and animals).

III. Personal Conclusion

Thought should be given to more familial/communitarian and social principles not just individual ethics and rights. See for example:

1) RENZONG, Qiu, "Presidential Message of ABA for ABC5", 14(1) (2004) *Eubios Journal of Asian and International Bioethics*, 3.
2) SASS, Hans-Martin, "Asian and Western Bioethics: Converging, Conflicting, Competing?", 14(1) (2004) *Eubios Journal of Asian and International Bioethics*, 13.
3) CHADWICK, R. and K. Berg "Solidarity and Equity: New Ethical Frameworks for Genetic Databases", 2(4) (2001) *Nature Review Genetics*, 318
4) As well as the principles for population genetics of the Quebec Network of Genetic Medicine in its recent Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations (2003) (www.humgen.umontreal.ca).

Principles and Definitions

INDIVIDUALITY: Recognition of the uniqueness of the person mandating respect for the autonomy of the individual within a given group.

DIVERSITY: Recognition and respect for difference through the fostering of a multidisciplinary approach.

COMPLEXITY: Interpretation of genetic information that recognizes its multi-variable nature and expression.

RECIPROCITY: Mutual exchange through consultation and communication.

SOLIDARITY: Protection from discrimination and from stigmatization.

SECURITY: Confidentiality of genetic data and strict control in the use or exchange thereof.

ACCOUNTABILITY: Adherence both to the recognized body of legal and ethical norms applying to research as well as to transparency and representation of the population in decision-making.

EQUITY: Participation, access, and the sharing of benefits and risks, taking into account the characteristics of each population.

CITIZENRY: Contribution to the public good and to the health of the population.

UNIVERSALITY: Knowledge dissemination and international collaboration.

FÉDÉRATION INTERNATIONALE
DES LIGUES DES DROITS DE L'HOMME (FIDH)

Intervention de Mme Monique Hérold,
Chargée de mission

Une déclaration relative à des normes universelles en matière de bioéthique contribuerait utilement à une meilleur prise en compte des enjeux éthiques des progrès scientifiques et de leurs applications par l'énoncé de principes directeurs en rapport avec des valeurs éthiques (dignité humaine, autonomie, consentement libre et éclairé, non-discrimination, solidarité, égalité d'accès aux soins, respect de la vie privée et confidentialité, refus d'instrumentalisation de l'être humain, liberté de la recherche et honnêteté intellectuelle, ...). La reconnaissance de valeurs communes à l'humanité permettrait l'élaboration d'une éthique commune et légitimerait les limites à apporter aux applications de nouvelles connaissances scientifiques, préparant ainsi le passage de l'éthique au droit, c'est-à-dire une régulation mondiale opposable aux forces politiques et économiques.

D'autant que, selon le rapport du CIB du 13 juin 2003, le champ de la bioéthique s'est étendu considérablement (§ 8 et 9) et veut s'élargir à des questions fort éloignées de la santé et de la recherche (§ 10).

Cette déclaration appellerait à la vigilance les chercheurs, les experts et les décideurs qui seraient amenés à évaluer les conséquences à terme d'applications technologiques; largement diffusée dans la société civile et relayée par les ONG, elle permettrait à un contrôle citoyen de s'exercer sur l'acceptabilité de ces conséquences en terme de « vivre ensemble ».

La déclaration devrait se limiter à l'être humain en tant que responsable des « valeurs morales qui guident le comportement des individus et des communautés » comme des valeurs morales et des priorités qui devraient à différents niveaux guider les politiques publiques » (§ 10). Il s'ensuit qu'elle devrait traiter non seulement de la personne humaine et du corps humain dans le contexte biologique ou médical, mais aussi de la relation de l'être humain avec les domaines animal et végétal (§ 10).

On doit ici souligner les dangers potentiels de l'élargissement du champ de la bioéthique si celui-ci ne s'accompagne pas d'énoncés juridiques. En effet on risque de cacher sous un langage à connotation morale le rôle essentiel des actions de promotion ou de lutte (cf. égalité entre les sexes ou exploitation des enfants) qui relèvent de décisions politiques indépendantes des avancées techno-scientifiques, décisions qui nécessitent une traduction normative efficace. On voit en effet à quel point l'application irréfléchie de ces avancées peut entraîner des dégâts irréversibles pour les générations futures (cas de la biodiversité ou de l'environnement par exemple).

Aussi est-il nécessaire d'envisager un préambule pour définir tant le rôle et la portée d'une telle déclaration que les principes généraux (§ 45) lui servant de soubassement pour tracer le cadre du permis et de l'interdit face au faisable et au possible et dégager ainsi un universalisme des valeurs reconnaissant la pluralité des « fonds culturels, philosophiques et religieux des communautés humaines » (§ 11).

La structure en sections est évidemment souhaitable d'une part pour faciliter l'appréhension du texte, d'autre part et surtout pour indiquer les domaines où s'appliquent les principes fondamentaux revendiqués. La détermination de ces sections dépendra du champ que voudra/pourra couvrir la déclaration ; mais celle-ci devrait en tout cas inclure les critères de son ré-examen à intervalles réguliers (§ 44), la recherche scientifique et ses applications, les soins de santé, la coopération internationale et la diffusion non marchande des connaissances, le rôle des sociétés civiles et leur consultation effective à partir d'exposés clairs des risques potentiels et des bénéfices attendus.

Si la finalité d'une telle déclaration est de « stimuler l'élaboration d'une signification commune à l'échelle mondiale afin de favoriser la compréhension et la cohésion autour des nouvelles catégories éthiques et des nouvelles possibilités concrètes offertes par la science et les technologies » (§39), cela implique que l'éthique du Nord ne peut se développer au détriment de la participation et de la santé des populations du Sud.

La déclaration ne devrait affirmer que des principes d'application générale et signaler les cas qui relèvent d'applications particulières sous la responsabilité des Etats.

Quant à la mention de sujets spécifiques tels que listés au chapitre IV du rapport, elle paraît certes nécessaire. Mais ces sujets apparaîtront au fur et à mesure de l'élaboration de la déclaration et devront tenir compte d'une hiérarchisation des urgences. Par ailleurs il faut rappeler que le danger inhérent à toute liste est sa non-exhaustivité.

INTERNATIONAL COUNCIL FOR SCIENCE (ICSU)

Towards a Declaration on Universal Norms in Bioethics: Submission to the Extraordinary Session of IBC

The ICSU membership includes 101 national science academies or science funding organisations and 27 International scientific Unions, representing millions of scientists from across the World. In responding to this request for input to the IBC, it has not been possible, because of time restraints, to consult with the entire ICSU membership. However, input has been sought from the international biological unions and selected individuals with expertise in bioethics. Responses from the International Union of Biological Sciences (IUBS) and the International Union of Physiological Sciences (IUPS) are attached as annexes to this document.

ICSU itself is currently conducting a strategic review of the "Rights and Responsibilities of Science and Society" and the potential for future partnerships with UNESCO COMEST and IBC are being considered as part of that review. Mr ten Have, Director of the Division of Ethics at UNESCO, attended a meeting of the ICSU review panel in February 2004 when, amongst other things, the plans to develop universal declarations and codes of practice were discussed. This response to the IBC questionnaire incorporates some of the issues that were raised in that discussion, as well as the responses of individual experts who were consulted specifically for their input.

1. Aims and Scope of a Declaration on Universal Norms in Bioethics

1.1. Any attempt to establish universal norms runs the risk of being seen as one part of the World – normally the North, trying to impose its thinking on the rest of the world. The more detailed the norms are the less likely they are to be universally applicable. Ethics are culturally and contextually influenced. Whilst there is some merit in articulating 'high level' principles for bioethics, any attempt to establish substantive universal guidelines or codes of practice is likely to be very contentious and ultimately impossible to implement. The efforts to produce a universal declaration on human cloning and the 'politicisation' of this process should serve as a warning in this regard.

Given its origin in UNESCO, it is clear, and perfectly understandable, that some governments want guidance in the area of bioethics. However, in order for even 'high level' principles to be credible and accepted by the scientific community, they need to be developed in close consultation with that community, i.e. with practicing experimental scientists as well as philosophers and ethicists. The principles should be developed with scientists for policy makers and not vice versa.

1.2 & 1.3 The declaration should not be limited to human beings but rather reflect the responsibility of human beings for the wellbeing of all living systems.

1.4 All of the proposed issues are appropriate for inclusion, provided that there is no attempt to develop detailed guidelines on specific practices.

II. Structure and Content of a Declaration on Universal Norms on Bioethics

II.1 The Declaration should be concise and written in language that is accessible to all audiences. It should not be prescriptive but should be a basis on which communities can develop their own guidelines and codes of practice.

II.2 See attached responses from IUBS and IUPS.

II.3 The declaration should only state general principles of broad application. These might include an expression of the desirability for more detailed guidance on specific issues to be developed at a national level. Some guidance on procedures for developing national guidelines might also be appropriate, e.g. the inclusion of the national scientific community should be a prerequisite.

II.5 The declaration should not provide detailed guidance on specific topics. Some of the listed areas, e.g. those relating to the beginning and end of life including cloning and embryo research, are extremely culturally and religion sensitive, and do not therefore lend themselves to universal norms. In other areas such as IPR and public health it may be easier to reach agreement on generic principles.

ANNEX I TO ICSU RESPONSE DATED 29/3/04

To: Carthage Smith, ICSU March 25, 2004

From: Ewald R. Weibel, Chair, IUPS Ethics Committee

RE: UNESCO BIOETHICS ENQUIRY

Dear Mr. Smith,

Thank you for your request for an input to ICSU's position on the UNESCO proposal about a Declaration on Universal Norms on Bioethics. I will try my best to comply but must say that I have insufficient background for an in depth consideration of the various questions posed. Furthermore, the time is very short and I have been away on a symposium I organized so that I was not able to consult my Committee on this. So this is my personal input.

I Aims and Scope of a Declaration:

I.1 A declaration on Universal Norms on Bioethics by UNESCO should be a broad statement of general principles that can form the basis for the development of Guidelines and Principles in the various fields of application, at all levels from policy makers to scientists, and in all parts of the world considering different cultures. It should be a reference framework open to all sectors of society, and should not attempt to replace Ethical Guidelines as these must address very specific practical issues.

I.2 No. Physiology applies to all living creatures, from cells to animals and humans, they are all part of the biosphere. Therefore Norms on Bioethics must relate to all living matter, but must make the necessary distinctions, such as level of organization, capacity for suffering, danger to other creatures etc.

I.4 Physiology deals with humans and animal organisms, such as mammals, birds, amphibians, worms, etc. The modern directions of physiology also use transgenic organisms to develop functional genomics.

II. Structure and Content.

II.1 I believe the Declaration should be very concise and should not attempt to deal with specific bioethical problems. It should be like a Constitution and not a Law.

II.2 One of the strongest principles in Bioethics is the "Respect of Life" as formulated by Albert Schweitzer. Its main virtue is that it imposes responsibility on those acting. And it can be developed to detailed ethical principles in relation to human and animal research or usage. In respect of research on humans principles related to free will, informed consent etc. must be addressed in general terms, also the principle of non-damage. I am not convinced, however, that so general principles as autonomy or freedom of research need to be developed beyond a very general statement that they must apply here as well.

II.3 Only general principles of broad "universal" application ("universal" as all-encompassing), but these principles must be stated strongly.

II.5 No. That must be left to special regulations, such as the Guidelines issued by CIOMS etc.

Respectfully submitted,

Ewald R. Weibel, MD, Dsc(hon)
Chair, IUPS Committee on Ethics in Physiology
Emeritus Professor of Anatomy, University of Berne
Formerly President of IUPS
Past-President of the Swiss Academy of Medical Sciences

ANNEX II TO ICSU RESPONSE DATED 29/3/04

Submission on:

A Declaration on Universal Norms on Bioethics

Prepared by on behalf of the Bioethics Committee of IUBS
John Buckeridge and Alan Bittles
IUBS Bioethics Committee

This paper seeks to address the specific questions raised in the International Council for Science document circulated on March 10th, 2004.

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1. Aims and Scope of a Declaration on Universal Norms on Bioethics:

1.1 Assessment of the implications of scientific progress:

The key parties to involve in this are **policy makers** (who are the direct representatives, through democratic government, of *society*: they are thus charged with upholding the rights of society), and the **scientific community**. Policy is determined, (and implemented), after input from various sources, including NGOs, religious bodies (and with a role for the media). Policy-makers thus reflect society's views, values and morality. The scientific community (in academia, public service and industry) includes those who develop and utilize technologies. This does not preclude the rights of individual citizens or groups to influence policies, or to effect change. Change must be anticipated as societal values evolve and will be reflected through government action and ultimately the passage of new legislation. Where there is urgency, targeted referenda remain the most effective mechanism to determine wider views. Ultimately it is the responsibility of society's representatives to ensure that advances in science are in accordance with the wishes of the wider community.

1.2 Scope of the declaration:

Humans have unique abilities to assess, interpret and predict phenomena. Amongst the Earth's biota, this has placed us in a position of governance. In general, it is humans who have the greatest impact on issues pertaining to management of the natural environment. However, humans must still be seen to be within, rather than external to, nature. We cannot exist in isolation and need to demonstrate acceptance and adoption of stewardship of the natural environment. In turn, this stewardship dictates that we are accountable for our activities.

Humans cannot and should not place themselves *ethically* above nature. Therefore any Declaration on Universal Norms (on Bioethics) must include non-human species as well as a consideration of ecosystems. Although in almost all cases, these parties will be represented through human advocacy.

In light of this, humans cannot place themselves *ethically* above nature. As such, any Declaration on Universal Norms (on Bioethics) must include species as well as a consideration of ecosystems. Clearly in almost all cases, these parties will be represented through human advocacy.

The need is for a declaration to ensure that all aspects of the living environment are afforded the respect and dignity appropriate.

Comprendre la nature, l'aimer, la protéger… (Muséum national d'histoire naturelle)

1.3 What "non-human" aspects should be considered:

A Declaration on Universal Norms on Bioethics must address issues such as:

- the use of animals in biomedical research
- the use of other species in transplantation
- the use of genetically modified organisms
- biodiversity management and enhancement
- environmental rehabilitation
- sustainable practice.

2. Structure and content of a Declaration on Universal Norms on Bioethics:

2.1 How should a declaration be structured:

A preamble is necessary which should place the declaration within context. It should also provide an overview of who is expected to make use of the document, and how this could best be done.

There will be multiple users, from individuals with a mandate (or opportunity) to effect change in governance, to persons who are able to effect change in methodologies (e.g. of biomedical techniques), to those who use the products (such as health and educational practitioners).

2.2 What fundamentals should be confirmed?

Key components of ethical manifestos on subjects of contemporary human concerns are constructed on the basis of a series of inter-related headings:

- Autonomy
- Benefit-sharing
- Confidentiality
- Freedom of speech
- Free and informed consent
- Justice
- Respect for privacy
- (Solidarity)
- The maintenance of human dignity
- Non-discrimination

As an example, these parameters are extensively discussed and individually evaluated in respect of 'The protection of Human Genetic Information', Discussion Document 66 of the Australian Law Revision Committee (2002).

2.3 Breadth of the declaration:

The declaration should state the fundamental, broad principles of application (such as the general principle of consent in research), but when opportunities and consensus permit, it additionally should provide guidance for specific cases, e.g. such as for xenotransplantation.

2.4 Categories for the declaration:

The list provided in the circular includes appropriate areas for consideration. Attention is also drawn to the categories previously approved in the 2002 IUBS co-sponsored *Eubios Declaration on International Bioethics.*

http://www.biol.tsukuba.ac.jp/~macer/eeidec.htm

DISABLED PEOPLES' INTERNATIONAL (DPI)

DPI Intervention in Regards to the UNESCO Declaration on Universal Norms on Bioethics[1]

I. Aims and Scope of a Declaration on Universal Norms on Bioethics

Introduction: Every person's life is touched by bioethics issues including disabled people. End of life decision-making, the allocation of healthcare resources, the use of genetic technology (gene therapy, genetic testing, genetic enhancement), research on non-competent people, questions of futile care, selective non-treatment of newborns, debates about personhood, mercy killing, disability adjusted life years and global burden of disease concepts, non-genetic therapy, testing and enhancement, ethics of access to clean water and sanitation, the convergence of nanotechnology, biotechnology, information technology and cognitive sciences, the governance of science, technology and biomedical research[2] and it's application to just name a few, are all issues that have significant implications for disabled people their quality of life, their self identity and how they are perceived and acted on by the so called non-disabled. Therefore a disabled people's rights approach to bioethics is essential to be integrated into any ethical guidelines.

I.1 How, in your opinion, could the declaration contribute to better assess the ethical implications of scientific progress and its applications?

Assessment of ethical implications:

We do not think that the declaration can help assess the ethical implications of scientific progress and it's applications. In order to be able to assess ethical implications this declaration would have to cover every single application possible and anticipate every issue and application arising in the future. That seems to be unrealistic. The declaration should provide ethical guidelines which can be applied to every application and to the process of the governance of science and technology and provide guidance as to what is ethical or unethical on all levels (policy-makers, scientific community, academic circles, media, society, etc).

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1. Dr Gregor Wolbring wrote this intervention on behalf of DPI. He is a member of the Executive of the Canadian Commission for UNESCO, a Biochemist at the Dept. of Biochemistry and Molecular Biology Faculty of Medicine University of Calgary, Canada, a Adjunct Assistant Professor for bioethical issues at the Dept. of Community Rehabilitation and Disability Studies Faculty of Education University of Calgary, Canada, a Adjunct Assistant Professor with the John Dossetor Health Ethic Center, University of Alberta, Edmonton, Canada, the Founder and Executive director of the International Center for Bioethics, Culture and Disability webpage: http://www.bioethicsanddisability.org , and Founder and Coordinator of the International Network on Bioethics and Disability. If you have questions in regards to this intervention please e-mail Dr. Wolbring at gwolbrin@ucalgary.ca

2. More on all of these issues can be found at the webpage of the International Centre for Bioethics Culture and Disabilities www.bioethicsanddisability.org

Cultural pluralism:

At its 32nd session in October 2003, the General Conference of UNESCO considered that it was *"opportune and desirable to set universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics"* (32 C/Res. 24).[3]

In order to make the cultural pluralism of bioethics a reality it has among other groups to include disabled people which it doesn't as of yet.

If one looks at how cultural pluralism would be inclusive of disabled people one has first to recognize that different self-perceptions by disabled people, different perceptions of disabled people, different interpretation of the relationship between disabled people non-disabled people and the environment, different definitions of the problems, and different solutions exist.[4]

However if we look at the debate around bioethics issues including documents from the UNESCO International Bioethics Committee[5] so called disabilities and disabled people are treated single minded within a medical model. The demand by disabled people to accept also other views of disability such as the social model is normally ignored or even rejected.[6]

It is of utter importance that the declaration guides towards a culture of bioethics which allows social groups (of which disabled people are one) to be respected for the cultural identity they choose and not imposes the views of one group onto another group. This would fit with the fact that according to the UNESCO International Declaration on Cultural diversity social groups should be allowed to choose cultural identities of their choice.[7]

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3. http://portal.unesco.org/shs/en/file_download.php/3880b5df8e0530134614da8d65c39d6aFinrep_UIB_en.pdf

4. The medical/patient perception of disability sees disabled people as inherently defect and subnormal as people with an inherent medical problem that leads to a low quality of life for the person and his or her relatives in need of fixing. Within the 'medical model of disability' management of the 'disability' is aimed at cure, prevention, or adaptation of the person to the norm (e.g. by provision of normative assistive devices).

The transhumanist perception of disability does not see the 'disabled person's body' as subnormal. It rather sees the human body in general as deficient in need of not just fixing to the norm but in need of augmentations above the norm with the addition of new abilities improvement. It believes in improving any human body if possible whether it's one of disabled people or that of the so-called non-disabled.

The social/human rights perception of disability sees disability mainly as a socially created problem and principally as a matter of the full integration of individuals into society. This model sees the biological reality of the person as a variation of being not deviation of being not in need of fixing but in need of having the physical environment, the interaction with the physical environment, and the societal climate changed to accommodate their biological reality. The social model demands social change, which at the political level becomes a question of human rights, where able-ism is comparable to racism, sexism, age-ism, homophobia and other other-isms see G.Wolbring "Disability rights approach to genetic discrimination" in J. Sandor, ed., Society and Genetic Information: Codes and Laws in the Genetic Era (CPS books Central European University Press, 2004 ISBN: 963924175X)

5. International Bioethics Committee of the UNESCO (2003) Report of the IBC on Pre-Implantation Genetic Diagnosis and Germ-Line Intervention, SHS-EST/02/CIB-9/2 (Rev. 3), April 24, 2003 (Paris: United Nations Educational, Scientific, and Cultural Organization), Available at http://unesdoc.unesco.org/images/0013/001302/130248e.pdf.

6. Roberto Rivera y Carlo "Targeting the Disabled," *Boundless*, December 5, 2002, available at http://www.boundless.org/2002_2003/features/a0000685.html. Compare also J. Harris "Is There A Coherent Social Conception of Disability?" 2000 *Journal of Medical Ethics*, 26(2): 95-100 <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10786318&dopt=Abstract; P. Singer, "Response to Mark Kuczewski." 2001 American Journal of Bioethics 1(3): 55-57

7. "Reaffirming that culture should be regarded as the set of distinctive spiritual, material, intellectual and emotional features of society or a social group, and that it encompasses, in addition to art and literature,

The ethical two tiered system of medical versus social reasons:

Beside the need to accept the different self identities of disabled people the universal norms in bioethics also have to discard a very problematic ethical approach as it pertains to disabled people. In this approach, ethical approval is ensured if something is done for medical reasons whereas something is ethically problematic if done for social reasons. For example sex selection is seen as ethically problematic as it is judged to be done for social reasons without any medical necessity. However disability (medical model) deselection is seen as acceptable as it is seen done for medical reasons. This approach makes the acceptance of a disability rights approach-an approach which perceives disability within a social justice framework rather than a medical one-impossible. This two tiered reasoning is also very problematic because the very concept of what is a medical condition is a societal construct. In some settings being gay is seen as a disease and in other settings it is seen as a disease. Taking into account the ambiguity of the concept of disease and medical condition and taking into account the UN Convention of disabled people rights in preparation and the UNESCO declaration on cultural diversity it is essential that the universal norms in bioethics discard this two tiered ethics.

I.2 Should the declaration be limited to human beings and why?

We think one has to distinguish between two different areas here a) whether we cover non human life issues such as animals and the environment and so forth and b) whether we limit the declaration to born human beings or whether we include different stages of human life in these universal norms in bioethics. There are pro and cons for a) on which we don't want to elaborate. We believe that b) should include all stages of human life. Reality is that science and technology interventions and many bioethics issues increasingly are not just limited to born human beings but are targeting different stages of human life. For example if we believe that genetic enhancement is wrong it should be wrong independent of whether we do it on the level of the embryo, a fetus, or a human being.

To give you another example. The avoidance of discrimination is seen as one ethical principle by many. However so far we treat discrimination as if it is happening just on the level of a born human being whereby discrimination against a certain characteristic can really happen on the level of a cell, a zygote, an embryo, a fetus, a person, or a human being e.g. if we prohibit sex selection but not disability deselection this disability discrimination plays itself out on the level of the embryo and the fetus but not really on the level of a human being.

I.4 If the answer to I.2 is no, what other issues could be covered

See our explanation under 1.2

II. <u>Structure and Content of a Declaration on Universal Norms on Bioethics</u>

II.1 How should the declaration be structured? Should it include a preamble?

Yes it should contain a preamble as the preamble can link the declaration to other important documents and can set some general ethical guidelines. The preamble should in particular

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lifestyles, ways of living together, value systems, traditions and beliefs" in UNESCO (2001) UNESCO UNIVERSAL DECLARATION ON CULTURAL DIVERSITY Adopted by the 31st Session of the General Conference of UNESCO PARIS, 2 NOVEMBER 2001

http://unesdoc.unesco.org/images/0012/001271/127160m.pdf; see also UNESCO (2004) What is Cultural Diversity http://portal.unesco.org/culture/en/ev.php@URL_ID=13031&URL_DO=DO_TOPIC&URL_SECTION=201.html

acknowledge UN human rights instruments[8] in particular the UN convention on the rights of disabled people[9] the UNESCO World conference on sciences documents, and the UNESCO declaration on cultural diversity.

Should it be organized into sections? If yes, please indicate which sections could be included and why (general provisions, health care, scientific research, public consultation, international cooperation, education and awareness-raising, promotion and implementation, etc.)?

This depends on the length one wants the declaration to be. We think a declaration should be written in such a way that it can apply to many areas. However whether or not we have sections, we need a Glossary which defines all the terms used in the declaration.

II.2 Which fundamental principles should be reaffirmed in the declaration

Autonomy, benefit sharing, confidentiality, cultural diversity, freedom of research, free and informed consent, justice, non-discrimination, respect for human dignity, respect for privacy, solidarity between human beings, respect for human beings, inclusive culture of deliberation. These are just a few fundamental principles which should be affirmed in the declaration. However as the above example of the term discrimination shows it is of the highest importance for disabled people that the terms are defined in a very concise way and are not used in a detrimental way against disabled people.

II.3 In reaffirming these fundamental principles, should the declaration state only general principles of broad application (such as the general principle of consent in research) or should it attempt, where appropriate, to define a more detailed framework (for example, requirements for consent in specific cases)*?*

More details where needed. Once we know what areas the declaration will cover we will be able to add in which case we feel a more detailed framework is warranted.

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8. The Universal Declaration of Human Rights, the International Covenants on Human Rights International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the International Convention on the Elimination of All forms of Racial Discrimination, the International Convention on the Elimination of All Forms of Discrimination Against Women, the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, the Convention on the Rights of the Child, and the International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities". Official Records of the General Assembly, Forty-eighth Session, Supplement No. 49 (A/48/49), vol. 1, chap. VII, General Assembly resolution 48/96, annex, of 20 December 1993 <http://www.un.org/esa/socdev/enable/dissre00.htm>. "Principles for the protection of persons with mental illness and the improvement of mental health care". Official Records of the General Assembly, Forty-sixth Session, Supplement No. 49 (A/46/49), vol. 1, chap. VII, General Assembly resolution 46/119 of 17 December 1991<http://www.unhchr.ch/html/menu3/b/68.htm>."Declaration on the Rights of Mentally Retarded Persons". Official Records of the General Assembly, Twenty-sixth Session, Supplement No. 29 (A/8429), Proclaimed by General Assembly resolution 2856 (XXVI) of 20 December 1971 <http://www.unhchr.ch/html/menu3/b/m_mental.htm>. "Declaration on the Rights of Disabled Persons". Official Records of the General Assembly, Thirtieth Session, Supplement No. 34 (A/10034), Proclaimed by General Assembly resolution 3447 (XXX) of 9 December 1975 <http://www.unhchr.ch/html/menu3/b/72.htm>.

9. http://www.un.org/esa/socdev/enable/rights/ahcwg.htm and for the latest Draft Comprehensive and Integral International Convention on the Protection and Promotion of the Rights and Dignity of Persons with Disabilities http://www.un.org/esa/socdev/enable/rights/ahcwgreportax1.htm

II.5 Whatever the structure and scope of the declaration may be, should it, where possible, provide guidance on specific subject areas? If yes, which subject areas could be explicitly mentioned and why?

Problem with listing particular areas is to decide which to mention. If the declaration should be user friendly it should be as concise as possible and the ethical guidance should be usable in many areas and for future developments of ethical contention which can not be listed in this declaration like how to deal with sentient beings developed through artificial intelligence.

However if we guide on particular areas the list given on the webpage of the UNESCO bioethics section for this declaration is a good starting point.

INTERNATIONAL ASSOCIATION OF BIOETHICS (IAB)

Towards a Declaration on Universal Norms on Bioethics

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On behalf of the International Association of Bioethics (IAB), I would like to thank UNESCO for their kind invitation to participate in this important meeting. Let me begin by explaining how the organization I preside functions because I think it is relevant for this meeting in particular. The IAB is an association of academics and persons working in bioethics. It is truly international with members from all over the world. One of the main objectives of the IAB is to facilitate contacts and the exchange of information between those working in bioethics in different parts of the world (Constitution, article 3.1). It was founded in 1992 following a display of intolerance and censorship toward a well-known academic. In this sense, the only substantive point the association upholds is the value of free, open, and rational discussion of issues in bioethics (Constitution, article 3.4). This position was endorsed in 2000 during the IV International Congress by the London Declaration and issued by the Board of Directors. In this Declaration the Association considered that bioethics is a unique international phenomenon and that freedom of discussion is necessary for reflection in the field of bioethics and an essential feature of democratic life. The Declaration affirmed that in public discourse, no individual or group can claim to hold the exclusive knowledge of the "right" ethical solution. Only free and open debate can lead to justifiable conclusions. One of the reasons for issuing this Declaration was the following: Even if the IAB recognizes that this fundamental freedom of discussion is accepted and promoted in many countries and cultures, in others this freedom is in danger and there is a broad resistance to discuss problems whose reflective solutions may challenge accepted opinions and traditions.

Hence when the Board of Directors of the IAB received this invitation, it was considered with a degree of skepticism … The IAB does not take a general position but focuses fundamentally on the importance of free and open discussion. It will be very difficult to take another, embracing as it does so many different views, cultures, and disciplines. We are concerned with diversity, plurality of views, tolerance… The endorsement of open discussion and diversity undoubtedly poses a challenge to what UNESCO is proposing to do at this meeting: how to write a meaningful Universal Declaration that can accept diversity, plurality, and tolerance.

Having presented the main position of the Association I preside, in what follows let me offer the views of a woman coming from a developing country regarding the UNESCO proposal. I will focus on the aims and scope of a Declaration on Universal Norms in Bioethics and will present some of the challenges this document will have to face.

The second point in the Introduction of the *Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics* proposes to start from the Universal Declaration on the Human Genome and Human Rights and to develop a universal instrument of bioethics. And

the Outline for the preparation of the written contribution provides a list of subject areas. In the "beginning of life" area it lists abortion, prenatal diagnosis, preimplantation genetic diagnosis, reproductive technologies and sex selection. How can they be handled? How can we cope with the challenge of a universal instrument?

Throughout the document there is the impression that the main concern lies with science. Undoubtedly there is a global concern for science, biotechnology, and new possibilities that may alter our "nature". Magazines and newspapers depict a brave new world. Science seems to be altering the limits of Nature. This lack of certainties provokes fear and anguish with which it is difficult to cope.

At first sight we might believe that our view of science today and its link to society is a simple issue. I say it is not and we should consider how different it is whether the analysis is made from the North or from the South. Consider a single fact: while the mean expenditures in research and development in industrialized countries is 2.3 of GDP, varying with Sweden's 3.8 or Japan's 2.8 , in Argentina it drops to 1.3, in Brazil to 0.8 and in the Philippines to 0.2. This strongly impacts on the goals of research, the orientation it is given and partly explains the infamous 90/10 gap, where 90 % of the 50 to 60 billion dollars invested in medical research is used for 10% of the global burden of disease. How are we to understand science?

Whose needs are we to address? The needs of rich, industrialized countries? What about the needs –always postponed–of poor countries? What are the main problems these countries face? For example, Point IV of the Report rightly recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[1] However, only one paragraph addresses human reproduction and it ignores some of the vital and basic issues. Those are the main concerns of many persons that live in the developing world. The above-mentioned paragraph centers on assisted reproductive technologies and genetic engineering while one of the most vital problems regarding reproductive health in developing countries is the refusal to offer sexual education, distribute contraceptives, and prohibit safe abortions. This is the reality of developing countries, and bioethical issues, even many of the scientific ones, are related to them.

Consider the case of Argentina: Abortion laws are highly restrictive. However, illegal abortions are carried out continuously. In Argentina between 450,000 to 500,000 illegal abortions are performed every year. The problem lies in the impact this has on the vulnerable population, especially poor women and teenagers. It is a serious problem regarding public health. Forty-five per cent of the beds in obstetric wards in public hospitals are occupied by women with post-abortion problems. Complications because of illegal abortions are the main cause of maternal death. The World Health Organization (WHO) indicates that Argentina has 38 maternal deaths per 100,000 born alive, while Canada, for instance, has 4 per 100,000. In some provinces of northern Argentina the situation is even worse: Formosa shows 177/100,000. If we consider the global situation, we can see that of the 45 million abortions taking place annually worldwide, 20 million are unsafe, and 90% of the latter take place in developing countries, accounting for 13% of maternal deaths. Maternal mortality as a whole is alarmingly high in developing countries, reaching catastrophic figures in Africa, with an average of 477 per 100,000 as compared with 13 per 100,000 in the industrialized world."[2] Note that these are easily preventable deaths.

1. International Covenant on Economic, Social and Cultural Rights, Art. 12.
2. UNFPA; 1998.

Another pressing issue is the matter of teenage pregnancies. In Argentina, they are on the rise at a rate of 20% of all children born alive. In the city of Rosario 30% of the deliveries occur with girls under 19 and a high percentage of them are single mothers. Babies born of mothers under 15 years old doubled the mortality rate of the average.[3] In Argentina cases of raped girls of thirteen years old and younger are denied the possibility of an abortion…. The law is interpreted as recognizing only two exceptions: the cases of raped mentally handicapped woman and when the life of the woman is in danger. Other Latin American countries are even tougher regarding their abortion laws. In Chile abortion is absolutely forbidden and no exception is made when the woman has been raped or when her life is in danger.

Obviously these women and girls are not the object of protection or the subjects of rights, much less their children.

These basic issues in reproductive health also impact on how "biotechnology" is used and the problems it generates. Ignoring them distorts the problems biotechnology poses in these countries. For example there is no possibility of choice or the free decision of parents. In Argentina and in many other developing countries prenatal diagnosis, as well as pre-implantatory tests, are performed. However, cases of fetuses with serious genetic problems or illnesses that will result in the death of the newborn are not seriously considered. Over the past few years some cases of anencephalic fetus pregnancies have been taken up by the media. Women or couples wanting to end pregnancies face endless legal battles. There is no chance of ending the pregnancy, hence no real choice. Not only are the physical problems that the woman may endure overlooked (say, the problems the altered anatomy of the fetus causes during delivery) but also her psychological stress. Health issues consider biological functions and psychological ones. A woman that does not wish to carry out the pregnancy of a deformed fetus who will die immediately upon delivery may have to endure great psychological suffering. The physical and psychological harm such a pregnancy can inflict on the woman is ignored.

A similar problem arises regarding assisted reproduction. A key problem many developing countries face is the problem of secondary infertility. Secondary infertility is preventable and sadly has high rates in many developing countries (Latin America-Africa). Secondary infertility is caused by sexually transmitted diseases and reproductive tract infections.[4] The social scientist, María Yolanda Makuch, quotes a Brazilian study where 42% of women who consulted for infertility had tubal obstruction because of reproductive tract infection. Illegal abortions practiced in deficient conditions may also leave this population with infertility problems. Hence, the causes of secondary infertility reflect what I mentioned earlier: the refusal of sexual education, access to fertility regulation, and unsafe abortions. Analyzing assisted reproduction as a neutral technique, independent of the social and legal context, does not reflect the actual problems that some developing countries should consider. In this case, we first have to avoid secondary infertility (which is preventable and more accessible than sophisticated techniques like in vitro fertilization or ICSI), and later have to cope with the challenges that assisted reproduction presents.

Bypassing these basic issues does not address the bioethical problems developing countries face. Is it possible to establish a universal instrument that continues to ignore the death and

3. Reporte Sombra on the Third Report by Argentina before the Human Rights Committee.

4. Makuch M., Botega N., Bahamondes L. "Physician-patient communication in the prevention of female reproductive tract infections: some limitations", Cadernos Saude Publica, Rio de Janeiro, 16 (1): 249-253, Jan-Mar 2000: Fernandez M.S, Bahamondes, L , 1996 "Incidência dos fatôres etiológicos de esterilidade conjugal nos hospitais universitários de Campinas, " *Revista Brasileira de Ginecologia e Obstetricia,* 18:29-36.

consequences owing to the lack of sexual education, contraception, and illegal abortions? It seems that if we want to respond to the real issues of developing countries, these bioethical problems should be clearly addressed and disseminated. It means protecting the life and physical and psychological health of women and children.

A second issue is health care systems in developing countries and the lack of access to them. Note that forty-two percent of deaths at all ages in developing countries are potentially avoidable (communicable diseases, maternal and perinatal conditions, and nutritional deficiencies). Note that, in contrast, in industrialized nations this is the case of only 6% of deaths. This is another problem that has to be clearly addressed. Both above mentioned issues, reproductive rights and access to health care are deeply related with human rights instruments and should be specified and endorsed in a universal declaration.

Finally, let me consider some doubts related to universal norms in bioethics. How can a universal instrument be achieved when there are so many conflicting positions and regulations. Are we to set limits on existing institutional and regulatory frameworks?

Different rational people, as well as different societies, may have quite different views regarding the same controversial topics. For example, take Europe, a region with a shared Western tradition, history, bonds and interrelationships. Consider the differences in policy and the acceptance of certain practices. While in the Netherlands and Belgium there is a tolerance, acceptance, and regulation of euthanasia; it is not accepted in the UK, France, or Italy and people that perform this practice face criminal proceedings. On the other hand, if we consider the situation of embryo research, we find a similar divide but with different associates. While France, Italy, the Netherlands, and Belgium do not accept this kind of research, the UK accepts and regulates it. Research in therapeutic cloning can be conducted until the 14th day of the embryo.

Are there more ethical people in one country than in the other? Clearly not. So, how can we establish norms when such antagonistic positions exist?

Even if we are considering different countries with particular idiosyncrasies, note that we are considering a region with a common tradition. What about the world and its vast diversity: Africa, Asia…very different cultures indeed!

Decent people disagree…how are to find specific guidelines? If we want to pursue this path, only abstract and general principles and norms can be drafted….but these might be too vague, ambiguous, and useless. If we want to issue a truly universal instrument, we will have to pay close attention to the needs we are addressing and not overlook the simple but essential problems that developing countries face.

COMITES NATIONAUX DE BIOETHIQUE ET INSTITUTIONS SIMILAIRES

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NATIONAL BIOETHICS COMMITTEES AND SIMILAR BODIES

COMITE NATIONALE DE BIOETHIQUE
CONSEIL DA LA POLITIQUE DES SCIENCES ET DE LA TECHNOLOGIE (JAPON)

Contributions pour une déclaration universelles de bioéthique

Comité national de bioéthique, Japon
(Ryuichi IDA, membre)

Le Comité nationale de bioéthique du Japon a l'honneur d'être invite à présenter ses contributions écrites sur une future déclaration universelle de bioéthique, et voudarais en remercier le C.I.B. et ses membres .

Les observations ci-dessous exprimées ne reflètent cependant pas nécessairement les opinions communes et concertées de tous les membres du Comité. Le Comité a conféré au Professur Ryuichi IDA, member et ex-Vice-Président, les soins d'examiner à fond le questionnaire présenté de la part du CIB., en tenant compte du contexte scientifique, culturel, spirituel, juridique et social actuel du débat bioéthique surtout au Japon et en Asie.

I. Objectifs et portée d'une future declaration:

1. Nature du travail du CIB et nature de l'instrument

L'idée de bioéthique, voire même le système de valeur humaine, se varie d'un pays à l'aitre, d'une civilization à l'autre, ou d'une communauté à l'autre. Un instrument de bioéthique ayant un caractère universel devrait être rédigé aur la base de diversité culturelle, étant donné que la bioéthique suppose le système de valeur sur la personne humaine et sur la vie humaine propre à chaque Etat ou à chaque communauté. Il en résulte qu'une tell déclaration aura de nature d'instrument de principes qui servirait comme un cadre fondamental universel en matière de bioéthique, et ne devrait pas entrer torp dans le détail. Une telle mesure permettrait les Etats de discuter dans leurs seins les normes éthiques applicables à chacun des contextes nationaux de recherche ou de pratique clinique, ou de compréhension de la science de la part de la population.

Il serait donc opportun pour le CIB, d'une part, de confirmer les principes existents généraux et communs à toutes les branches de bioéthique ainsi que ceux de spécifiques de chaque branche. Cependant, il ne fut pas oublier le fait que la rapidité des avancements de la science et de la technologie de la vie est telle que de nouvelles reflexions éthiques sont toujours nécessaires. Le CIB en prendra en compte pour établir nouveaux principes de bioéthiques adaptés aux nouvelles étapes de la science de la vie. En un mot, Le CIB dans son travail actuel de rédaction devrait accomplir à la fois la codification des principes existants et le développement progressif des conceptions bioéthiques.

2. Destinataires de la déclaration

La bioéthique est comme ses premiers destinataires les personnes directement intéressées, c'est-à-dire, d'une part, les chercheurs, les médecins et ceux qui sont impliqués dans la recherche et ses applications, voire la communauté scientifiques et médicale, et, d'autre part, les participants dans la recherches et les patients et leurs familles et relatives. C'est ainsi que les normes bioéthiques servent à permettre la science et la technologie de la vie s'avancer de façon appropriée et acceptée par la communauté pour le bien-être humain des générations présente et futures.

La déclaration devrait également destinée aux décideurs qui encadrent en même temps le développement scientifique et technologique et le respect à et la protection de la valeur fondamentale de la communauté donnée concernant l'existence et la vie de l'humanité et de chaque individu.

Les principes bioéthiques proclamés dans une future déclaration s'adressent également à tous les autres membres de la communauté donnée, voire même à toutes les personnes humaines sur notre Terre. Car, premièrement, les résultats de la recherché scientifico-médicale sont appliqués faite aux fins de prévention, diagnostique et de traitement médicaux et pharmaçeutiques, et que, deuxièmement, la valeur fondamentale dans cette communauté est souvent mise en enjeux face aux progrès scientifique.

La déclaration devrait aussi avoir comme destinataire le média. Puisque le public en general n'a pas suffisamment de connaissance ni de critère d'appréciation sur les implications éthique, juridique et sociale des avancées bio-scientifiques, le rôle du média dans l'éducation et la dissemination des normes bioéthiques universelles est aussi essentiel que de l'information du développement scientifique et l'utilisation industrielle des résultats de recherches. Le média est aisni doté du rôle à la fois de promoteur de la science et de protecteur du public. La future déclaration de l'UNESCO servirait comme document important de réference pour ce rôle.

En un mot, la déclaration devrait être omni-présente, soit pour l'appréciation éthique des activités scientifiques tel que dans le cadre de comité d'éthique, soit pour nous assurer de notre conduite en tant que scientifique, participants ou familles, le média ou ceux de tout autre statut, soit pour vérifier les conséquences ultérieures.

3. Portée de la déclaration

La déclaration devrait se limiter pour le moment à l'être humain, vu du temps imprégnié à sa rédaction, et des sujets intéressés par le Comité. Il est certain que la bioéthique dans un sens large couvre tous les êtres vivants, humains ou non-humains, puisque le terme « bio- » signifie la vie. Cependant, le problématique actuel consiste en la protection des personnes humaines face au progrès scientifique et technique concernant l'être humain et ses applications médicales, tel que la science génomique, la transplantation d'organes, la médicine regénérative, etc..

Il est à noter que se posent un certain nombre de questions lié à la vie des personnes humaines. Il s'agit surtout des organismes génétiquement modifiés (OGMs) et de la xéno-transplantation. Si les premiers sont relatifs en pasrticulier aux alimentations et à l'environnement écologiques, qui ne touchent qu'indirectement au corps humain, la seconde est un substistut ou un moyen temporaire des organes humains. Certains affirment que ces deux questions auraient le même poids que les autres questions qui touchent à l'être humain. L'on ferait remarquer ici que l'élément éthique central de ces deux hypothèses est la sécurité biologique ou médicale. Pour le premier, si la sécurité de consommation et d'utilisation des OGMs est garantie, les autres qustions relatives aux alimentations semblent moins compliqués. Par contre, l'on n'ignore nullement la gravité de l'implication de l'introduction dans la nature des OGMs sur la vie humaine quotidiennes, sur les situations agronomique et industrielles, voire économiques, entre autres. Dans cette hypothèse, d'autres considérations entrent en ligne. Il n'est pas apprprié pour le moment que le CIB prenne en considération les OGMs dans la déclaration. D'autres instances telle que le PNUE ou l'ONU conviendraient plus, compte tenu de l'étendu très vaste du sujet.

Pour la seconde, la sécurité hygiénique et médicale devrrait être assurée à légard des risques inconnus relevant surtout des nouvelles infections virales ou microbiennes. Les considérations bioéthiques restantes se diffèrent peu de celles de la transplantation entre des personnes humaines.

Cela étant entendu, l'UNESCO et son CIB aurait parfaitement raison de tenir en compte dans son project de déclaration les principes pertinents à ces deux sujets, tel que le principe de précaution, celui de sureté biologique et environnemental, celui de sureté médicale ou infectieuse.

II. Structure et contenu de la déclaration

1. Structure de la déclaration

La déclaration en tant qu'instrument universel proclamant les principes et les normes de bioéthiques générale aura, dans la mesude de possible, la forme quasi-conventionnelle, c'est-à-dire, composition en différents chapitres ou sections et en articles, ayant un préambule, et avec une section de dispositions générales ainsi que celle de terminologie. En outre, devrait s'ajouter comme annexe une Note explicative détaillé présentatnt la clarification interprétative de chaque article avec l'explication du contexte et du processus de rédaction de la déclaratuion.

Le nom de la déclaration seraiit préférablement la « Déclaration universelle de la bioéthique », étant donné qu'elle sera le premier instrument à l'echelle globale et à la portée générale des normes bioéthique dans son ensemble. Du fait que, comme nous avons vu au début de ces pages, les normes et les principes énoncés dans la déclaration aura comme destinataire chacun des membres de la communauté humaine, que ce soit scientifiques, participants, familles, le public ou le média, la déclaration portera dans son titre l'adjectif « universelle ». Nous avons déjà comme modèle « La Déclaration universelle sur le génome humain et les droits de l'homme » : elle a son application au niveau, non seulement de l'Etat, mais surtout de chaque personne,

L'on proposerait une structure possible de la déclaration dans l'Annexe de ces pages. Les chapitres sont présenté en ordre « chronologique » de la vie humaine, et les sections montrent les domaines concernés. Ceci n'est qu'une tentative, et le CIB a toute la liberté d'appréciation.

2. Contenu de la déclaration

La déclaration devrait comprendre à la fois les principes généraux et les principes et les normes spécifiques dans chaque domaine à traiter.

En ce qui concerne les principes genéraux, unc ertain nombre de principes fondamentaux de bioéthique sont déjà suffisament manifestés dans beaucoup d'instances internationales, nationales ou locales. Ce sont notamment (ordre alphabétique): autonomie, bienfaisance, confidentialité, consentement libre et éclairé, dignité humaine, droit à la vie privée, droit au bonheur, droits de l'homme, équité, justice, liberte de recherche, malfaisance, non-commercialisation du corps humain, partage des intérêts, respect au corps humain, solidarité, etc.. La déclaration inscrira ces principes le plus largement possible, puisque ces principes ont leurs bases académiques, pratiques, culturelle ou traditionnelles

Cependant, nous devrions pas se contenter d'énumérer ces principes. Ces concepts ont souvent leurs connotations propres à la civilisation et aux pensées occidentales. Puisque nous sommes dans un monde de diversité de culture et de valeur, le CIB doit avoir la prudence de

vérifier la validité de ces principes dans l'ensemble des communautés du monde. Ainsi, les relations entre l'autonomie et la valeur commune d'une communauté donnée peuvent être différentes selon des civilisation ou des modes de vie. L'inséparabilité du corps et de l'esprit est une notion important propre à de certaines communautés, y compris le Japon, où la transplantation d'organe du cadavre se trouve en difficulté. L'idée du sacrifice volontaire pour les intérêts de l'autrui pourrait servir l'appui pour l'avancement d'approvisionnement des organes à greffer ou des matériaux humains pour la recherches ou traitements médicaux. Autres examples sont la notion de l'incarnation et la valeur de la divinité, dont il n'est plus place ici de développer.

Il ne faudrait pas ignorer d'autre éléments sociaux à tenir compte. Un des points difficiles est l'utilisation des termes souvent concus acquis, tel que la dignité humaine. La dignité humaine est un concept apparemment né dans la civilisation occidentale et devenu comme terme universel. Cependant, même pour les occidentaux il est particulièrement difficile de définir ce concept. Aussi bien ce terme n'est-il pas facilement compris ni accepté dans les populations non-occidentales. Par conséquent, il existe une sorte d'inconfort ou d'hésitation d'utiliser ce terme dans le langauage normatif dans certaines communautés étatique. Un example qui nous concerne est la discussion sur la notion de la dignité humaine au moment de la législation de la prohibition du clonage reproductif human. Il s'est avéré pour le public japonais la difficulté de comprendre la valeur de ce terme, puisque ce terme ne se trouvait pas dans leur langage ordinaire. Cela ne signifie nullement que la population japonaise ne respecte pas la valeur du processus dela naissance de la vie humaine ou l'individualité d'une personne humaine.

Il est dinc à noter que la compréhension et l'application de certains concepts ne soient toujours aisément assurées. Cela ne veut pas dire que le CIB n'est pas autorisé de retenir ces conceptes et ces termes fondamentaux. Le CIB, dans leur travail de rédaction, tentera de clarifier autant que possible la définition et la signification des termes qui sont généralement considérés comme acquis et acceptés.

Il y a également des concepts sur lesquels de différentes communautés donnent de différentes valeurs suivant la tradition ou la mode de vie. Tels sont, par example, les consentements individuel, de la famille, ou celui de la communauté, les relations médecins-patients, la valeur de la liberté individuelle et celle de la communauté donnée. Que l'on n'oublie pas la diversité de conception et de valeur que chaque spiritualité reconnaît à la vie humaine, à l'existence humaine ou au commencement ou à la fin de la vie, ou encore, aux modes de la vie et de la mort. Toutes ces différences pèsent sur le travail du CIB pour la rédaction. Néanmoins, le CIB est un organe doté de l'universalité dans sa composition et dans son objectif pour qu'il soit capable, nous tous l'admet et en aommes fiers, d' accomplir cette tâche lourde.

3. Mise en oeuvre de la déclaration

La déclaration elle-même ne pourrait être un instrument de l'application directe sur place de recherche ou de traitement médical. La déclaration présente les normes universelles de bioéthique qui servent d'un cadre de base sur lequel chaque Etat ou chaque communauté ou encore chaque institution devrait examiner et discuter par eux-mêmes, afin d'établir les codes éthiques applicables dans chaque instance appropriée suivant leurs propres systèmes de valeurs concernant la vie humaine, tant dans l'organe législatif, tant dans le comité national de bioéthique ou les comités locaux, tant dans l'administration nationale ou locale, tant dans les institutions de recherche ou dans les hôpitaux, ou dans les entreprises médico-pharmaceutiques, ou encore dans le media ou dans l'education à la bioéthique, ou même dans la famille. La responsabilité de l'application sur place devrait être conférée à tous ceux qui sont concernés dans la recherche et ses applications à chaque niveau.

Les normes bioéthiques ne sont pas forcément en forme de droit ou d'instrument législatif. Elles pourraient être soit en forme législative, soit en forme de directives ou des règles ministrérielles contraignantes ou non-contraignantes, soit en forme d'auto-régulation professionnelle, ou bien en toute autre forme possible si la communauté donnée décide ainsi. Il est à noter, toutefois, que l'application effective des normes bioéthiques que l'UNESCO va codifier dans sa prochaine déclaration dépend, surtout et avant tout, de la compréhension et la réflexion sincère sur la valeur de la vie humaine et des considérations bioéthiques non seulement par les intéressés mais aussi par le public dans son ensemble. C'est ainsi que le rôle de l'éducation à la bioéthique a le ploids le plus lord dans la dissemination et l'application dee principes et des normes bioéthiques universelles. Le CIB devrait le promouvoir dans la déclaration.

CONCLUSION

Nous sommes dans l'ère de post-séquencage du génome humain, où, selon certains, la médecine sur mesure, ou personalisée est toute proche. Il est d'autant plus nécessaire que l'humanité et chaque personne humaine devrait réfléchir la valeur de la vie humaine et le respect à l'existence de l'humanité. Car la science et la technologie est avec nous et pour nous lorsque nous sommes conscient de la valeur de l'homme et des avancements scientifiques. Dans le cas contarire, nous serions en proie de la science. Nous félicitons le travail inlassable du CIB depuis sa création et encourageons le CIB dans son chemin vers la bioéthique universelle.

Annexe

Proposition sur la structure de la « Déclaration universelle de la bioéthique »

Préambule

Chapitre 1er : Dispositions générales

- Section 1 : Portée de la déclaration
  - Objets et buts; Portée d'application; Terminologie utilisée
- Section 2 : Principes généraux de bioéthique

Chapitre 2 : Application médicale de la science et de la technologie de la vie

- Section 3 : Début de la Vie
  - Technologie de reproduction assistée ;
  - Diagnostic prénatal, y compris Diagnostic pré-implantatoire
  - Interruption volontaire de grossesse
- Section 4 : Soins médicaux et de la santé
  - Sous-Setion 1 : Soins médicaux généraux
    - Accès aux soins médicaux
    - Accès aux médicaments
    - Interventions chirurgicales
  - Sous-Section 2 : Soins médicaux spécialisés
    - Transplantation d'organes et de tissus
    - VIH/SIDA
    - Maladies infectieuses (SRAS et autres)
    - Maladies psychiques
  - Sous-Section 3 : Soins médicaus d'application génétique et de biologie moléculaire
    - Test et diagnostic génétiques
    - Thérapie génique

Conseil génétique
Médecine regénerative
Sous-Section 4 : Système de prévention de la maladie et Santé publique
Dépistage médical de la santé
Assistance médicale ou sociale
Formation des professions médicales et co-médicales

Chapitre 3 : Fin de la vie
Conception de la mort ; prolongement de la vie ; Euthanasie ;
Soins palliatifs

Chapitre 4 : Recherche scientifique et technologique de la vie
Section 1 : Recherche sur les sujets humains
Recherche clinique et traitement d'expérimentation; Recherche translationelle ; Recherche épidémiologique ; Recherche sur le comportement
Section 2 : Recherche utilisant des matériaux humains (autre que l'embryon)
Collection des tissus et des cellules; Traitement ; Conservation ; Accès ; Utilisation ; Banque de tissus et de cellules
Section 3 : Recherche sur l'embryon humain
Recherche sur la reproduction naturelle ; Recherche sur la technique de reproduction assistée ; Technologie de clonage ou d'autre sorte d'intervention sur les gamètes

Section 4 : Recherche génétique
Séquencage génomique; Données génétiques personnelles et collectives ; Banque de données génétiques, Génétique de population ; Génétique de comportements

Chapitre 5 : Coopération internationale
Recherche internationale et transnationale ; Développement de la capacité scientfique et tehcnologique de la vie ; Co-opération internationale des soins médicaux ;

Chapitre 6 : Mise en oeuvre de la déclaration et dispositions finales
Dissemination ; Système national de bioéthique ; Comité d'éthique ;
Education et formation à la bioéthique ; Rôle du média ; Dispositions finales

COMMENTS ON THE ELABORATION OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

Prepared:

For the Health Research Council Ethics Committee ("HRCEC"), New Zealand

With the purpose of submission to the International Bioethics Committee of UNESCO

By Prof Sylvia Rumball*, Bruce Scoggins**, and Richman Wee***

* ONZM PhD, HRCEC Member
** PhD, HRC Chief Executive
*** LLM, HRC Policy Advisor

1. The Health Research Council Ethics Committee ("HRCEC") is a statutory committee of the Health Research Council of New Zealand. For more information, refer to the Health Research Council Act 1990, particularly sections 25 – 26 at www.legislation.govt.nz and see generally www.hrc.govt.nz/ethics.

2. We welcome the International Bioethics Committee's initiative on the elaboration of a Declaration on Universal Norms on Bioethics which has our support in principle. Further support would be dependent on the final form and substance of the declaration.

3. Our comments that follow below are provided under the following headings:

   - General Comments
   - Aims and Scope of a Declaration on Universal Norms on Bioethics
   - Structure and Content of such a Declaration

GENERAL COMMENTS

4. Bioethics is not about narrow-mindedly pursuing and determining a single, correct ethical stance. Ethical dilemmas involve situations where a choice needs to be made between different courses of action. The choice that needs to be exercised is made more difficult where individual, professional and societal value systems differ and have to be taken into account yet at the same time the dignity of and respect for the people involved must be maintained. A statement or declaration on norms of bioethics would assist the resolution of ethical dilemmas by providing principles that would inform the ethical analysis of the situations involved.

5. When confronted with new knowledge and the discovery of new technologies, we need to consider how to make choices, how to act on them well for humane ends, and how to live with others in a way that encourages further pursuit of new knowledge and technologies. We will need encouragement and guidance to understand the particular context and features of the ethical dilemmas which will emerge from scientific and technological progress so that eventually consensual agreements can be reached which take into account diverse needs and views.

6. We conceive a Declaration on Universal Norms of Bioethics as a document that serves as a moral lighthouse which will guide the search for solutions to ethical dilemmas that allow for social justice and progress among communities.

AIMS AND SCOPE OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

7. A Declaration on Universal Norms on Bioethics which is formulated as basic and foundational for the continuing development of bioethics would be equivalent, in significance and status, to the Universal Declaration of Human Rights 1948 which has been responsible for the promotion of human rights law within member States.

8. A Declaration on Universal Norms on Bioethics ("the Declaration"), carefully formulated and articulated, would contribute to the development and strengthening of the international bioethical infrastructure and in so doing would contribute to the promotion of technological achievement compatible with greater social understanding, harmony, and progress.

9. The Declaration should focus on the enhancement of human relationships. In New Zealand, there is a *whakatauki* (i.e. proverb) that is central to being Maori which states:

> He aha te mea nui te Ao?
> He tangata, he tangata, he tangata.

We understand this translates to:

> What is the most important thing in the world?
> It is people, it is people, it is people.

10. The Declaration should also make reference to the relationship between humans and other species of life, and the environment.

11. With regard to paragraph 10, the extent or scope of the language drafted should be general but sufficiently enabling to allow for subsequent statements or declarations of greater specificity to be proposed and formulated.

STRUCTURE AND CONTENT OF SUCH A DECLARATION

12. It is our view that the Declaration should be similar in form to, and not exceed in size, previous declarations made by the International Bioethics Committee, i.e. the Declaration on Human Genome and Human Rights, and the International Declaration on Human Genetic Data. Hence, the Declaration should contain a preamble and a comparable number of sections.

13. With regard to the content of the sections, careful thought should be given so as to ensure that the Declaration does not become diffuse as a result of long or exhaustive references. The six specific areas mentioned (health care, scientific research, public consultation, international cooperation, education and awareness-raising, promotion and implementation) are acceptable. We do not have others to add presently but are open to suggestions. We note that the approach suggested by paragraph 11 (see above) is applicable here also in that the relevant articles should be general but sufficiently enabling to allow for subsequent statements or declarations of greater specificity to be proposed and formulated.

14. Similar considerations apply to the articulation of fundamental principles that should be reaffirmed; the temptation to be exhaustive should be resisted, yet the generally known and frequently invoked principles should be stated. We support the inclusion of the ten fundamental principles proposed (i.e. autonomy, benefit sharing, confidentiality, freedom of research, free and informed consent, justice, non-discrimination, respect for human dignity, respect for privacy, solidarity) and take the view that, for emphasis, they be stated as general principles of broad application.

15. Nevertheless, even when drafted in terms of broad application, it may be helpful to reinforce the general principles by reference to some context, for example,

- free and informed consent *in research*,
- respect for human dignity *in therapeutic contexts*,
- benefit sharing *in accessing new technologies and innovations*,
- justice *in closing disparities and inequalities*.

Again, the approach suggested in paragraph 11 (see above) would be applicable here.

16. On the question of guidance on specific subject areas, we feel it would be useful to elaborate on a small number of areas but we suggest that a sense of balance and proportion should be kept within the overall structure and content of the Declaration. The rationale underlying our view that guidance be given for a small number of areas is based on our thinking that it is vital for the proposed Declaration to have widespread support right from the outset. Identifying and elaborating particular subject areas for which ethical standards already attract strong support, for example in scientific research, would help ensure endorsement of the Declaration and hence provide the opportunity for building consensus in other challenging areas in the future.

KOREAN BIOETHICS ASSOCIATION (KBA)

UNESCO IBC "Towards a Declaration on Universal Norms on Bioethics"
(UNESCO House, Paris 27 - 29 April 2004)

The Korean Bioethics Association has mission to study philosophical, ethical, legal, social, economic, medical, environmental, religious and anthropological problems arising when trying to apply the biomedical technologies to human beings and the biosphere. It also tries to put the result of these considerations into practice.

Founded in February 1998
Membership: 165 (Philosophy, Medicine, Law, Sociology, Biology, Education, NGO etc.)
President: Professor SONG Sang-yong, Distinguished Professor of Philosophy,
Hanyang University
Website: http://www.koreabioethics.net/

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vol.4 no.1(June 2003), vol.4 no. 2(December, 2003)

Activities: Annual Meeting on Bioethics, September 1998
Participation in IAB4, November 1998
Participation in ABA3, November 1998
The KBA Declaration on Cloning*, March 1999
Annual Meeting on Biotechnology, May 1999
Biannual Meeting on Cloning, June 2000
Biannual Meeting on Physicians' Strike, November 2000
KBA Session in the 13th Korean Philosophers Congress, November 2000
Annual Meeting on Issues in Bioethics, May 2001
KBA-Toji Foundation Joint Seminar Series on Bioethics, Summer 2001
Annual Meeting on Bioethics and Stem Cell Research, May 2002
Participation in IV Asian Conference of Bioethics, November 2002
Workshop for Journalists, June 2003
Workshop for Congressmen, July 2003
Annual Meeting on Organ Transplantation, September 2003
Participation in the 5th Asian Bioethics Conference, February 2004
Ad-hoc Committee on Embryonic Stem Cell Research Ethics, March 2004*
Annual Meeting on the Bioethics and Biosafety Act, May 2004 (scheduled)

Appendix 1

1999 Bioethics Declaration on Cloning

March 28, 1999

The Korean Bioethics Association (KBA)

The cloning technology may be a useful tool for the promotion of well-being of humankind. However, it may also cause serious ethical problems. KBA invited experts and had a series of comprehensive discussions on these problems. As a result, we reached a consensus and express our opinions. We would like this to be taken into consideration in the ongoing process of revising the Act for the Promotion of Biotechnology.

1. We oppose to all research activities that intend to clone any human individual.

2. We demand a Bioethics Committee to be established under the direct control of the President of Korea, which will review and supervise all the matters concerning biotechnology.

3. We propose to establish a professional research institute that will work on the ethical, legal and social problems having to do with biotechnology.

Appendix 2

Letter to the Editor of *Science*

March 26, 2004

Last February, a group of Korean scientists led by Dr. Hwang and Dr. Moon surprised the world by establishing a human embryonic stem cell line (SCNT hES-1) derived from a cloned blastocyst.[1] This is the first case showing potential success in human "therapeutic cloning", and therefore it captured the attention of the world media. In response to the announcement, many people and groups raised questions about the ethical and social environment of Korea, with regard to such advanced researches done in the biotechnology field.

The Korean National Assembly passed the <Biosafety and Bioethics Act> in December 2003. According to the Act, human individual cloning and other experiments such as fusion of human and animal embryos are strictly banned.[2] However, "therapeutic cloning" is permitted in very limited cases for the cure of serious diseases after a review of the National Bioethics Committee (NBC).[3] Every researcher and research institution attempting such research should be registered to the responsible governmental agency.[4] Since the Act will take into effect in early 2005, the research done by Dr. Hwang ducked out without any legal control/restriction and was unnoticed by the public.

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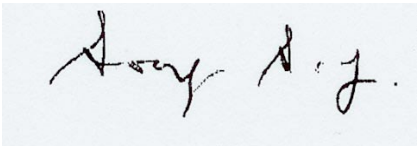
[1]. WS HWANG, YJ RYU, JH PARK et al., Evidence of a human embryonic stem cell line derived from a cloned blastocyst, Science Express, 12 Feb. 2004, 1094515.
[2]. Biosafety and Bioethics Act, Articles 11, 12.
[3]. Ibid., Article 22.
[4]. Ibid., Article 23.

The Korean Bioethics Association (http://www.koreabioethics.net/), a leading bioethics group in Korea, consisting of bioethicists, philosophers, jurists and scientists, announced "The Seoul Declaration on Human Cloning"[5] in 1999 demanding the ban of human reproductive cloning and the study of socio-ethical implication of cloning research. Many NGOs and religious groups in Korea agreed with and supported the declaration.

We regret that Dr. Hwang and Dr. Moon did not take the social consensus into account although they were fully aware of it. Moreover, Dr. Hwang is Chairperson of the Bioethics Committee of the Korean Society for Molecular Biology and Dr. Moon is President of the Stem Cell Research Center of Korea, and a member of its Ethics Committee as well. They argue that their research protocol was approved by an IRB. However, we are not convinced that this controversial research could be done only with one single IRB's approval. We believe that they should have waited until social consensus builds up, or the NBC's decision is made.

We Koreans are working to prepare the regulations and guidelines, as well as review systems for biotechnology research in keeping with global standards.[6] For example, major research projects funded by the government have their own ethics committee. We hope that there will be no more ethically dubious research reports generated by Korean scientists.

Sang-yong Song
President
The Korean Bioethics Association



Appendix 3

Vol. 1 No. 1 of the *Journal of the Korean Bioethics Association*

June, 2000

Foreword:

- PARK Ynhui/ The Ethical Challenge of Bioengineering and the Role of Bioethics

Special Issue: Cloning

- KU In-Hoe/ Ethical Issues on the Cloning of Human Beings
- JUNG Kyu Won/ A Legal Discussion on Human Embryonic Cell Cloning by Somatic Cell Nuclear Transfer Technique
- PARK Byung Sang/ Debates on Animal Cloning: from Amphibian to Mammalian

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[5]. The Korean Bioethics Association, "The Seoul Declaration on Human Cloning", *Journal of the Korean Bioethics Association* 2000, 1(1): 195.
[6]. Korean Association of Institutional Review Boards, Guidelines for IRB Management, 10 Feb. 2003.

General Articles:

- KIM Sangdeug and SOHN Myong-Sei/ Euthanasia: Its Definition, Classification and Ethical Justification
- KANG Mi-Jung/ An Ethical Review of Gene Therapy
- PARK Un-Jong/ Research Ethics and Policy Involving Vulnerable Subjects and Human Body Components
- CHOI Kyunghee and CHO Hee-hyung/ A Model and Strategies for Teaching/Learning of Ethical Aspect of Sciences

Invited Lectures:

- Kenzo Hamano/ Insufficient Response to Mammalian Cloning in Japan
- Kenzo Hamano/ Fundamental Problems in Organ Transplantation from Brain Dead Persons in Japan
- Frederick B. Churchill/ Shifting the Boundaries of Moral Behavior: The Case of Alfred Kinsey

Appendix:

- The Belmont Report
- 1999 Bioethics Declaration on Cloning
- Short History of the Korean Bioethics Association
- Constitution of the Korean Bioethics Association

Vol. 1 No. 2 of the *Journal of the Korean Bioethics Association*

December, 2000

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- CHO Byong-Hee/ Conflicts between Civil Society and Medical Doctors Shown in the Doctors' Strike
- YI Sang-Don/ Legal Implications of the Doctors' Strike
- KANG Shinik/ The Physicians' Autonomy and Responsibilities

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- PARK Sang-Eun/ Is Doctors' Strike Morally Permissible?
- PARK Hee-Joo/ Eugenics and New Genetics
- KIM Mi Ju/ Analysis of Nursing Research on Ethics Conducted in Korea

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General Articles:

- CHIN Kyo-Hun/ The Relationship between Medical Anthropology and Psychoanalysis
- KIM Sea-jeong/ Mutual Aid between Eco-philosophy and Han-mom Philosophy
- NAM Hyun/ An analysis of the Bioethics Contents in the High School Ethics Text Book
- CHOI Kyunghee & CHO Hee-hyung/ The Perceptions of Secondary School Students Regarding Ethical Themes in Science

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- CHIN Kyo-Hun/ What does a Life mean?
- CHO Kyu-Man/ The view of Life in the catholic theology
- HUH Ra-Keum/ "life", view from feminist perspective
- KIM Hwan-Suk/ Research Ethics in the Era of Science and Technology: Focusing on Biotechnology Area
- PARK Yong-Ha/ Policy Assessment of Natural Ecosystem and Biodiversity Conservation of Korea
- CHOI Kyunghee & CHO Hee-hyung/ The Educational Investigation on the Ethical Characteristics of Biotechnology - Focusing on STS approach -

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General Articles:

- KIM Sang-Deuk/ A Study on an Ethical Relationship between Nurse and Physician
- Jung Kyu-Won/ Legal Issues in Human Genome Research
- PARK Hee-Joo/ Cloning Controversies in S. Korea
- John Michael McGuire/ An analysis of the British and American policies on human cloning: What are the lessons for Korea

Special Issue: Biotechnology and Ecological Environment

- Seo Hyoung-Won/ from exploitative development to alternative development of human & natural commune
- Cho Wan-Hyoung/ problems and correspondent solutions of Genetically Modified Crops
- Han Jae-Kak/ Ethics of clinical study

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- KANG Shin-ik/ The Body seen from East Asian and Western Medical Perspectives
- KANG Mi-Jung/ A Critique on the causes of the development of Genetic Engineering - Focusing on the modern world view and value system.
- Choi Jongduck/ On the Biological Identity - A Immunological Warning against Stem Cell Research -
- HONG Suk-Young/ A Study of the Person Status of the Human Embryo
- KOO Young-Mo/ To What Extent Is Growth Hormone Therapy Morally Acceptable?

A Memoir:

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COMITE NATIONAL D'ETHIQUE MEDICALE (TUNISIE)

Contribution du Comité nationale d'éthique médicale de Tunisie sur la portée et la structure d'une déclaration relative à des normes universelles en matière de bioéthique

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1. Objectif et portée d'une déclaration relative à des normes nouvelles en matière de bioéthique

La nécessité de **telle déclaration** s'impose d'elle-même. En effet, comme l'a souligné la Conférence Générale à l'occasion de sa 32ème session en octobre 2003, il devient : « opportun et souhaitable *de définir les normes universelles en matière de bioéthique dans le respect de la dignité humaine et des droits des libertés de la personne humaine dans l'esprit du pluralisme culturel et bioéthique* » et a invité le Directeur Général « à poursuivre la préparation d'une déclaration relative à des normes universelles en matière de bioéthique ».

Sans aucun doute, **cette déclaration** *contribuera à une meilleure prise de conscience des enjeux éthiques des progrès scientifiques et de leurs applications* aussi bien par les décideurs que par la communauté scientifique, les cercles académiques, les médias et la société civile de tous les pays.

Etant la seule organisation internationale du système des Nations Unies, investie d'un mandat éthique, l'UNESCO et singulièrement son Comité International de Bioéthique (CIB), il devient impératif pour tous les pays de disposer d'un texte à caractère universel sur la bioéthique servant de référence aux Etats pour légiférer à seule fin de protéger la dignité humaine et les droits fondamentaux de l'homme.

De par le monde, les sociétés sont au quotidien très fortement interpellées par les questions de « bioéthique ». Il n'est pas de jour où les médias ne s'en fassent pas l'écho. Hier, la question des organismes génétiquement modifiés (OGM), le problème du clonage de la brebis « Dolly » pour ne citer que ces deux exemples. Aujourd'hui l'annonce par le gynécologue italien Severino ANTINORI de la naissance du premier bébé cloné — même si elle ne s'est jamais vérifiée — relance la polémique en Italie et ailleurs où le clonage à visée reproductive est strictement interdit et certaines dérives dans l'exploitation des données génétiques humaines par les firmes pharmaceutiques et également leur utilisation abusive dans le domaine de la médecine prédictive sont dénoncées. Demain les « nanotechnologies » pourraient être utilisées dans le domaine des technologies du **vivant**. Leurs applications seraient larges et à certains égards … fantasmogoriques. Les « *nano-*

robots » seraient appelés à naviguer librement dans notre système sanguin avec pour mission de maintenir en vie et en bonne santé le corps humain en le protégeant contre les défaillances et les maladies grâce à l'administration, suivant des protocoles d'une précision et d'une efficacité jamais atteinte, de médicaments appropriés, en lui fournissant les éléments nutritifs et l'oxygène dont il a besoin et en le débarrassant des rejets qui l'encombrent avec au bout, l'immortalité garantie !!!

Si les remarquables découvertes dans le domaine du vivant suscitent des espérances, elles ont quelquefois des implications éthiques qui appellent des choix tant au niveau des décideurs qu'au niveau des chercheurs, des praticiens et de la société.

La bioéthique doit alors s'adapter à des situations pour accompagner les recherches scientifiques, anticipe les risques de dérapage, les dévoiements et relever les défis posés par les progrès scientifiques et technologiques et ce, par **l'adoption de règles**, de **normes** qui respectent les **valeurs de l'homme**.

La déclaration relative à des **normes universelles en matière de bioéthique** doit donc contribuer à une meilleure prise de connaissance des enjeux éthiques des progrès scientifiques et de leurs applications à tous les niveaux (décideurs, communauté scientifique, médias, société,…) en suivant le même processus adopté pour les déclarations élaborées à l'occasion des travaux du CIB et adoptées par la Conférence générale de l'UNESCO telles que la : « **Déclaration Universelle sur le génome humain et les Droits de l'Homme**, la **Déclaration Internationale sur les Données Génétiques Humaines** ».

Nul doute que la participation de tous les acteurs concernés permettra d'assurer la prise en compte des diverses perceptions des enjeux éthiques et juridiques des avancées dans les sciences de la vie.

Déjà, la CIB a mené en 2001-2003 des études préliminaires sur la possibilité d'élaborer un instrument universel sur la bioéthique.

Une première étape de réflexion sur l'élaboration du projet de la Déclaration a consisté notamment en l'organisation d'une *« Table ronde des Ministres de la Science »* à l'UNESCO les 22 et 23 octobre 2001 sur « **la Bioéthique : enjeu international** ». Dans le communiqué final de la « Table ronde » les participants ont invité l'UNESCO : *« à examiner la possibilité d'élaborer, en prenant comme point de départ la Déclaration universelle sur le génome humain et les droits de l'homme, un instrument universel sur la bioéthique, en y associant les comités nationaux d'éthique et instances assimilées, en coopérant avec les gouvernements des Etats membres et les organisations internationales concernées — en premier lieu l'ONU, les institutions spécialisés du système des Nations Unies et d'autres organisations compétentes aux niveaux international et régional — et en consultant le secteur public et privé, la communauté scientifique ainsi que les représentants de la société civile »*.

Il y a lieu de rappeler qu'ayant participé à cette « Table ronde », j'ai pleinement adhéré à cette recommandation.

A sa huitième session tenue à Paris du 12 au 14 septembre 2001, le CIB a décidé d'inclure cette question dans son programme de travail et de mettre en place un groupe de travail *ad hoc*. Au cours de ses deux réunions tenues an avril 2002 et en mars 2003 le groupe de travail a étudié la possibilité d'élaborer un instrument universel sur la bioéthique et un **rapport préliminaire sur cette question a été examiné** par le CIB à ses neuvième et dixième sessions tenues successivement à Montréal du 22 au 28 novembre 2002 et à Paris du 12 au 14 mai 2003.

Ce rapport du CIB sur « la possibilité d'élaborer un instrument universel sur la bioéthique » qui peut être une « convention-cadre» élaboré à partir des discussions du groupe du travail et du CIB traite de la faisabilité d'un instrument universel sur la bioéthique dans le contexte des instruments internationaux existant en la matière et aborde ensuite certaines questions de bioéthique susceptibles d'être traitées par un tel instrument afin d'illustrer la façon dont l'élaboration dudit instrument pourrait contribuer aux efforts internationaux visant à établir les principes d'orientation éthique sur les aspects liés aux progrès scientifiques récents. Enfin, il analyse la forme et la portée du texte à envisager ainsi que son intérêt en termes d'éducation, de diffusion de l'information, de sensibilisation et de débat public et présente les conclusions et les recommandations du CIB.

Sans aucun doute, ce rapport du CIB (SHS/EST/02/CIB.9/5 [Rev.3] Paris, le 13 juin 2003) peut être un document de travail très utile aux débats de la Session extraordinaire du CIB prévue à Paris du 27 au 29 avril 2004 à la Maison de l'UNESCO.

▸ La déclaration ne doit pas se limiter à l'être humain, c'est-à-dire traiter uniquement des questions éthiques relatives à la personne humaine et au corps humain dans le contexte biologique et médical et aux questions éthiques concernant la relation de l'être humain avec les autres organismes vivants mais elle doit aborder d'autres questions telles que l'introduction dans l'agriculture et l'élevage de la *transgénèse* et des *organismes génétiquement modifiés* (OGM), la question de l'utilisation des *animaux dans la recherche biomédicale*, la question de « *la thérapie par substitution d'organes* et le recours à des *thérapies alternatives* : **la xénogreffe, la thérapie cellulaire xénogénique**, la transplantation des cellules fœtales humaines, l'utilisation des **cellules souches embryonnaires** qui marque la croissance d'une médecine regénératrice.

2. Structure et contenu d'une déclaration relative à des normes universelles en matière de bioéthique

▸ Articulation de la déclaration

▸ La Déclaration doit comporter un préambule dans lequel peuvent être rappelés — comme dans le préambule de la **Déclaration Universelle sur le génome humain et les droits de l'homme** — le préambule de l'Acte constitutif de l'UNESCO et son attachement aux *principes universels des droits de l'homme affirmés en particulier*, par la *Déclaration Universelle des droits de l'homme* du 10 décembre 1948 et tous les instruments internationaux élaborés par les Organisations internationales et ratifiés par la communauté internationale.

— La déclaration doit être structurée en **sections**. Comme le champ de la bioéthique s'est considérablement étendu, le besoin de repères éthiques universels couvrant l'ensemble des questions qui se posent dans ce domaine est de plus en plus ressenti tant par les spécialistes et les décideurs que par la société civile et la communauté internationale.

Un exemple : Traditionnellement confrontés aux problèmes déontologiques et moraux qu'accompagnent la plupart de leurs actes, les médecins sont aujourd'hui de plus en plus conscients qu'ils se doivent d'abandonner inspiration et improvisation pour répondre aux multiples questions d'éthique qui leur sont posées et que leurs décisions dans ce domaine comme dans les autres doivent relever de règles scientifiques et de normes **bioéthiques**.

Actuellement la bioéthique couvre toutes les questions d'éthique médicales. Son originalité est d'aller bien au-delà de la **déontologie** propre aux diverses pratiques professionnelles concernées. Elle implique une réflexion sur les évolutions des sociétés, voire les équilibres mondiaux induits par les développements scientifiques et technologiques.

Ainsi après des dispositions générales rappelant le domaine de la bioéthique qui traite des aspects éthiques juridiques, sociaux et culturels des sciences du vivant et des sciences médicales mais aussi des technologies qui leur sont associées, il serait souhaitable d'aborder les problèmes rencontrés dans les domaines où il importe de trouver un terrain d'entente fournissant le point de départ d'une harmonisation des positions divergentes en matière de bioéthique.

Les sections proposées peuvent être :

- **Les soins de santé**.

- **La recherche scientifique**.

- **La coopération internationale**.

- **L'éducation et la sensibilisation du public**. Dans cette section, il convient de préciser qu'il appartient aux Etats membres d'encourager l'éducation, la sensibilisation, la formation et l'enseignement relatif à la bioéthique sous toutes les formes (éducation formelle et informelle) éducation des adultes, (formation continue, formation des maîtres, …) et à tous les niveaux (enseignements primaire et secondaire, enseignement supérieur).

  En Tunisie par exemple, la bioéthique est enseignée dans les cursus de formation de base des médecins des quatre Facultés de Médecine et un **mastère spécialisé** de « Bioéthique » a été créé à la Faculté des Sciences Humaines et Sociales de Tunis.

  Il revient aux Etats de favoriser les programmes d'information et de diffusion des connaissances auprès tant de publics cibles que du grand public. Il importe que les Etats aient recours dans cette entreprise aux organisations intergouvernementales, internationales et régionales et aux organisations non gouvernementales internationales, régionales et nationales.

  Cette dimension avait d'ailleurs été fortement soulignée lors de la « Table ronde » des Ministres de la Science sur la **bioéthique**.

-**La promotion et la mise en œuvre des normes de bioéthique**.

Cette section doit souligner le devoir des Etats de s'impliquer dans la mise en œuvre de la *Déclaration*. Ces Etats membres doivent prendre des mesures appropriées afin de donner effet aux mesures énoncées de la Déclaration internationale. Il importe de souligner que l'expérience prouve que les lois et règlementations ne sont effectivement appliquées que s'ils sont appuyés par une action en matière **d'éducation**, de **formation et d'information**.

De plus, il convient que les Etats mettent toute en œuvre pour conclure des accords bilatéraux et multilatéraux afin de renforcer la capacité du pays en développement à partager les connaissances scientifiques dans tous les domaines des progrès de la science ainsi que les **savoir-faire** qui sont nécessaires et à protéger les bienfaits.

- Dans la déclaration, certains principes fondamentaux doivent être réaffirmés tels que le **consentement libre et éclairé**, l'absence de gains pécuniaires, la confidentialité, la non-discrimination, la solidarité, le respect de la dignité humaine, **l'innocuité** et **l'utilité de l'application** de la recherche entreprise.

- En réaffirmant ces principes fondamentaux, la déclaration devrait essayer, le cas échéant, de définir un cadre plus détaillé par exemple les conditions requises pour le consentement dans des cas spécifiques tels que celui des mineurs, des incapables majeurs, …

‣ Quelles que soient la structure et la portée de la déclaration, elle devrait — quand cela s'avère possible — proposée des orientations sur des sujets spécifiques tels que :

- L'accès obligatoire aux soins de santé primaires.
- L'accès aux médicaments.
- La santé publique : infection VIH, paludisme, tuberculose…
- La reproduction humaine, début et fin de la vie.
- Les données génétiques et autres données personnelles relatives aux soins de santé.
- La recherche notamment de la thématique **recherche internationale et transnationale**.
- Les politiques relatives aux personnes vulnérables.
- Les usages potentiels dont la révolution *nanotechnologique* **est porteuse dans le domaine des technologies du vivant**.

THE EGYPTIAN NATIONAL COMMITTEE FOR BIOETHICS

Introduction

The main concepts of the Egyptian National Bioethics Committee (NBC) are basically concerned with scientific, technological, legal, economic, moral and above all religious principles.

The religious principles in Egypt roots back to the teachings of Abraham the father of the three heavenly prescribed religions, Judaism, Christianity and Islam, that descended sequentially as the Unitarian belief.

These teachings abide with the principles of truth, love, compassion, justice, equity, dignity, human and health rights.

Egypt specifically entertained ethical basic principles since the early pharaonic civilization, thousands of years ago.

Major objectives:

- Functioning as the National counterpart to the UNESCO International Bioethics Committee (IBC)
- Harmonization of national policies on the bioethics issues related to promotion of life sciences and their applications.
- Undertaking studies and extending advices to decision makers on the bioethical measures to be taken on the national level, in order to ensure full respect to human rights in undertaking scientific research in life sciences and their technological applications.
- Establishing close cooperation with concerned sectorial bodies including: the National Biosafety Committee headed by H.E. Deputy Prime Minister, Minister of Agriculture and Land Reclamation, Committee of Ethics in Medical Profession, concerned non-governmental organizations and others.
- Raising public awareness on the ethical measures for controlling progress in scientific knowledge in life sciences and their technological applications with particular emphasis on human rights, moral and religious aspects as well as indigenous moral and traditional values.
- Members of the Egyptian National Committee for Bioethics represent a wide spectrum of eminent university professors and high ranking officials belonging to many domains including: medicine, agriculture, biology, biotechnology, genetic engineering, law, social sciences, religion, information and education.
- The committee has formed 3 working group on:
    - medical and pharmaceutical applications
    - food and agriculture applications
    - information

Major activities (period: 1997-2001):

- Since its formulation, the Egyptian National Committee for Bioethics is holding a monthly meeting at the headquarters of the Egyptian National Commission for UNESCO.
  During the period 27-30 September 1997 the EGY/NCB sponsored the organization of a national seminar entitled "Bioethics: contributing to protection of Human Rights and Promotion of Sustainable Development"

The seminar has been organized in collaboration with UNESCO Paris. The seminar covered a wide spectrum of biological sciences and their technological applications in medicine, pharmacy, food and agriculture, environment and experimental research. Ethical measures were discussed in relation to environmental pollution, technologically aided fertility, abortion, human gene therapy, organ and tissue transplantation. Drugs, cytogenetics and molecular biology, socio-economic implications, cultural, legal, social and religious aspects as well as education and public information.

The EGY/NCB through intensive studies and deliberations endorsed the following final reports:

- Ethics in conducting biological and medical research
- Ethics in human organ transplantation
- Ethics in surrogate motherhood
- Ethics in scientific research on gene therapy

The EGY/NCB is currently finalizing its reports on

- Arabic terms in research on human embryo
- Ethics in biotechnologies and genetic engineering in food and agriculture
- The EGY/NCB is considering to issue a quarterly periodical for dissemination of information on the bioethical issues related to progress in biological sciences and their technological applications. This started in 2002.
- The EGY/NCB has been following up the activities undertaken on the international levels including those by the International Bioethics Committee (IBC), and the Intergovernmental Bioethics Committee (IGBC), UNESCO, Paris.
- The agenda of the committee includes an extended programme to undertake studies on other topics with particular emphasis on educational aspects and public information. These include among others: gene therapy and embryonic stem cells – genetically modified foods – genetically modified organisams (GMO's° - genetic mapping and protection of genetic information.
- The EGT/NCB has contributed to efforts currently undertaken to formulate the Regional Arab Committee for Bioethics in collaboration with ALECSO.
- The EGY/NCB has established a close collaboration with the UNESCO Regional Office for Science and Technology ant Aairo in view of promoting collaboration along that field or the regional level.

Request:

UNESCO Headquarters is kindly requested to support the EGY/NCB activities particularly in the following domains:

- **Supporting the issue of a bioethical periodical intended for a wide dissemination to the public and concerned institutions on the national and regional levels.**

- **The organization of a regional seminar on bioethics in view of stimulating harmonization and interchange of experience and views between neighbouring countries in the appropriate ethical measures for controlling progress in scientific research in biological sciences and their technological applications.**
- **Translation into Arabic for the main documents issued by the International Bioethics Committee of UNESCO in the hope of their wider circulation and utilization in the Arab world**
- **Establishment of a UNESCO Chair on bioethics at one of the Egyptian universities.**

New activities added in recent years by NBC:

- **Ethics and bioethics in health services and pharmaceutical production**
- **Bioethics as related to organic agriculture.**
- **Bioethics as related to genetic therapy**
- **Bioethics as related to human embryo sciences, research and intervention**
- **Bioethics as related to the deformed embryo**

Next phase will be concerned with two entities:

- **Bioethics and consumer protection**
- **Bioethics and hospital accreditation**

COMITE CONSULTATIF NATIONAL D'ETHIQUE FRANÇAIS (CCNE)

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par Mireille Delmas-Marty
Professeur au Collège de France, membre du CCNE

Contribution à la Session extraordinaire du CIB
« Vers une déclaration relative à des normes universelles en matière bioéthique »
(27 – 29 avril 2004)

Même s'il ne s'agit pas d'un instrument juridique directement contraignant, une Déclaration relative à des normes universelles en matière bioéthique aura à terme vocation supranationale car elle devra inspirer les futures conventions internationales destinées, sinon à unifier, du moins à harmoniser les pratiques actuelles. Il est donc nécessaire de s'interroger sur les raisons d'un tel changement (pourquoi ?) et ses conditions (comment ?).

Pourquoi ?

Si l'on en croit le débat qui eut lieu en 1947 à l'Unesco, en marge de l'élaboration de la DUDH[1], entre des penseurs de diverses parties du monde (dont Pierre Theilhard de Chardin, Aldous Huxley, Mahatma Ghandhi, ou le chinois Chung-Sho Lo), la question du fondement de la future Déclaration devrait être soigneusement évitée car elle est sans réponse. Jacques Maritain, dans son introduction, résumait le débat en disant, malicieux, qu'un accord sur les droits de l'homme semble possible, mais à la condition que personne ne demande pourquoi.

Les questions posées par le développement de la bioéthique sont encore plus incertaines, car elle renvoient en partie à des interventions que l'on croit possibles, mais sans les avoir encore pleinement réalisées, et le risque de « sous-détermination de la théorie par les faits », pour reprendre l'expression d'Henri Atlan[2], n'en est que plus fort. La question éthique se réfère simultanément au processus d'évolution biologique de l'espèce humaine (*hominisation*) et au processus de construction symbolique qui sépare l'homme des autres espèces vivantes (*humanisation*) et place le refus de l'instrumentalisation de l'homme au dessus des autres valeurs, y compris la vie[3]. On sait que juridiquement la protection de la vie n'a pas un caractère absolu : la peine de mort n'est que partiellement abolie, en outre les exceptions de la guerre et de la légitime défense sont admises par les instruments internationaux de protection des droits de l'homme ; en revanche sont interdits, sans exception ni dérogation (quelles que soient les circonstances), la torture, l'esclavage, ou encore les crimes « contre l'humanité » (qui n'impliquent pas nécessairement le meurtre, l'assassinat ou l'extermination), autrement dit les atteintes à la dignité humaine, au sens le plus fort du terme.

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[1] *Human rights, comments and interpretations*, Wingate, Londres, 1949.
[2] H. Atlan, *Les étincelles du hasard,* t.2, Athéisme de l'écriture, Seuil, 2003, p. 57.
[3] M. Delmas-Marty , « Faut-il interdire le clonage humain? », *D.* 2003. Chr. 2517.

Il semble néanmoins possible de s'entendre, sinon d'emblée sur les fondements d'une future Déclaration, du moins sur les raisons qui la rendent nécessaire à nos yeux : non pas au nom d'un universalisme qui aurait définitivement vaincu, pour des raisons théoriques, toute aspiration à un relativisme éthique pourtant attesté par les pratiques ; mais précisément pour des raisons pratiques liées aux interdépendances, scientifiques et politiques, imposées par la globalisation économique et technologique (ubiquité et immédiateté des flux d'information et des flux financiers, risques globaux, globalisation des crimes).

Le relatif et l'universel

Pendant longtemps, la contradiction entre un relativisme inscrit au cœur des systèmes de droit et l'universalisme abstrait de la raison, portée en Occident par la philosophie grecque et la philosophie des Lumières, ne posait guère problème : bien au contraire, la figure majestueuse et un peu lointaine du « droit de la nature et des gens » pouvait donner l'illusion d'une légitimité qui ne menaçait pas les pratiques normatives nationales car elle n'en impliquait aucune mise en cause directe et chaque législateur pouvait s'y référer, comme le firent, par exemple, les rédacteurs du code civil français dans sa première version : « Il existe un droit universel et immuable, source de toutes les lois positives : il n'est que la raison naturelle, en tant qu'elle gouverne tous les hommes ».

En somme la raison universelle restait du domaine des idées et les normes particulières du domaine des pratiques. Ces normes, juridiques et éthiques, essentiellement relatives, pouvaient ainsi rester attachées à la souveraineté de chaque Etat, et le droit international classique, attaché à une stricte égalité entre Etats souverains, pouvait postuler l'équivalence des divers systèmes.

L'adoption en 1948 d'une Déclaration « universelle » des droits de l'homme a fait évoluer la réflexion. La référence à toute forme de création – qu'elle soit fondée sur Dieu ou sur la nature – sera finalement supprimée à l'article 1er de la Déclaration universelle des droits de l'homme, sur la proposition de plusieurs intervenants, dont le représentant chinois Chang Pengchun[4] : pour être « universelle », dit-il, la déclaration ne doit pas prendre parti sur la création et/ou l'évolution. Chang obtint aussi qu'à la raison soit ajoutée la conscience (*liang xin*), au sens confucéen du sentiment de compassion que la raison doit cultiver dans un souci de l'autre qui évoque d'ailleurs aussi le *suum cuique* gréco-latin[5].

La Déclaration universelle de l'Unesco sur le génome humain et les droits de l'homme adoptée en 1997 se réfère d'ailleurs explicitement à celle de 1948. Mais elle intervient précisément dans un contexte nouveau, lié à la globalisation, donc aux interdépendances qui marquent les limites du relativisme normatif.

Relativisme et universalisme dans un monde interdépendant

Il faut d'abord tenir compte des enjeux scientifiques et économiques, donc à la fois de la dynamique créée par l'esprit de compétition et des risques liés aux inégalités sociales. Ayant entrepris une recherche comparative sur le clonage humain[6], nous fûmes étonnés de constater qu'un pays déjà surpeuplé comme la Chine s'intéressait au clonage humain, y compris le clonage reproductif. Nous avons vite compris qu'il s'agissait d'affirmer la qualité

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[4] Mary Ann Glendon, *A world made new*, *Eleanor Roosevelt and the Universel declaration of human rights*, Random house, 2001. Egalement P. E. Will et M. Delmas-Marty, « La Chine et la DUDH », in *La tradition chinoise, la démocratie et l'Etat de droit*, Séminaire Collège de France, à paraître, Fayard, 2004.

[5] Voir *Confucianism and human rights*, eds. Th. Bary and Tu Weiming, Columbia university Press, 1998, p.41; également Li Xiaoping, L'esprit du droit chinois : perspectives comparatives, *RIDC* 1997.7.

[6] *Clonage humain, droits et sociétés, étude franco-chinoise*, dir. M. Delmas-Marty et Zhang Naigen, vol. I - *Introduction*, *SLC* 2002, p. 46s. ; vol.II – *Comparaison*, SLC, 2004.

de la recherche scientifique et de conquérir un marché potentiel considérable[7]. D'ailleurs la séparation entre un secteur public réglementé et un secteur privé libre relève sans doute aux Etats Unis de considérations analogues.

La bioéthique relance en effet le débat sur le relatif et l'universel, mais dans des conditions nouvelles. D'une part la globalisation a créé de fortes interdépendances économiques ; d'autre part le développement des biotechnologies incite à débattre, comme on l'a souligné plus haut, de pratiques, comme le clonage reproductif humain, qui deviennent possibles mais ne sont pas encore réalisées. La gravité des conséquences potentielles, et le caractère irréversible de certaines d'entre elles, incite à prendre en compte l'incertitude scientifique, au nom d'un principe dit « de précaution », mais qu'il conviendrait mieux de nommer principe « d'anticipation », car il ne s'agit pas de bloquer mais d'accompagner le mouvement inhérent au vivant. Enfin le droit international a beaucoup évolué depuis un demi-siècle.

Si d'un côté le relativisme reste inscrit dans la notion même de droit, et le droit identifié à l'Etat, de l'autre l'universalisme devient juridique, donc normatif, tant à travers le développement d'un droit des droits de l'homme et d'une justice pénale internationale qu'en raison d'un droit du commerce qui tend à faire du marché un véritable concept universel. Même s'il ne s'agit là que de fragments d'un futur droit mondial, ces fragments ont déjà vocation à s'appliquer sur l'ensemble du territoire planétaire. Ils appellent donc l'adoption de normes communes en matière bioéthique, mais sans indiquer la voie à suivre.

Comment ?

A partir du moment où l'universalisme devient ainsi juridique et pas seulement philosophique, la question première devient celle des méthodes. Ouvert par les philosophes, le débat doit être repris en termes éthiques puis juridiques.

En termes philosophiques, Jurgen Habermas, reprenant l'idée lancée au XVIIIème siècle par Emmanuel Kant d'un droit « cosmopolitique », propose de fonder cette conception cosmopolitique du droit sur le fait que la globalisation des risques a désormais objectivement uni le monde en une « communauté involontaire » (formule surprenante) fondée sur les risques encourus par tous[8]. Sa conception sera nuancée par le philosophe américain Rawls qui tente d'appliquer sa théorie de « la justice comme équité » au droit des gens, c'est-à-dire au droit international[9] : rejetant l'idée d'un véritable Etat mondial, pour les mêmes raisons que Kant qui craignait le risque de despotisme, il développe cependant une conception « constructiviste » d'un droit mondial sans Etat mondial : un droit qui reposerait sur les principes et les conceptions de la raison pratique, par ajustements successifs, ce qui lui permettra d'expliquer comment une doctrine du contrat social peut-être « universelle dans sa portée».

La nouveauté tient dans cette approche « constructiviste », qui ne prétend pas imposer un droit universel d'en haut, à partir du droit de l'Etat le plus fort (universalisme de type impérialiste), mais rechercher un accord progressif, à mesure que les questions concrètes se posent et que des solutions émergent au confluent des traditions les plus diverses, fût-ce au prix de malentendus provisoires. La démarche est donc inversée : l'universalisme n'est ni démontré empiriquement, ni fondé philosophiquement, mais construit de façon progressive, tout en ayant d'emblée une fonction normative. Tout se passe comme si la globalisation, celle

[7] Xie Jianping et autres, « Biotechnologies liées aux cellules souches et protection de la propriété intellectuelle en Chine », in *Clonage humain*..., précité, vol. I, p. 164s.
[8] J. Habermas, *La paix perpétuelle ente les nations, le bicentenaire d'une idée kantienne*, Cerf, 1996, p.75.
[9] J. Rawls, *Le droit des gens*, éd. Esprit, 1996.

des flux économiques mais aussi celle des risques et notamment des risques criminels, rendait nécessaire une communauté de droit, sous la forme de fragments de droit positif communs, et comme si cette communauté de droit, encore très partielle et très ponctuelle, devait finir par conduire vers une communauté des valeurs.

Alors que l'école historique du droit[10] a longtemps fondé le droit commun sur une communauté de droit préexistante, il s'agirait désormais de fonder sur le droit commun existant, même partiel, une communauté universelle qui reste à construire et qui n'impose pas une vision unifiée de l'universalisme philosophique.

En termes éthiques, le CCNE a déjà proposé des pistes de réflexion. Dès 1997 le CCNE avait consacré ses Journées annuelles à la question « Une même éthique pour tous ? » et souligné la nécessité d'une conception pluraliste, non seulement dans la forme mais dans la nature même des références éthiques[11]. Dans un récent avis sur « Les inégalités d'accès aux soins et dans la participation à la recherche à l'échelle mondiale » le CCNE, rappelant le poids d'une interdépendance économique et scientifique croissante, insiste sur la nécessité d'une démarche de reconnaissance mutuelle », soulignant qu'elle devra se garder de deux illusions : « l'illusion souverainiste face à la mondialisation des pratiques et l'illusion d'une autonomie éthique face aux enjeux économiques »[12]. Insistant notamment sur « le problème des brevets » et « les difficultés de transfert de technologie », cet avis conclut que « l'exemple des relations Nord/Sud démontre la nécessité d'une régulation mondiale à géométrie variable : unifiée mais aussi harmonisée pour réglementer les pratiques médicales et de recherches ». L'objectif devrait être de rendre opposables les considérations éthiques, non seulement aux Etats, mais encore aux forces économiques et politiques[13].

En termes juridiques, cette question de l'opposabilité aux Etats et aux entreprises transnationales s'inscrit dans le prolongement de la réflexion actuelle sur les relations entre l'ONU et l'OMC et sur l'extension de l'applicabilité des droits fondamentaux aux sociétés transnationales. Elle nous rappelle l'impossibilité de dissocier globalisation économique et universalisme de l'éthique et des droits de l'homme[14] et nous incite à réfléchir à terme sur le type de contrôle et de sanctions applicables en cas de violation des futurs principes universels en matière de bioéthique.

En conclusion, et pour résumer nos réponses au questionnaire, la future Déclaration devrait être à la fois concise, pluraliste et évolutive.

- ***Une Déclaration concise***, énonçant des principes fondamentaux sans prétendre donner d'emblée la réponse à des questions spécifiques, est le seul moyen d'éviter un universalisme de surplomb et de privilégier l'approche « constructiviste » préconisée ci-dessus.

- ***Une Déclaration pluraliste*** paraît la seule forme réaliste face à la diversité des pratiques et des cultures. Le pluralisme implique d'une part une gradation entre principes à protection absolue et principes assortis de dérogations, exceptions et restrictions, d'autre part une combinaison de différents modèles d'intégration impliquant *tantôt* l'unification, c'est-à-dire

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[10] Jean-Louis Halpérin, L'approche historique et la problématique du jus commune, in *Variations autour d'un droit commun,* dir. M. Delmas-Marty, SLC 2001, p. 17 et s. ; également *Nationalisme juridique contre communauté de droit,* PUF1999.

[11] J.P. Changeux, « Introduction, le débat éthique dans une société pluraliste » », in CCNE, *Une même éthique pour tous?*, éd. Odile Jacob, 1997, p. 9s.

[12] CCNE, « Les inégalités d'accès aux soins et dans la participation à la recherche à l'échelle mondiale, problèmes éthiques », Avis n° 78, 18 sept. 2003, *Les cahiers du CCNE*, 2003, n° 37, p. 4s.

[13] J.-P. Changeux, « Le point de vue éthique », *in Crimes internationaux et juridictions internationales*, dir. A. Cassese et M. Delmas- Marty, PUF 2002, p. 83.

[14] Voir *Trois défis pour un droit mondial*, Seuil, 1998.

des règles communes précises appelant des réponses identiques (modèle applicable, par exemple, au clonage reproductif), *tantôt* l'harmonisation, limitée à des principes directeurs à caractère plus général, appliqués avec une marge nationale d'appréciation, mais en respectant un seuil de compatibilité à ne pas franchir (modèle applicable, par exemple, au clonage dit thérapeutique).

- ***Une Déclaration évolutive*** devrait enfin permettre de tenir compte du caractère non obligatoire d'un tel instrument, tout en préparant sa future mise en œuvre par la mise en place d'un mécanisme de suivi, incluant une fonction prospective. Cette prospective devrait plus particulièrement s'attacher d'une part à rendre la Déclaration opposable aux Etats et aux entreprises multinationales (notamment par un jeu de sanctions qui pourraient être appliquées par des juridictions nationales ou internationales selon un principe de compétence universelle), d'autre part à faciliter une coordination mondiale des différents instruments juridiques, qu'il s'agisse de la protection des droits fondamentaux (ONU), y compris en matière de santé (OMS), ou des règles applicables au commerce (OMC) et à la propriété intellectuelle (OMPI).

THE PRESIDENT'S COUNCIL ON BIOETHICS [USA]

Testimony of
Mr. O. Carter Snead, Esq.
General Counsel of the President's Council on Bioethics [USA]
before the UNESCO International Bioethics Committee
Paris, France, April 2004

Mr. Director-General and Members of the Committee:

On behalf of the United States, and of the President's Council on Bioethics, thank you for this opportunity to testify.

I should make clear at the start that I speak in two capacities today. I am an employee of the United States Government, and I am also an employee of the President's Council on Bioethics, which, while part of the government, also has a certain measure of independence from it. The members of our committee are distinguished private citizens not employed by the government. They are free to be critical of the government or to disagree with current policy. To prevent confusion, I will try to be very clear about who I am speaking for at any given moment. For the most part in the present testimony, I shall speak only for the Council and not for the U.S. Government.

Your main purpose in inviting me, I am aware, is to discuss the idea of a Universal Instrument on Bioethics. Because the President's Council has taken no position on such an instrument, and because the U.S. Government has already, through other channels, communicated to you its specific concerns with this idea, I will remain largely silent on this subject. I will, however, be happy to discuss my government's concerns about the Universal Instrument, to the extent I am authorized to do so, during the question and answer period.

My purpose in these remarks will be to describe the President's Council on Bioethics, its purposes, duties, and activities to date. This, I hope, will help you understand the role of the President's Council in American decision-making on questions of bioethics, and thus perhaps also give you a sense of how the Council may be of relevance to the Universal Instrument process.

The President's Council: A Basic Description

The President's Council on Bioethics was created by President George W. Bush on November 28, 2001, to "advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology."

In connection with its advisory role, the mission of the Council includes the following functions:

1. to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology;
2. to explore specific ethical and policy questions related to these developments;
3. to provide a forum for a national discussion of bioethical issues;
4. to facilitate a greater understanding of bioethical issues; and
5. to explore possibilities for useful international collaboration on bioethical issues.

The Council has 18 members, all named by President Bush, from various fields, such as biology, law, theology, and ethics. Its chairman is Dr. Leon Kass, M.D., of the University of Chicago. It is a temporary body, and its reports are purely advisory.

In the United States, there has been little desire to create a permanent bioethics commission or agency. Instead, at various times Congress or the President has found it convenient to create a temporary advisory committee to address certain specific questions. This council is in fact the fourth bioethics advisory body at the national level. The first national bioethics commission was created by Congress in the 1970s to improve protections of human subjects in research. It produced the Belmont Report that led to the institution of important protections for human subjects in federally funded research. A second national bioethics commission was created by Congress in the late 1970s to advise the President on bioethics issues generally. It issued important reports on gene splicing, end-of-life treatment, and other issues. A third national bioethics advisory commission, called by that name, and commonly known by the acronym "NBAC," was created by President Clinton in the mid-1990s. It had 15 members, later expanded to 18. It issued reports on cloning, stem cells, and the protection of human subjects in international research. It expired in the autumn of 2001. Soon after, President Bush created the fourth national commission, the President's Council on Bioethics, to serve a purpose similar to that of NBAC, but with an entirely different set of 18 members and expanded terms of reference.

In support of its mission, the President's Council may study specific ethical issues connected with specific technological activities, such as embryo and stem cell research, assisted reproduction, cloning, uses of knowledge and techniques derived from human genetics or the neurosciences, and end of life issues. The Council may also study broader ethical and social issues not tied to a specific technology, such as questions regarding the protection of human subjects in research, the appropriate uses of biomedical technologies, the moral implications of biomedical technologies, and the consequences of limiting scientific research. Thus, the Council is not restricted to traditional "medical ethics" questions, but may also focus on "philosophy of technology" questions, and even social-justice and economic-distribution questions, as these relate to biomedicine.

Unlike its predecessors, the President's Council has tended to focus on questions of ends rather than of means, and to be more interested in "the humane" than in "the technical." That is, it has been more concerned about "how technology affects what it means to be human" than about "how can we slow down, speed up, or manage technological change." This more reflective or philosophical approach reflects a desire to identify the human goods we all hold dear, so that we may be better able to discover how best to preserve those goods in a rapidly changing world. The committee has tried to be a council on bioethics, not a council of bioethicists. In fact, very few of its members are trained "bioethicists." They come to the domain of bioethics not as "experts" but as thoughtful human beings who recognize the supreme importance of the issues that arise at the many junctions between biology, biotechnology, and life as humanly lived. They are seekers for wisdom and prudence regarding deep human matters. The committee's subject matter has been "the ethics of life," understood not as biological life merely but rather in the ancient Greek sense: the ethics of "bios," of a course of life or a manner of living, or a human life as lived. Animals have life, zoe; human beings alone have a life, a "bios," a life lived not merely physiologically, but also mentally, socially, culturally, politically, and spiritually.

The Council is not required to reach consensus when formulating a formal recommendation for the President. All serious relevant opinions, carefully considered, are welcome. Moral positions rooted in religious faith or in philosophy or in ordinary personal experience of life are equally welcome, as well; provided that the arguments and insights

offered enter our public discourse in ways that do not appeal to special privilege or authority. By law, all of the Council's meetings are open to the public. Transcripts are made available to the public, via our website, http://www.bioethics.gov.

The Council has issued four policy-oriented reports to date on the following topics: (1) cloning; (2) stem cells; (3) enhancement technologies; and (4) assisted reproduction and (5) human embryo research.

Cloning

In its report Human Cloning and Human Dignity: An Ethical Inquiry (July 2002), the Council found that (1) cloning-to-produce-children is unethical, ought not to be attempted, and should be indefinitely banned by federal law, regardless of who performs the act or whether federal funds are involved; and (2) on the related question of the ethics of cloning-for-biomedical research, a majority of the Council recommended the institution, by law, of a four-year ban on cloning-for-biomedical-research, applicable to all researchers regardless of whether federal funds are involved. The Council also recommended a federal review of current and projected practices of human embryo research, preimplantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field. (As I shall make clear below, the Council later initiated this kind of review in its report on assisted reproduction.)

Stem Cells

In the United States, federal law forbids the use of federal funds in any research that involves injuring or destroying a live human embryo. With the isolation of human embryo-derived stem cells in the late 1990s, the question arose of whether the federal law prohibits funding for research where the embryos have already been destroyed without federal funds. The Clinton Administration reviewed the situation and answered, "Yes," but did not actually make federal funds available for any embryo-derived stem cell research before leaving office. The Bush Administration, upon entering into office, reviewed the question a second time, and answered, "Yes and No." On August 9, 2001, President Bush announced he was making federal funds available for research on human embryo-derived stem cell lines for the first time, provided that the embryos had been destroyed prior to the date of his announcement. About 78 stem cell lines are eligible for federal funding under this policy, though not all are sufficiently well characterized and stabilized to be usable at the time of this writing. Currently 18 lines are available for use in research, and this number is growing.

The Council's report on *Monitoring Stem Cell Research* (January 2004) provides a detailed update on this important area of research. Both the field and the current (Bush) policy are young. Therefore, the report contains no proposed guidelines and regulations, nor indeed any specific recommendations for public policy. Rather, it seeks to shed light on where matters stand now—ethically, legally, scientifically, and medically—in order that policymakers may be better informed as they consider where to go in the future.

Enhancement of Human Traits

In *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (October 2003), the Council considers a series of medical technologies that can or may also be usable for "enhancement" purposes. Among the biotechnical powers considered are techniques for screening genes and testing embryos, choosing sex of children, modifying the behavior of children, augmenting muscle size and strength, enhancing athletic performance, slowing senescence, blunting painful memories, brightening mood, and altering basic temperaments. In a quartet of four central chapters, the report considers how pursuing certain goals or aspirations—for better children, superior performance, ageless bodies, or happy souls—might

be aided or hindered, elevated or degraded, by seeking them through a wide variety of technological means. In a concluding chapter, the report asks what kinds of human beings and what sort of society we might be creating in the coming age of biotechnology. It questions whether life will really be better if we turn to biotechnology to fulfill our deepest human desires. As Chairman Kass writes in his letter transmitting the report to the President:

> We want better children—but not by turning procreation into manufacture or by altering their brains to gain them an edge over their peers. We want to perform better in the activities of life—but not by becoming mere creatures of our chemists or by turning ourselves into tools designed to win or achieve in inhuman ways. We want longer lives—but not at the cost of living carelessly or shallowly with diminished aspiration for living well, and not by becoming people so obsessed with our own longevity that we care little about the next generations. We want to be happy—but not because of a drug that gives us happy feelings without the real loves, attachments, and achievements that are essential for true human flourishing.
>
> In enjoying the benefits of biotechnology, we will need to hold fast to an account of the human being, seen not in material or mechanistic or medical terms but in psychic and moral and spiritual ones.

Assisted Reproduction and Human Embryo Research

The Council's most recent report, issued in March 2004, is entitled, *Reproduction and Responsibility: The Regulation of New Biotechnologies,* and contains a set of unanimous policy recommendations. The report focuses on the intersection of assisted reproduction, human genomic knowledge, and embryo research, and in particular on how the United States currently does and does not, but perhaps should, regulate these new technologies, which are arming mankind with profound new capacities to alter and influence the beginnings of human life when initiated outside the body. Unlike its counterparts in Great Britain and Canada, this American report refrains from proposing major new regulatory institutions (such as the HFEA in the U.K.). Rather, the Council finds that much more information is needed before design of new regulatory institutions can be undertaken. In the interim, the Council presents a series of recommendations—addressed both to government and to the relevant scientific and medical practitioners—for data gathering, reporting, and professional self-scrutiny.

At the end of the report, the Council proposes a series of targeted interim legislative measures that would safeguard certain important ethical boundaries, proposals designed to forestall certain unethical or disquieting practices in human reproduction— lines should be crossed, it should only be after clear public deliberation and assent, not by the private decision of some adventurous or renegade researchers. The recommendations are not meant to be a repudiation of any of the Council's prior reports (for example, the 2002 report on Human Cloning remains the Council's official position), and is intentionally silent on many of the more contentious questions (for example, the Council does not endorse or express support for destructive human embryo research). Instead, the Council's recommendations are meant to suggest at least temporary limitations on certain outlier practices, while principled disagreement persists on other important foundational questions. Specifically, the Council recommends that Congress should:

- Prohibit the transfer, for any purpose, of any human embryo into the body of any member of a non-human species.
- Prohibit the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm.

- Prohibit the transfer of a human embryo (produced ex vivo) to a woman's uterus for any purpose other than to attempt to produce a live-born child.
- Prohibit attempts to conceive a child by any means other than the union of egg and sperm.
- Prohibit attempts to conceive a child by using gametes obtained from a human fetus or derived from human embryonic stem cells.
- Prohibit attempts to conceive a child by fusing blastomeres from two or more embryos.
- Prohibit the use of human embryos in research beyond a designated stage in their development (between 10 and 14 days after fertilization).
- Prohibit the buying and selling of human embryos.
- Prohibit the United States Patent and Trademark Office from issuing patents on claims directed to or encompassing human embryos or fetuses at any stage of development.

This completes my brief review of the President's Council on Bioethics. I hope you now have a better understanding of the Council's purpose, duties, and activities to date.

NUFFIELD COUNCIL ON BIOETHICS

Commentary on the proposal for a Declaration on Universal Norms on Bioethics by the International Bioethics Committee of UNESCO

The Nuffield Council on Bioethics[1] is grateful to the International Bioethics Committee (IBC) of UNESCO for the invitation to contribute to the deliberations towards a proposal for a Declaration on Universal Norms on Bioethics.

Due to the tight timetable of the IBC's consultation, the comments from the Nuffield Council are, at this stage, brief. They relate to the questions posed under I and II of page two of the *Outline Document*[2], circulated in preparation for the meeting.

Aims and scope of a Declaration on Universal Norms on Bioethics

The Nuffield Council has not formally considered a possible Declaration on Universal Norms on Bioethics (henceforth: *the Declaration*). Accordingly, the Council is not in a position to make a recommendation about the scope of the Declaration, or whether it should be extended to include animals, other living organisms, the environment and, for example, the use of GMOs.

However, we offer the following observations. To some degree, decisions about the scope of the Declaration would appear to depend on its intended function. II.5 of the Outline Document considers the possibility of providing guidance on specific subject areas by means of the Declaration. If such a function is indeed envisaged by the IBC, it might be appropriate to focus the Declaration on responsibilities of humans towards other humans only. The reason for this would be entirely pragmatic in nature. The Nuffield Council has recently considered issues arising from the use of genetically modified crops and is currently examining the ethics of research involving animals. As is well known, views differ considerably on these topics, both within the UK and internationally. If the IBC intends to cover these areas in its Declaration, and furthermore to provide guidance on them, the challenge to achieve consensus should not be underestimated.

Structure and Content of a Declaration on Universal Norms on Bioethics

As already stated, the Nuffield Council has not come to a formal opinion on the structure and content of the Declaration. However, we trust that some general observations as well as examples of important legal and ethical principles and concepts referred to in previous work of the Council might be of use to the IBC in its deliberations.

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1. More detailed information about the Nuffield Council is at Annex B.

2. *Outline for the preparation of the written contribution of organisations and institutions on the possible scope and structure of a declaration on universal norms on bioethics*, see http://portal.unesco.org/shs/en/file_download.php/f0a34803b0302b1f8d3928e44014f450O outline_en.pdf
It might be easier to achieve an extension of the scope of the Declaration beyond responsibilities of humans towards other humans, if the Declaration were confined to stating only "fundamental principles of broad application" (II.3).

Specific comments regarding sections II.1, II.3., II.5 of the Outline Document

A preamble might be a useful means of clarifying the relation of the Declaration to other relevant documents such as UNESCO's ***Universal Declaration on the Human Genome and Human Rights*** and its ***International Declaration on Human Genetic Data***; the Council of Europe's ***Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine***; the World Medical Association's (WMA) ***Declaration of Helsinki***; and the recent ***Charter of Fundamental Rights of the European Union***.

Furthermore, a preamble might be a useful means of explaining the function of the Declaration. The importance of clarity is illustrated by recent controversies concerning the ***Declaration of Helsinki*** (DoH).

As is widely recognised, views differ as to whether the DoH should be understood in the spirit of a Declaration, formulating a set of aspirational ideals, or whether it is more appropriately seen as a device which is virtually regulatory in nature, suitable for direct application to the conduct of research involving human participants. In practice, the DoH is often used in the latter way. It has, therefore, very real implications for the policy and practice of healthcare related research. However, due to the ambiguity of its status, a number of problems have arisen in interpreting the DoH's provisions. The Nuffield Council addressed some of these in its 2002 Report ***The ethics of research related to healthcare in developing countries***[3]**.**

One controversial area concerns the provision of treatment at the conclusion of a study. The DoH addresses this topic in Paragraph 30[4]. Due to continuing disagreement about the meaning of this paragraph, the WMA established a Workgroup to provide guidance on how to clarify it. The Workgroup reported to the WMA General Assembly in 2003 with a proposal for a revision of Paragraph 30. However, the WMA was not able to agree on the proposal and established a second Workgroup, to report back in May 2004. The draft report of this Workgroup, published in January 2004[5], listed three options to resolve the disagreements:

- not to revise Paragraph 30, but to issue instead a separate statement or report on equitable access to healthcare
- to add a note of clarification setting out 'the intention of Paragraph 30', as attempted at the previous meeting;
- to add a preamble explaining that the Declaration is primarily a set of ethical principles, rather than a regulatory or legal device.

The draft report suggested that the preamble might read as follows:

> 'As a statement of principles, the Declaration of Helsinki is intended to establish high ethical standards that guide physicians and other participants in medical research involving human subjects. These ethical principles provide the basis of moral reflection on the means and goals of research involving human subjects, distinct from

3. www.nuffieldbioethics.org/developingcountries The relevance of the discussion in this Report has been underlined at a recent international Workshop on the same topic. The Workshop was co-hosted by the Nuffield Council and the South African Medical Research Council, in Cape Town from 12-14 February 2004.
4. 'At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study'
5. WG/DoH/Jan2004, Workgroup report on the revision of Paragraph 30 of the Declaration of Helsinki, available at: http://www.wma.net/e/ethicsunit/pdf/wg_doh_jan2004.pdf

> national legal and regulatory requirements. Interpreting the provisions of the Declaration regarding the design, conduct or completion of the research requires careful balancing of all of the Declaration's ethical principles. Differences in interpretation should be resolved by physicians and other participants involved in the research who are most familiar with all relevant factors, including the needs of research participants and of the host population.' WG/DoH/Jan2004, p. 3-4.

There may be merit in considering whether a similar preamble preceding the main provisions of IBC's Declaration might be a useful means of avoiding problems due to ambiguities. This section could clearly state what function the Declaration is intended to have. A clarification of its purpose would be particularly relevant with regard to Section II.5 of IBC's Outline Document, which considers the option of providing guidance on specific subject areas through the Declaration. If IBC indeed intends to pursue this option, it seems advisable to state so clearly. If not, it would seem similarly advisable to declare this.

The suggestion of providing guidance on specific subject areas by means of the Declaration raises one further issue which the Nuffield Council would like to bring to IBC's attention. We have noted above that achieving agreement on detailed provisions in relation to animal experimentation and the use of GM crops is unlikely to be straightforward. Similarly, reaching agreement will pose challenges in relation to issues raised by embryo and stem cell research. These topics are listed under II.5 of the Outline Document as possible areas which could be covered by guidance of the Declaration. Reaching agreement on these issues will pose significant challenges. As the IBC may be aware, the Nuffield Council argued in its 2000 Discussion Paper ***Stem cell therapy: the ethical issues***[6], among other things, that:

> 'The proposed creation of embryos using SCNT (Somatic Cell Nuclear Transfer) for research into the derivation of stem cells offers such significant potential medical benefits that research for such purposes should be licensed' (paragraph 36).

Clearly, there is no agreement either within the EU, or globally, on the acceptability of such research, as was most recently apparent in discussions concerning a UN resolution on cloning. With regard to the possibility of including specific guidance in the Declaration on areas such as 'therapeutic' cloning, it would therefore appear unlikely, in the near future, to achieve the necessary consensus. Furthermore, the Nuffield Council notes that when IBC received the mandate to develop the Declaration at UNESCO's 32nd session in October 2003, the General Conference considered that universal standards should be set "in the spirit of cultural pluralism inherent in bioethics"[7]. The Nuffield Council endorses the recommendation to strive for universal standards which reflect sensitivity to cultural differences. With regard to issues raised by cloning and stem cell therapy, we interpret the General Conference's provision as stating that it would be inappropriate to ignore the diversity of views on such research. For example, the inclusion of principles or guidance which would limit research that some States perceive as valuable, responsible, and justifiable would not be acceptable in the Declaration. The Nuffield Council would therefore not be able to support a Declaration which provided restrictive guidance in this area.

Specific comments regarding section II.3 of the Outline Document

The question of which fundamental principles should be affirmed in the Declaration clearly depends on its aims and scope. Since such decisions are yet to be made, and since the Nuffield Council has so far not yet formally come to an opinion on the matter, we therefore cannot recommend specific principles. However, the IBC may find the following notes useful in its

6. http://www.nuffieldbioethics.org/publications/pp_0000000007.asp
7. (32 C/Res. 24).

deliberations.

Depending on the topic examined, Reports of the Nuffield Council have placed different emphasis on a range of ethical concepts and principles, as well as legal norms and rights. The list below gives some detail of relevant reference points, as referred to in the respective publications. Depending on the final scope of the Declaration, the IBC may wish to consider some of these in more detail.

- **Respect for persons, human dignity, free will and individual responsibility**

  The Nuffield Council has discussed the concepts of 'personhood' and 'human dignity' exclusively in relation to born human beings.

  - Mental disorders and genetics: the ethical context (1998)
  - The ethics of research related to healthcare in developing countries (2002)
  - Genetics and human behaviour the ethical context (2002)

- **The importance of genuine consent**

  Consent is a cornerstone of ethical conduct in biomedical research involving human participants. The commonly used concept 'informed consent' can be misleading as consent can be given to a course of action only as described in a specific way and this description can never be exhaustive. 'Fully informed consent' is therefore an unattainable ideal. Consent should therefore be genuine. This requires primarily care in detecting and eliminating lack of consent.

  - Genetic screening: ethical issues (1993)
  - Human tissue: ethical and legal issues (1995)
  - Animal-to-human transplants: the ethics of xenotransplantation (1996)
  - Mental disorders and genetics: the ethical context (1998)
  - Stem cell therapy: the ethical issues (2000)
  - The ethics of research related to healthcare in developing countries (2002)
  - Pharmacogenetics: ethical issues (2003)

- **Respect for autonomy, individual choice and freedom of conscience**

  When considering the proper role of political authority in enforcing particular bioethical approaches, it is crucial to ensure that, as far as possible, individuals can exercise freedom of conscience in decisions relating to the use of new technologies.

  - Genetic screening: ethical issues (1993)
  - Animal-to-human transplants the ethics of xenotransplantation (1996)
  - Genetically modified crops: the ethical and social issues (1999)
  - Pharmacogenetics: ethical issues (2003)
  - The use of genetically modified crops in developing countries (2003)

- **The right of the consumers and patients to adequate information about risks and benefits of new technologies**

  In order for people to make informed judgements and decisions about the use of new technologies it is important that factual and balanced information be provided by independent and trusted bodies

  - Genetically modified crops: the ethical and social issues (1999)
  - Genetics and human behaviour: the ethical context (2002)
  - Pharmacogenetics: ethical issues (2003)
  - The use of genetically modified crops in developing countries (2003)

- **The importance of ensuring non-discrimination**

  Medical research and especially genetic research entails the possibility that groups of people are discriminated unjustifiably on the basis of their genotype. Appropriate safeguards need to be put in place to prevent and counteract discrimination.

  - Genetic screening: ethical issues (1993)
  - Mental disorders and genetics: the ethical context (1998)
  - Genetics and human behaviour: the ethical context (2002)
  - Pharmacogenetics: ethical issues (2003)

- **The importance of ensuring confidentiality and privacy**

  Electronic means of storing and accessing personal biological and medical data have become increasingly common, especially with regard to genetic research. A careful balance needs to be struck to ensure that the conduct of important research is protected and that personal data of individuals participating in research is not used in inappropriate ways.

  - Genetic screening: ethical issues (1993)
  - Genetics and human behaviour: the ethical context (2002)
  - Pharmacogenetics: ethical issues (2003)

- **The duty to safeguard human health**

  In conducting biomedical research it is important to ensure that risks to the health of those participating as well as to the wider community are considered carefully. Failure to do so would show lack of respect for research participants, and may contribute to an unhelpful and negative perception of biomedical research.

  - Animal-to-human transplants: the ethics of xenotransplantation (1996)
  - Genetically modified crops: the ethical and social issues (1999)
  - The use of genetically modified crops in developing countries (2003)

- **The duty to safeguard animal health and welfare**

  In advancing the biomedical sciences, the species-specific capacities of animals involved in research need to be considered carefully, in order to reduce negative welfare implications as far as possible. This can mean that certain animals should not be used for specific kinds of research.

  - Animal-to-human transplants: the ethics of xenotransplantation (1996)

- **The importance of protecting the environment**

  The consequences of using new technologies that can influence the environment need to be considered carefully. With regard to the consequences of agriculture and new technologies such as genetically modified crops, the Council is not persuaded that arguments based on 'naturalness' are useful in decision making. Rather, the focus should be on the acceptability of the consequences of new technologies on biodiversity.

  - Genetically modified crops: the ethical and social issues (1999)
  - The use of genetically modified crops in developing countries (2003)

- **The importance of furthering human welfare and the duty to alleviate suffering**

  Technological advances in the biomedical sciences can contribute significantly to the improvement of human welfare in developed countries as well as in developing countries. It is important to explore the potential of new technologies in a responsible way.

  - Genetically modified crops: the ethical and social issues (1999)
  - Stem cell therapy: the ethical issues (2000)
  - The ethics of research related to healthcare in developing countries (2002)
  - The ethics of patenting DNA (2002)
  - The use of genetically modified crops in developing countries (2003)

- **The duty to be sensitive to cultural differences, and the duty to avoid exploitation, especially of the vulnerable**

  When applying principles or norms that are widely accepted in western traditions of bioethics to research taking place in other contexts, it is important to take into account the respective social, cultural and economic context.

  - The ethics of research related to healthcare in developing countries (2002)

- **The importance of achieving a balance between the private and the public interest**

  Research undertaken by the private sector has contributed significantly to furthering human welfare. Devices need to be in place to stimulate further research. However, it is important that the effect of such policies on the public interest are monitored. Some provisions, such as overly broad patents may be to the detriment of the public interest and inhibit research activity.

Specific attention is required when considering the effects of respective policies on developing countries.

- The ethics of research related to healthcare in developing countries (2002)
- Genetically modified crops: the ethical and social issues (1999)
- The ethics of patenting DNA (2002)
- Pharmacogenetics: ethical issues (2003)
- The use of genetically modified crops in developing countries (2003)

The importance of assessing carefully costs and benefits of using new technologies

There may be certain courses of action that should be ruled out whatever their potential benefits. Such decisions require careful justification. Important questions to consider are: does the potential good outweigh the possible harm? What are the costs of not using a new technology?

- Genetic screening: ethical issues (1993)
- Animal-to-human transplants: the ethics of xenotransplantation (1996)
- The ethics of research related to healthcare in developing countries (2002)
- Genetically modified crops: the ethical and social issues (1999)
- Genetics and human behaviour the ethical context (2002)
- The use of genetically modified crops in developing countries (2003)
- Pharmacogenetics: ethical issues (2003)

The importance of achieving justice and equity, both locally and globally

The dramatic differences in welfare of people living in developed and those living in developing countries are unacceptable. There are also significant global differences in the development of scientific and technological expertise. It is vital that the gap between countries at different stages of development is bridged. Some policies of European countries, for example with regard to agriculture, offer advantages to European consumers, but have a harmful effect on people in developing countries. Such polices need to be amended accordingly.

- Genetically modified crops: the ethical and social issues (1999)
- The use of genetically modified crops in developing countries (2003)
- The ethics of research related to healthcare in developing countries (2002)
- Genetics and human behaviour the ethical context (2002)
- Pharmacogenetics: ethical issues (2003)

Annex B

Brief information about the Nuffield Council on Bioethics

The Nuffield Council on Bioethics was established by the Trustees of the Nuffield Foundation in 1991 to identify, examine and report on ethical questions raised by recent advances in biological and medical research. Since 1994, it has been funded jointly by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust. The Council seeks to play a role in contributing to policy-making and stimulating debate in bioethics. It has published eight major reports on ethical issues associated with: genetic screening; ownership of tissue; xenotransplantation; genetics and mental disorders; genetically modified crops; research related to healthcare in developing countries; genetics and human behaviour and pharmacogenetics. The Council has also published four discussion papers dealing with ethical issues raised respectively by clinical research in developing countries, by research on human stem cells, patenting DNA and the use of GM crops in developing countries.

The terms of reference are as follows:

1. 1. to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
2. 2. to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
3. 3. in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

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COMITE CONSULTATIF NATIONAL DE BIOETHIQUE
DE LA REPUBLIQUE DE COTE D'IVOIRE

Contribution du Comité consultatif national de bioéthique de la République de Côte d'Ivoire (CCNB –CI) à la session extraordinaire du Comité international de bioéthique « Vers une déclaration relative à des normes universelles en matière de bioéthique »

Liminaire

- ***L'universel est le sel commun des hommes qui, faisant un plein usage de leur raison, parviennent à la pleine conscience de leur responsabilité et de leur place dans l'univers.***

- ***L'accès à l'universel appelle élévation d'esprit et sursomption (au sens hégélien de Aufhebung) des particularismes culturels.***

- ***L'universalité des normes n'est pas de l'ordre du donné, mais du construit collectif.***

- ***La bioéthique étant fondamentalement laïque, le mode d'établissement des normes en la matière devrait être la délibération argumentée.***

I. Objectifs et portée d'une déclaration relative à des normes universelles en matière de Bioéthique

I .1. La Déclaration pourrait contribuer à une meilleure prise de conscience des enjeux des progrès technoscientifiques si elle fait l'objet :

- d'une large diffusion auprès des décideurs (qui doivent veiller à l'application des normes et prendre les sanctions qui s'imposent), des communautés scientifiques (concepteurs des projets de recherche en matière bio-médicale), de la société civile (bénéficiaire de l'application des progrès scientifiques) et des hommes de media ;
- d'ateliers de formation à caractère pédagogique organisés (entre autres par les Comités nationaux de Bioéthique ayant contribué à l'élaboration de la Déclaration) à l'intention des décideurs, des chercheurs et des journalistes scientifiques.

I.2. La Déclaration ne devrait pas se limiter à l'être humain sauf si elle s'arroge le droit de prendre de la liberté par rapport au sens originel de la bioéthique.

Force est en effet de rappeler que :

a) La bioéthique n'est pas une éthique anthropocentrée et la particule « bio » du mot désigne à la fois la vie humaine et celle des autres êtres vivants non humains.

b) Ce qui est en jeu dans la maîtrise du vivant et qui appelle une seconde maîtrise (la maîtrise de la maîtrise technique du vivant) englobe et dépasse l'être humain qui ne constitue qu'un maillon (le plus actif certes, voire capable de mettre en péril le Tout qui l'englobe) d'un ensemble plus vaste, la biosphère. De fait, on ne peut ignorer l'interdépendance qui existe entre l'homme et son environnement (animal et végétal). Des manipulations génétiques touchant aussi bien des végétaux que des animaux autres que l'homme sont issus des nouveaux organismes (céréales transgéniques, virus, bactéries, insectes, brebis clonées,…) qui une fois transférés dans la nature sans maîtrise de leur adaptation, de leur mutation et de leurs effets secondaires, peuvent s'avérer dangereux à la fois pour l'environnement et pour l'homme.

c) Les conséquences de l'agir humain dont se préoccupe la réflexion bioéthique débordent de très loin la sphère de l'humain en raison de leur influence sur la biosphère.

I.3. Question rendue caduque par la réponse donnée au point I.2.

I.4. La déclaration devrait aborder à grand trait les questions liées à l'expérimentation sur les animaux, à la biodiversité et aux Organismes Génétiquement Modifiés (cas des aliments transgéniques). C'est ici le lieu de souligner que toute mutation génétique touchant ADN – ARN est irréversible et transmissible aux descendants sur des générations.

II. <u>Structure et contenu d'une déclaration relative à des normes universelles en matière de Bioéthique</u>

II.1. La déclaration devrait être structurée de la façon suivante :

- un préambule qui en dévoile l'esprit et les enjeux
- des sections mettant en évidence les idées-forces de la Déclaration et les cadres généraux de leur application.

Les sections qui pourraient y être incluses sont de toute évidence les soins de santé, la recherche scientifique et l'éducation.

Les deux premiers points (soins de santé et recherche scientifique) sont au cœur de la problématique bioéthique.

Le troisième point, à savoir l'éducation, constitue à la fois le fer de lance de la sensibilisation et le moyen le plus approprié pour promouvoir durablement la bioéthique.

II.2. Les principes fondamentaux qui devraient être réaffirmés dans la déclaration sont :

- Le respect de la Personne et de la Vie
- L'autonomie (consentement libre et éclairé)
- L'égalité (non discrimination)
- La solidarité anthropo-bio-cosmique (partage des bienfaits).

II.3. En réaffirmant ces principes fondamentaux, la Déclaration devrait s'en tenir uniquement aux principes d'application générale. De la sorte, elle éviterait les écueils de la casuistique.

Une déclaration à vocation universelle, faut-il le rappeler, n'est pas à confondre avec un texte de loi ou un code de déontologie.

Si les circonstances l'exigent, l'UNESCO pourrait, dans le prolongement de la Déclaration, stimuler ou favoriser l'établissement de conventions régionales destinées à traiter des cas spécifiques comme a su le faire l'Europe avec la Convention sur les Droits de l'Homme et la Biomédecine adoptée en 1996 par les Etats du Conseil de l'Europe.

II.4. Inexistant

II.5. Quelles que soient la structure et la portée de la Déclaration, elle devrait proposer des orientations générales sur les sujets tels que :

- La recherche sur et avec des sujets humains
- La sélection du sexe (capable de bouleverser l'équilibre des sociétés contemporaines et de menacer par contrecoup la survie de l'espèce)
- La brevetabilité du vivant
- Les aliments transgéniques
- Le clonage
- Les transplantations d'organes et de tissus
- La prise en charge thérapeutique et herméneutique des personnes infectées par le VIH SIDA.

Fait à Abidjan, le 29 mars 2003

Etaient présents :

Prof. Lazare Marcelin POAME, Philosophe-(Bio)éthicien, **Président**
Dr Innocent POTEY, Médecin, **Secrétaire Général**
Dr Anzoumana OUATTARA, Philosophe politique, **Secrétaire Général Adjoint**
Dr Assaba SECA, Economiste, **Trésorie**r
Me Kouamé NGUESSAN-KLEMET, Avocat, Docteur en Droit, **Chargé des relations publiques**
Prof. Yao DJAHAN, Agrégé de Médecine, **Chargé des relations avec les Facultés de Médecine**
Prof. Méliane Marie-Louise NDHATZ-SANOGO, Agrégée de Médecine, **Chargée des relations avec les Centres hospitaliers**
Dr Annick TAHIRI, Biologiste, **Chargée des relations avec les Centres hospitaliers**.

Etaient absents :

Prof. Augustin DIBI, Philosophe, **Chargé des relations avec les institutions académiques extra-médicales.**
Dr Patricia ARKHURST NEBOUT, Spécialiste des Sciences de l'Education, **Chargée des relations publiques**

COMITE NATIONAL DE BIOETHIQUE DE LA REPUBLIQUE DEMOCRATIQUE DU CONGO

Vers une déclaration sur des normes universelles en matière de bioéthique

Evariste Likinda Bofonda
Président du Comité national de bioéthique
République démocratique du Congo

Le projet d'élaboration d'une déclaration sur les « normes universelles en matière de bioéthique » appelée à servir de référence à toute l'humanité représente un véritable défi (qu'il faudrait pourtant relever), tenant compte de la grande diversité des cultures qui caractérisent les différents peuples de la terre, et surtout du grand décalage en terme de développement techno scientifique entre pays pauvres et pays industrialisés, établissant une nette différence dans la hiérarchie des valeurs.

La bioéthique est née dans le contexte des sociétés industrialisées où se mènent notamment des recherches scientifiques et technologiques de pointe en biologie et en médecine. Actuellement, notre pays, à l'instar d'un grand nombre de pays de l'Afrique noire, est encore en marge des expériences biotechnologiques. Hormis quelques expériences faites dans le domaine des procréations médicalement assistées (inséminations artificielles fécondations in vitro), nous ne disposons pas encore d'infrastructures appropriées pour prétendre à un véritable génie génétique. Nous sommes donc encore loin de ces technologies avancées dont les dérives possibles suscitent un vrai débat éthique par le fait qu'elles font craindre la manipulation de la vie humaine et l'atteinte à la dignité de la personne humaine. L'importance des questions bioéthiques commence à peine à être perçue en Afrique, surtout à la lumière des informations sur les incessantes découvertes scientifiques et innovations en biotechnologie. L'intérêt de plus en plus grandissant porté sur ces questions s'observe aujourd'hui dans notre pays à travers l'organisation depuis quelques années des forums de réflexion entre médecins, philosophes, juristes et autres personnes qualifiées en sciences humaines, et aujourd'hui avec la mise sur pied d'un comité national de bioéthique. Il reste cependant que dans une société où l'on meurt encore de paludisme et autres maladies infectieuses pourtant curables, faute de moyens pourtant scientifiquement disponibles, où la majorité des populations croupit dans l'ignorance et la misère, ne mangeant pas à sa faim ni ne buvant à sa soif, certains pourraient trouver très discutable la pertinence d'un véritable débat bioéthique sur des sujets comme le clonage, les manipulations du génome humain, les recherches sur les cellules souches embryonnaires.

Nonobstant ce grand retard qu'accusent nos pays aujourd'hui par rapport à ces avancées techno scientifiques, nous sommes conscients de la facilité avec laquelle peut se faire à notre époque le transfert de technologie, et nous prenons au sérieux le phénomène de la mondialisation qui, par le fait de la puissance accrue des moyens de communication en temps réel, tend à universaliser les problèmes, à uniformiser les valeurs et à brasser les mentalités.

Nous sommes donc forcément appelés à entrer dans ce débat. *Aussi, accueillons-nous avec intérêt et attention ce projet d'élaboration des normes universelles en bioéthique. Nous relevons ci-après quelques observations soulignées lors du séminaire consacré à l'examen du questionnaire que le CIB nous a fait parvenir à ce sujet.

Concernant le point I (*objectifs d'une déclaration…)*

Les questions relatives à la biodiversité, aux OGM, à l'environnement ont un impact certain sur la réalisation de l'homme. Nous pensons cependant que ces questions pourraient faire l'objet d'autres déclarations. Toutefois, les questions relatives à l'utilisation des animaux dans la recherche biomédicale ainsi que dans le cadre des transplantations devraient être mentionnées dans l'actuelle déclaration en cours d'élaboration.

Concernant le point II (*structure d'une déclaration…)*

Il y est fait mention d'une section concernant l'éducation et la sensibilisation. Il y a effectivement une grande nécessité de la formation et de l'information de nos populations au débat bioéthique. On peut par exemple constater que les deux déclarations antérieures, celle sur le *génome humain et les droits de l'homme* ainsi que celle sur les *données génétiques humaines* ne sont presque pas diffusées, ni les principes qu'elles contiennent ne sont promus dans nos pays. Le public est concerné au premier chef par les sciences et les techniques en ce qu'elles concourent à l'amélioration de ses conditions de vie ; il doit dès lors s'approprier ce savoir dans le dialogue avec les chercheurs à propos des implications, des retombées et des répercussions qui s'y rapportent. Alors seulement il pourra donner son point de vue.

Concernant le point III du questionnaire (*Principes fondamentaux)*

Les progrès en biotechnologie exercent une réelle influence sur l'évolution des mentalités, et même un déplacement du champ de la pensée aujourd'hui bien perceptible dans les pays industrialisés, aussi bien chez les scientifiques que chez les citoyens, de telle sorte que ce qui devient techniquement possible tend à devenir « faisable » pour être mis en application effectivement et même être revendiqué légitimement. Les progrès réalisés en médecine amènent petit à petit les gens à refuser toute incommodité, tout gène ou tout échec thérapeutique. Il en résulte que des réalités existentielles comme la maladie, la mort, la vieillesse, la stérilité, le handicap etc. deviennent non plus des problèmes auxquels il convient de chercher des solutions, mais des maux qu'il faut absolument enrayer. Au médecin on demande aujourd'hui diverses choses divergentes ; les uns la vie sans fin (acharnement thérapeutique), les autres la mort aussi vite que possible (euthanasie) ; les uns une progéniture sur mesure (choix des embryons), même sans connexion sexuelle (fécondations in vitro, clonage), les autres une vie sans souci de la progéniture (stérilisations, avortements). Il y a donc urgence de faire un mouvement de retour critique pour fixer les limites des demandes des uns et des autres.

En Afrique, nos conceptions traditionnelles considèrent la vie simplement comme un don de Dieu. La vie humaine, dès sa conception, doit être respectée et protégée dans son intégrité et dans sa dignité quelle que soit les caractéristiques qu'elle présente. Quelle que soit la distance qu'ait pris le champ de la pensée sur ce principe, poussée par les avancées techno scientifiques, il nous semble essentiel d'y revenir et de le réaffirmer explicitement. La vie n'a pas de prix. Elle est une fin-en-soi. Tout ce qui y concourt procède de la même symbolique : l'amour, le sexe, la parenté, la famille, le corps, les relations. La question de

savoir si l'embryon est une personne relève d'un débat plutôt théorique, car chez nous l'embryon est déjà un enfant faisant partie de la famille ; d'ailleurs notre code de la famille le reconnaît comme personne. En Afrique noire, quand la vie s'annonce, on l'accueille ; quand elle s'incline, on la redresse ; quand elle s'en va, on l'accompagne. C'est aussi simple que ça. C'est ainsi que, concernant ce point III (*principes fondamentaux en bioéthique)*, nous pensons que le premier principe fondamental, qui devrait absolument et explicitement être réaffirmé, est celui de **respect de la personne humaine** impliquant au premier chef le **respect de la vie humaine** et aussi le **respect** et la **protection de la famille**. Les autres principes énoncés (autonomie, confidentialité, liberté de recherche, consentement libre et éclairé, égalité, intégrité de la recherche, justice, non-discrimination, partage des bienfaits, solidarité, transparence, honnêteté intellectuelle) sont subalternes et devraient aussi être réaffirmés. L'**autonomie** se conçoit dans le cadre du lien social de l'individu dans la communauté, dont la famille est l'élément important où se conçoit et s'épanouit la vie de l'être humain : elle ne peut pas être érigée en principe suprême, car la communauté est appelée à protéger l'individu. La **liberté de recherche** doit être encadrée de telle sorte qu'elle ne porte pas atteinte à la vie humaine et à la dignité de la personne humaine.

Concernant la *recherche internationale et transnationale.*

Il y a lieu de considérer toutes les questions liées au don d'organes, à la location des utérus, aux banques de sperme, et à toutes celles qui sont susceptibles de faire l'objet d'un certain commerce lucratif entre le Nord et le Sud. Face à la pauvreté et la misère qui les accablent, les pays du tiers monde pourraient servir de terrain d'expérimentation, et leur peuples affamés, moyennant très peu, accepteraient facilement de servir de cobayes grandeur humaine. Il y a donc lieu de faire figurer ces questions relatives aux rapports entre pays pauvres du Sud et pays riches du Nord.

RUSSIAN NATIONAL COMMITTEE ON BIOETHICS
OF THE RUSSIAN ACADEMY OF SCIENCES

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SUGGESTIONS ON THE POSSIBLE SCOPE AND STRUCTURE OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

It is not clear now whether UNESCO will succeed or not in elaboration and adoption of Declaration on Universal Norms on Bioethics. Many members of the world bioethics community have rather serious doubts and reservations regarding, firstly, possibility of elaboration of such instrument and, secondly, usefulness and practical efficacy of it in case it will be prepared and adopted.

It seems that main reasons of these doubts are tremendous cultural variety (hence, essential divergences in value systems) of humankind and presumably non-obligatory, non-binding nature of the declaration. At the same time it is evident that it will be almost impossible to create more binding document. For instance, Europe has so much in common in sense of culture and values. Nevertheless, some of European countries refuse to sign and ratify legally binding document in the field of bioethics, namely, Convention for the Protection of Human Rights and the Dignity of Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, which was drawn up by the Council of Europe as long as more than five years ago. These countries have various principal disagreements with some norms and provisions of the Convention.

Yet, even in case it will be impossible to come to terms with text of the declaration, the very process of its elaboration, of discussions of its structure and content will have, to our opinion, essential meaning. The process will allow to reveal and to estimate differences in understanding of problems of bioethics and possible ways of dealing with them. In any words, we shall receive an opportunity to build a kind of map, showing us prevailing values of different cultures in treating bioethical issues and main areas of disagreement. It will be interesting and important also to have rationale of every existing position on these topics. In other words, we think it would be very important to organize maximally wide discussion of the project of declaration at all stages of its elaboration, because such discussion would have value in itself.

I. As for aims and scope of the declaration, it will be addressed not just to academic and scientific circles or politicians, but also to society at large. It will be very important if the document would promote and somehow direct, organize public discussions of the most urgent and perplexing issues of bioethics in different countries and regions of the globe. More than that, we can hope also that the declaration would allow to begin discussions of these issues in countries where up to now they are still not become the subject matter of public concern.

To our opinion, the declaration should not be limited to human beings. It should include also such traditional areas of bioethics debate as use of animals in biomedical research and in xenotransplantation. At the same time we think that the declaration should not include such areas as genetically modified organisms, biodiversity and environment. There are other

international structures and forums, which are more suitable for and more experienced in tackling such rather specific areas, as biodiversity and protection of environment. So, inclusion of these issues in a document, devoted to bioethics, could generate contradictions with existing national and international regulations.

Regarding GMOs: the rationale of our position is not only remoteness of this area from traditional agenda of bioethics. It seems also that for the time being this area cannot be effectively regulated at international level, taking into account lack of approved data on danger of these organisms and huge difference of opinions among parties involved in current discussions.

II. The declaration definitely should include a preamble. The preamble should contain references to previous international documents related with human rights, especially in the context of manifold scientific and technical developments in the present-day biomedicine. The preamble also should say something about degree of binding force, attributable to the document.

We support the view about organization of the declaration into distinct thematic sections. The document can include such sections, as general provisions; health care; biomedical research (it seems that such title would be more appropriate and more definite then scientific research in general); international cooperation; promotion and implementation. We consider also that such topics as "public consultation" and "education and awareness-rising" should be combined in one section.

Some of fundamental principles, which are included in the list, proposed by IBC, can be reaffirmed in the declaration. Yet the whole list seems too extensive and detailed. Besides, it would be difficult to draw concise distinctions between some of the proposed principles, for instance, between principles of equality, justice, solidarity etc. Sure, special analysis can elucidate rather subtle distinctions, yet it would be difficult to grasp these distinctions for general public. Besides, we cannot agree with fundamentality of some of the proposed principles. In general, one can expect that it is this list of fundamental principles which would generate the most serious discussions.

To our opinion, it would be preferable to include in the text only limited number of thoroughly selected genuinely fundamental principles. We would propose to present these principles in the text of declaration in general form, without excessive details for specific cases. The presentation and characterization of the fundamental principles, in our view, should precede the description of specific subject areas. Speaking more generally, we would agree with a position preferring to speak in the declaration (and, by the way, in its title) about universal *principles* rather than *norms* of bioethics.

We want to propose to think also about possibility to have in the declaration two chapters. The first one will include characterization of aims and scope of the document and general definitions as well as presentation of the universal (and fundamental!) principles. The second chapter in this case will be devoted to specific subject areas. The first chapter will have more basic and more stable nature, where as the second chapter can be more flexible. Such structure would allow in future to make, if needed, amendments in the second chapter for putting the declaration into accordance with possible new scientific and technological developments in the field of biomedicine.

III. As it is clear from the above, we support the idea of including in the text of declaration norms related to specific subject area. Yet as for concrete areas presented in the list, which was prepared by IBC, we, having in mind existing disagreements, as well as discrepancies in national laws, think that in some cases it would be impossible to come to international agreement.

The beginning of life is, to our understanding, one of the most controversial areas. We have now a lot of differences in regulation of corresponding practices in different cultural and religious settings. This is especially true regarding laws on abortion. So, discussion of common norms for regulation of abortions can provoke too hot and unpromising debates. Besides, it seems rather dubious to speak about abortion in chapter, devoted to abortions, i.e. destruction of life. Prenatal diagnostics also seems too controversial area for seeking widely accepted norms. On the other hand, we think that discussions on preimplantation diagnostics and on reproductive technologies can bring some benefits, at least for elucidation of existing differences, if not for producing satisfactory decision. To our opinion, it will be much easier to come to terms in the field of sex selection.

As for *the end of life*, we think that the only prospective topic for seeking of a wide international consent among topics, proposed by IBC, is palliative care. It would be difficult to define common position regarding euthanasia. To our opinion, having in mind vast cultural and religious differences, there is no sense in seeking at the international level for definite norms in such fields as concepts of death and prolongation of life.

Among fields, presented in the area of *genetic and molecular biology*, we regard screening and testing, gene therapy and reproductive cloning as more amenable for introducing international regulations. We think also that rather important and interesting discussions can take place in fields of genetic consulting, gene patenting, genetic enhancement and non-reproductive cloning; nevertheless, the possibility of reaching wide and meaningful consensus in these fields seems non-evident.

We think it will be rather difficult (and yet desirable) to come to meaningful agreement in areas of *intellectual property rights* and *health care systems*. As for the last area, it seems that specific national and cultural traits play decisive role in it; that will create many complexities in elaboration of common norms for this particular field. Such area, as ethical regulation of gathering, storage and use of *genetic and other personal data*, to our opinion, will attract more and more attention; yet in many regions of the globe, including our country, these problems now is not perceived as really acute.

Taking into account rather widespread practices of trafficking of human organs (including transborder flow of organs), as well as often heard suggestions to legalize commercial use of human organs and tissue, we think it would be important to try to find agreement on regulations and norms in the area of *organ and tissue transplantation*.

One of the main difficulties in the area of *public health* is necessity to find a balance between rights of an individual and interests of the communities. Due to the existence of huge cultural diversity in understanding of such balance we think that attempt to develop meaningful common norms and guidelines for this area will demand enormous efforts.

International biomedical *research* now is becoming more and more widespread phenomenon. In this area we are witnessing a lot of attempt to elaborate ethical norms. To our opinion, area of research must be one of the most essential for the whole declaration. It will be important to develop reasonable and practical guidelines for just sharing of risks, burdens and benefits (at the levels of individuals as well as populations), associated with research.

Regardless of heading, whether in relation to molecular biology or to behavioral research, it need to be discussed, to our opinion, possibility of development of ethical norms and guidelines for such field, as molecular basis of human behavior (or, may be, for possible applications of neuroscience in general).

Boris Yudin, Prof.,
Vice-chairman, Russian National Committee on Bioethics,
Russian Academy of Sciences.

NATIONAL BIOETHICS COMMITTEE FOR MEDICINE OF CROTIA

DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

Professor B. Vrhovac
Co-chairman, National Bioethics Committee for Medicine
ZAGREB, Croatia

I Aims and Scope of the Declaration

I.1. All levels mentioned in the Outline are important for better assessment of the ethical implications of scientific progress and its implications.A better (these days practically not existing!) collaboration between numerous ethical bodies which exist in Europe (Table) and in the world is of utmost importance.

I.2. and I.3. The Declaration should not be limited only to human beings!
The problems of relationship with other living organisms should be included and mentioned to an extent which indicates the understanding that humans cannot live and survive without care for other living beings, enviroment and natural resources.

I.4. Enviroment issues should find their place in the Declaration.

II. Structure and Content of a Declaration on Universal Norms on bioethics

II.1. A preamble stressing the need and the aim of the Declaration would be useful. Sections of the Declaration listed in the Ooutline are good. The section about the problem of affordability should be added. The wide variations of wealth and poverty in the world, also of UNESCO members is a big problem making various declarations, attitudes and opinions not realistic. For example Art. 12 of the International Covernant on Economic, Social and Cultural rights asking for recognition of»the right of everyone to the enjoyment of the highest attainable standard of physical and mental health» is in spite of the word «attainable» difficult to achieve and sounds idealistic probably even nonrealistic,

II.2.All principles listed in the Outline are important and should be mentioned in the Declaration.

II.3. It is difficult to define all details of fundamental principles. Probably it is more realistic to state general principles and later write down a discussion or comment explaining details.

II.4. (this number is missing in the Outline- but is presented as II.5.)

Again all subject areas mentioned in the Outline are important. The importance is not equal for all UNESCO members. Again very bigg differences between various countries(culture, resources....) must be borne in mind . For some basic aspects of a health system are most important, for orther genetic and molecular biology.The «end of life»

Section is probably important for all, however more for developed countries.

Table

ETHICAL BODIES IN EUROPE INCLUDING WHO (elaborated by B. Vrhovac)

Name	Organization	No of countries
COMETH, CDBI, Bureau	Council of Europe	45
-International Bioethics committee -Intergovernmental bioethics committee	UNESCO	36
Forum of National Ethics Councils	?	?
Dept. of Ethics, Trade, Human rights and Law	WHO	? (all UN members)
European Group for Ethics(EGE) Unit: Ethics and Science, European Commission DG Research	EU	soon 25 (now 15)

Beside that (almost) every country has one or more national ethical body the activity of which is different probably sometimes non existent. No reliable data are available.

What should be criticized and discussed is that in important questions various bodies have different opinions for example concerning research:

	EU	CoE
organs	forbidden	allowed
embryos	allowed	forbidden
germ cells	forbidden	forbidden

NATIONAL BIOETHICS COMMISSION OF MEXICO

EXTRAORDINARY SESSION OF THE INTERNATIONAL BIOETHICS COMMITTEE

"TOWARDS A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS"

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Guidelines:

- Establishment of the National Bioethics Commission
- Some relevant actions
- National Bioethics Network
- Issues related to the possible structure and scope of a Declaration on Universal Norms on Bioethics.

Background

30 March 1992. **Establishment of the National Bioethics Commission,** through an agreement of the Health Ministry under the auspices of the **General Health Board** in order to study, research and communicate Bioethics for the development of human beings in connection with all aspects of life, health and well-being.
23 October 2000. The National Bioethics Commission, according to a **Presidential Agreement** published in the Official Gazette, was incorporated as a **professional and autonomous association of the Health Ministry**, whose aim is **to promote the study and observance of bioethical values and principles both for health care practices and health research.**

Duties or Faculties (Powers)

- To propose guidelines on ethics for health care and research practices;
- To set the minimum ethical criteria/principles for compliance by the public and private health institutions when providing health care services;
- To communicate across society and the health care professionals, technicians and assistants the ruling values and principles of their professional practice;
- To promote the respect of ethical principles in medical practice;
- To give an opinion about research protocols on human beings;
- To express its views about the research and development of new drugs and their appropriate use on medical practice;
- To communicate the criteria that the ethics and biosafety committees of the health institutions should embrace;
- To support the performance of the health institutions' ethics committees;
- To make general recommendations of the criteria to be included in the regulations for research on human beings;
- To issue the Commission's operating framework and
- Any others as determined by the Federal Executive Branch.

Vision

To develop a bioethical culture on health care and health students and professionals, through the creation of the National Bioethics Commission as the national ruling body on this matter.

Mission

To study, research, teach and regulate all aspects of human behavior in relation to life and health interventions with respect to human dignity and nature. As well as to review, under ethical and moral principles, the scientific and technological breakthroughs in life sciences, in order to meet the needs and expectations of the population, by issuing guidelines and regulations based on the regulatory framework in force.

Structure

President.

• Dr. Julio Frenk, Health Minister

General Coordination of the National Institutes of Health

– Dr. Jaime Sepúlveda

Seven Commission Members and 10 guests.

Executive Secretary.

Juan Garza (Person in charge)

The organization of the National Bioethics Commission of Mexico, as part of the Federal Government, has gained experience that may contribute to other participants at this UNESCO meeting.

The discussions, recommendations and exchange of ideas should give the participants a better understanding of the scope of Mexican Bioethics Evolution both at the academic and government levels.

Integration of values with scientific knowledge in Bioethics guides conducts in favor of nature, health and quality of life.

Bioethics directed to individual and population welfare, with emphasis to vulnerable groups, taking advantage of nature, preserving ecosystems and promoting health with equity.

Bioethics may be considered the missing link to solve the problems of globalization.
With scientific and technological knowledge not all that becomes possible is desirable. Humanism was left behind.
Devastating examples are found in war, terrorism and traffic of drugs, of people and of endangered species.
Bioethics allows the study of priorities in health, guides research issues, gives directions to public policies and assists decision makers.
Bioethic principles allow reaching with equity the respect to nature, human dignity and universal values.
Since all living organisms depend on each other, humans must act with prudence but urgency as well.
A point of reference of Bioethics is complementarity among individuals, society and all living organisms.

Relevant Actions include:

The academic program is organized yearly through
- Meetings,
- Academic sessions,
- Seminars,
- Workshops and
- National and International Congresses.

- Some Relevant Actions
- Creation of State Bioethics Commissions by agreement with the National Health Board.
- On-going promotion for the creation of Bioethics Committees in health care institutions and higher education institutions.
- Bioethics Code for health care personnel
- Code of Conduct for health care personnel
- On-going participation in national and international meetings on bioethics.

- Publications
- Proceedings from seven National and International Bioethics Congresses since 1994.
- Bioethics Code for health care personnel, 2002
- Code of Conduct for health care personnel, 2002
- Journal *Summa Bioética* published quarterly since 2003
- Website: www.bioetica.salud.gob.mx
  (under reconstruction).

Program 2001-2006

Action lines

- In order to meet the objectives and strategies of the National Health Program 2001-2006, the **National Bioethics Commission** is engaged in strengthening the intra and extra sectorial mechanisms and in issuing recommendations, guidelines and standards in bioethics matters in order to:

- Consolidate the Commission as a national reference body for the study, analysis, reflection and training of human resources in the bioethics domain to improve the overall quality of health care services.
- Strengthen the Commission as a liaison with national, regional and international organizations in the bioethics domain.
- Develop the legal and administrative instruments for the proper operation of the Commission.
- Promote training in bioethics for health care employees.
- Establish coordination mechanisms with public and private health care institutions, in order to promote the appropriate operation of the Bioethics Committees and the assessment of bioethical implications in basic, clinical and socio-medical research.
- Promote the bioethical foundations to strengthen the values and principles of the National Health System.

Priority Activities

Regulations:

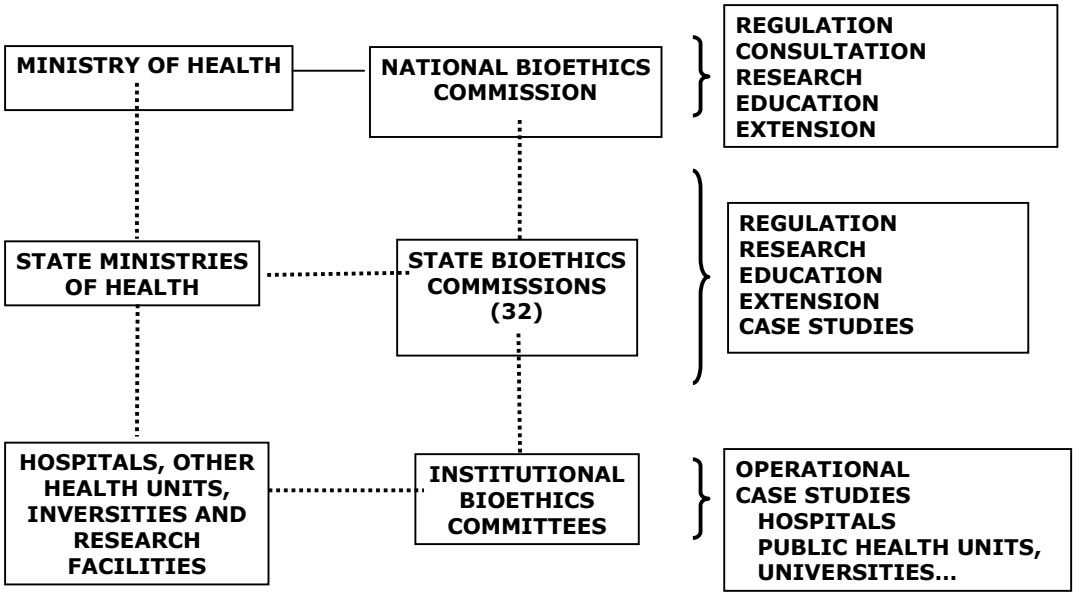
- General Health Law
- Presidential approval
- Internal regulations
- Organization manual
- Procedures manual
- Operating Standards for State Bioethics Committees

NATIONAL BIOETHICS NETWORK

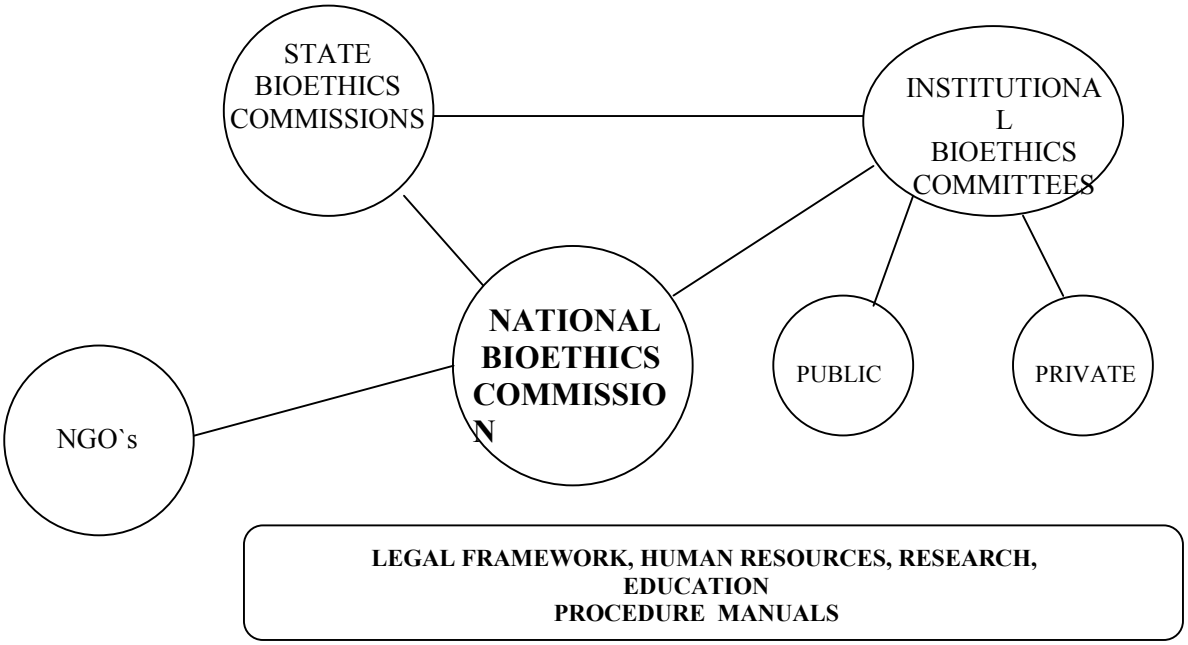
Conceived as an organized system to regulate, consult, inform, extend, teach and research in Bioethics applied to health.

The model is built through the integration of the National Bioethics Commission, State Bioethics Commissions and institutional committees.

- **Development of the model**



National Bioethics Model



We must articulate an organization model for the linkage of the different levels of attention of the Health system.
This statement is supported by an agreement of the General Health Body that approved that each State of Mexico should have a State Bioethics Commission.
At this time we are validating the model at the National Institutes of Health and in the States where the Bioethics work at institutional, research and education levels has reached higher standards.
We have a draft of the operational guidelines of the State Bioethics Commissions as well as the minimum standards of the Institutional Bioethics Committees.
Bioethics Commissions and Committees should be organized according to local priorities.
Autonomy, geographical, political, economical and social development conditions should be taken into account when establishing priorities.
Case studies should lead to decisions and recommendations according to Bioethics principles.

In Mexico we are convinced that having group studies in Bioethics is not enough.
A Declaration on Universal Norms on Bioethics is not enough by itself.
Bioethics requires a rational and systemic impulse.
Bioethics has had a heterogeneous development.
In order to reach Bioethics everywhere for everyone there is need to build an organization model that impels Bioethics in a coherent and articulated way.
The answer is International and National Bioethics Networks in order to have **discussion bodies to solve dilemmas in an informed manner.**

ISSUES RELATED TO THE SCOPE AND STRUCTURE OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

We agree with what is mentioned in the questionnaire with the exception of:

I. Aims and Scope of a Declaration on Universal Norms on Bioethics

I.1 The declaration should not be limited to human beings.

I.2 Attention should be given to vulnerable communities and their areas of influence ("communities" refers as a whole to human beings, environment, infrastructure, services, biodiversity).

II. Structure of a Declaration on Universal Norms on Bioethics

II.2. International Cooperation and Promotion and Implementation **assuming autonomy of Local and National decisions.**

III. Content of a Declaration on Universal Norms on Bioethics

III.1 Freedom of research assuming it is oriented to beneficence and not to Maleficence. Add two principles**: Tolerance, Equity.**

III.2. Other topics: **Concepts of life's beginning**

Public health: Zoonoses, accidents, chronic-degenerative disorders (cervix and mammary cancers, mental disorders, obesity).

IV. Other comments

Need to establish National Bioethics Commissions, State Bioethics Commissions and Institutional Bioethics Committees integrated in a network to assure that case studies lead to decisions and recommendations according to Bioethics principles.

NATIONAL BIOETHICS COMMISSION OF THE DOMINICAN REPUBLIC

UNESCO DECLARATION OF UNIVERSAL NORMS OF BIOETHICS

SCIENTIFIC PROGRESS: BENEFITS AND RISKS.

Throughout the history of the human race scientific advances have let us achieve a better quality of life; have allowed us to prevent and treat countless diseases; and have given us the means to correct damage from congenital defects and from alterations of the normal biological processes in the human body. Those advances made possible the improved birth survival, longer life expectancy, and those fuller, healthier and happier lives that we humans presently enjoy, as compared to the ones in the past. Medical advances in chronic and palliative care have also made longer lives not only possible but also healthier, making death for many a delayed and more dignified proposition.

Technical and scientific progress, being essential to the progress of humanity, should be stimulated and freed from obstacles and interference. This progress must be complemented by and referenced against a global anthropology linked to the other dimensions of man (Jonas). This will require a future man capable of integrating technical and scientific developments without becoming dehumanized or absolutist (E.Greccia).

Following the precepts of bioethics, scientific projects can't be configured only as either deductive or inductive, but their methodology must be also anchored in three interconnected points. Firstly, the project must be scientifically proven, consistent and exact. Secondly, their anthropological significance must be determined by analyzing the human values and principles involved and their respective roles reinforcing the life, integrity and dignity of human beings. From these two points we will be able to determine the values to be defended and how to normalize the actions and the agents involved in the personal and the social plains to achieve this. Thirdly, these values, norms and principles must be harmonically organized in a hierarchy. (E.Greccia)

Despite its undeniable benefits, technological and scientific progress presently puts man in more serious dangers than at any other time since his appearance on earth millions of years ago.

Because of the scientific advances in medicine in the last and the present centuries, especially in the ability to modify the genome, the human race is at risk of losing its uniqueness, totality and genetic and biological identity.

The influence of logical positivism, a philosophical school now without a following, is still presently felt. It promoted the concept that pure science, among which it included medicine, should always be belligerent in matters of fact and neutral in matters of value, above good and evil. As a consequence of this assumption we are presently facing major ethical conflicts. Science is really not above good and evil. Medicine in particular is a field where values and judgments are constantly in play, and where decisions based on those values and judgments are frequently made. (Cf. Graham).

THE CONTRIBUTION OF BIOETHICS

Bioethics, being founded on the principles of respect of human life, dignity and autonomy, and intent on promoting equity and justice, tries to avoid alteration and irreparable damage to human existence. In this way bioethics promotes a life of quality, wholesomeness, and health; and free of preventable risks. At the same time bioethics assumes the defence of the fundamental human rights from conception, through the process of dying with dignity, and until the natural end of the life cycle.

Techno-science allows our present culture to develop knowledge systems in the absence of value systems. In the words of Ladriere: "…the present power of science and technology is so far-reaching that it puts the future of the world and of man at risk: the whole of humanity must respond to [this power] with it's total presence, or resign to its total absence…"

Humanity is now immersed in the culture of the technology, which, contrary to theoretical science that can be seen as neutral, is essentially belligerent. Technology, to avoid losing its identity, must adjust reality by actualizing the impossible, the reproducible, the reconstructable, and the modifiable. Since techno science has no memory, its aim is to increase power, to be progressive and transgressive. (F.Garzon) We must look for the conscience in science, because science without a conscience only creates ruin and dehumanization (3 Cely)

In writing the declaration it is important to assign a hierarchy to the four principles in bioethics: autonomy, beneficence, non-malfeasance and justice. Beauchamp and Childress originally presented these principles as "prima facie duties", without prioritization or hierarchical ranking. Some authors, among them Diego Gracia, have separated the four in two levels. First is the private morality level of autonomy and beneficence. The second is the hierarchically higher public morality level of non-malfeasance and justice. In case of conflicts between a principle of the private level and one of the public, the public one will always have priority.

UNIVERSAL BIOETHICAL NORMS

When we talk about writing the declaration of the Universal Norms of Bioethics, we place ourselves in the field of normative ethics, the discipline that studies values, principles and norms of behavior vis-à-vis to what is lawful or unlawful, and searches for their basis and justifications. In this field, among the special ethics, is bioethics, which concerns itself with the life and health sciences (E.Greccia).

We have to notice the constant unbalance between life and will, between action and the ultimate goal, which is Goodness. In this context, the action, as an expression of free will, is still restrained by the freedom of man to decide to perform it or not.

The particular good obtained from an action doesn't produce by itself total goodness, the ultimate ethical goal. It may in fact in some cases drive you farther from it. Because of this we can't lose sight of the precise connection of each particular goal to that ultimate goal of Goodness.

As we call attention to the concept of responsibility, particularly the responsibility of the scientist, we must remember that every free action implies a moral responsibility. Moral responsibility in itself obliges the scientist to evaluate the goodness to come from his free choice of action and also to respond to his own conscience.

The specialist in bioethics, and even more the educator, must keep in mind two methodological musts. One is objective, ensuring that the action has a value, that it will produce goodness. The other is the subjective judgment that takes place internally the moment that the action is conceived and decided on. Harmonizing in an internal analysis the action's objective value with the subjective judgment will guarantee the integral morality of the action. This is the moral obligation of the ethical investigator.

The elaboration of a judgment concerning the objective value of a specific action comes out of a process of knowledge that can have varying degrees of certainty and differing modes of comprehension. It can initially present itself as an immediate, pre-cognitive, natural reaction or it could be a reasoned, conscious process of reflection. The elaboration of a judgment can sometimes become bogged down by doubt.

Each advance generated by scientific and technological progress demands new ethical considerations. We consider that UNESCO's initiative in creating a universal declaration of bioethical norms will significantly contribute to the framework needed to evaluate the ethical implications of scientific progress. International policies and universally applicable ethical norms are important not only to the scientific community, but also to academia, the media, and societies in general.

We agree that the declaration should not be limited to the ethical aspects of the respect to dignity, liberty and the fundamental rights of man, but should also address issues concerning man's relationship with his habitat, the preservation of biodiversity, the use of genetically modified organisms, the use of animals in biomedical research and the transplanting of organs and tissues.

Concerning structure and content, the declaration should be as wide and far-reaching as possible, to guarantee its long-term impact and validity. It must include a preamble, general provisions and topics relating to healthcare and scientific investigation. It must also promote international cooperation and its implementation and promotion must be based in education and creation of conscience at every level.

THE PRINCIPLES OF BIOETHICS

Each of the fundamental principles of bioethics must be widely addressed, and precise recommendations for their application by governments, institutions and individuals must be provided.

1- The principle of beneficence in the naturalist vision is aimed at the main purpose of medicine, which is to promote what's good for the patient and society and to prevent what's bad.

2- The principle of autonomy. It refers to the proper respect of the fundamental right of man to self-determination and it's based in a morality inspired mutual respect. The patient-doctor relationship and informed consent for diagnosis, treatment and research in humans are based on this principle. It is also integral for and at the service of the principle of beneficence.

3- The principle of justice refers, among others, to the obligation to equality in medical treatments, research and the distribution of resources in healthcare services. The value of life and respect to proportionality in actions are some of the objectives attached to the principle of justice.

Other principles to be taken into account when humans act on human life in the bioethical field are:

4- The principle of defence of physical life states that corporeal life doesn't represent something extrinsic to the person, but a fundamental value of that person. A fundamental value because it must be understood that (life is not only corporeal, but most of all, spirit, and as such transcends the body and temporality).

5- The principle of liberty and responsibility as the origin of the ethical act says that in the field of bioethics, before the right to liberty comes the right to the defence of life. Liberty must first take responsible charge of life, our own and other's. This principle sanctions the moral obligation of the patient to take part in safeguarding life and health.(Both, the patients and the physician are responsible of life and health as a personal and social good) cannot violate the conscience of the patient, nor can the patient force the physician's conscience. They are both responsible of life and health as a personal and a social good.

6- The principle of totality or therapeutic principle is one of the basic principles of medical ethics. It is based on the fact that human corporality is a whole made up of different parts that are organically and hierarchically unified by the unique, personal existence. This principle dictates all (the interventions that are permitted in medical and surgical therapies) that is permitted and mandatory in medical and surgical therapies.

7- Sociability and subsidiary principle are presently defined by the dictates emanating from international agencies when health assistance plans are formulated. The principle of sociability obliges every person to participate in the attainment of goodness by everybody else. Concerning health promotion it says that every citizen must consider his and other people's lives as belonging to the society, and as that society must care for every citizen's health as part of a common good. The principle of subsidiary principle states that society must help more where the need is higher.

These principles provide general guidelines of behaviour, but what gives final sense to the action is its ethical value, its influence on the goodness for the person, the ultimate goal to be achieved.

Each of these principles must be addressed profoundly, reaffirmed and justified by the declaration. Besides analyzing the general principles, which have wide application, detailed frameworks must be defined for other specific matters.

Some authors propose that the traditional model of ethics, based on the virtue and vice, must actually be underlie as ethics of rights and duties, that is, an ethics of responsibility (D.Gracia). Nevertheless, ethics should not be seen only as an endless search for foundations and justifications, but as an acquisition of patterns of behavior, of character traits (A. MacIntyre).

The conceptual nucleus of the origin of bioethics is the belief that the biological sciences need to consider ethical questions concerning the moral relevance of its interventions on life. "It tries to supersede the pragmatic tendency of the modern world to immediately apply knowledge without the mediation of reason or morals… the use of scientific knowledge can have unforeseen consequences for humanity, even just by concentrating biotechnological power in the hands of a few" (E. Greccia)

Since the declaration has the higher purpose of defending dignity, liberty and human rights, it must define orientations, guides and norms for specific aspects of human life from birth to natural death. These guides and norms must address aspects of genetics, molecular biology, healthcare systems and confidentiality of health information, especially genetic information. Ethical aspects of organ donation and transplantation, policies to manage Public Health, particularly for vulnerable populations, biomedical investigation and intellectual property rights of scientific discoveries should also be included.

There are documents published by inter-governmental organisms, non-governmental organizations, and scientific associations that provide norms and guidance (in biomedical research. These include the 2000 Edinburgh version of the Helsinki Declaration, CIOMS 2002, TDR/WHO 2000 and ECFMG Good Clinical Practice guide lines). These must be taken into account when deciding specific aspects of the UNESCO declaration. It is also important to make reference of the organizations working to develop standardized operating procedures to evaluate ethical aspects of biomedical investigations, such as TDR/WHO thru SIDCER in Asia (FERCAP), Africa (PABIN), Latin America (FLACEIS), Eastern Europe Oriental (FECCIS) and North America (FOCA). These institutional models may facilitate the diffusion, promotion and implementation of the recommendations to come from the declaration.

The declaration must preserve the norms established by international organisms to protect the rights of research subjects, especially in developing countries, for example WMA paragraphs 29 and 30 of the Edinburgh 2000 version of the Helsinki Declaration. The first one assures participants in the control arms of clinical trials the most effective therapy during the trial, and the second one assures that participants in the control arms of positive trials receive the most effective treatment at the conclusion of the trial.

In closing, we propose that human dignity, as a supreme value, requires utmost respect for the person and an effective vigilance throughout life's cycle. On that foundation we must build a bioethics that fully respects life dignity, Goodness and values of the human being.

The fundamental principles of this personalistic bioethics, discussed before, are the fundamental value of life, the principle of totality, liberty, responsibility, sociability and subsidiary principle, which implies the care of those most at need.

AUTRES CONTRIBUTIONS

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OTHER CONTRIBUTIONS

Scottish Council on Human Bioethics

15 Morningside Road, Edinburgh EH10 4DP, SCOTLAND, UK

Date: 20 March 2004 - International Bioethics Committee (IBC)

Possible Scope and Structure of a Declaration on Universal Norms on Bioethics

Consultation response on behalf of the Scottish Council on Human Bioethics:

I. Aims and Scope of a Declaration on Universal Norms on Bioethics

I.1 How, in your opinion, could the declaration contribute to better assess the ethical implications of scientific progress and its applications? At what level (policy-makers, scientific community, academic circles, media, society, etc.) and how?

Scottish Council on Human Bioethics Response:
A Declaration on Universal Norms on Bioethics would, if constructed ethically, ground scientific progress and its applications on the principle of human dignity which should represent the basis of all bioethical reflection. Such a declaration could then be used as a normative standard against which all biomedical interventions and procedures could be appraised and assessed. To do this, all levels and sections of society should be encouraged to seriously consider their involvement, commitment and engagement in bioethics since the ethical issues relating to the consequences of being human and human dignity cannot be separated from the whole of society.

I.2 Should the declaration be limited to human beings and why?

Scottish Council on Human Bioethics Response:
Yes, the UNESCO declaration should only be limited to human beings in order to specifically address the crucial and unique importance of human dignity with which only humans are endowed. It would also limit the scope of the declaration which would, otherwise, become too broad, complex and heterogeneous. The only exception should be the consideration of human-animal hybrid embryos and the issues relating to xenotransplantation which raise serious questions with respect to human dignity.

I.3 If the answer to I.2 is yes, does this mean that the declaration should deal only with ethical issues related to the human person and the human body in a biological and medical context? Or, should the declaration also deal with ethical issues concerning the human being's relationship with other living organisms? And to what extent?

Scottish Council on Human Bioethics Response:
Yes, the UNESCO declaration should only deal with ethical issues related to the human person and the human body (including the brain) in a biological and medical context in order to specifically address the particular issues pertaining to humanity which are not shared with the animal species.
Maybe an additional declaration or recommendation could be considered, at a later stage, by the UNESCO to address the ethical issues concerning the relationship between human beings and other living organisms.

I.4 If the answer to I.2 is no, what other issues could be covered (for example, issues such as the use of animals in biomedical research, the use of animals in transplantation, biodiversity, genetically modified organisms (GMOs), environment, etc.)?

II. Structure and Content of a Declaration on Universal Norms on Bioethics

II.1 How should the declaration be structured? Should it include a preamble? Should it be organized into sections? If yes, please indicate which sections could be included and why (general provisions, health care, scientific research, public consultation, international cooperation, education and awareness-raising, promotion and implementation, etc.)?

Scottish Council on Human Bioethics Response:

The UNESCO declaration should be structured to include a preamble and be organized into relevant sections which could, for example, be added to a general declaration. This would enable a more flexible and subject-specific approach to be established.

In other words, the declaration should be structured into similar sections and in a similar manner to the Council of Europe's Convention on Human Rights and Biomedicine (ETS - No. 164) and its additional protocols (1) On The Prohibition of Cloning Human Beings (ETS - No. 168), (2) Concerning Transplantation of Organs and Tissues of Human Origin (ETS - 186) and (3) the forthcoming additional protocol on Biomedical Research.

In this respect, it should be noted that many years of international co-operation and investment in debates and discussions, at the uppermost levels, have gone into the drafting of the legally binding texts of the Council of Europe. Therefore, these important documents should be used as a basis and foundation for the proposed UNESCO declaration.

If this is not done, much time will be wasted on "reinventing the wheel". Moreover, the proposed wording in the proposed UNESCO declaration should be similar to that of the Council of Europe texts in order to obtain an international standard and common language in bioethics. In doing so, the creation of misunderstandings and confusion between national and international legal texts will be avoided.

II.2 Which fundamental principles should be reaffirmed in the declaration (autonomy, benefit sharing, confidentiality, freedom of research, free and informed consent, justice, non-discrimination, respect for human dignity, respect for privacy, solidarity, etc.)?

Scottish Council on Human Bioethics Response:

The principle of 'human dignity' should be the most important fundamental principle to be affirmed in the UNESCO declaration. All other principles are the result and consequence of this fundamental principle.

Human dignity, in this respect, should also be considered as being associated to the concept of personhood which does not have as its source a limited reality constrained by biological or physical substance. Instead, personhood should be understood as the primary and absolute concept of existence which enables human dignity to exist.

The term 'person' also implies a relationship between human individuals; a person can never exist in isolation. Thus, human dignity is based on the existence of what is in 'essence' human and with which others can have a relationship. In other words, in a relationship between persons, each *individual* obtains his or her *personal* identity from the *other*.

In this regard it should additionally be noted that human dignity does not change or develop within the 'time' of existence of a person.

II.3 In reaffirming these fundamental principles, should the declaration state only general principles of broad application (such as the general principle of consent in research) or should it attempt, where appropriate, to define a more detailed framework (for example, requirements for consent in specific cases)?

Scottish Council on Human Bioethics Response:
In affirming the bioethical principles, the UNESCO declaration should state only general principles of broad application and leave the more detailed framework to national legislation. The document would, otherwise, become too rigid whereby some countries may find it difficult to implement the relevant provisions.

II.5 Whatever the structure and scope of the declaration may be, should it, where possible, provide guidance on specific subject areas? If yes, which subject areas could be explicitly mentioned and why?

Scottish Council on Human Bioethics Response:
The UNESCO declaration should, where possible, give guidance on specific subject areas in order to provide universal norms on ethical procedures.
And in this respect, it should be noted that only a universal declaration on bioethics from the UNESCO will be able to appropriately address the very grave ethical challenges already facing the international community such as organ trafficking, the lack of appropriate care in psychiatry, the new threats relating to the protection of human embryos, bioethical tourism and the lack of public engagement in bioethics.
Other subject areas which can be addressed are (additional subjects in italics):

- beginning of life
o abortion
o prenatal diagnosis
o preimplantation genetic diagnosis
o reproductive technologies
o sex selection
o new procedures for the creation of human embryos (parthenogenesis, use of gametes created from stem cells, etc.)

- end of life
o concepts of death
o prolongation of life
o euthanasia
o palliative care
o assisted suicide

- genetics and molecular biology
o genetic counseling
o genetic screening and testing
o gene therapy
o gene patenting
o genetic enhancement *and eugenics*

o population genetics
o cloning, reproductive cloning, non-reproductive cloning
o human-animal hybrid embryos

- intellectual property rights
- health care systems
o access to drugs
o access to health care
o allocation of health care resources
o quality of care
o right to health care
o rights of vulnerable persons

- human genetic data and other personal healthcare data
- organ and tissue transplantation
- public health
o HIV infection and AIDS
o other infectious diseases
(malaria, tuberculosis…)
o policies regarding vulnerable populations

- research
o research with human subjects
o embryo research
o behavioural research
o international and transnational research
o research in emergency situations

The Bioethics Advisory Committee
of the Israel Academy of Sciences and Humanities
Jerusalem, Israel

March 31, 2004

ANSWERS TO THE QUESTIONNAIRE CONCERNING THE ELABORATION OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

The Bioethics Advisory Committee of the Israel Academy of Sciences and Humanities held a special session to prepare its answer to the document of Unesco International Bioethics Committee asking for contributions of organizations and institutions on the possible scope and structure of a Declaration on Universal Norms on Bioethics.

I Aims and Scope of a Declaration on Universal Norms on Bioethics

I.1 How could the Declaration contribute to better assess the ethical implications of scientific progress and its applications?
Principally by promoting at all level the confidence that Bioethics is an effective partner, accompanying the progress of Scientific and Medical Research, and insuring that its possible applications are made with respect of Human Rights and Human Dignity, for the welfare of the individual who can benefit from the medical advances. This confidence in the functioning of Bioethics Institutions - at the International level, at the National level and at the local level in hospitals and research centers - can be promoted by a Declaration on the Norms to which Bioethics adheres. The Declaration should include a request for establishment of pluridisciplinary Bioethics Committees (scientists, philosophers, lawyers, representatives of public life, of religions or other cultural bodies) in every country, as well as creation of a network to promote communication and cooperation.

This confidence building task is of utmost importance in the modern world to alleviate fears in the public, fears spread by media and often influencing lawmakers. The task is to give to each individual in the society the reassurance that there is an Ethical control of what is desirable and applicable, how much and for what purpose. The task is also directed to the scientific community to proceed with respect of the Bioethics Institutions and their directives, in the interest of free scientific inquiry and to ensure a positive view of the public on Science. In this respect, it would be appropriate to encourage the creation of International Forums for research on specific areas that include both scientific, medical and ethical aspects (such as the International Forum for Embryonic Stem [ES] cell research recently created and based at the MRC in the UK).

The Declaration should further indicate that there are Universal Norms based on Human Rights, but that there are also issues of Bioethics where only a pluralistic approach is desirable, reflecting cultural, religious and legal differences between countries (as the IBC did for the ES cell research and for PGD). There ought not to be contradictions between the two, provided that the Universal Norms express general principles, without taking one-sided views in issues which have been deemed as worthy of a pluralistic approach at the level of International Bioethics Committees.

There is one area where the Declaration on Universal Norms has a unique and important role, namely issues of international nature such as across-borders exchanges (the providing of technologies in one country and "medical tourism" from countries were this is banned; the

severe danger of trade of organs across borders, etc..). Most importantly, and on the positive side, benefit-sharing, solidarity and cooperation between developed and developing countries should be addressed in-depth in the Declaration.

I.2 The Declaration should be limited to Human Beings. This because the ethical and moral obligations towards human beings are on a different plane (spiritually and legally) than the ethical considerations one may have toward other living organisms and animals. Bioethics has the vocation of ensuring that the advancement of science be an instrument to promote human welfare and human dignity. A clear separation should be made with regulations against cruelty to animals, and regulations for the ethical use of laboratory animals for the purpose of scientific and medical research.

I.3 The Declaration should deal with issues such as xenotransplantation, inasmuch it may expose humans to danger. Issues of food safety and development of genetically modified plants, animals or microorganisms should certainly be included, to address the fears and indicate the benefits. Bioethics has here as well a role to promote the confidence of the public that there is an ethical control in scientific applications to provide food in sufficient quantity and quality for the welfare of mankind.

II. Structure and content of the Declaration

II. 1 A preamble should indicate the basis of Bioethics in the Human Rights Chart, the World Medical Association Helsinki declaration and so on.

Sections indicated are all appropriate. Much of what has been said above can find its place in the different sections. It may be appropriate to add a section on Bioethics Institutions in order to better define the functioning of Bioethics as a partner in the applications of scientific advances in Medicine, Health care, Welfare and Food supply.

The section on Public Consultation should indicate that properly constituted Bioethics Committees are representatives of the Public, especially if the members are selected by elected governments. Public consultations are tools for Bioethics Committees to define a consensus, but are not to be used as such for deciding an issue that the public at large may not be able to understand in all its scientific and societal aspects.

II. 2 The fundamental principles listed are all appropriate, but some deserve a comment and addition.
In particular the last two principles in the Questionnaire are transparency and truth-telling.
Transparency is a good principle provided it does not conflict with confidentiality, especially in the realm of genetic information.
Truth-telling is problematic if what is meant is an obligation of telling the truth to patients. It should be remembered that the Right not to know of a genetic test result is fundamental and should not be preempted by Truth-telling.

Respect for human dignity is best defined within the framework of Human Rights. The use of respect of human dignity has been sometimes poorly defined when banning new emerging technologies. Bioethics has the power to ensure that medical applications of new technologies be done solely in respect of Human Dignity. Denying upfront the emergence of such new medical applications of technologies may sometime be itself a violation of Human Dignity and the human right to benefit from the advancement of Science.

Additional principles could be added:

- Sensitivity to community values, including religious beliefs.
- Not restricting human beings to their genetic characteristics.
- Respect of the diversity of human beings within the fundamental unity of the human family (including issues related to handicapped individuals).
- Cautiousness in interpretation of scientific findings with regards to their social impact (in particular with regard to behavioral genetics and excessive belief that human behavioral and cognitive traits are determined irreversibly by genes, or that persons with identical genomes, like genetic twins, are excessively determined).
- Risk assessment of new medical technologies versus their benefit and the right of the individual to freely use these techniques (e.g. gender selection by PGD).
- Fundamental difference in the Medical versus Non-medical use of technologies (especially in genetics, reproduction, etc..)
- Avoidance of Eugenic measures by Society that would be imposed on individuals and statement that free-willing and informed use of genetics by the consenting individual is not a Eugenic practice.
- Altruistic donations of biological material from one individual to another as distinct from "trade of organs or oocytes".

II. 3 The Declaration should attempt, where appropriate to define requirement for informed and free-willing consent in specific cases.

II. 4 The Declaration should minimize to the utmost addressing specific subject areas and stating a strict position. Specification of subject areas could hinder reaching a consensus on general Universal Norms.

Therefore the Declaration should not refer explicitly to specific technologies. It should certainly avoid to the utmost pinpointing some research subjects in particular for upfront banning without weighing all the possible future developments and possibly medically important applications which may not be apparent today.

Instead the Declaration should base itself on the general fundamental principles to indicate the basis on which guidelines could be established by Bioethics Institutions in different countries for ensuring the use of Science only for Medical and Welfare applications in full respect of Human Rights and Human Dignity. For example, it could state that "use of genetics and assisted reproduction technologies shall always be only for the benefit and welfare of the individual requiring medical assistance, with informed and free-willing consent of the individual or legally authorized representative."

In conclusion, the main message of the Declaration should be to increase the confidence of the Public and Lawmakers in the power of Bioethics to ensure the use of Life Sciences for the good of the individual.

Gezondheidsraad
Health Council of the Netherlands

Subject : Declaration on universal norms on bioethics

Your reference : SHS/EST/04/084

Our reference : U-582/WD/ts/125-N15

Date : March 30, 2004

Dear dr Ten Have,

Thank you very much for your letter and for the invitation for next month's hearings session of the IBC in Paris. In its meeting of March 2004, the Standing Committee on Medical Ethics and Health Law of the Health Council has discussed the proposal of a declaration on universal norms on bioethics, both in response to your letter and on request of the Dutch State Secretary of Health, mrs CIJM Ross-van Dorp.

The Committee welcomes the initiative taken by Unesco's International Bioethics Committee. Apart from setting standards in areas where those are needed, the declaration may serve to strengthen people's awareness of bioethical issues and provide a framework for the fostering of international and cross-cultural dialogue.

The Committee understands the need for a declaration on universal norms as something which may be felt more urgently in countries of the developing world rather than, for instance, in Europe, where several other instruments relevant to bioethical issues are already in place. While this does not diminish the importance of the initiative from a global perspective, it is a reason for focussing on those issues which are most relevant to the daily lives of people living in the developing world. The most important issue to be addressed would then be the availability and accessibility of basic health care provisions. The fact that the envisaged instrument would have the status of a declaration rather than a legally binding text, might give scope for spelling out in more detail than has until now been done, the responsibilities of governments in this respect.

The Committee observes that the preparatory background report discusses two types of issues: those about which there are divergent bioethical positions between countries or communities and those of which the difficulty is not so much a matter of fundamental dissensus, but rather the fact that their solution requires international cooperation and harmonization. The former of these include issues such as preimplantation genetic diagnosis, embryo research, therapeutic cloning, and euthanasia. Since one would not want part of the international community to impose its views on others, convergence of positions on those issues can only be expected on a level of abstraction which is at cross-purposes with the aim of an instrument of practical relevance. These issues call for further dialogue rather than for universal norms. Instances of the second type are (biomedical) research involving human subjects, intellectual property rights, and the global flow of tissues and GMOs. According to the Committee, there is indeed an urgent need for standard setting with regard to such boundary transcending

issues. The declaration would serve an important purpose by contributing to this, while also addressing the practice of ‘shopping’ for countries with lower standards for biomedical research.

The Committee welcomes the balanced survey character of most of the background report. However, some of it seems to depart from this. The phrasing of the last line of the End of life section can be understood as prejudging the morality of euthanasia as accepted in the Netherlands and Belgium. Another example is the section on Behavioural Genetics. This sees only dangers, which makes it unbalanced. Also, research using hES-cells as a possible source of cell therapeutic material is discussed in isolation from related developments in fundamental research (other stem cell types, xenotransplantation). This gives the impression that the moral acceptability of the use of hES cells can be assessed without also considering the merits of those other attempts at finding a way to the same end.

The Committee very much agrees that the subject matter of the proposed declaration calls for encouraging the public at large to take part in informed debate. How this can best be achieved, is indeed a difficult question, which requires special attention and further research. More generally, the Committee finds that, in order to avoid blunting the instrument of an international declaration, due attention should be given to whether and how its recommendations can in fact be implemented, and to the follow-up of the whole process of awareness-raising, education and participation to which it ideally would lead.

Yours sincerely,

JA Knottnerus, MD PhD
president

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April 13, 2004

Comments on Possible UNESCO Declaration on Universal Norms on Bioethics

Global Lawyers and Physicians (GLP), a transnational organization of lawyers and physicians dedicated to promoting human rights and health, appreciates the opportunity of comment on the possibility of developing a "Declaration on Universal Norms on Bioethics." Our organization was founded on the conviction that physicians and lawyers have special obligations to promote human rights and health, especially those rights articulated in the Universal Declaration of Human Rights and the two subsequent human rights treaties. In our own work on a possible treaty prohibiting human replication cloning and inheritable genetic alterations we have found UNESCO's Declaration on the Human Genome and Human Rights of singular importance. We also support a related, ongoing project to encourage the implementation of patient rights by developing a statement of the universal rights of patients, a project which has relied heavily on Europe's Convention on Human Rights and Biomedicine. Thus, as an organization, GLP believes that both regional and universal conventions and declarations can be of significant importance in defining, protecting, and promoting human rights in health.

Nonetheless, as prior reports from your organization have made clear, the enunciation of universal principles of bioethics is an extraordinarily difficult task. Since bioethics is fundamentally an applied field, i.e. ethics applied to medicine and the biological sciences, the question of what ethics to apply quickly becomes a central consideration. This consideration, for example, has led to at least a temporary halt at the United Nations in the search for language to go forward on a convention to outlaw human cloning. The almost 50:50 split among nations has centered on just one ethical issue: the status of the human embryo and whether one must outlaw the creation of embryos for medical research as a necessary condition to prohibiting replication cloning to make a child. In short, when specific bioethical issues are joined at the international level, especially those related to the status of the human embryo and a woman's right to abortion, no universal consensus seems possible at this point because the ethical systems that individual countries use to reach their "bioethical" conclusions are incompatible, and many are founded on religious doctrine which does not permit compromise.

The lack of universal agreement on fundamental ethics precepts, however, is simply a pragmatic reason why devoting too much energy to universalizing bioethics may not pay off. On the more central theoretical level, a reading of the considerations to date that you have engaged in demonstrates that any additional declarations by UNESCO on bioethics would take as their starting point the Universal Declaration of Human Rights. As Professor Ryuichi

Ida, former chair of the IBC put it last year, the UNESCO Universal Declaration on the Human Genome and Human Rights "has its place in the series of international instruments for the protection of human rights in the same way as the 1948 Universal Declaration of Human Rights, whose legal force is today universally recognized. The UNESCO Declaration represents an extension of human rights protection to the field of biological science."

We agree, but would go further: all bioethics declarations will spring from the Universal Declaration of Human Rights, because the UDHR itself is founded on universal principles of human dignity and nondiscrimination. No universal declaration of bioethics could be inconsistent with the principles of the UDHR, but could only seek to apply them in a particular context, such as biomedical research, including genomic research. For this reason, GLP believes the current international need is not for a new or competing universal declaration, but for declarations and conventions, such as UNESCO's Declaration on the Human Genome and Human Rights, that apply the human rights principles of the UDHR to specific bioethics arenas and controversies. Nor is the June 13, 2003 "Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics" inconsistent with this view. Indeed each of the ten examples the documents uses to illustrate "fields that might be addressed by a universal instrument" could themselves be the subject of separate declarations. Equally important, new methods of implementation and enforcement are required to make such declarations more than pious pronouncements. As Professor Ida also properly observed, "in the field of bioethics the most important thing is to enforce ethical standards."

In this regard, GLP urges you to recognize the Universal Declaration of Human Rights as the fundamental universal declaration of bioethics as well, and to see your charge as articulating how the universal principles of the declaration can be applied to bioethics and bioethical controversies. GLP believes it is more important to concentrate on new and creative ways to promote and enforce the UDHR, and to use it to develop more specific instruments like the Universal Declaration on the Human Genome and Human Rights, than to attempt to create what may be perceived as a competing set of universal standards for medicine and bioethics.

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RESPONSE TO THE INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO REGARDING A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

Comment on Reproductive Ethics (CORE) is grateful to the International Bioethics Committee of UNESCO for the opportunity to contribute to its consultation on the possible scope and structure of the planned Declaration on Universal Norms on Bioethics.

CORE was founded in the United Kingdom in 1994 to encourage informed debate on the ethical dilemmas associated with the new reproductive technologies, dilemmas that have escalated since the advent in 1978 of *in vitro* fertilisation of the human embryo. As well as monitoring new practices, CORE is also involved in analysis of the governance of this specific field of bioethics, and where necessary works towards reform or implementation of relevant legislation. CORE is possibly the only bioethics organisation, certainly in the United Kingdom, specialising in this sphere.

The issue that most concerns CORE is the inadequacy at an international level of definitions in law to cover early human life, a concern that includes both the *in vitro* and *in vivo* embryo as well as the developing foetus in the womb.

There is no worldwide consensus on the permissibility of embryo research. Some countries do not allow such research at all. Others allow research on embryos surplus to fertility treatment but do not permit the creation of embryos expressly for the purpose of research. In relation to the cloned human embryo, whilst the majority of countries are opposed to cloning for full pregnancy, some have created an arbitrary distinction between the embryo cloned for reproduction and the embryo cloned for research, as a subsequent source of stem cells. The cloning process is the same in either case, even of the ends are different.

There is similar divergence of opinion in relation to the status of the foetus in international abortion legislation. In some countries abortion is prohibited. In countries where it is allowed, the upper time limit varies considerably, some permitting it only in the first three months of pregnancy, others allowing it up to birth. The United Kingdom, for example, distinguishes legislatively between the healthy and the disabled foetus.

Our response to the questions below reflects our primary concerns and limited remit, as broadly contained within your categories of 'beginning of life', 'genetics and molecular biology' and 'research'.

1. Aims and Scope of a Declaration on Universal Norms on Bioethics

I.1. In our opinion it is important that the Declaration is addressed primarily to policy makers, academic centres, and to the medical and scientific community involved in research and healthcare provision. This said, it is also extremely important to inform the general public and enable it to partake in debates on the ethical issues that concern us all.

1.2. The Declaration should be limited to ethical issues related to the human being, or it risks becoming unwieldy. Not only is it imperative that a universal declaration of this kind has a clear focus, but the primary concern of bioethics today is the question of the moral status of

the human being at whichever stage of development. And in order to reach a common understanding on this question, agreement must be sought on the definition of the term **human being.** Unless we have a generally recognised definition of this term it is impossible to arrive at any consensus about basic human rights or about the beginning and end of life. Nor can there be any discussion concerning the question of to whom basic human rights should be ascribed.

1.3. To retain a clear focus, the remit of the Declaration should be restricted as far as possible to ethical issues concerning the human being and the human body in the biomedical context, but it is impossible to exclude concerns about xeno-transplantation, human/animal hybrids (chimeras), and the introduction of animal DNA into humans (and vice versa) from discussion.

II. Structure and Content of a Declaration on Universal Norms on Bioethics

II.1. The Declaration should include a preamble stating primary aims and why a universal declaration on bioethics is called for.

It should be organised into sections, including a primary section defining the term **human being.** The same section should also spell out the basic human rights that should be ascribed to a live human being; what protection should be afforded a live human being at any stage of life; and what respect should be afforded the human body at any stage in life and also after death.

A section specifically on the rights of the disabled should also be included, as should sections on research involving human beings, body parts and human tissue and on donation of organs, tissue, human cells, including, in particular, gametes.

Sections on social and political issues such as education, provision of health care and national and international cooperation and implementation should also be included.

II.2 Among the fundamental principles to be reaffirmed in the Declaration, CORE would emphasise the following:

1. Respect for the bodily integrity of the human being at any stage in life, including a prohibition on using a human being as a research subject without his or her consent.

2. The need to prohibit those techniques, such as the creation of human/animal chimeras, which compromise the dignity of the human being.

3. Respect for the mentally or physically disabled person at any stage in life.

4. Respect for the principle of informed consent on the part of the autonomous human being, and vicariously on the part of those who are not capable of making informed decisions.

II.3. The Declaration should rest at a general level, since the biomedical sciences and clinical possibilities are constantly evolving, but we would welcome recommendations for some key issues.

II.4. Not provided.

II.5 Core would like to see more specific guidance on issues relating to the beginning of life, most of which will be dependent on the acceptance of appropriate definitions and subsequent establishment of rights.

A universal norm on abortion, for instance, must depend on a universal definition of the foetus and its rights.

The welfare of children must be paramount in any declaration associated with human reproduction, and this includes their right to know their genetic background. Given the endless possibilities of assisted reproduction, we must also look to the issue of the child's need for a father and a mother, as both these social roles have the potential to be eliminated through national legislation.

Prenatal diagnosis and preimplantation genetic diagnosis are controversial fields within the new reproductive technologies, and need to be addressed not just from a scientific perspective but within the wider context of disability rights and non-discrimination.

Sex selection is a particularly contentious arena, made possible by preimplantation diagnosis. There are polarized positions on this issue depending on the status and rights of women in the various countries involved.

We would like to include greater focus on the causes of infertility and more varied approaches to cures, which go beyond simply *in vitro* fertilisation. The correlation between sexually transmitted diseases and infertility is a clear example where a more holistic approach to health care is indicated. The widespread decline in sperm quality is another instance worthy of international concern.

Cloning of the human embryo must be included in the deliberations and it is vital that we work towards an international consensus on human cloning, otherwise so-called 'reproductive tourism' will make a mockery of any national attempts to ban or limit this practice.

In the area of embryo and foetal research we are particularly concerned that the complex issues of consent and intellectual property rights are not being adequately addressed.

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SOCIETY, RELIGION AND TECHNOLOGY PROJECT, CHURCH OF SCOTLAND AND CONFERENCE OF EUROPEAN CHURCHES WORKING GROUP ON BIOETHICS

Universal Norms

Christian Belief and Universal Norms

From the point of view of Christian belief, there is a strong concept of universal norms. These reside in God the creator of everything that exists. God is the source of truth, of all morality, goodness, wisdom and virtue. God has revealed these to humankind over a period of about 1000 years in the writings of the Old and New Testaments of the Bible, but supremely in God himself coming to earth as a human person, Jesus Christ, the divine word, the organising principle of the universe made flesh (the gospel of John chapter 1). In his teachings Christians believe we have the source of all norms for human behaviour, society and indeed of science and technology.

Christians recognise that the world contains a variety of belief systems, religions and world views, all with their claims to truth and many insights to life and morals, but they believe the ultimate truth is found in Jesus Christ, as the only person in history who fully unites the transcendence of God with immediacy and intimacy of bodily human life, and who is God's ultimate revelation to humankind.

Seeking Norms in a Plural Context

I wish to highlight two particular ways in which the churches are working actively and sensitively in a plural, international and inter-disciplinary context in bioethics - the Church of Scotland and the Conference of European Churches..

In particular, the Society Religion and Technology Project of the Church of Scotland (a Protestant Reformed church) has sought since 1970 to explore the ethical dimension of science and technology and in particular has been a pioneer in bioethical reflection on genetic modification in crops, food and animals, in the debates on cloning, stem cells, genetic databases, information and patenting, and on genetic enhancement. In these areas we have sought to identify where there are basic norms which may be applied to a plural and partly secular society.

The Conference of European Churches also has also sought to establish bioethics norms in its working group on bioethics and biotechnology, since 1993. Its membership is drawn from Protestant, Anglican and Orthodox Christian traditions from churches across the whole of Europe. It has observer status with the Council of Europe's committee on bioethics (CDBI) and has contributed significantly to the development of the Convention on Human Rights and Biomedicine of the Council of Europe, both to its original articles and to various subsequent protocols. Our group has produced its own "White Paper" outlining the approach it takes to bioethics in the plural religious context of the membership of the Conference of European Churches. (This enclosed as a second attachment to this email). In that sense we have very immediate practical experience of dealing with issues of norms in a plural religious international context, and would be willing to offer our insights to UNESCO.

The four principles of Beecham and Childress have been criticised widely for having too limited a view of necessary ethical norms and for being empirically based, rather than standing on a firm intellectual footing. They highlight the problem that, starting with humanity, it is hard to establish universal norms which would hold sway for all people, and if one is realistic about the finitude and perversity of the human condition. Philosophies of the late

20th century such as existentialism and post-modernism have rejected the very notion on norms. We have some sympathy with this viewpoint, if you start from humanity alone, because it is only God who, as the ultimate being can sustain universals. Nonetheless we do not consider that the pursuit of norms as futile, and offer a few insights. These are by way of examples, not as an exhaustive list.

Beginning of life :
- the principle that the early embryo should be viewed more than just functionally - it is not "just a ball of cells".
- the need to avoid the instrumentality of the embryo and early human life

Selection
- the recognition that in embryo selection a potential life has been rejected, not merely some cells
- the principle that all humans are equally valid and important regardless of whatever genetic "defects" might be found
- to be against any form of stigmatisation
- to avoid "liberal" eugenics (i.e. the sum of individual choices)

Genetic and other Changes
To maintain a strict line as possible between the use of genetic change, sex selection, and other techniques for medical purposes as against personal preference. The Bioethics Convention is correct for example to disallow sex selection for non-medical reasons. The same should apply to genetic enhancement.

Cloning
The principle that reproductive cloning is fundamentally wrong, because it denies the cloned person the right to their own unique genetic make-up and because it is enforced by a third party.

Non-Human Genetics
The norms should include norms affecting genetic modification in crops, animals and other non-human life forms. That genetic modification is not disallowed, but equally is to be undertaken only with precaution and where no better alternative exists.

Animals
Respect for the intrinsic value of all animals
The need to balance human use and violation of animal integrity, not merely animal harm
The recognition that there is a moral distinction between humans and animals

Medical Research
The principle of realism that recognition that suffering and mortality will not be overcome by medical research and that therefore there eventually limits to what may be justified

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CIVIL SOCIETY NETWORK 'BERLIN BIOPOLITICS CONFERENCE 2003'

for the
Extraordinary Session of the International Bioethics Committee
"Towards a Declaration on Universal Nom on Bioethics"
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At the beginning of the process of drafting a universal Declaration on bioethics it seems to be important to get as many inputs from as many perspectives as possible. If this Declaration is thought to be a powerful instrument it should not confine itself to providing only few and broad guiding principles that by and large are not controversial. We are convinced that we can take advantage of the existing guiding principles of the international community – the human rights instruments, UNESO Univ. Declaration on the Human Genome, Oviedo Convention, Declaration of Helsinki, Declaration on the Rights of the Patient, and Int. Ethical Guidelines for Biomedical Research Involving Human Subjects. But these guidelines have to be used to help articulate stakeholder perspectives that are usually ignored. In this proposal we restrict ourselves to three important stakeholder perspectives: Women's Rights, International Justice and Rights of Disabled People.

I. Women's bodies - women's rights

I.1 **The right to bodily integrity of women has to be garuanteed**

Women's bodies are at the center of the latest biomedical developments, such as embryo research and cloning. Without women, such technologies would cease to exist: Women meet the great demand for reproductive raw materials by providing eggs and embryos, at the same time they are also consumers of reproductive materials and technologies.

The justification of reproductive technologies and genetic diagnosis is often supported by reference to procreative autonomy of women.

A right to reproductive autonomy was postulated by the women's movement in the context of the discussion about the legal regulation of abortion. This meant the assertion of a right not to be hindered in following a particular way of life such as, for example, having children or, alternatively, leading a life without children. Furthermore, the particular physical involvement of the woman in the case of a pregnancy was made a topic of concern. If an external party were to decide on whether a pregnancy was to be continued or aborted, the physical integrity of the woman would be violated. Thus, the demand that the woman have the sole right to decide in the case of a conflict of interests regarding a pregnancy was supported and has to be supported as well today and in the future.

In the case of biomedical technologies such as cloning and perhaps in the future germ line interventions, however, no pregnancy as yet exists. The notion of reproductive autonomy does not include a right to the fulfilment of the desire for children with the help of medical technology, nor for women neither for men.

In case of an unfulfilled desires for healthy or even perfect children, one is dealing not with a form of organic suffering requiring medical treatment, but rather with a set of social and personal value judgements about what it means to live a successful life as a woman, man, or couple. There is however no right to pursue a particular course of life, for example as a mother or father. Thus, a right to the fulfilment of the desire for children – from an ethical point of view – can not be successfully defended.

Under current social conditions, raising a disabled child constitutes a risk of poverty for women. This poverty risk is increased by the fact that women still bear the brunt of raising children, that families as an institution in many countries no longer guarantee social support, and by the ongoing dismantling of social welfare systems. This creates social pressures on women to have recourse to prenatal diagnostic procedures and thus undermines the possibility of genuinely free decision making. Furthermore, the widespread impression that chronic diseases and disability can be prevented through prenatal diagnosis contributes to the individualisation of responsibility by placing the burden on the woman or parents. It also contributes to the legitimisation of decreasing solidarity on the part of society with those members of society who are chronically ill or disabled and their families.

Prenatal "selection" takes on an entirely new quality through pre-implantation genetic diagnosis. For pre-implantation genetic diagnosis, it is fertile women who have to undergo in-vitro-fertilisation treatment with all of the above-mentioned burdens and risks. In addition, the single cell genetic diagnosis is rather unreliable (7 to 36 percent false positive results). There is no guarantee that pre-implantation genetic diagnosis prevents abortion following prenatal diagnosis later in the course of a pregnancy or living with a disabled child. We do not consider pre-implantation genetic diagnosis to be a better alternative to prenatal diagnosis.

There is evidence that couples using prenatal diagnosis and in-vitro fertilisation often have unrealistic perceptions about the success rates and about the negative consequences of both procedures. This may be due to misinformation in the media or due to insufficient counselling and information by the physicians offering the procedures.

Embryonic stem cell research promises new therapeutic possibilities for many severe diseases. However, these promises cannot be scientifically substantiated. If these new therapies can ever be developed, it is entirely unclear who will have access to them in our time of cut backs in health care budgets.

The discussion of stem cell research is based on the assumption that the 'raw materials,' egg cells and embryos, are just 'out there'. It overlooks the fact that, in order for research to have access to egg cells and embryos, women have to undergo in-vitro-fertilisation. We are highly concerned that the interests of third parties in reproductive medicine will result in increased disrespect for women's dignity and rights. In particular therapeutic cloning demands a significant number of egg cells which women would have to 'donate'. We know that donated egg cells are already in short supply for other infertile women — in countries which do allow egg cell donation. This means that incentive systems will have to be created in order to gain enough egg cells as 'raw material' for therapeutic cloning. 'Production' and 'harvesting' of egg cells are procedures which are invasive and risky for the women involved. From an ethical perspective this cannot be justified for third party use. We hold that embryonic stem cell research degrades women to 'producers of raw material' for the third parties.

To guarantee the right to bodily integrity of women we demand that egg cell donation, cloning and embryo research — for all purposes — have to be prohibited.

II. SOCIAL JUSTICE – INTERNATIONAL EQUITY

Much about the applications of the human genome is speculative and both positive and negative effects can be expected. It is prudent to be precautionary and to formulate positions and proposals which ensure that the knowledge and applications of the human genome will be to the benefit of all mankind, before it is too late to turn the tide. A leading principle ought to be that equity, both internationally and nationally, and the right to health as well as the right to access to drugs should dictate technology and its applications, not the other way around.

The current crisis in health and health care makes this even more acute, especially for poor people in poor countries, who are suffering severely from worsening health and decreased access to health care as a result of global political and economic changes. It is often said that ethical concerns, moratoria, or even legal bans of technological developments are withholding the fulfilment of wishes from other people, and that they are hampering progress and innovation, so that any obstacle to these individual driving forces means lost innovative chances for humanity. But if technology is seen as a means to an end stifling these driving forces could be reasonable. The inherent leadership by the fastest process in science and technology development produces scarcity of time in decision-making process, time that is needed to find criteria for the quality of a technology as a means fitting ends. This in particular holds true to the fast innovation process of genetic technology.

Potential benefits of research into the human genome include the development of drugs which can improve (or prevent) diseases which are caused, wholly or partly, by genetic factors. This involves the identification of genetic variation (sequence variants) and the study of their significance. Also, genetic profiling may help to identify individuals who are likely to respond well (or badly) to particular kinds of drugs and vaccines. It may also help to identify individuals who are likely to respond well to other forms of treatment, health promotion, or efforts aimed at social change and behavioural change, e.g. being at higher risk to ill effects of alcohol and smoking, or being at a higher risk for cardiovascular disease.

Inappropriate redistribution of resources

Too much may be expected of medical interventions based on knowledge of the human genome and its technical application. Social and environmental factors will remain most important for the health of populations, and are likely to remain much more important than therapeutics based on the human genome in most diseases. History may repeat itself and society, hoping for a magic bullet, may lose sight of the need for organised efforts to improve health through political action. In turn, medicine and health care, more and more aiming at fitting the demands of western life style, may loose its social and public health function, and fail to contribute to an overall improvement in health at community, national and international levels. It is unethical that 90% of resources for pharmaceutical research is focussed on the diseases and life style demands of 10% of world population in the developed countries while the diseases of 90% of world population are merely neglected.

Rich countries and middle income developing countries

In many countries, people depend increasingly for their material security on information about their health status, for example health screening when applying for a job. Medical information is also asked for health care insurance in countries where a for-profit health sector exists as well as for home mortgages and life insurances. This involves risk assessment in order to differentiate insurance premiums. Those deemed at high risk but unable to pay will de facto be excluded by prohibitively high fees. A person's individual health may benefit from knowing about certain aspects of their health status, including genetic aspects, but they may ruin themselves financially - and their dependants - by becoming uninsurable. This problem is not new, and has already been highlighted in the case of HIV/AIDS.

Poor developing countries

Poor developing countries may not benefit at all, except a tiny elite, and may become further disenfranchised. Furthermore, research into genetic variations and medical applications, while likely to benefit rich countries, may divert yet more funds away from research and development into developing countries' needs.

The international system of distribution of health care has to be a means to the end of meeting people's needs: World Trade Order and TRIPS

Everyone has the right to appropriate and accessible health care

Diagnostic and therapeutic pharmaceuticals (including vaccines) have come under the remit of the rules of the trade-related intellectual property rights (TRIPS) agreement of the World Trade Organisation. It is our opinion that TRIPS is worsening access to pharmaceuticals for poor people in developing and other countries unless trade rules are governed by the basic right of access. Problems introduced by the TRIPS agreement include the effective extension of patents from the usual 12 years to 20 years; the extension of patents beyond chemical composition to production processes, and the fact that the WTO/TRIPS does not have a mechanism to actively protect poor countries from pressure by rich countries, donor organisations and large companies to forego their right to obtain affordable necessary pharmaceuticals by compulsory licensing or parallel imports. This endangers the right to the highest attainable standard of health.

There is also the problem that the TRIPS agreement will increase incentives for research and development into conditions affecting rich people in high-income countries, whilst leaving untouched the disease problems of poorer countries.

III. Enhancing human performance – Risk of discrimination and marginalisation.

III.1 Disabled People should not be stigmatized and discriminated by biomedical research and practice

A situation may arise where genetic profiling will be perceived as an important factor in predicting a person's future health and the possibilities of improving it, or preventing harm. People with an unfavourable risk profile, or people whose health can only be contained or improved by medical interventions which are beyond their financial reach, may become outcasts and form a "genetic underclass". This is a problem both within countries and between countries. Everything possible should be done to prevent this from happening.

Medical solutions via augmentation or enhancement of ones body must be framed by social solutions. Social justice principles demand societal cures of equal rights and respect. Offering medical solutions e.g. for disabled people where social solutions are refused might lead to discrimination and the obligation to fix oneself.

Biomedical research have been widely criticised by groups of disabled people to reduce the notion of “illness” and “disability” to physical functions and genes. Thus, psychological, environmental and social factors of illness and disability are being ignored. The medical and scientific view on “illness” and “disability” is stigmatising by recognising only objective “defects” and not the subjective situation of the individual ill or disabled person. Social models of “illness” and “disease” have to be put forward as “better” alternatives. Instead of any normative models of “illness” and “disability” the diversity of forms of (human) life should be seen as a good as such.

SESSION EXTRAORDINAIRE DU COMITE INTERNATIONAL D'ETHIQUE
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BIOETHIQUE, DROITS DE L'HOMME, DROIT INTERNATIONAL : HARMONISER VERS LE HAUT

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par
Maxime TARDU[*]

L'initiative de l'UNESCO visant à formuler des « Normes universelles en matière de Bioéthique » doit être fortement encouragée. Il est grand temps pour le système multilatéral de combler son retard d'adaptation au progrès scientifique et de reprendre sa mission de guide éthique et juridique en ce domaine.

Première condition : faire une « remise à plat » des textes internationaux en vigueur sur les Droits de l'Homme et la Bioéthique, préciser leur sens, identifier doublons, ambiguïtés, lacunes et contradictions.

Or les traités internationaux en la matière sont rédigés en termes très généraux, fréquemment ambigus et, partant, susceptibles de se prêter à des interprétations abusives, voire à de dangereuses dérives (eugénisme, discriminations). C'est là, en partie, l'effet de la recherche du consensus à tout prix dans les enceintes si hétérogènes des Nations Unies. S'y ajoute la perplexité du législateur international (et national) face à la haute technicité des questions. Enfin, de manière croissante, les replis identitaires, religieux, idéologiques ou politiques donnent du débat une forte coloration émotionnelle : avortement, fécondation assistée, diagnostic pré-implantatoire, recherches sur l'embryon, clonage, etc. Des formules si générales qu'elles en deviennent non signifiantes peuvent alors apparaître comme le seul dénominateur commun.

Les normes concernant la prévention et les soins de santé pourraient s'imposer comme base de notre « remise à plat ». Le Pacte des Nations Unies sur les Droits Economiques, Sociaux et Culturels, en son article 12, donne à ces droits de l'homme une portée très large : après consultation avec l'OMS, il définit la santé comme un état de bien-être physique aussi bien que « social ».

Pour atteindre cet objectif, l'Article 16 paragraphe 1 de ce même traité affirme le droit de « bénéficier du progrès scientifique ». Dernier maillon de cette chaîne logique, l'alinéa 2 de ce même article souligne l'obligation pour les Etats de « respecter la liberté indispensable à la recherche scientifique ». Termes particulièrement forts, qui paraissent traduire une obligation immédiate (« *self-executing* »), par contraste avec la mise en œuvre graduelle admise pour les autres dispositions du Pacte[1]. On ne saurait relier plus clairement la liberté de recherche au droit à la santé.

Cette liberté ne saurait cependant ignorer le droit à la vie, proclamé dans l'autre Pacte des Nations Unies, sur les Droits Civils et Politiques comme dans tous les autres traités. Ce qui pose en particulier la question cruciale du « *dies ad quo* » et du statut de l'embryon.

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Ici commencent les ambiguïtés. Il est clair que le droit à la vie, dans le Pacte sur les Droits Civils et Politiques, n'est pas reconnu « dès la conception » : des amendements en ce sens ont été rejetés formellement[2]. En revanche, le préambule de la Convention sur les Droits de l'Enfant déclare que l'enfant a besoin « ... d'une protection juridique appropriée, avant comme après la naissance ». Certains Etats y voient la consécration de l'inviolabilité de l'embryon dès la conception, alors que d'autres, s'appuyant sur les débats concernant le dispositif, contestent cette interprétation[3].

De telles divergences ou incertitudes existent au plan régional.

Le statut de « personne » bénéficiaire de la Convention Européenne des Droits de l'Homme de 1950 n'a pas été reconnu « dès la conception » par la Commission Européenne des Droits de l'Homme. Par contre, la Convention Américaine des Droits de l'Homme de 1969, en son Article 4(1), affirme le droit à la vie « en général dès la conception ». La Commission interaméricaine des Droits de l'Homme paraît, dans sa pratique, avoir nuancé le sens de ce texte[4]. La Convention Européenne sur les Droits de l'Homme et la Biomédecine de 1996 ne proclame pas le droit à la vie de l'embryon, mais une exigence apparemment moins forte de « protection adéquate ».

La liberté de recherche biologique doit en outre respecter l'interdiction de la « torture et autres traitements cruels, inhumains ou dégradants », norme exprimée dans tous les grands traités sur les Droits de l'Homme. Ces concepts clés insuffisamment clarifiés seraient-ils ou non, ou en quelque mesure, applicables à l'embryon ? Certains le soutiennent.

L'incertitude est maximale quant à la notion de « dignité humaine », souvent proclamée dans les lois et traités de bioéthique. Ce concept, qui avait surtout une fonction explicative et justificative des Droits de l'Homme dans les instruments initiaux (Déclaration universelle de 1948, Pactes de 1966) semble élevé au rang de droit distinct, aux contours trop vagues, dans les textes récents (Convention Européenne sur les Droits de l'Homme et Biomédecine de 1996, Protocole sur le clonage de 1998, projet de Charte des Droits Fondamentaux de l'Union Européenne, Déclaration de l'Unesco sur le Génome Humain).

La liberté de recherche peut de surcroît être limitée par « la loi en vue de favoriser le bien-être général dans une société démocratique » (Art. 4 Pacte sur les Droits Economiques, Sociaux et Culturels) et, encore plus largement semble-t-il, en raison d'autres exigences d'ordre public, selon d'autres instruments.

Les modalités d'application du « consentement éclairé », surtout quant aux incapables, donnent lieu à maintes difficultés de rédaction et d'interprétation. La Convention Européenne sur les Droits de l'Homme et la Biomédecine, par exemple, reflète de telles difficultés.

De nombreux autres problèmes de bioéthique font l'objet de normes internationales incomplètes ou ambiguës, par exemple : propriété intellectuelle et accès du plus grand nombre aux soins de santé (cf. problème des médicaments génériques) ; choix entre le financement de la recherche de pointe et celui des soins de base pour l'ensemble de la population ; droits des patients et marge discrétionnaire des médecins quant aux stratégies de soins ; protection de la sphère privée contre la communication abusive de données médicales, p. ex. aux compagnies d'assurances et aux autorités fiscales ; enfin, portée du principe de non-discrimination.

Ce dernier principe mérite un examen plus rigoureux. Notons d'abord que la règle de non-discrimination n'a pas la même portée dans les différents traités. Le Pacte des Nations Unies sur les Droits Civils et Politiques a une portée illimitée, sa liste de motifs discriminatoires condamnables étant non exhaustive. Cette approche d'ouverture se retrouve dans la Charte des Droits projetée de l'Union Européenne. Il n'en va pas de même pour le

Pacte sur les Droits Economiques, Sociaux et Culturels et d'autres textes. Des listes fermées excluent par avance la protection contre de nouveaux types, ou des formes nouvellement perçues, de discrimination (p. ex. pour cause de handicap ou d'orientation sexuelle).

On devrait examiner en profondeur l'applicabilité de ce principe au regard des dernières avancées scientifiques. Par exemple, le refus de faire bénéficier des malades isolés des bienfaits (espérés) du clonage à but thérapeutique (par exemple greffes d'organes obtenus par des cellules souches issues de leurs propres corps), alors que cela représenterait leur seule chance de guérison ne serait-il pas discriminatoire, alors que d'autres personnes souffrant des mêmes maux mais tolérant d'autres traitements, ou disposant d'une famille proche donatrice d'organes, elles, survivraient ?

Les règles ordinaires du droit international coutumier et de la Convention de Vienne concernant les problèmes de coexistence et de hiérarchie entre traités (*lex posterior* et *lex specialis*) sembleraient trop rigides pour traduire la volonté nuancée des Etats, parties à plusieurs traités, sur des problèmes éthiques aussi complexes que ceux touchant à la procréation assistée ou aux recherches sur les embryons. Les Conventions sur les Droits de l'Homme ont certes leurs propres règles de coexistence, accordant la primauté aux dispositions nationales ou internationales les plus généreuses pour les droits et libertés de la personne. Cependant, l'application de ce critère butte sur l'identification incertaine de la « personne » bénéficiaire : s'agit-il, par exemple, du malade en attente d'une greffe provenant de cellules souches ou de l'embryon, « personne potentielle » ?

Ambiguïtés et contradictions apparaissent encore plus nombreuses dans les innombrables Déclarations, non contraignantes mais à vocation proclamée de « *soft law* ».

Pour ne citer qu'un seul exemple, la Déclaration de l'Unesco sur le Génome Humain (Art. 11) comme les résolutions de l'OMS notamment en 1997 interdisent le clonage reproductif comme contraire à la dignité humaine. Par contre, les Déclarations et Programmes d'action des grandes conférences mondiales des Nations Unies sur la population (Bucarest, Mexico), sur l'égalité entre hommes et femmes (Nairobi et Beijing) et en d'autres domaines placent fortement l'accent sur le libre choix et sur le droit aux informations « et aux moyens », en matière de reproduction humaine. Même si leurs motivations concernent peut-être surtout les méthodes contraceptives, ces instruments pourraient être perçus comme ouverts a priori au principe du clonage reproductif.

L'effort de clarification et d'harmonisation est donc indispensable. Il est essentiel, cependant, de rejeter la tentation du simple « toilettage ». Il s'agit d'entreprendre une analyse plus rigoureuse des concepts de base et de leurs rapports réciproques, sans esquiver le risque temporaire d'affrontements idéologiques ou d'un regain du relativisme culturel. C'est à ce prix, en gardant le cap sur l'universel, qu'une harmonisation vers le haut pourra vraiment répondre au défi du progrès scientifique accéléré.

Notes

1. Voir Doc. des Nations Unies A/2929, Commentaire des projets de pactes par le Secrétaire général, 1955, p. 115, para. 55, et documents cités.
2. Amendement de la Belgique, du Brésil, du Maroc, du Mexique et du Salvador à l'Article 6 du Pacte sur les droits civils et politiques, rejeté par 31 voix contre, 20 voix pour et 17 abstentions. Doc. des Nations Unies A/C.3/SR.820.

3. Voir le rapport du Groupe de travail sur ce projet de traité à la Commission des Droits de l'Homme des Nations Unies, 1989, Doc. des Nations Unies E/CN4/1989/48, paras 32-47 et 75-85.

4. Voir Résolution n° 23/81, affaire 2141 (Etats-Unis), Rapport annuel de la Commission interaméricaine des Droits de l'Homme 1980-81, doc. OEA/Sér. L/V/11.54, Doc. 9 rév. 1 du 16 octobre 1981.

5. Parmi l'abondante exégèse contemporaine du concept juridique de « dignité humaine » dans les textes en vigueur, citons à titre purement illustratif les articles de Stephen Malby et de Stephen Marks dans la revue *Health and Human Rights*, Vol. 6, N° 1, 2002, Harvard, Institute of Public Health. Voir aussi le rapport du Groupe d'experts du Haut Commissariat des Nations Unies pour les Droits de l'Homme sur « Les Droits de l'Homme et la Biotechnologie », 25 janvier 2002, reproduit par cette même revue.

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Towards a Declaration on Universal Norms in Bioethics

BIOTECHNOLOGY AND HUMAN DIGNITY: THE GLOBAL POLICY CHALLENGE

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The challenges confronting the human race as we move into the "biotech century" can hardly better be expressed than in some of the sober reflections gathered in the European Union's recent conference volume, *Modern Biology and Visions of Humanity.*[1] In the United States, the several profound volumes issued by the President's Council on Bioethics[2] offer a parallel engagement with the challenges facing civil society and those who set public policy in the face of the new bioscience. This point was well-made in a recent speech by President George W. Bush, in which he called for a comprehensive ban on human cloning in the United States: "Science has set before us decisions of immense consequence. We can pursue medical research with a clear sense of moral purpose or we can travel without an ethical compass into a world we could live to regret. Science now presses forward the issue of human cloning. How we answer the question of human cloning will place us on one path or the other."[3]

In *Modern Biology*, Lewis Wolpert harks back to Sir Joseph Rotblat's call for a "Hippocratic Oath" for scientists.[4] Sophie Bessis worries on the one hand that scientists are becoming "science workers" while holding out hope that they may as "scientist-citizens" succeed in welcoming Prometheus while staving off the projects of sorcerers' apprentices.[5] Yet in calling for science to be "brought back into the polis" she seems aware of how tall an order this may prove to be, since "science" has in the past served as context and justification for atrocities. The haunting narrative of German Nobelist Fritz Haber, Jewish developer of Zyklon B, hangs over the volume from its early appearance in Axel Kahn's opening chapter.[6]

The central contribution of the German experience to the shaping of the global conscience on issues of medicine and biotechnology is hard to overstate, not least in the hope that it offers for the future. Of course, the story of Nazi "race hygiene," the euthanasia of the sick and handicapped, the vivisection in the camps, are not without parallel. The eugenic ideology was in substantial degree an import from the creative energies and foundation funding of the

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[1] *Modern Biology and Visions of Humanity,* European Commission, 2004
[2] See bioethics.gov for details of the work of the Council, including the report *Beyond Therapy: Biotechnology and the Pursuit of Happiness*, the volume of narrative and poetry *Being Human*, and their most recent report on *Reproduction & Responsibility: The Regulation of New Biotechnologies*.
[3] April, 2002
[4] *Modern Biology*, p. 149.
[5] *Modern Biology*, pp. 146,7.
[6] *Modern Biology*, pp 26,7.

American cultural elite, as has recently been powerfully re-stated.[7] The uniqueness and greatness of Germany lies in the nature of its national response, which has no parallels in conscientious reflection on the past elsewhere in the world.

Policy choices for the human community do not present in isolation, but in a dynamic matrix of cultural, corporate and policy pressures a proper response with always be to argue for some variety of the "precautionary principle."

Visions of the Future

There has long been a simmering debate about the respective merits of the two most influential books about the future that were written in English during the 20th century. They are both alike in one respect: they are dystopias, visions of a world that has gone profoundly wrong, warnings from the future to the present.

George Orwell's *1984* sets out a vision of political oppression and control that foresees the triumph of technology in the service of totalitarianism. Big Brother is watching you. By contrast, Aldous Huxley's *Brave New World* offers a more subtle nightmare, in which technology and choice have combined to bring about a world in which, as one commentator has written, pain and suffering have been almost entirely alleviated, at the cost of everything that makes life worth living.

In the closing years of the 20th century it became obvious who was right. As totalitarianisms crumbled around the world, the biotech revolution set out on its exponential path. We have reason to be grateful that Orwell seems to have been wrong. We have reason to be fearful that Huxley may have been right.

If it is true that the closing years of the 20th century demonstrated that Orwell's totalitarian vision did not represent the human future, it lies in our hands at the start of the 21st to ensure that Huxley is also proved wrong. But to do so will require sustained engagement in the development of policy on our part, both at the national level and through the multilaterals.

In that context, the intent of the UNESCO International Bioethics Committee to produce a "universal instrument on bioethics" is admirable, although its desire to do so in a manner that operates by consensus is problematic. This plan is also complicated by the work of the Council of Europe bioethics committee, which in 1997 opened for signature the one international convention on bioethics, the European Convention on Human Rights and Biomedicine; and by the initiative of the United Nations General Assembly in approving a Franco-German proposal to develop a process that is intended to result in a convention on the single most pressing question of bioethics, that of human cloning. At the same time, both these processes illustrate the problem of a consensus-based approach at a time of dynamic shifts in technology and opinion.

Three Principles

1. The regulation of cloning and other questions in biotechnology offers a major challenge to democracy and the capacity of our institutions to handle something as new as it is fundamental. One reason lies in the global character of science and technology, and of the corporate interests that seek to resist regulation – which offers a strong argument for multilateral policy development. Another is the problem of the expertise required to

[7] Edwin Black, *The War against the Weak* (2003)

understand the questions. It is easy for scientists and corporate technology advocates to dominate the discussion. Yet, to take a parallel case, we do not leave decisions about the morality of war to the generals. Neither must we leave biotechnology policy to the biotech interests and the science community. The need is urgent for a global biopolicy statement that centers on human dignity.

2. Partly for that reason, we must struggle for honest and clear use of language. Terminology is crucial to these debates, as is well illustrated by the distinction promoted by supporters of research cloning between "reproductive cloning" and "therapeutic cloning." It is confusing and has led many to believe that these are indeed two fundamentally different scientific processes rather than simply alternative uses to which clonal embryos can be put.

3. Moreover, as the cloning debate has shown, there are broad consonances across cultures and around the world. One of the most important features of this debate is the way in which it has brought together into common cause people of conscience from different sectors of the culture who are often in disagreement about other issues (such as abortion). This fact is of enormous significance for the future of biotech policy debate around the world, since it is bringing into growing alliance two powerful cultural-political movements. The United States, which presently accounts for around 75% of global biotech revenues and R and D, is led by a federal government strongly opposed to the so-called "therapeutic cloning" that the largest biotech trade group, BIO (the Biotechnology Industry Organization) has been lobbying to protect. One effect of the cloning debate in the US has been to bring together leaders of "pro-life" and "pro-choice" constituencies across the typically wide divide of US culture and politics, to work together to build a human framework for biopolicy.[8]

The Unfolding Agenda

A series of questions from science and policy cluster together in the agenda for biotechnology and society. One reason why cloning has proved such a significant issue lies in its close connection with the prospect of germline genetic engineering – making inheritable changes in human nature. In parallel, research in nanotechnology and artificial intelligence has raised the prospect of enhancements and changes to human nature from another source than genetics. The provocative thinking of "transhumanists" and some outspoken biomedical scientists has set in sharp contrast the positions of those who seek to benefit from science to nurture and yet not transcend human nature as we know it, and those who boldly seek changes in human being itself.

Intellectual property questions such as the patenting of human genes and organisms have become yet more important as bioscience has continued its steady migration from universities and other public research institutions to the private sector, and the interests of university-based scientists become more complex with their ownership of patents and participation in profit-seeking ventures.

And haunting every one of these questions is the steadily growing pressure of a new eugenics, which has led to a spate of legislation and proposals to safeguard genetic data and undermine the possibilities for discrimination based on factors in the human genome.

[8] The Institute on Biotechnology and the Human Future was recently established at the Illinois Institute of Technology as a focal point for that conversation; fellows include leading environmentalist activists, liberal feminists, and cultural conservatives from the "pro-life" movement. www.biotechhumanfuture.org

Biotechnology confronts the human community with unique prospects for good and for ill. It should not surprise us that we find it difficult to grasp the challenges that result, yet we have in cloning a relatively simple opportunity to set the pace for the biotech century by saying No to a technique that people on many sides of our political, cultural, and religious divides agree is wrong. The prospect of a human biotechnology will be enhanced by every policy decision taken by the human community that secures options for the human future, perhaps by foreclosing them today. That is the challenge confronting biotechnology policy.

UNESCO Extraordinary Meeting 26-28 April 2004, Paris, France
"Towards a declaration of universal norms on bioethics"

Submission from members of the "Towards a Nexus of Law and Biology" group (LAB), Brisbane, Qld Australia (Barbara Hocking, Hamish McCallum, Joseph Vogel)
1 April 2004

Aims and scope of a declaration

1.1 In our opinion a declaration of universal principles in this area is essential to assess the ethical implications of human and scientific progress. As an example, the universal declaration on human rights, whilst frequently unobserved, has been essential to establishing a basis for progressing discussions about human rights. So this Declaration will galvanise understanding and knowledge – particularly of the appropriate limits of human and scientific endeavors and actions.

1.2 Such a declaration should not be limited to human beings as the objects to whom ethical obligations are owed. If it were, it would not constitute a universal declaration on bioethics.

1.3 We argue strongly that the declaration needs to deal with bioethics in the widest possible sense. As David Healy has observed, 'Bioethics began within healthcare, when philosophers in the 1960's were called out of the ivory towers in which they had previously been debating moral theory to get involved in real moral dilemmas.'[1] So we would argue in this submission that if the Universal Declaration is limited only to the human person and human body, then it becomes a declaration on medical ethics, which is an entirely different thing. As we will discuss later, there are numerous substantial ethical issues concerning human relationships with other living organisms, populations of organisms, communities of organisms and ecosystems. Ethical issues concerning ecological problems are likely to become particularly pressing in the next few decades and it is of crucial importance that there should be a generally agreed ethical basis for making such decisions.

1.4. We are of the opinion that we need to deal with ethical issues in a series of concentric circles expanding from the individual human. Thus, there are ethical issues concerned with each individual human's own body, issues concerned with close relatives, issues concerned with other humans and third parties, those concerned with animals and plants that we directly use in our sustenance, our shelter, and our medical and biology research. Beyond this circle, there are very significant ethical issues associated with the maintenance of natural populations, communities and ecosystems. For example, moving beyond utilitarian issues of sustainable use and maintenance of ecosystem services, there is a very strong argument that there are ethical issues involved when a natural species becomes extinct, or a particular community or ecosystem is irrevocably destroyed.

II structure and content of a declaration on the universal norms on bioethics.

II.1 Such a declaration will need a preamble, which will essentially and concisely state the need for the document - and the overall goals of UNESCO in preparing such a document. Self-evidently, it will need to be organised into sections or it will become unworkable. In our

[1] David Healy, Review of Rahul K. Dhanda, Guiding Icarus: Merging Bioethics with Corporate Interests' New York: Wiles-Liss, 2002, pp. 270, IABN 0-471-22380-8, in (2004) 23 *Monash Bioethics Review* (No 1), pp. 47-50 at p. 47

opinion, the central concept of a series of concentric circles of ethical obligation surrounding the individual human would form a reasonable model for the overall structure of such a document. The alternative structure, which seems to be the structure suggested in the information document presented by UNESCO, is to structure a declaration around applications (healthcare, scientific research, education etc). In our opinion, it is more logical to structure the declaration around the groups of organisms and populations (including of course, other human beings) to whom ethical obligations exist.

II.2 The fundamental principles listed in the information document prepared by UNESCO (autonomy, benefit sharing, confidentiality, free of research, free informed consent, justice, nondiscrimination, respect for human dignity, respect for privacy) are all essential. However, they are very human-centric. Certainly, it is human beings to which the document is being directed, and who have ethical obligations (we do not want to become involved in discussions as to whether it is ethical for a lion to eat an antelope). Undoubtedly, human beings owe ethical obligations to organisms beyond their own species. This is not a radical or novel suggestion: all developed countries have "ethics" committees that deal with use of animals in experimentation and scientific research. Thus, some of the fundamental principles that need to be included are that humans have an obligation not to cause unnecessary suffering to other animals, that humans have an ethical obligation not to drive other species of organisms to extinction, and that humans have an ethical obligation to maintain the integrity of the ecosystems that occur upon the earth. We could point here to Australian philosopher Peter Singer's work on extending human rights to our primate cousins (Great Ape Project), or to E.O. Wilson's comment that appeared in the introduction to his edited volume BIODIVERSITY(1988), that in reference to the ongoing mass extinction crisis:

"In the end, I suspect it will come down to a question of ethics".

We would like to mention also that in our view, ethics implies that we embrace limits, and here we might perhaps advance a mention of "the ethics of the commons" and the late Garrett Hardin's idea of "living within limits".

II. 3. In our opinion, the declaration should concentrate upon establishing some fundamental bases for bioethics. If it becomes bogged down in details, it will not only become unwieldy, but will also be a document that rapidly dates as scientific knowledge and technology develop. It is hard to imagine for example, that a declaration on bioethics even as recently as 20 years ago would have been concerned with issues such as human cloning and genetic engineering. Such concepts at that time belonged in the fiction of Aldous Huxley's *Brave New World*.

II.5 Whilst we are of the opinion that it is undesirable to define a detailed framework of precise requirements as is considered above, guidance on specific subject areas such as those listed is highly desirable. However, the list as currently included remains centered around humans as the object to whom ethical obligations exist. If we are to move beyond such a human centric proposal, then it will be necessary to considerably add to this list.

We would therefore add sections on the use of animals in scientific research, for medical therapies, for food, for clothing, and for amusement. This would represent a relatively straightforward codification of principles that are enacted in most countries in animal welfare regulations.

More importantly, however, we would require guidance on ethical obligations to natural populations and communities of organisms. Areas that would require coverage include:

- exposure of natural populations to novel genetic material produced by genetic engineering

- introduction of novel predators, pathogens or competitors
- destruction of habitat
- over-exploitation of natural populations.
- exposure of ecosystems to pollutants
- global climatic change.

We are strongly of the opinion that a key principle that needs to be established by such a declaration of universal norms on bioethics is that there is an ethical dimension to loss of biodiversity and destruction of natural ecosystems. It is inappropriate to view biodiversity loss as being only a problem when it is possible to demonstrate some utilitarian loss to human beings. We are also of the view that in framing the Declaration attention must be paid to the obligations of both individuals and of corporations, particularly transnational corporations.

UNESCO
Extraordinary Session of the International Bioethics Committee
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Gene Patents and Bioethics

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"Our society acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique human persona," wrote California Supreme Court Justice Mosk. "One manifestation of that respect…is our prohibition against indirect abuse of the body by its economic exploitations for the sole benefit of another person. The most abhorrent form of such exploitation, of course, was the institution of slavery. Lesser forms, such as indentured servitude…have also disappeared. Yet their specter haunts the laboratories and boardrooms of today's biotechnological research-industrial complex. It arises wherever scientists or industrialists claim…the right to appropriate and exploit a patient's tissue for their sole economic benefit—the right, in other words, to freely mine or harvest valuable physical properties of the patient's body."

Gene patents represent an unethical exploitation of the human body. In addition, important practical considerations caution against the further allowance of gene patents. While it may be appropriate to award patent rights to a genetic diagnostic kit or a genetic therapy, it is not appropriate to award protection over an isolated sequence or a clone of a gene. The disallowance of gene patents would be permissible under the public health exceptions in the World Trade Organization's TRIPS agreement.[1] UNESCO, in its reconsideration of a bioethics code, should prohibit the patenting of any subpart of the human genetic make-up, such as genes or isolated or cloned DNA.

There is significant support for banning gene patents, including the position that genes are an inherent product of nature. For example, numerous international organizations, such as the Council of Europe's Committee on Legal Affairs and Human Rights and UNESCO, view genes as belonging to the common heritage of mankind.[2] Intense opposition to gene patents is also coming from researchers,[3] politicians, [4] indigenous groups, [5] patient groups,[6] and medical professional organizations.[7]

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[1] World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property (TRIPS*), Article 27 (1994).
[2] UNESCO General Conference, *Universal Declaration on the Human Genome and Human Rights* (November 11, 1997).
[3] Declan Butler & Sally Goodman, *French Researchers Take a Stand against the Cancer Gene Patent*, 413 NATURE 95, 95 (2001).
[4] Paul Willcocks, *Canadian Premiers Wade Into Gene Patenting Debate*, REUTERS (Aug. 3, 2001).
[5] Debra Harry, *Letter to Commissioner of Patents and Trademarks, Indigenous Peoples Council on Biocolonialism,* Comment 39 (Mar. 21, 2000).
[6] Greenberg v. Miami Children's Hospital, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).
[7] Association for Molecular Pathology, Clinical Practice Committee, *AMP Position on Patenting of Genetic*

The Incentive of a Patent is Not Necessary for Gene Discovery

There are many practical reasons why patents should not be granted for genetic material. First, patents are not necessary to provide incentives for the discovery of genetic sequences. Molecular biologists were attempting to identify genes long before patents were being award for genetic material. When biologists began the Human Genome Project, they had no idea they would be able to patent genes. They had other reasons to search for genes—medical interests and the potential for Nobel Prizes, academic advancement, and status. The U. S. Supreme Court's Chakrabarty decision, allowing the patent on a genetically engineered bacteria, gave molecular biologists in the United States the assurance they would own any life forms they invented by combining genes in ways that did not occur in nature. [8]

The discovery of genes does not require the same incentives as drug development. The development of drugs is undertaken primarily with private funds (for which investors expect a commercial return), while the discovery of genes has been undertaken with vast quantities of public funds. For example, there has been massive international public funding for genetics research. In the United States alone, over $1.8 billion of taxpayer money was spent by the government and non-profit institutions on genomics in 2000. Myriad, the U.S. genetics company that first patented BRCA1, utilized over $5 million from a government agency, the National Institutes of Health.[9] If gene patents continue to be allowed, the public will pay twice: once for the research and then for the high royalty costs once they undertake a genetic test.

Unlike drug development, gene discovery and use do not require clinical trials. In some cases, a disease gene has been identified one day and testing begun almost immediately. Thus, the need to financially compensate a gene-discoverer is not as great as the need to compensate the developer of a drug that must take it through costly clinical trials, with only a small number of drugs actually becoming commercially-viable products. Patents should be allowed on true inventions—genetic diagnostic test kits and gene therapies.

Moreover, there are fewer downsides to granting a patent on a drug or a medical device than granting a patent on a gene. Other researchers can create alternatives to drugs and devices. There are no alternatives to the patented human genes in genetic diagnosis and gene therapy.

Gene Patents are Harmful to the Public Health

Gene Patents Impede the Delivery of Quality Health Care

Gene patents additionally raise ethical issues due to their detrimental impact on health care and research. Gene patent holders often use their exclusive control over genetic material to charge excessive fees for diagnostic testing of medical patients and to prevent other researchers from utilizing the specific genetic sequence for further research. Many researchers refuse to share patient tissue samples or preliminary findings because they each want to be the first one to discover the profitable gene.

Increasingly, the appropriate treatment of an individual patient may include diagnostic genetic testing. Most predictive genetic tests offer only the general estimated chances of developing a particular disease and must take into account the influence of other genes and environmental

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Tests (Dec. 17, 1999).

[8] Diamond v. Chakrabarty, 447 U.S. 303; 100 S. Ct. 2204; 65 L. Ed. 2d 144 (1980).

[9] Bryn Williams Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 131 (2002).

factors.[10] For example, the predictive power of the test for BRCA breast cancer mutations is very low for women without a family history of breast cancer, meaning that many women who test positive for a BRCA1 mutation do not ever manifest symptoms of the disease.[11]

In addition to the generally low predictive value of predictive genetic testing for the general population, many tests fail to detect specific mutations. The Myriad Genetics test for BRCA1 and BRCA2 mutations, for example, reportedly fails to detect between 10-20% of expected mutations.[12] The failure to detect such a large percentage of mutations seriously jeopardizes the test quality and also significantly falls short of appropriate patient care when alternative, more effective tests, could be readily available to the patient. However, because gene patent claims often cover all diagnostics based on the genetic sequence, patentees can prevent the marketing and use of tests derived by other research institutions that are more effective.

Allowing for-profit corporations to exclusively supply genetic testing for hereditary diseases dissociates actual testing from genetic counseling, high-risk patient care, and follow-up, all of which are essential to many national approaches to medical care. In European countries, for example, healthcare workers follow a model that integrates biological research, clinical investigation, and patient care, especially considering the psychological aspects of diagnosis, both for the individual patient and the patient's family. In contrast, many patent holders are accused of separating genetic testing from patient care in providing diagnostic test results without any significant follow-up individualized genetic counseling. Such dissociation seriously impedes the quality of patient care.

Gene Patents Increase Test Cost

One commercial aspect of diagnostic gene patents is that doctors must either obtain a license to provide such a test or else charge the patient a fee for sending a sample to be tested at the corporation or research institution that holds the patent. In many situations, this fee can be exorbitant. Myriad requires that all BRCA1 and BRCA2 diagnostic testing to be performed by their Utah laboratories at an average cost of about $2,760.[13] In European nations, Myriad charges 2,744 euros for BCRA testing services to be done solely at the Utah labs, which is three times the amount of the 914 euros that it costs French laboratories to undertake the tests on their own.[14]

As an alternative to utilizing a patented procedure that may cost the patient, the insurance company, managed care organization, or the government a significant amount of money, the doctor may even choose to perform an inferior procedure, perhaps resulting in inaccurate results or even failure to screen for the specific disease.

Gene Patents Impede Medical Research

Furthermore, there is concern that the monopoly over genetic testing will inevitably lead to a loss of expertise and information among researchers and physicians. This arises from the fact that researchers and physicians are most often completely barred from using any gene or protein sequence claimed within the patent and thus prevented from undertaking or improving

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[10] Michael J. Malinowski & Robin J.R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards,* 71 TUL. L. REV. 1211 (1997).
[11] Wylie Burke, *Genetic Testing*, 347 NEW ENG. J. MED. 1867, 1872 (2002).
[12] D. Stoppa-Lyonnet et al., *Identification Of A Large Rearrangement Of The BRCA1 Gene Using Colour Bar Code On Combed DNA In An American Breast/Ovarian Cancer Family Previously Studied By Direct Sequencing*, 38 J.MED.GEN. 388-391 (2001).
[13] Myriad Genetics, Inc., *SEC Annual Report (Form 10-K)* for fiscal year ending June 30, 2002, at 10.
[14] Institut Curie Press Release, *Against Myriad Genetics' Monopoly On Tests For Predisposition To Breast And Ovarian Cancer Associated With The BRCA1 Gene,* 6 (September 26, 2002).

diagnostic technology relating to that particular gene. The complete bar to use may have a deleterious effect on innovation and future research and ultimately result in an intellectual standstill. Because researchers and physicians are barred from the use of the patented gene itself, no improvements to the inaccuracies of the current testing mechanisms will be discovered.

Research and diagnosis has undoubtedly been hindered in the U.S. by exclusivity of genetic material essential to human disease detection. In the United States, 35% of geneticists report that even the sharing of basic data and research material has substantially decreased in the last decade, and 21% claim that failure to access such data from another researcher has resulted in their abandonment of a promising line of research.[15] A survey of 200 genetic-testing laboratories found that twenty-five percent of the laboratories have been prevented from offering a test due to the enforcement of a patent or license. In addition, approximately fifty percent reported that they did not attempt to develop new tests due to commercial constraints brought on by a patent.[16]

For example, beginning in 1998, SmithKline Beecham Clinical Laboratories sent letters to labs ordering them to stop performing or developing tests for the hemochromatosis (HFE) gene. The patent holder was asking for an up-front fee of $25,000 from academic laboratories and as much as $250,000 from commercial laboratories, plus a fee of $20 per test. As a result of SmithKline's letter, 30% of labs discontinued testing and/or ceased development of HFE testing services.[17] The patent interfered with clinical adoption of the test and potentially compromised the quality of testing by limiting the development of higher quality or lower cost alternative testing methods.

Research collaboration is being stifled as well. A 2002 study found that forty-seven percent of geneticists surveyed had been denied requests from other faculty members for information, data, or materials regarding published research. When geneticists were asked why they intentionally withheld data, more than twenty percent listed the need to protect the commercial value of their results. Even more troubling is the finding that twenty-eight percent of geneticists surveyed reported that they were unable to duplicate published research because other academic scientists refused to share information, data, or materials.[18] This goes to the heart of science – which is supposed to involve hypothesis-testing and replication.

UNESCO should not let the specter of exploitation rear its head in the biotechnology industry. UNESCO should adopt a bioethics policy that prohibits the patenting of any subpart of the human genetic make-up, such as genes or isolated or cloned DNA.

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[15] David Blumenthal et al., *Data Withholding in Academic Genetics*, 287 JAMA 473, 473, 478 (2002).
[16] M.K. Cho, Preparing For the Millennium: Laboratory Medicine in the 21st Century, 47-58 (AACC Press, 2d ed. 1998).
[17] Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577-578 (2002).
[18] David Blumenthal et al., *Data Withholding in Academic Genetics*, 287 JAMA 473, 473, 477-478 (2002).

Contribution to the
Extraordinary Session of the International Bioethics Committee (IBC)
"Towards a declaration on universal norms on bioethics"

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I. Aims and Scope of a Declaration on Universal Norms on Bioethics

I.1. Collaboration of different groups is necessary for advancement and successful follow-up of the main aims in the field of bioethics.

Most important groups in our country consist of: policy–makers (particularly health policy–makers), religious leaders and cultural authorities, academic faculties (especially bioethics professionals), general population and non-governmental social groups.

The duties and goals of each group must be determined and the progress reports must be evaluated.

Religion and ethics joined together. There is no doubt anymore that religious leaders viewpoints could be certainly an impressive guidance in some countries. Therefore, it is necessary that we make strides for drawing their attention to bioethical issues.

On the other hand, the joint influence of cultural backgrounds and social insight of the ethics must be also considered.

I.2. & **I.3.** & **I.4.** Most emphasis should be given to 'human bioethics' and the declaration should also deal with ethical issues concerning the human being's relationship with other living organisms. Issues such as xenotransplantation, GMOs, must be certainly addressed.

II. Structure and Contents of a Declaration on Universal Norms on Bioethics

II.1. The Declaration must consist of:

A. A brief preamble

B. Several separate chapters , each chapter addressing one special subject (such as beginning of life, end of life, genetics and molecular biology, intellectual property rights, health care systems, human genetic data, public health, research , organ transplantation)

In each chapter, two important parts also required:

A. General provisions and articles

B. Principles of practical guidelines

II.2. Respecting human dignity and respect for cultural values are the most important principles which must be consider in the declaration. The declaration must set out the principles which should guide the countries in the formulation of their legislation and policies on special issues, but it must not intervene in internal affairs of the countries in no way.

The common frame work is essential for the declaration but given the cultural diversity in different countries, it must be flexible as much as sufficient.

II.3. Subjects are divided into two groups:

A: In some subjects (such as consent), there are universal agreements about general principle and most of the details. In these cases, detailed explanation is not only feasible but also necessary and beneficial.

We ought to pay special attention to some issues (such as genetic data) that non-observance or neglecting them is likely in some countries.

B. In several subjects (such as euthanasia, stem cell research, etc.), there are significant disagreements and debates in different countries, therefore it is better to proceed to only general principles at present.

The declaration could be reviewed from time to time, for example every 5 years, and the more details would be added to it.

II.5. The practical guidelines must be set, where possible, because they have a good impact on the sanction of the declaration. Guidance on ethics in heath care systems, genetic research and public health could be emphasized.

Research ethics must be also enunciated in detail as a separate chapter with specific guideline. Researchers must be aware of the fundamental ethical principles governing research with human beings, and they must establish proper procedures for assessing and monitoring the ethical aspects of research project.

Observance of ethics principles is necessary in different phases of research from selection of study object to publication of results. For example, the following heading must be considered in object selection:

1. national research priorities
2. social traditions, believes and behaviors
3. perspective and consent of people who are involved in research

In order to ensure that the guidelines for research ethics are followed in practice, it is essential to institute adequate procedures for protocols to be assessed by properly constituted committees.

In education fields, one specific practical guideline is necessary. Number of authorized persons in some countries is insufficient. Specific programs for education of different groups (policy–makers, religious and cultural scholars, scientific community, and general population) must be scheduled (for example as online educational courses). Participation in the courses could be documented by credits. Executive responsibilities might be handled by these educated persons.

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Submission to Extraordinary session of IBC, Paris 27-29 April 2004

Towards a Declaration on Universal Norms of Bioethics

On 27-29 April 2004 the IBC of UNESCO will be conducting an extraordinary session involving hearings with stakeholders concerning its movement towards a Declaration on Universal Norms on Bioethics. The IBC was entrusted with this task by the UNESCO Director-General after the General Conference of UNESCO at its 32nd session in October 2003 recommended that it was "opportune and desirable to set universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics."

Set out below are comments on the various questions on which the IBC sought input relevant to this issue.

I. Aims and Scope of a Declaration on Universal Norms on Bioethics

I.1 How, in your opinion, could the Declaration contribute to a better assessment of the ethical implications of scientific progress and its applications? At what level (policy-makers, scientific community, academic circles, media, society etc) and how?

Scientific progress in the medical sphere is increasingly dominated by globalised commercial interests, particularly in the area of pharmaceuticals. The linkage of intellectual property protections with trade in multilateral and bilateral trade agreements creates direct clashes with norms of bioethics, to the extent that scientific progress and its applications are increasingly hampered, rather than facilitated, by patents. If the Declaration encouraged research or experimental exemptions in patent law, that might greatly facilitate scientific progress in the medical sphere being applied to the generally non-lucrative infective diseases and healthcare problems of developing nations. Similarly, the Declaration might enunciate a principle that encouraged all corporations involved in profiting from healthcare in developed nations to contribute a proportion of their income to the alleviation of health problems in developing nations. This would particularly apply to the makers of life-saving equipment such as the pulse oximeter (in anaesthesia monitoring), the cardiac defibrillator, or the manufacturers of essential pharmaceuticals.

Another principle in the Declaration might encourage research scientists and the developed world institutions that fund them and publish their research, to routinely set their individual projects in the context of welfare of a majority of persons world-wide. This principle should also mandate that the publishers of those randomised clinical trials that are becoming the gold standard for development of the medical standard of care under the doctrine of evidence-based medicine, automatically request authors include details of the extent to which the human rights protections of this Declaration have been complied with. Presently authors are allowed to publish by merely stating that an ethics committee has approved the terms of their trial. This does not facilitate transparency and uniformity in the application of principles such as those likely to be set out in this Declaration. Perhaps this Declaration could become unique by focusing more on such mechanisms for monitoring the global application of basic principles of bioethics.

Other important principles in this context might seek to reduce the division between developed and developing nation standards in clinical trials and ensure local benefit in developed nation funded research in developing countries. Many of these are already enunciated in important international statements such as the Helsinki Declaration and the CIOMS guidelines on research.

One of the current problems with norms of bioethics is that they have not been formulated in language that easily meshes with that of laws, institutional guidelines, cultural norms and human rights obligations world-wide. The Declaration will be most useful if it is written in a form that facilitates its use by the major research ethics review and professional standards bodies of each nation. The chairs of such bodies would be crucial stakeholders who should be involved in the development of the Declaration.

I.2 Should the Declaration be limited to human beings and why?

Yes, chiefly because extension to animals and the natural world would take the content beyond the realm of the medical and allied health professionals. On many influential interpretations the attribution of ethical status to an object depends upon its capacity to suffer, causing an obvious problem for environmental ethics. ? Making the instrument apply to fields of ethics generally normative force in particular professions may be diminished. One difficulty will involve whether the definition includes the fetus. No superior court has yet held it should. Another is to what extent should it include the bodies of deceased humans.

I.3 If the answer to I.2 is "yes," does this mean that the declaration should deal only with ethical issues related to the human person and the human body in a biological and medical context? Or, should the Declaration also deal with ethical issues concerning the human being's relationship with other living organisms? And to what extent?

Dealing to some extent with man's relationship to animals is inevitable due to the important issues surrounding xenotransplantation in organ donation. Also likely to be of growing importance is the relationship between human, animal and other DNA. Ethical prohibitions, for example, on animal/human chimeras are an important dividing line. Another important issue concerns patents over stretches of DNA that may be similar between species. Control of infective organisms and problems of antibiotic resistance may require the statement of principles concerning the use of drugs relevant to humans in animal populations. The United Nations Convention on Biological Diversity of 5 June 1992 and the UNESCO Declaration on the Human Genome and Human Rights emphasize in that connection that the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question 'the inherent dignity and ... the equal and inalienable rights of all members of the human family', in accordance with the Preamble to the Universal Declaration of Human Rights.

I.4 If the answer to I.2 is "no," what other issues could be covered (for example, issues such as the use of animals in biomedical research, the use of animals in transplantation, biodiversity, genetically modified organisms (GMOs), environment, etc) ?

Answer was "yes."

II. Structure and Content of a Declaration on Universal Norms on Bioethics

II.1 How should the Declaration be structured? Should it include a preamble? Should it be organized in sections? If yes, please indicate which sections could be included and why (general provisions, health care, scientific research, public consultation, international co-operation, education and awareness-raising, promotion and implementation etc)?

There are significant advantages in terms of developing a consistent body of jurisprudence to formulating the Declaration closely along the lines of the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. The preamble would gain stature by referring to the great historically significant statements of medical ethics: the modern restatement of the Hippocratic Oath as the World Medical Association's Geneva Declaration, the Cairo Declaration of Islamic Medical Ethics, the early statement of Chinese medical ethics by Sun Simiao, the Nuremberg and Helsinki Declarations, the World Medical Association's International Code of Medical Ethics Universal Declaration of Human Genome and Human Rights, the United Nations statement of principles of medical ethics for physicians in relation to torture.

The preamble should emphasise professional virtues as well as principles. In particular it should emphasise loyalty to the relief of patient suffering as a unifying professional virtue. This is particularly important as major inquiries into deficiencies in health care quality and safety consistently refer to the inhibiting effect of a negative professional ethos.

II.2 Which fundamental principles should be reaffirmed in the Declaration (autonomy, benefit sharing, confidentiality, freedom of research, free and informed consent, justice, non-discrimination, respect for human dignity, respect for privacy, solidarity, etc)?

Rather than attempting to create new principles perhaps the Declaration should focus on what is needed to ensure practical enjoyment of existing principles. There should be no diminution of existing standards. Links should be made to the most significant existing treaties and declarations in this area. What will make the Declaration unique is that these principles of bioethics are for the first time being phrased as human rights. How the language of bioethics metamorphoses into that of human rights will be one of the major issues.

As well as principles, the Declaration should emphasise virtues, including, specifically, the unifying professional virtue of loyalty to the relief of patient suffering. This is important to the process of "internalising" norms and assisting educators to change the professional ethos toward one where the enunciated principles are routinely applied as part of the professional's life narrative.

The difficulty will not be finding principles but selecting which ones to emphasise. Some that have not been highlighted sufficiently are importance of health professions to place care of the patient above unjust superior orders or legal commands and the importance of peer review, the need to acknowledge and report medical error and the need to report impaired colleagues. Similarly important, but as yet underemphasized, is the need for a principle

ensuring that only research adequately confirming its adherence to the Declaration should be published.

II.3 In reaffirming these fundamental principles, should the Declaration state only general principles of broad application (such as the general principle of consent in research) or should it attempt, where appropriate, to define a more detailed framework (for example, requirements for consent in specific cases)?

The more detailed framework should be left to the International Bioethics Convention. The Declaration should focus on signifying the intersections between bioethics and existing human rights. It should not attempt to restate bioethics at the international level. Drafting bodies must include adequate representation from non-Western traditions of medicine, including Islamic and Asian perspectives.

The Declaration should focus on implementation and monitoring issues. Some examples of this approach may be drawn from UNESCO's Declaration on the Human Genome. States, for example, should be required to make every effort to promote the principles set out in the Bioethics Declaration and should, by means of all appropriate measures, promote their implementation.

States should similarly be required to take appropriate measures to promote, through education, training and information dissemination, respect for the principles of the Bioethics Declaration and to foster their recognition and effective application. States should also encourage exchanges and networks among independent ethics committees, as they are established, to foster full collaboration.

The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in the Bioethics Declaration and further examination of issues raised by their applications. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of the Bioethics Declaration, in particular regarding the identification of practices that could be contrary to human dignity.

II.4 Whatever the structure and scope of the Declaration may be, should it, where possible, provide guidance on specific subject areas? If yes, which subject areas could be explicitly mentioned and why?

General statements relevant to human dignity, justice and loyalty to the relief of human suffering in healthcare.

The Declaration were it to follow the general terms of the European Bioethics Convention should initially emphasise that Parties to it shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. The interests and welfare of the human being shall prevail over the sole interest of society or science. Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality. Any intervention in the health field, including research, must be carried out and reported in accordance with relevant professional obligations and standards. The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity. The human genome in its natural state shall not give rise to financial gains.

Reason: relates to the important role of the Declaration in setting the ethos for the profession in an era dominated by the contrary ethical standpoint of global commercialism.

Principles of informed consent/disclosure of material risk

Unless where an emergency renders such impractical, an intervention in the health field may only be carried out after the person concerned (or their legally authorised representative or substitute) has given free consent after understanding the nature of the intervention and its reasonably likely material risks, as well as those of particular concern to the patient. The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

Reason: principles of informed consent are commonly imperilled by commercial exigency, underfunding of healthcare, law reform focused on costs of medical indemnity payments and lack of education of patients and healthcare providers.

Principles for care of the mentally ill

May be included in the planned United Nations Disability Convention and should be congruent with those there stated.

Reason: need to avoid duplication and to ensure congruence of norms.

Access to and privacy of healthcare information

Everyone has the right to respect for private life in relation to information about his or her health. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed. The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected. Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.

Reason: vitally important area for patient rights, especially given the potentially deleterious effects of revelations about the genome of individuals.

Specific genetic and assisted reproductive technology issues

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants. Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited. Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo. The creation of human embryos for research purposes is prohibited.

Reason: some of the most contentious bioethics debates and the greatest need for authoritative guidance occur in this area.

Specific issues concerning scientific research

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being. Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.

The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Reason: scientific research drives the goals and ethos of the health acre profession. It is vital to preserve the capacity to carry out such research for the benefit of all human beings and not just the shareholders of large corporations or the scientists they fund.

Organ and tissue removal from living donors for transplantation purposes

Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

Reason: shortage of organ donors and the ethically contentious methods contemplated to alleviate this problem make this another crucial area.

Prohibition of financial gain and disposal of a part of the human body

The general existing principle is that the human body and its parts shall not, as such, give rise to financial gain. This is now increasingly being challenged as a principle of bioethics that however well intentioned, has allowed health care providers and researchers to profit at the expense of their patients. If patents are being allowed over stretches of DNA, perhaps individual humans should be recognised as having rights over their own genome, at least to the extent of preventing exploitation by others. When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Reason: given the widespread exploitation of DNA through patents this is now an increasingly controversial area and one that the Declaration should reasonably be expected to give guidance upon.

VERS UNE DECLARATION RELATIVE A DES NORMES UNIVERSELLES EN MATIERE DE BIOETHIQUE

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Préambule

Le règne animal, dont l'Homme est le sommet, le règne végétal dont procède toute source alimentaire, l'atmosphère comme milieu vital au deux règnes et le règne minéral comme ressource bioénergétique, ne peuvent connaître de changement radicaux sans rompre la symbiose qui a permis à la vie, sous toutes ses formes, de se développer. La charte devrait avoir pour ambition de veiller à ce que soient maintenues les conditions de la perpétuation de la vie, dans toutes ses harmoniques, dans le respect des nécessités de chaque espèce et de l'équilibre de leur ensemble. La logique de cet équilibre repose sur le fait indubitable que la nature, dans son ensemble est son propre produit de renouvellement constant et des conséquences biochimiques de l'évolution de la planète Terre, depuis son avènement et l'apparition de la vie. L'Homme doit être le garant de la pérennité de la logique naturelle s'il veut continuer à en être le bénéficiaire. L'ordre universel a crée la vie ; l'Homme, comme sommet de cette création sur cette planète, doit accepter d'en être responsable pour survivre.

1. OBJECTIF ET PORTEE

1.1 Trop d'entre nous oublions que nous sommes le produit de notre planète, l'aboutissement d'un processus intégrant l'ensemble des conditions du développement de la vie. Notre manque d'humilité nous fait croire que bien que ne comprenant qu'à un niveau élémentaire les phénomènes de la vie, nous sommes compétents pour en décider la remise en cause dans ses principes (génétiques par exemple). La prise de conscience devrait être au niveau de tous les hommes vivants. Rien n'autorise à penser que la civilisation technologique est l'orientation actuelle de l'humanité soit celle qui est préférable pour l'humanité. Cette question n'est pas de nature culturelle mais instinctuelle. Tous les êtres humains, quel que soit leur niveau culturel ou technologique sont compétents pour apprécier leurs relations à leur écosphère et les conditions de leur bien être. La première injustice serait de permettre que le monde technologiquement avancé décide pour l'ensemble de l'humanité ce qui est bon pour elle. C'est donc **toutes les sociétés** qui sont concernées et qui doivent être impliquées.

1.2 Non, la déclaration ne peut se limiter à l'être humain, puisqu'il est interdépendant du reste des autres espèces et des autres règnes (préambule).

1.3 La réalité oblige à relativiser, dans une telle déclaration, les relations de l'Homme avec certaines parties de son milieu (le règne minéral par exemple) et il serait logique qu'après une évocation en préambule, l'Homme s'attache davantage à ce qui le concerne,

pour sa survivances dans les meilleures conditions. La structure de la vie sur cette planète fait qu'on ne peut se dispenser de s'alimenter. Il serait infantile et irresponsable de nier certaines réalités bloquantes, si on les viole. Par exemple, l'imparable continuité de la chaîne alimentaire : on peut discuter des façons les plus humaines de disposer de la vie des animaux que l'on consomme (abattage, conditions d'élevage…) mais on ne peut pas remettre en cause le fait que ces animaux n'ont droit à l a vie que jusqu'à ce qu'elle nous soit nécessaire pour poursuivre la notre. Il ne suffit donc pas de respecter la vie, mais il convient de respecter l'ordre des choses concernant la vie.

1.4 C'est la suite logique à ce qui précède. Tout devrait procéder, dans ce domaine, d'une définition d'une sorte **de tableau général de la vie** ou s'établissent les relations entre les être vivants et même le monde minéral. Ce tableau qui rendrait compte du monde en équilibre, réglerait la question des déséquilibres.

2. STRUCTURE ET CONTENU

2.1 La déclaration devrait comporter un préambule et être structurée en sections, à titre d'exemple on peut avoir les sections suivantes :

- dispositions générales ;
- une section par domaine : PMA, génie génétique etc… ;
- système de santé et de soins ;
- recherche scientifique ;
- coopération internationale ;
- éducation et sensibilisation ;
- promotion et mise en œuvre ;
- viols de la présente déclaration et leurs conséquences.

2.2 Les principes fondamentaux qui devraient être réaffirmés dans la déclaration :

- respect de la dignité humaine ;
- partage des bienfaits ;
- justice et non discrimination ;
- respect de la vie privée ;
- solidarité ;
- autonomie.

2.3 Il faudrait rester dans les principes fondamentaux et légiférer (ou pas, il n'est pas sûr qu'il faille toujours légiférer) à mesure du développement des choses.

2.5 Il est indispensable que la déclaration puisse proposer des orientations sur des sujets spécifiques voire fondateur, comme par exemple :

- le début de la vie ;
- la fin de vie ;
- le système de soins de santé.

Contribution of Asian Bioethics Association (ABA) to UNESCO IBC "Towards a Declaration on Universal Norms on Bioethics" 27 to 29 April 2004

1. Asian Bioethics Association

The Asian Bioethics Association (ABA) is an international academic organization founded in 1995, and having members across the world. It has great interest in bioethics discussion, and in the work of UNESCO in bioethics. In our constitution we define "Bioethics is the interdisciplinary study of philosophical, ethical, social, legal, economic, medical, therapeutic, ethnological, religious, environmental, and other related issues arising from biological sciences and technologies, and their applications in human society and the biosphere.", and "Asia is the regions, peoples, and cultures which constitute the geographically largest continent of the world." We should note that many members, both individual and institutional, come from outside of Asia.

Article 3 (Objectives) states "The basic objective of the Association is to promote scientific research in bioethics in Asia through open and international exchanges of ideas among those working in bioethics in various fields of study and different regions of the world. In order to achieve this end the Association will encourage the following work and projects: (1) to organize and support international conferences in bioethics in Asia; (2) to assist the development and linkage of regional organizations for bioethics; (3) to encourage other academic and educational work or projects to accomplish their goals consistent with the objectives of the Association."

The current Board includes persons from different cultures:

President: Renzong Qiu (China)
Vice President for China: Xiaomei Zhai
Vice President for India: Jayapaul Azariah
Vice President for Japan: Noritoshi Tanida
Vice President for Korea: Sang-yong Song
Vice President for West Asia (West of India): Sahin Aksoy (Turkey)
Vice-President for South Asia (East of India, excluding other named regions): Leonardo de Castro (Philippines) (in his absence)
Vice President for Asian Ethnic and Religious Minorities (e.g. Jews, Kurds, other ethnic groups or religious minorities): Frank Leavitt (Israel)
Secretary: Darryl Macer (Japan/New Zealand)
Founding President: Hyakudai Sakamoto (Japan).
We also have country representatives in many regions and countries not represented formally on the Board.

Contact point under the constitution is the secretariat:
Contact: Darryl Macer, Ph.D., Director, Eubios Ethics Institute; P.O. Box 125, Tsukuba Science City 305-8691, Japan
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Eubios Ethics Institute http://www.biol.tsukuba.ac.jp/~macer/index.html
Asian Bioethics Association http://www.biol.tsukuba.ac.jp/~macer/ABA.htm

2. Comments on Aims and Scope of a Declaration on Universal Norms on Bioethics

1) The existence of a Declaration would highlight attention upon ethical implications of scientific progress, and it could be a tool used by persons at all levels suggested. It is unclear whether it would help better "assess" the ethical issues because of a diverse way of viewing

ethics, and because we have found a wide range of ethical codes and norms in different professions and in different member countries. We note that one of the most typical Asian ethical norms may be to recognize diversity of decisions that individuals and societies can take about these bioethical issues, which in itself, is a worthy Declaration. Also that despite diverse decisions, harmony and tolerance are socially valued.

2) The Declaration on Universal Norms on Bioethics should not be limited to human beings. Human beings are one of the members of a wide biodiversity, and many applications of life technology touch other living organisms besides human beings. There are some general principles such as respect for life, and to minimize harm to living organisms that could be included. For some peoples and countries the measure of an ethical society includes the way animals are treated and the way the environment is protected.

Given the vast variety of human views, it would be unfair to dictate any one, or any set of, substantive views as the official view of a declaration. Instead, declarations should concentrate on procedural matters having to do with the right to have, and mechanisms for facilitate the expression of, many different points of view.

3) Some examples of issues that we would raise for consideration to this process include:

a) the treatment of animals, in their natural environment, in cities, farms, research, therapy, as companions and for human entertainment.

b) the use of genetically modified organisms.

c) the extent of tolerating human chimeras with other organisms, as cell fusion hybrids, and including gene and/or chromosomal transfer. We note that in ancient Indian mythology chimeras are described.

d) the transfer of human genes, including genes that convey "human properties" to other organisms.

e) agreements to protect the common environment, reducing pollution, minimizing impact upon the environment, protecting biodiversity. This could include recollections from a range of existing international treaties relating to this area, as well as any new work to highlight and explore ethical norms.

f) spiritual aspects of changing living organisms, especially with regard to the variety of religions found in Asia.

As reference in the appendix we refer to the Muttukadu Declaration that recently was the outcome of an ABA-cosponsorred conference in India, which may be useful in deriving some common ecological principles.

3. Comments on Structure and Content of a Declaration on Universal Norms on Bioethics

1) The structure of the Declaration should include a preamble with following sections, and an explanatory document attached to the declaration to explain the process. There is room for both descriptive statements that represent the reality of global thinking, and some prescriptive recommendations on what are norms. A wide range of topics should be included, but in some areas where agreement and consensus is not expected, then a description of diversity of views would still be useful. We do not think the name of any country should be in the Declaration, however, in one of the explanatory documents it may be useful to review positions of different countries.

2) We would support the inclusion of the following principles (this is not an exclusive list). UNU also notes that the principles proposed by different persons vary in their number, names, and organization, yet sufficient convergence exists to allow us to endorse the ethical values of:

a) respect for persons, families, groups and communities,
b) doing good (beneficence),
c) doing no harm (non-maleficence),
d) justice,
e) harmony and listening to each other with tolerance and acceptance of diverse conclusions,
f) diversity of views is a positive sign of the bioethical maturity of a society.

The examination of these principles in a frank but harmonious interaction is part of bioethics, so the precise application of these principles for different societies for different applications of science and technology is an essential part of the living process of bioethics. There does not need to be a dogmatic definition of these principles but rather general recognition, and encouragement for study to examine these and other principles that may be useful for decision-making.

Asian perspectives cherish the value of family and community, and emphasize the interrelationship between individuals and family/community and prefer to resolve their possible conflicts through discussion and negotiation. The same method is also used between different moral, ethnic or cultural communities: they should resolve their possible conflicts by means of negotiation and consultation not by force, rather seeking common grounds while reserving differences, being ready to make compromises. This spirit we think is important in all aspects of the wording of a Declaration from the United Nations.

There are also principles for children's rights, refugee rights, and vulnerable groups within society that could be adopted from other international treaties. The ideal of solidarity is often promoted in UN declarations, but sadly there are many deficiencies in practice. However, a declaration of ethics should be a goal for individuals and societies to achieve, but balancing needs of individuals and society might never be accomplished perfectly. Please note that in Asia the society is often given more weight when balancing with individual choices.

3) If there exists international consensus than the most detailed possible consensus should be written. While there are some areas of consensus that we can see between the policies of national ethics committees, there is academic debate over many points. This cultural diversity is something UNESCO was set up to value.

Please refer to point 3(1) above, on the role of an explanatory document. There are areas where there is agreement, and the previous Declarations of the IBC provide some examples where details may be possible.

4) Subject areas that we would suggest considering to include all those mentioned in the UNESCO IBC questionnaire, but with environmental and animal issues, and more focus on general principles on freedom of open (public) bioethics discussion.

Please refer to the "Eubios Declaration on International Bioethics" <http://www.biol.tsukuba.ac.jp/~macer/eeidec.htm> that was agreed at an ABA cosponsored international bioethics meeting in 2002, given in the appendix 1, and the "The Muttukadu Statement on Our Common Bioethical Future in our Shared Environment with Technology" < http://www.biol.tsukuba.ac.jp/~macer/mutt.htm>, agreed at an ABA cosponsored international bioethics meeting in 2003, given in the appendix 2. We humbly offer these as a source of possible common values.

5) Should such a Declaration be developed it is important to circulate calls for input in more than just the major United Nations languages, otherwise the English and French speakers will dominate the discussion, and the diversity of views will be smaller.

Appendix 1: Eubios Declaration for International Bioethics

Preamble

The life and medical sciences present many important educational, ethical, legal and social issues, which need to be considered at local, national and international levels. Following the closure of the Seventh International Tsukuba Bioethics Roundtable (TRT7), and the discussion at the preceding six TRT meetings, and consistent with the stated goals of the *Eubios Journal of Asian and International Bioethics* (*EJAIB*) and the decade of debate that has appeared in *EJAIB*, the members of Eubios Ethics Institute, and the further undersigned persons, wish to highlight the following principles for international bioethics:

Descriptions of Bioethics

1. Bioethics is an interdisciplinary field that needs to be nourished by debate among all disciplines and people, not limited to any academic specialty or professionals.

2. There are a variety of definitions of bioethics, and this variety is part of the intrinsic value of the field of bioethics. We consider bioethics to be the process of reflection over ethical issues raised in our relationships with other living organisms; the consideration of the ethical issues in spheres including environmental ethics, health care ethics, social ethics, and in the use of technologies that affect life; and the love of life.

3. Bioethics has grown rapidly throughout the world, and should play a central role in professional and public discussions and debates, and bioethical issues feature prominently in legal, medical, scientific, and policy agendas worldwide.

4. Bioethical principles proposed by bioethicists may vary in their number, names, and organization, yet sufficient convergence exists to allow us to endorse the ethical values of respect for persons, doing good (beneficence), doing no harm (non-maleficence), and justice. Moreover, the virtues of the moral agent and his/her relationship to others and the environment are emphasized. The examination of these principles is part of bioethics.

5. There are different ways to view bioethics and in discussions of bioethics we should be clear which approach we are addressing. These include:

Descriptive bioethics – understanding the way people view life, their ethical interactions and responsibilities with living organisms in their life.

Prescriptive bioethics or normative bioethics examines what is ethically good or bad, or what principles are most important in making such decisions. It may also be to inquire into when to say something or someone has rights, and others have duties to them.

When one person tells another what is ethically good or bad they are prescribing bioethics. If prescriptive bioethics leads to paternalistic elitism, then we reject it.

6. There are at least two essential approaches to bioethics:

Interactive bioethics is discussion and debate between people, groups within society, and communities about descriptive and prescriptive bioethics.

Practical bioethics is action to make the world more bioethical, for example, health projects for medically deprived populations, and environmental activism.

Personal and Global Bioethics

7. Every person has a lifelong responsibility to develop his or her own bioethical maturityand values. We could define bioethical maturity as the ability to balance the benefits and risks of ethical choices, considering the parties involved and the consequences. At the societal level, public policy and law need to be developed, which requires a social mechanism for balancing conflicting ethical principles.

8. International cross-cultural bioethics should be developed, including studies and discussions, which respect individual cultures as long as they do not conflict with fundamental human rights, as outlined in the United Nations Declaration of Human Rights. Nations and members of every society (communities) should honestly reflect on the bioethical lessons of the past. Honest reflection on the bioethical lessons of the past should be encouraged together with efforts to promote reconciliation on all levels.

9. Research on the thinking and reasoning of all people should be more emphasized in order to understand the diversity of people's thinking. This is necessary for determining the degree of universality that is possible, and should be used to complement other research approaches in bioethics. There is no inherent reason to believe a priori that the views of one person are intrinsically more valuable than another, based on gender, age, educational background, physical, mental, or psychological condition or life experience.

10. Such ethical understanding is necessary to develop international cross-cultural bioethics, and no one culture should claim to be the dominant source of the concept of bioethics.

Freedom of dialogue

11. Freedom of discussion is necessary for bioethical reflection and an essential feature of democratic life. We uphold the value of free, open and reasoned discussion, so that any position is worthy of consideration. In public discourse, no individual or group can claim to have exclusive knowledge of the right ethical solution. Only open discussion can lead to justifiable conclusions.

12. All nations and communities are encouraged to vigilantly defend the basic freedom of open discussion and disagreement. Often, this freedom is imperiled and there is widespread reluctance to discuss problems openly, the reasoned solution of which may run counter to received opinions and traditions.

Life as a Whole

13. We recognize the dependence of all life (biota) on intact, functioning ecosystems, and the essential services that ecosystems provide. We urge action to halt environmental damage by humans that reduces biodiversity or degrades ecosystem processes.

14. Whereas wildlife provide numerous free services that make our life possible and pleasant, cleaning the air, water, and the soil of pollutants, providing food, medicines and a beautiful place to live, wildlife are in grave danger from the loss of habitat, the spread of exotic species, pollution, and direct consumption by humans. Wildlife often cannot protect themselves from humans, so without our help they cannot survive. The presence of humans greatly reduces the usefulness of a habitat to wildlife. Wildlife reserves act as sources for replenishing our supplies of animals and plants. Therefore, we urge all nations and peoples to make the protection of wildlife and wildlife habitat a top priority. In particular we urge them to set aside a large portion of their territory, interconnected by the wildlife travel corridors, for the exclusive use of wildlife, off limits to humans.

Intellectual Property

15. We believe that life is the common heritage of life, and no one group of persons can claim to own a living organism so as to stop others growing similar organisms.

16. No part of the human body (DNA, gametes, genes, cells, tissues or organs) should be exploited as a source of profit. We oppose exploiting people from some countries or groups to do things that are unacceptable in other countries, for example trade in human organs, unethical or dangerous drug trials, or dumping of hazardous wastes, including nuclear wastes.

Technology assessment

17. We applaud the development of science and technology if for the betterment of all, and urge the better sharing of the benefits of technology with all. Practical methods for appropriate technology (both new and traditional) transfer should be effected, together with mechanisms to assess the cultural, environmental, ethical, social and health impacts of such technology. Encouraging simpler technologies can often be preferable to transfer of advanced scientific technology.

18. In particular, we call upon all those in the research community to use any appropriate technology to reduce the burden of diseases and afflictions, both mental and physical, that afflict persons in all societies, and in particular in developing and least developed countries.

19. We do not think that any one technology with the same general goals, like feeding hungry people or curing a given individual patient, should be singled out for more critical examination, rather that bioethical principles should be applied to protect the interests of living organisms today, and the future generations.

Ethics Committees and Consent

20. In order to effect this, ethics committees with full community and ethnic representation, for the purpose of reviewing research proposals, and monitoring the impact of science and technology, should be established immediately.

21. In principle, all research on humans that has the rational potential to harm should be validated by the documented, informed consent from competent participants, which is voluntary and noncoerced. There are important issues to discuss regarding consent from communities, and we urge further study on these issues. We must devote more research to the topic of research on human subjects who lack the capacity for fully informed consent, such as in pediatric and psychiatric medicine.

Human reproduction and genetic heritage

22. Somatic cell gene therapy for treatment of disease is a useful medical therapy and may be used when needed and chosen by patients. However, germ-line gene therapy should not be attempted until it is technically safe, and a truly international public consensus has been sought and achieved for what specific cases would be considered ethical.

23. Therapeutic cloning, for example of tissues or organs, may be a useful medical therapy and may be used when needed and chosen by patients. However, human reproductive cloning should not be attempted until it is technically safe, and a truly international public consensus has been sought and achieved for what specific cases would be considered ethical.

Duties to all persons

24. We respect the life of all living organisms, When considering organisms we have to think of not only those on the planet Earth now, those that will be brought back to alive from the state of being extinct, those made in the future through natural or deliberate creation, and those that exist in other places. We should consider all persons, no matter their body or mental composition, for their intrinsic value and not their makeup. Society should consider the use of technology to reintroduce extinct species or introduce new species to the ecosystem.

25. We urge reflection on the way that we will treat non-organic (e.g. robots) or hybrid (e.g. cyborgs) persons, before they are made. All persons who work towards the love of others should be valued as a member of the moral community. Many persons in this world are not valued because of speciesism and we uphold the rights of all Great Apes and other beings capable of loving others and conscious thought.

Bioethics Education

26. To work towards a social consensus requires participation of informed citizens, which requires education about issues of bioethical importance. We applaud the public discussion on bioethics that has started to emerge in a number of countries, but these efforts need further support.

27. In order to achieve the above goals, greater effort is required to educate all members of society about the scientific and clinical background, and the ethical principles and social and legal problems involved, in the life and medical sciences. This will enable the active collaboration of all individual members of society, many academic disciplines, and the international community.

28. Education of bioethics is to empower people to face ethical dilemmas. Ethical challenges come to everyone. The process of debate and discussion is important for developing good minds to face bioethical dilemmas. It also develops tolerance and respect of others. In these troubled international times, it is very important to develop tolerance of others, and to learn that everyone as a human being is the same regardless of race, sex or religion. Same in this sense means equally diverse, it does not mean identical.

29. The process of debate and discussion in classrooms is particularly valuable and we urge all persons, organizations, institutions and countries to take appropriate measures to promote the principles set out in the Declaration, through promotion of education in bioethics.

A call to practical ethics now

30. States and institutions should take appropriate measures to encourage all forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to bioethics, in an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.

31. These goals require the cooperation of all, particularly in those with more resources, such as multinational corporations, and rich countries. We urge all to work together for all.

Open to improvement and signature

32. We note that progress towards reflection of bioethics can be made by every person, in both official and unofficial ways, and the undersigned endeavour to help all who want to progress the development of bioethics through the social network of members of the ever diverse, growing and non-exclusive Eubios family.

33. This Declaration will be open to signature and text agreement until a period two months after the publication of the draft Declaration in *EJAIB* (March issue), when the Declaration will be published. Further persons and organizations are welcome to endorse, second, or otherwise use the principles in this Declaration to promote bioethics in the spirit of this Declaration. This Declaration will also be known by its simple form, the *Eubios Declaration for International Bioethics.* As knowledge and experience progress, this Declaration will always be open to revision. We invite the world to participate.

Declared on the 1 March 2002, and open to signature. On-line: **http://www.biol.tsukuba.ac.jp/~macer/eeidec.htm**

APPENDIX 2: THE MUTTUKADU STATEMENT ON OUR COMMON BIOETHICAL FUTURE IN OUR SHARED ENVIRONMENT WITH TECHNOLOGY

A) There are irrevocable directives common to people of all religions who share a bioethics of love of life:

1) Commitment to a culture of non-violence and respect for life;

2) Commitment to a culture of solidarity and a just economic order;

3) Commitment to a culture of tolerance and a life of truthfulness; and

4) Commitment to a culture of equal rights and a partnership between men and women, and between all peoples and groups.

B) Bioethics is an interdisciplinary field that needs to be nourished by open debate among all disciplines and people, not limited to any academic specialty, religious or philosophical belief, or professionals. We should consider the long period of biological, social and spiritual heritage of development of human ethical sense, and the relationships to other living organisms who share these origins.

C) There are a variety of definitions of bioethics, and this variety is part of the intrinsic value of the field of bioethics. We consider bioethics to be the process of reflection over ethical issues raised in our relationships with other living organisms; the consideration of the ethical issues in spheres including environmental ethics, health care ethics, social ethics, and in the use of technologies that affect life; and the love of life.

D) Bioethics has grown rapidly throughout the world, and should play a central role in professional and public discussions and debates, and bioethical issues feature prominently in legal, medical, scientific, and policy agendas worldwide.

E) Bioethical principles proposed by bioethicists may vary in their number, names, and organization, yet sufficient convergence exists to allow us to endorse the ethical values of respect for persons, doing good (beneficence), doing no harm (non-maleficence), and justice. Moreover, the virtues of the moral agent and his/her relationship to others and the environment are emphasized. The examination of these principles is part of bioethics.

F) We respect the life of all living organisms, When considering organisms we have to think of not only those on the planet Earth now, those that will be brought back to alive from the state of being extinct, those made in the future through natural or deliberate creation, and those that exist in other places. We should consider all persons, no matter their body or mental composition, for their intrinsic value and not their makeup. We should limit the consumption of resources in order to minimize our impact on this planet and its ecosystems, in order to live sustainably. Bioethicists should set an example for sustainable living. Those organizing bioethics conferences should consider the appropriate balance between frequency of conference meetings in order to limit air travel, and using simple conference venues, food and housing.

G) We urge reflection on the way that we will treat non-organic (e.g. robots) or hybrid (e.g. cyborgs) persons, before they are made. All persons who work towards the love of others should be valued as a member of the moral community. Many persons in this world are not valued because of speciesism and we uphold the rights of all beings capable of loving others and conscious thought. We also recognize there is a need for more scientific studies of spirituality, but there may always be questions we cannot answer properly in the way of scientific falsifiability, but these questions of love, altruism, harmony and holism are common goods.

H) To work towards a social consensus requires participation of informed citizens, which requires education about issues of bioethical importance. We applaud the public and academic discussion on bioethics that has started to emerge in a number of countries, but these efforts need further support.

I) In order to achieve the above goals, greater effort is required to educate all members of society about the scientific, clinical, cultural, and environmental background, and the ethical principles and social and legal problems involved, in the life and medical sciences. This will enable the active collaboration of all individual members of society, many academic disciplines, and the international community. This includes people without access to electronic communication. Open-minded bioethics discussions, together with health education, should be encouraged for deprived populations in developing and other countries.

J) Education of bioethics is to empower people to face ethical dilemmas. Ethical challenges come to everyone. The process of debate and discussion is important for developing good minds to face bioethical dilemmas. It also develops tolerance and respect of others. In these troubled international times, it is very important to develop tolerance of others, and to learn that everyone as a human being is the same regardless of social status, race, sex or religion. Same in this sense means equally diverse, it does not mean identical.

K) The process of debate and discussion in classrooms is particularly valuable and we urge all persons, organizations, institutions and countries to take appropriate measures to promote the principles set out in the Statement, through promotion of education in bioethics.

L) States and institutions should take appropriate measures to encourage all forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to bioethics, in an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions. These goals require the cooperation of all. We urge all to work together for all. We need a more humble standing of all nations committed to serve humanity.

M) In order to effect this, ethics committees with full community and ethnic representation, for the purpose of reviewing research proposals, and monitoring the impact of science and technology, should be established immediately. In principle, all research on humans that has the rational potential to harm should be validated by the documented, informed consent from competent participants, which is voluntary and noncoerced. There are important issues to discuss regarding consent from communities, and we urge further study on these issues. We must devote more research to the topic of research on human subjects who lack the capacity for fully informed consent, such as in pediatric and psychiatric medicine.

N) We believe that life is the common heritage of life, and no one group of persons can claim to own a living organism so as to stop others growing similar organisms. No part of the human body (DNA, gametes, genes, cells, tissues or organs) should be exploited as a source of profit. We oppose exploiting people from some countries or groups to do things that are unacceptable in other countries, for example trade in human organs, unethical or dangerous drug trials, or dumping of hazardous wastes, including nuclear wastes. The Indian custom of 'sacred groves' should be examined as a possible conservation practice to be emulated.

O) We recognize the dependence of all life (biota) on intact, functioning ecosystems, and the essential services that ecosystems provide. We urge action to halt environmental damage by humans that reduces biodiversity or degrades ecosystem processes. Whereas wildlife provide numerous free services that make our life possible and pleasant, cleaning the air, water, and the soil of pollutants, providing food, medicines and a beautiful place to live, wildlife are in grave danger from the loss of habitat, the spread of exotic species, pollution, and direct consumption by humans. Wildlife often cannot protect themselves from humans, so without our help they cannot survive. The presence of humans greatly reduces the usefulness of a

habitat to wildlife. Wildlife reserves act as sources for replenishing our supplies of animals and plants. Therefore, we urge all nations and peoples to make the protection of wildlife and wildlife habitat a top priority. In particular we urge them to set aside a large portion of their territory, interconnected by the wildlife travel corridors, for the exclusive use of wildlife, off limits to humans.

P) We call upon states not to allow exemptions in regulations to protect the environment and living organisms, including human beings, by states to the military or other special interest groups. We especially urge proper ethical and scientific evaluation of sonar technology against its reported adverse impact on marine mammals, and for immediate reduction in the energy levels that are utilized.

Q) We applaud the development of science and technology if for the betterment of all, and urge the better sharing of the benefits of technology with all. Practical methods for appropriate technology (both new and traditional) transfer should be effected, together with mechanisms to assess the cultural, environmental, ethical, social and health impacts of such technology. Encouraging simpler technologies can often be preferable to transfer of advanced scientific technology. Effective risk management is essential for all avenues of life, with sound scientific risk assessment and appropriate consideration of the interests of all.

R) In particular, we call upon all those in the research community to use any appropriate technology to reduce the burden of diseases and afflictions, both mental and physical, that afflict persons in all societies, and in particular in developing and least developed countries. We do not think that any one technology with the same general goals, like feeding hungry people or curing a given individual patient, should be singled out for more critical examination, rather that bioethical principles should be applied to protect the interests of living organisms today, and the future generations. This includes so-called high tech and low tech applications.

S) The rights of indigenous people, the ecology of rural areas, bioethical management of the coastal zones, and knowledge of indigenous fisherpeople, hunters, gatherers, and farmers of their ecosystems must be respected, protected and documented.

T) Every person has a lifelong responsibility to develop his or her own bioethical maturity and values. We could define bioethical maturity as the ability to balance the benefits and risks of ethical choices, considering the parties involved and the consequences. At the societal level, public policy and law need to be developed, which requires a social mechanism for balancing conflicting ethical principles. We undertake to develop our maturity together, and to work towards peace among all.

U) We strongly advocate the setting up of bioethical-monitoring groups comprising scientists, religious persons, philosophers, bureaucrats, politicians, social activists and others, who can act as watchdogs, not only affirming the bioethical principles but also countering every development in the society which is likely to negate these principles.

Declared in December, 2003, and open to signature. On-line: **http://www.biol.tsukuba.ac.jp/~macer/mutt.htm**