United Nations Educational, Scientific and Cultural Organisation
Organisation des Nations Unies pour l'éducation, la science et la culture

International Bioethics Committee (IBC)

Comité international de bioéthique (CIB)

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PUBLIC HEARINGS DAY
on Human Genetic Data

Monte-Carlo (Principality of Monaco), 28 February 2003

FINAL REPORT

Division of the Ethics of Science and Technology

I. INTRODUCTION

1. Aware of the importance of involving the main actors in the drafting of the future international declaration on human genetic data, the International Bioethics Committee (IBC) decided to organize a Public Hearings Day on human genetic data which, at the kind invitation of the Principality of Monaco, was held on 28 February in Monte-Carlo in the framework of the fifth meeting of the Drafting Group of the IBC responsible for drafting the international declaration on human genetic data (see Programme, Annex I).

2. Chaired by Ms Nicole Questiaux, Co-Chairperson of the IBC Drafting Group, the Day brought together some 50 participants, who included members of the IBC Drafting Group, the principal speakers and some 30 observers – representatives of intergovernmental and non-governmental organizations and specialists (see List of Participants, Annex II).

3. The Day opened in the presence of the Minister for the Interior of the Principality of Monaco, Mr Philippe Deslandes, who recalled his country's commitment with respect to bioethics, citing in particular the adoption in December 2002 of a law on the protection of persons in biomedical research. In his opening address, Mr Pierre Sané, Assistant Director-General for Social and Human Sciences, representing the Director-General of UNESCO, stressed the importance of organizing such Days, which reflect the importance that should be attached to the involvement of civil society in the bioethical debate and the transparency of the IBC's work. Lastly, Ms Michèle Jean, Chairperson of the IBC, recalled that the Day was part of the broader context of an international consultation on the Revised Outline of the International Declaration on Human Genetic Data (see opening addresses, Annex III).

II. MAIN STATEMENTS

4. A total of nine main speakers had been invited to address the meeting, namely: the international bodies which are forums for debate on bioethics (the International Society of Bioethics – SIBI), doctors (the World Medical Association – WMA), clinicians (the European Forum for Good Clinical Practice), children (the World Association of Children's Friends – AMADE), women (the International Federation of University Women – IFUW), persons with disabilities (Inclusion International), researchers (particularly from the developing countries), insurance companies (the French Federation of Insurance Companies) and the pharmaceutical industry (EuropaBio). Each speaker delivered a statement focusing on his or her organization's or institution's view on the subject of human genetic data and made specific comments on the Revised Outline of the Declaration. The statements were followed by discussion with the members of the Drafting Group and the observers present, the results of which were taken into consideration during the Drafting Group meeting that followed (all statements available are to be found in their original language in Annex IV).

5. Mr Marcelo Palacios, President of the International Society of Bioethics (SIBI), first discussed the essential concepts involved in the debate, such as human dignity, the protection of privacy and the principle of autonomy. He then made a few comments on the Revised Outline. He considered that the use of the term "handicapped" in the context of consent could lead to confusion, since a physically handicapped person may be perfectly capable of giving free, informed and express consent. It would therefore be preferable to speak of persons unable to consent. Mr Palacios also raised the issue of the ownership of human genetic data, of patents and of their use in legal proceedings.

6. Ms Kati Myllymaki, President of the World Medical Association (WMA), referred to several other international instruments drafted by the WMA – such as the Helsinki Declaration – Ethical Principles for Medical Research Involving Human Subjects (1964), the Declaration on the Rights of the Patient (Lisbon, 1981), the Statement on Genetic Counselling and Genetic Engineering (Madrid, 1987), the Declaration on Ethical Considerations Regarding Health Databases (Washington, 2002) and the Declaration on the Human Genome Project (Marbella, 1992) – in order to stress principles such as the patient's right to be informed and the right not to know, the duty to obtain the patient's consent and the need to guarantee the integrity of data. More specifically concerning the Revised Outline, the President of the WMA liked the idea of a glossary but at the same time wanted to see a clear definition of human genetic data at the very beginning of the text.

7. Mr Jean Michaud, representing the World Association of Children's Friends (AMADE), began by recalling the United Nations Convention on the Rights of the Child (1989) and referred to the debates and conclusions of the International Symposium on Bioethics and the Rights of the Child, held jointly by AMADE and UNESCO (Monaco, April, 2000), reflected in the document entitled "Monaco Statement: Considerations on Bioethics and the Rights of the Child". In the field of genetic data, the concept of childhood requires examination at two levels, with respect, firstly, to the child's health and, secondly, to his or her identity. With respect to health, ethical questions arise particularly in terms of the consent of the child, whose maturity should be taken into consideration, and where the role of the supervising authorities might deprive the child of his or her right not to be informed. Regarding the child's identity, human genetic data could contribute to exercise of the right, laid down in the 1989 Convention, to know who his or her parents were. With respect to the future declaration, Mr Michaud particularly wished the term "childhood" to appear in the Preamble.

8. The European Forum for Good Clinical Practice, an organization concerned with protecting patients in clinical research at European level and which is contributing to the development of ethical and scientific principles on the subject, represented by its Secretary-General, Mr Francis Crawley, was invited in order to discuss the ethical problems presented by human genetic data with respect to patients. Mr Crawley stressed the respect for human dignity and fundamental freedoms which should be unrestrictedly promoted and appreciated in all their aspects. With respect to the Revised Outline, he believed that, while a fairly broad definition of human genetic data might have some advantages, the specific nature of such data should nevertheless be highlighted and explained, as should the distinction between biological material – samples – and the genetic data derived from them. Furthermore, if the future declaration was to be applied in every field – health, research, clinical applications and civil proceedings – it should also be applied in the framework of state security.

9. Ms Georgette Mordovanaky-Karam, Coordinator of the Lebanese Faculty of Agronomy, represented the International Federation of University Women (IFUW) and spoke on behalf of women. She emphasized the impact of bioethics on the lives of women who were increasingly confronted with crucial ethical choices. In the specific case of human genetic data, the question of their commercialization was fundamental, especially in the developing countries, so great was the danger that the prospects opened up by human genetic data would result in women being exploited: to obtain ovocytes for research, for example. In addition, in many countries congenital diseases were perceived as being transmitted only by women, who therefore often had to bring up sick children single-handed. That was why it was important to take all the necessary precautions appropriate to the culture and traditions of the country. The principles of non-discrimination and non-stigmatization should be strongly asserted, particularly with respect to the risk of sex selection.

10. The organization Inclusion International was represented by Mr Klaus Lachwitz, President of the Task Force on Human Rights. He recalled the relevant articles of the Universal Declaration on the Human Genome and Human Rights (1997), the Council of Europe Convention on Human Rights and Biomedicine (1997) and the Charter of Fundamental Rights of the European Union (2000), which prohibit all forms of discrimination and eugenics. Disability should be regarded, not as an evil to be eradicated, but as a factor in human diversity. Since many disabilities appear after birth, social responsibility should be at the heart of the debate. More precisely concerning the future declaration on human genetic data, Mr Lachwitz believed that the main ethical problem arises in connection with free, informed and express consent. Those terms should be clearly defined in the text in order to avoid any abuse.

11. The private sector necessarily has a place in the present debate on human genetic data since the economic and social issues concern it so closely. Representatives of the private sector, in particular the pharmaceutical industry and insurance companies, were therefore invited to the Public Hearings Day. Mr Klaus Lindpaintner represented the European Association for Bioindustries (EuropaBio). He began by saying that he considered that, since human genetic data are part of the complex spectrum of biological data, they should be handled with care and in such a way as to respect human dignity, but that they do not require special protected status. He recalled that other factors, particularly environmental ones, cause genetic diseases and that this variability should be stressed. In any case, social debate is needed to determine the degree of protection such data should be given.

12. Mr François Ewald, Director of Strategy, French Federation of Insurance Companies, said in his statement that, if too restrictive a position were taken with respect to insurers, the very economy of the insurance contract might be placed in jeopardy. In particular, life insurance policies involved the prediction of risk and were based on a declaration of risk which is itself dependent on a duty of honesty. That duty is absolute and consequently cannot allow any exception, for three reasons: ethical – the insured person asks to be affiliated to a mutual insurance system which therefore assumes he or she does not cheat; economic – honesty enables a fair price to be set; fairness – the assessment is not discriminatory since each risk is assessed at its true value in relation to others. In that connection, genetic data constitutes medical information which enables predictions to be made and as such does not require special treatment. Furthermore, knowledge of genetics is a developing field for which codes of conduct would be more appropriate than legislation. Moreover, in reality, debate is anticipating practice, since at present the use of genetic data by insurers is prohibited in some countries, such as France, and, even where it is authorized, as in the United Kingdom, it is very infrequent.

13. Finally, the last speaker, Ms Genoveva Keyeux, a geneticist from the Institute of Genetics, Universidad Nacional de Colombia, while emphasizing the difficulties specific to developing countries, considered the issue of human genetic data in the field of scientific research at three levels: genetic predisposition, international cooperation and indigenous populations. She explained that, while it is certain that social and environmental factors play a crucial role in the development of disease, in the developing countries there is a danger that too great an emphasis on genetic predisposition would be harmful to health policies and that preventive research could be favoured to the detriment of research into treatments or setting up of infrastructure. That being the case, a greater effort should nonetheless be made at international level to encourage genetic screening in developing countries and to help those countries train experts and obtain the often costly equipment needed for genetic research. With respect to genetic population studies, it is indispensable to lay down guidelines in order to avoid any form of genetic determinism. Culture and tradition are far more reliable indicators of a population's identity than genetic data. Furthermore, care should be taken to prohibit commercialization of the value of genetic data – otherwise the developing countries might see such studies as a considerable source of profit.

III. SUMMARY OF THE DISCUSSIONS

14. The discussions provided an opportunity for a wide-ranging debate among speakers, observers and the Drafting Group. The difficulty of drafting a definition of such data and explaining their specific nature was highlighted, but was considered to be one that had to be overcome. While the title of the Outline indicated that the international declaration dealt with human genetic data, the declaration applied equally to the data and information derived from them, or which could be so derived, as well as the biological samples on the basis of which such data were generated. The distinction could be made more clearly in the text by using two different terms.

15. The discussion also covered the wording and terminology used, which needed to be explained. The wording of the different purposes of collection, processing, use and storage of human genetic data was considered too restrictive in the light of current research. For example, anthropological research should also be included.

16. Furthermore, taking as a starting-point Article 4 of the Universal Declaration on the Human Genome and Human Rights, which stipulates "the human genome in its natural state shall not give rise to financial gains", and drawing inspiration from the IBC Report on Ethics, Intellectual Property and Genomics (2002), the future declaration should mention the implications of the ownership regime or some other regime applying to human genetic data, even if it was for Member States to specify its scope and the limitations on it.

17. Finally, the accent was placed on international cooperation and the right of populations to benefit from the results of the research carried out on them. It was not, however, considered necessary to devote a specific section to the question of population-based genetic studies, since the Revised Outline already dealt fully with such problems in various articles.

IV. CONCLUSION

18. Ms Nicole Questiaux closed the day's work by thanking and congratulating the speakers and all the participants whose comments had enabled the IBC Drafting Group to gather observations that would be valuable when the Revised Outline was finalized. The Day had also provided a further opportunity to ensure the transparency of the IBC's work. Ms Questiaux noted that the form chosen for the instrument, namely, a declaration, had been the subject of unanimous agreement. The same was also true of the structure of the text, which drew a clear distinction, both between the different purposes for which human genetic data are collected and used, and the various stages of their collection, processing, use and storage, despite the inevitable overlaps those distinctions might produce in the formulation of various articles.

19. The Drafting Group, which met after the Public Hearings Day, re-examined the Revised Outline on the basis of the comments and observations made at the public hearings. It paid particular attention to the question of the definition of human genetic data, and the distinction between data, information and samples, and their specific nature. In order not to create confusion, it was thought necessary to revise the Outline so as to include, as a necessity, a reference to the biological samples on the basis of which genetic data are generated. The specific nature of such data could be summarized under three headings: they enable predictions to be made which are valid throughout life; they have an impact, not only on the individual, but also on his or her family, descendants and in some circumstances the group to which the person concerned belongs; they contained potential information which might not be known at the time they are collected. The Drafting Group made a number of other changes to all the articles in order, in particular, to introduce a reference to the rights of children and women, to state more clearly the purposes for which data are collected and used, and to clarify the concepts of consent and ownership.

20. A new version of the text of the declaration taking into account the results of the Day and the written consultation will be examined by the IBC at its tenth session in Paris, scheduled to be held from 12 to 14 May 2003.

ANNEXES

Annex I

"Public Hearings Day"
Monaco, 28 February 2003

Programme

Led by Mrs Nicole Questiaux,
Co-Chairperson of the Drafting Group of the IBC

I. MORNING

10:00 – 10:30 **Opening**

Addresses by

- ***Mr Philippe Deslandes,***
  Minister of the Interior of the Principality of Monaco
- ***Mr Pierre Sané***
  Representative of the Director-General of UNESCO
- ***Mrs Michèle Jean***
  Chairperson of the International Bioethics Committee (IBC)

10:30 – 10:50	Presentation by	**Mr Marcelo Palacios** President INTERNATIONAL SOCIETY OF BIOETHICS (SIBI)
10:50 – 11:05	Discussion	
11:05 – 11:25	Presentation by	**Mrs Kati Myllymaki** President WORLD MEDICAL ASSOCIATION (WMA)
11:25 – 11:40	Discussion	
11:40 – 12:00	Break	
12:00 – 12:20	Presentation by	**Mr Jean Michaud** Member of the French National Ethics Advisory Committee World ASSOCIATION OF CHILDREN'S FRIENDS (AMADE)
12:20 – 12:35	Discussion	
12:35 – 12:55	Presentation by	**Mr Francis Crawley** Secretary-General EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE
12:55 – 1:10	Discussion	

II. AFTERNOON

2:30 – 2:50	Presentation by	**Ms Georgette Mordovanaky-Karam** Coordinator at the Lebanese Faculty of Agronomy INTERNATIONAL FEDERATION OF UNIVERSITY WOMEN (IFUW)
2:50 – 3:05	Discussion	
3:05 – 3:25	Presentation by	**Mr Klaus Lachwitz** President of the Task Force on Human Rights INCLUSION INTERNATIONAL
3:25 – 3:40	Discussion	
3:40 – 4:00	Presentation by	**Mr Klaus Lindpainter** Roche Genetics and Roche Centre for Medical Genomics EUROPEAN ASSOCIATION FOR BIOINDUSTRIES (EUROPABIO)
4:00 – 4:15	Discussion	
4:15 – 4:30	Break	
4:30 – 4:50	Presentation by	**Mr François Ewald** Director of Strategy FRENCH FEDERATION OF INSURANCE COMPANIES
4:50 – 5:05	Discussion	
5:05 – 5:25	Presentation by	**Mr Parekura White** Senior Policy Analyst Environmental Risk Management Authority NATIONAL ASSOCIATION OF MAORI MATHEMATICIANS, SCIENTISTS AND TECHNOLOGISTS
5:25 – 5:40	Discussion	
5:40 – 6:05	Presentation by	**Ms Genoveva Keyeux** Institute of Genetics UNIVERSIDAD NACIONAL DE COLOMBIA
6:05 – 6:15	Discussion	
6:15 – 6:30	Closure	

6:30 p.m.
Cocktail offered by the Chairperson of the IBC and the Assistant Director-General of UNESCO for Social and Human Sciences

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Venue of the meeting:
Métropole Palace – 4, avenue de la Madone – MC 98000 MONACO

Annex II

LISTE DES PARTICIPANTS / LIST OF PARTICIPANTS

I. INTERVENANTS / SPEAKERS

M. / Mr Francis CRAWLEY
Secretaire-général / Secretary-General
European Forum for Good Clinical Practice

M. / Mr François EWALD
Directeur de la stratégie / Director of Strategy

Fédération française des sociétés d'assurances /
French Federation of Insurance Companies

Mme / Ms Genoveva KEYEUX
Institut de génétique / Institute of Genetics
Universidad Nacional de Colombia

M. / Mr Klaus LACHWITZ
Président du Groupe spécial sur les droits de l'homme, Inclusion International /
President of the Task Force on Human Rights, Inclusion International

M. / Mr Klaus LINDPAINTNER
Roche Genetics and Roche Centre for Medical Genomics
Association européenne de bioindustries /
European Association for Bioindustries (EUROPABIO)

M. / Mr Jean MICHAUD
Membre du Comité consultatif national d'éthique français /
Member of the French National Ethics Committee
Association mondiale des amis de l'enfance /
World Association of Children's Friends (AMADE)

Mme / Ms Georgette MORDOVANAKY-KARAM
Coordinatrice générale à la Faculté d'agronomie libanaise /
General Coordinator of the Lebanese Faculty of Agronomy
Fédération internationale des femmes diplomées des universities (FIFDU) /
International Federation of University Women (IFUW)

Mme / Ms Kati MYLLYMAKI
Présidente / President
Association médicale mondiale (AMM) /
World Medical Association (WMA)

M. / Mr Marcelo PALACIOS
Président / President
Société internationale de bioéthique (SIBI) /
International Bioethics Society (SIBI)

II. MEMBRES DU GROUPE DE RÉDACTION DU CIB / MEMBERS OF THE DRAFTING GROUP OF THE IBC

ANDORNO Dr (M.) Roberto Luis (Argentine / Argentina)
Professeur de droit civil / Professor of Civil Law

DE CASTRO Dr (Mr) Leonardo (Philippines)
Professeur de philosophie / Professor of Philosophy
Président de l'Association philippine des sciences de la santé /
President of the Philippine Health Social Science Association
Vice-président du *Forum for Ethics Review Committees in Asia and the Pacific* /
Vice-Chairman of the Forum for Ethics Review Committees in Asia and the Pacific
Membre du Comité national d'éthique /
Member of the National Ethics Committee

GALJAARD Prof. (Mr) Hans (Pays-Bas / The Netherlands)
Professeur émérite de génétique humaine / Emeritus Professor of Human Genetics
Ancien Chef du Département de génétique clinique, Hôpital universitaire de Rotterdam /
Former Head of the Department of Clinical Genetics, University Hospital Rotterdam

IDA Prof. (M.) Ryuichi (Japon / Japan)
Professeur de droit international / Professor of International Law
Rapporteur du Comité du droit du développement économique régional de l'Association de droit international /
Rapporteur of the Committee of Regional Economic Development Law of the International Law Association

IJALAYE Prof. (Mr) David Adedayo (Nigeria)
Professeur de droit international / Professor of International Law
Membre de la Société de droit international du Nigeria /
Member of the Nigerian Society of International Law
Ancien conseiller juridique pour les opérations des Nations Unies en Somalie /
Former Legal Counsel to the UN Operations in Somalia

JEAN (Mme) Michèle (Canada)
Conseillère en développement de programmes, Faculté des études supérieures de l'Université de Montréal /
Adviser in programme development, Faculty of Higher Education, University of Montreal
Membre de la Commission de l'éthique de la science et de la technologie
Member of the Commission of Ethics of Science and Technology
Ancienne conseillère spéciale du Ministre des Affaires étrangères du Canada auprès de la Commission européenne /
Former Special Adviser to the Minister of Foreign Affairs of Canada to the European Commission
Ancien Sous-Ministre de la Santé / Former Vice-Minister of Health

KOSZTOLANYI Dr (Mr) György (Hongrie / Hungary)
Professeur et Chef du Département de génétique médicale et de développement enfantin de l'Université de Pecs /
Professor and Chair of the Department of Medical Genetics and Child Development, University of Pecs
Vice-président de la Faculté de médecine de l'Université de Pecs /
Vice-President of the Faculty of Medicine of the University of Pecs
Ancien Président de la Société hongroise de génétique humaine /
Former President of the Hungarian Society of Human Genetics

MAJUMDER Dr (Mr) Partha M. (Inde / India)
Unité de génétique humaine / Human Genetics Unit
Indian Statistical Institute, Calcutta

QUESTIAUX (Mme) Nicole (France)
Présidente de Section honoraire au Conseil d'Etat /
Honorary Chairperson of Section of the State Council
Vice-présidente du Comité consultatif national d'éthique des sciences de la vie et de la santé / Vice-President of the National Consultative Ethics Committee for Health and Life Sciences
Ancienne Présidente de la Conférence permanente européenne des comités nationaux d'éthique / Former Chairperson of the Permanent European Conference of National Ethics Committees
Ancien Ministre des affaires sociales / Former Minister of Social Affairs

REVEL Prof. (M.) Michel (Israël / Israel)
Professeur de génétique moléculaire, Institut Weizmann des sciences /
Professor of Molecular Genetics, Weizmann Institute of Science
Lauréat du Prix israélien de médecine (1999) /
Israeli Prize for Medicine (1999)
Directeur scientifique, *Interpharm* / Chief Scientist, *Interpharm*
Président du Comité national des biotechnologies /
President of the National Committee for Biotechnology

RUMBALL Prof. (Mrs) Sylvia (Nouvelle-Zélande / New Zealand)
Professeur de chimie / Professor of Chemistry
Assistante du Vice-chancelier de l'Université de Massey /
Assistant to the Vice-Chancellor (Equity and Ethics), Massey University
Présidente du Comité d'éthique humaine de l'Université Massey /
Chair of the Massey University Human Ethics Committee
Présidente du Comité d'éthique national d'éthique sur l'assistance médicale à la procréation /
Chairperson of the National Ethics Committee on Assisted Human Reproduction
Membre du Comité d'éthique du Conseil de la recherche en santé /
Member of the Health Research Council Ethics Committee
Ancien Doyen de la Faculté des sciences de l'Université de Massey /
Former Dean, Faculty of Science, Massey University

SANDOR Prof. (Ms) Judit (Hongrie / Hungary)
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Central European University Budapest

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Professeur et Chef du Service de parasitologie-mycologie de la Faculté de médecine et pharmacie de Casablanca /
Professor and Head of Parasitology-Mycology Laboratory, Faculty of Medicine and Pharmacy of Casablanca
Membre fondateur de l'Organisation marocaine des droits de l'homme /
Founding Member of the Moroccan Organization of Human Rights

III. OBSERVATEURS DES ORGANISATIONS DU SYSTEME DES NATIONS UNIES / OBSERVERS FROM THE ORGANIZATIONS OF THE UNITED NATIONS SYSTEM

ORGANIZATION INTERNATIONALE DU TRAVAIL (OIT) /
INTERNATIONAL LABOUR ORGANIZATION (ILO)

M. / Mr Andrew DALE
Bureau des relations extérieures et partenariat /
Bureau for External Relations and Partnerships

ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)

Mme / Mrs Nikola BILLER-ANDORNO
Ethics and Health Unit

IV. OBSERVATEURS DES ETATS MEMBRES ET DES MISSIONS PERMANENTES D'OBSERVATION / OBSERVERS FROM MEMBER STATES AND PERMANENT MISSIONS OF OBSERVATION

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EGYPTE / EGYPT

S. Exc. M. / H. E. Dr Helmy AL-HADIDY
Ancien Ministre de la santé /
Former Minister of Health

FEDERATION DE RUSSIE / RUSSIAN FEDERATION

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Délégation permanente auprès de l'UNESCO /
Permanent Delegation to UNESCO

KAZAKHSTAN

M. / Mr Valery TOLMACHEV
Premier Secrétaire / First Secretary
Délégation permanente auprès de l'UNESCO /
Permanent Delegation to UNESCO

MONACO

M. / Mr Philippe DESLANDES
Ministre de l'intérieur de la Principauté de Monaco /
Minister for the Interior of the Principality of Monaco

S. Exc. M. / H.E. Mr Jean PASTORELLI
Ministre plénipotentiaire / Minister Plenipotentiary
Délégué permanent auprès de l'UNESCO /
Permanent Delegate to UNESCO

SAINT-SIEGE / HOLY SEE

Mgr Jean-Marie MPENDAWATU
Conseil Pontifical pour la Pastorale de la Santé /
Pontifical Adviser for Pastoral Health
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V. OBSERVATEURS / OBSERVERS

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Mr Likinda EVARISTE
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République démocratique du Congo

Mme / Ms A. GRINDA
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World Association of Children's Friends

M. / Mr Hubert HARDEN
Service gynécologie – obstétrique, Centre hospitalier Princesse Grace /
Gynaecology – Obstetrics Service, Princess Grace Hospital
Principauté de Monaco / Principality of Monaco

Mme / Ms Corinne LAFOREST DE MINOTTY
Secrétaire général / Secretary-General
Commission consultative des informations nominatives (CCIN)
Principauté de Monaco / Principality of Monaco

M. / Mr M. PIERSON
Professeur / Professor
Hôpital d'enfants C.H.U. de Nancy
Vandoeuvre
France

Mlle / Miss Margherita COLOMBO PASTORELLI
Etudiante / Student
Principauté de Monaco / Principality of Monaco

VII. PRESSE / PRESS

Mme / Ms Ann-Marie ANCIAN
Responsable Centre de Presse de la Principauté de Monaco /
Responsible for the Press Centre of the Principality of Monaco

La Gazette de Monaco
Milena Radoman

MC Press
Olivier Almondo

Monaco Hebdo
Cécile Morana

Monaco Info
Jean-Christophe
Stevan Djordjevic
Sylvain Péroumal
Dimino Sylvain

Monaco Interactive
Martin de Kérimel

Monaco Matin
Gaëlle Arama
Marc Mehran

Monaco Madame
Claudia Albuquerque

The Riviera Times
Loïs Bolton

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Doctorante en science politique /
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Université de Nice / University of Nice

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Annex III

Opening Address by Mr Philippe Deslandes,

Minister of the Interior of the Principality of Monaco

Madam Chairperson,
Mr Representative of the Director-General of UNESCO,
Madam Chairperson of the International Bioethics Committee,
Ladies and Gentlemen,

I am very happy to welcome to Monaco, on behalf of the Government of the Principality, the participants in the meetings of the three working groups of UNESCO's International Bioethics Committee, whose expertise is recognized internationally.

Fully aware of the issues at stake and convinced of the primacy of ethical questions, the Principality unreservedly and unhesitatingly associates itself with your work.

The last few years have set fresh challenges in the field of biology and genetics, for the ambivalent nature of all progress in science or medicine means that the immense hopes raised by the advances of medical research are accompanied by no less troubling risks of its serious misuse.

There is no doubt that the collection, processing, storage and use of human genetic data constitute operations that are vital for scientific progress. At the same time, the misuse of such data may undermine human dignity. It is in this context that ethical thinking takes on its full significance, especially when we regard ethics, to use the phrase of Professor Axel Kahn, as the morality of action.

At the meeting point of science, law and morality, the function of bioethics is to regulate the use of new techniques by constantly trying to strike a balance between the rights of patients, the freedom of research and respect for the essential values of our society.

Genetic data, through their very nature and the possibilities they open up, are of an extremely sensitive nature. The medical and personal information they provide, which retains its relevance throughout a person's life and may also concern his or her family and descendants, is decisive for a large number of applications. Since genetic data imply concepts such as the identity of the individual, their use is clearly at the heart of that duality in the progress of the biomedical sciences. We must be assured of the transparency of their end purpose.

This is particularly true in the case of pre-implantation genetic diagnosis and germ-line interventions, an area to which one of the working groups will quite rightly devote its attention.

This is the very purpose of the International Bioethics Committee, whose role it is to monitor the progress of research in the life sciences and its applications in order to ensure that the principles of human dignity and freedom are protected against abuses.

I take the opportunity of this opening session to pay tribute to the work done by the Committee, particularly during the preparation of the Universal Declaration on the Human Genome and Human Rights, adopted by the UNESCO General Conference in 1997. That Declaration, which was endorsed by the United Nations General Assembly in 1998, laid down the basic principles governing the status of the human genome. It has provided a solid basis for all reflection that has taken place since then.

The work beginning today is part of the follow-up to the implementation of that Declaration, which it might be considered advisable to back up by a further declaration on genetic data. Those of you who will be working on this theme realize the vast scope of the discussions to come on the protection of personal data in a world in which such data is obtained and disseminated with increasing ease.

Because of their very nature and the fact that they affect both each individual and humanity as a whole, ethical questions know no frontiers. They require the close coordination of national efforts and the harmonization of national legal instruments. It is in this context that the discussions to be conducted by one of the working groups on the possibility of preparing a universal instrument on bioethics take on their full meaning. I hope they will find a significant echo.

Convinced as it is of the absolute need to reaffirm the principles of human dignity, consent, non-discrimination, justice and solidarity, the Principality of Monaco wishes to be a leading international player in the field of biomedical ethics.

Its keen interest in all these issues, which are undoubtedly crucial to the future of humanity, was already apparent at the International Symposium on Bioethics and the Rights of the Child organized by the World Association of Children's Friends (AMADE) and UNESCO in April 2000.

It was on that occasion that the Monaco Statement was drawn up proclaiming that the use of the data of genetic and foetal medicine should respect the principle of non-discrimination and should not seek to reduce or eliminate human diversity or the element of chance that is intrinsic to life.

As regards its national legislation, the Principality passed a law on 23 December 2002 concerning the protection of individuals in biomedical research. This law organizes and regulates the conditions governing all biomedical research on human beings, which must respect the rights of the individual, and explicitly introduces the concept of ethics into a Monagasque legislative text.

An Advisory Committee on ethics in biomedical research has been set up. It provides the Principality with a structure empowered to give an opinion regarding any clinical trial, which must be conducted not only in accordance with the laws and regulations in force but also in keeping with ethical principles that ensure respect for the human person and the protection of his or her health and rights.

The adoption of this law constitutes a most important advance in legislation and the first step towards the establishment of legal instruments designed to regulate all scientific activities that impact on human beings and their dignity.

Allow me to welcome you once again and to express the hope that your work will meet with the success you look forward to and reap the benefits of an enlightened approach to the advances made by the life sciences.

Thank you for your attention.

Opening Address by Mr Pierre Sané,

Assistant Director-General of UNESCO for the Social and Human Sciences
Representative of the Director-General of UNESCO

Mr Minister,
Mr Ambassador,
Madam Chairperson of the International Bioethics Committee,
Madam Chairperson,
Ladies and Gentlemen,

On behalf of the Director-General of UNESCO, Mr Koïchiro Matsuura, it gives me great pleasure to address you on the occasion of this day of public hearings which exemplifies – if that were necessary – the climate of openness in which UNESCO's International Bioethics Committee carries out its work.

First of all I should like to warmly thank the Monegasque authorities, who have provided us with a setting conducive to a constructive exchange of views on the highly sensitive issue of human genetic data. Scarcely three years after the International Symposium on Bioethics and the Rights of the Child, the Principality of Monaco has once again demonstrated its determination to further the ethical debate within the international community by inviting all those involved in the future international declaration on human genetic data for a day of reflection on that theme.

Allow me also, on behalf of UNESCO's Secretariat, to extend my thanks to the entire Monegasque team who have worked efficiently and in a cheerful spirit of cooperation for the success of this day.

The human genome has been the target of increasingly sophisticated research since the beginning of the 1980s. UNESCO has already looked deeply into the legal and ethical issues raised by such research during the process culminating in the adoption of the Universal Declaration on the Human Genome and Human Rights. In that connection, I am delighted to remind you, since Mr Palacios has given us the pleasure of his company today, that the International Society of Bioethics – of which he is the President – last year awarded the SIBI Prize to UNESCO specifically for its work on bioethics that led to the adoption of the Declaration by the UNESCO General Conference in 1997 and to the subsequent efforts to implement it.

It is as part of the follow-up to that declaration on the human genome that UNESCO has embarked on the preparation of an international declaration on human genetic data, which the IBC has been asked to draw up. An IBC Drafting Group was also set up to reflect on the matter and prepare an initial outline of the declaration that was submitted to the IBC for examination at a public meeting during its ninth session in Montreal last November.

That initial public debate enabled the IBC to gather some precious comments from the various participants and confirmed the top priority that the Committee must continue to give to the public nature and transparency of its work. It was in this spirit that, at the fifth meeting of the Drafting Group on the preparation of the international declaration on human genetic data, the IBC expressed the desire to associate with its work a number of actors particularly concerned by the future declaration.

The fact is that, at a more general level, UNESCO organizes activities, to which it attaches considerable importance, aimed at involving the different forces in society in bioethical issues. By organizing meetings, training courses and debates on topical questions

(such as the one we are dealing with today), UNESCO should increasingly strive to facilitate the exchange of data, experience and ideas in complete freedom between scientists, decision-makers and specialists on the one hand and the representatives of civil society in all its diversity on the other.

This "appeal to the public" was felt to be indispensable in view of the special problems raised by human genetic data. That is why we have gathered here today representatives of groups that are directly concerned by the collection, processing, use and preservation of human genetic data.

Ladies and Gentlemen,

This Day is not intended to present the case – for or against – the revised outline of the international declaration on human genetic data but has rather been envisaged in terms of a comparison of the different positions adopted on the subject by the groups concerned. Each statement will be followed by a debate whose results will be taken into account in finalizing the text of the declaration.

This Day also forms part of a broader process of international consultation. In parallel to the present hearing, UNESCO launched at the beginning of the year a written consultation of Member States, other intergovernmental organizations, several non-governmental organizations, national ethics committees, commissions for the protection of privacy, other national organizations, and numerous experts and specialists. Indeed, you will find the questionnaire relating to that consultation in your package of documents.

The replies received during the consultation, as well as all the comments gathered today, will be taken into account by the IBC Drafting Group in finalizing the text to be submitted at the tenth session of the IBC in Paris from 12 to 14 May next. In June 2003, an analysis of those replies will also be brought to the attention of the Intergovernmental Bioethics Committee (IGBC) and all States at a meeting of governmental experts entrusted with drawing up the draft international declaration that will be submitted for adoption to the General Conference of UNESCO in October 2003.

Ladies and Gentlemen,

Before I conclude, may I once again express the gratitude of UNESCO to the Principality of Monaco for its warm welcome. I shall now make way for Ms Michèle Jean, newly elected Chairperson of the International Bioethics Committee. In doing so, I should like to repeat the words she used in her closing speech at the ninth session of the IBC, when she expressed the hope that "the values of solidarity, education, cooperation and participation by civil society" would continue to guide the work of the IBC.

Thank you.

Opening Address by Mrs Michèle S. Jean,

Chairperson of the UNESCO International Bioethics Committee (IBC)

Mr Minister,
Mr Ambassador,
Mr Assistant Director-General,
Ms Questiaux,
Colleagues, Ladies and Gentlemen,

At its Ninth Session held in Montreal from 23 to 25 November last, the International Bioethics Committee (IBC) examined a preliminary outline of the international declaration on human genetic data prepared by the working group here present co-chaired by Ms Nicole Questiaux and Judge Patrick Robinson.

The preparation of this declaration is a logical follow-up to the Universal Declaration on the Human Genome and Human Rights and the IBC reports on "Confidentiality and Genetic Data" (1999) and on "Human Genetic Data: Preliminary Study by the IBC on its Collection, Treatment, Storage and Use" (2002).

As mentioned by Mr Sané, today we would like to hear the viewpoints of different associations and institutions. This is very important for the IBC. In every report produced so far, the IBC has mentioned the importance of public education and consultation. To begin with, the representatives of bodies that constitute forums of reflection on subjects related to bioethics have been invited to take the floor. Among them is the International Society of Bioethics, whose President Marcelo Palacios has done us the honour to be in our midst, and which has sought since 1996 to promote reflection, analysis and free and open discussion on bioethical problems and to publicize the Oviedo Convention adopted by the Council of Europe in 1996.

The World Medical Association, an organization that represents health professionals and doctors, will be represented by its President, Ms Kati Myllymäki. Indeed, doctors are the best placed to analyze what patients want and more especially changing attitudes to the new technologies and their uses. In this connection, the European Forum for Good Clinical Practice, an organization which is concerned with the protection of patients in clinical research in Europe and which is helping to develop ethical and scientific standards in that area, will be represented by its Secretary-General, Mr Francis Crawley.

Children, women, the disabled and indigenous populations are all groups that are particularly affected by the applications of research on human genetic data. Such data are fundamental to individual and family genetic diagnosis, whether in tests to reveal a specific genetic mutation or in tests to determine susceptibility or genetic predisposition to possible pathologies.

Today children – who are the first to suffer or benefit, depending on one's point of view, from the possibilities opened up by research findings on human genetic data – will be represented by AMADE, the World Association of Children's Friends, in the person of Mr Jean Michaud. Ms Georgette Mordovanaky-Karam, representative of the International Federation of University Women and herself a geneticist, will speak for women, who are increasingly finding themselves confronted with crucial ethical decisions as a result of possible applications of genetic research. The disabled, who demand in particular that primacy be given to principles of non-discrimination and non-stigmatization, will be represented by Mr Klaus Lachwitz of Inclusion International. Lastly the indigenous

populations, the first to be affected by the possible misuse of research in population genetics, should have been represented by Mr Parekura White, representative of the National Association of Maori Mathematicians, Scientists and Technologists. Unfortunately, he has been unable to attend.

We must not forget, of course, all the researchers and academics working in the field of genetic data. We have in our midst Ms Genoveva Keyeux of the National University of Colombia, whose research is focused more particularly on projects in the field of population genetics and, what is more, in a developing country.

Lastly, it seemed advisable to the IBC to involve the private sector too, which necessarily has a part to play in the current debate on genetic data on account of the close interest it takes in the economic and social issues at stake. The European Association for Bioindustries (EuropaBio), representing the economic groups involved in the human genetic data market, and the Fédération française des sociétés d'assurances, represented by Mr François Ewald, will be given an opportunity here to express their positions on these matters.

Ladies and Gentlemen,

I should like to thank the Principality of Monaco for hosting this meeting and for the warm welcome extended to us by its Ambassador, the Ministry and the organizers.

Today's hearings are part of a consultation process that will involve governments and other international and national organizations. The Director-General of UNESCO intends to submit the declaration for adoption at the next session of the General Conference in October 2003. It is with great interest that we will hear your views today, and we thank you for coming.

Annex IV

MARCELO PALACIOS
President of the Scientific Committee of the International Society of Bioethics
INTERNATIONAL SOCIETY OF BIOETHICS (SIBI)

Minister,
Representative of the Director-General of UNESCO,
Madam Chairperson of the International Bioethics Committee (IBC),
Ladies and Gentlemen,

First of all, allow me to greet UNESCO's Director General, Mr Koïchiro Matsuura, and to you all on behalf of the International Society of Bioethics (SIBI). On my behalf, please accept a most sincere acknowledgment for having invited me to take an active part in this important Public Hearings Day.

The Brief Presentation of the Revised Outline of the Declaration on Human Genetic Data (22 January 2003) highlights the capital importance of human genetic data: to science, medicine, and other fields, such as forensic medicine or judicial purposes in civil or criminal proceedings.

The likely repercussions are noted as well as those with regard to the respect for human rights and fundamental freedoms of the individual, families, social groups and different cultures. It views the latter from an *anthropological* perspective (which seems to me a better way of addressing the issue as opposed to "sensitive"), which applies, namely, to indigenous peoples and ethnic groups.

I will not insist further on that. Rather, I intend to make a few remarks with regard to the Revised Outline of the International Declaration on Human Genetic Data we are discussing.

But before I do so, please allow me to introduce some reflections on the following issues, which I consider crucial and inexcusable to that end:

A) Human dignity, the main and essential attribute of "humanness" and from which the other human rights and fundamental freedoms stem. In that context, one must seek reference in the following documents, *inter alia*:

- Article 12 of the Universal Declaration on Human Rights states:

"No one shall be subjected to arbitrary interference with his privacy, family … Everyone has the right to the protection of the law against such interference or attacks."
(Note: this is consistent with Article 8 of the Convention on the Protection of Human Rights and Fundamental Freedoms)

- The 1997 Convention on Human Rights and Biomedicine (Bioethics Convention of Asturias) of the Council of Europe:

"Conscious that the misuse of biology and medicine may lead to acts endangering human dignity ;
Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine …;
Article 1
Parties to this Convention 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 Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997)

Article 1 sets forth that: "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."

Article 2 goes on to state that:

"a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity."

- The revised edition of the Declaration of Helsinki of the World Medical Association:

B.10 "It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject".

- The Directive 44/98/EC of the European Parliament and Council, which some countries within the Union have adopted and transposed to the national legislation, although others have not, also makes reference to the protection of human dignity (see Article 4).

B) Privacy, private life, or individual privacy, familial privacy, or the privacy owed to groups or to specific populations has various and yet distinct conceptual scenarios:

* *Idealized* privacy, which is self-assessed, self-defended and cannot be renounced and yet is somewhat false/imaginary, is perhaps best described in words by Miguel Hernández, the poet: "To live within a pitch-black pit/ in solitude, I wish/ where no one can see my voice/ or my eyes be witness of the tears I shed".

* Privacy which is *socially conditioned/determined* exhibits at least four features, namely:

- it is conditioned/determined by *changes in habits and customs*; most of us are urban beings, close to one another, somehow transnational beings and we are immersed, in Laín's words, in "a culture of the sight and the hearing" and are under the influence of the mass-media, Internet, etc., which, in my opinion, often place "privacy in the realm of the common";
- it is determined/conditioned by *science and technology,* as science or technology invade or may eventually come to invade the most hidden within us: our molecules, enzymes, substances and functions. Science and technology can reach that far within to get where they want to; they can dissect and expose the most intimate spheres in us with no major control whatsoever over their potential;
- it is conditioned/determined by *legislation*, in the best interests of law and order, good habits and public morality, public health, the rights of others, etc. It is a sort of privacy often contested by sectors of society. To illustrate the point, suffice to mention:
  - Health-condition testing:
    In Iceland they passed the Human Data Control Act (2001) for population-based health surveys. Now, these data are made accessible to private companies and the issue, thus, aroused a strong opposition.
  - Racial testing
    In Israel, where according to some sources "there is a real national psychosis" to demonstrate "Jewish racial traits and ancestorship", genetic testing is carried out so that people may have recourse to the Return Act (that aside, a "real Jew" is he/she whose mother or two grandparents are Jewish).
- and then there is *captive privacy*, which is conditioned by different situations: the arbitrary loss of freedom, imprisonment, intolerance, abuse, lack of solidarity, impoverishment, racism and xenophobia, forced emigration and refuge, wars and armed conflicts, and so on and so forth.

C) Autonomy or self-determination to make choices and decisions, which can present as *"conferred or delegated privacy"*, and which for the purpose under discussion can be best illustrated in *informed consent:*

- Individual consent (provided by the person involved);
- Guardianship consent (provided by the family, legal guardians or even judges, in the case of proven incompetency by the under-age, the mentally ill, in the event of contingency, etc.);
- Temporary consent research purposes (basic or applied research), diagnostic purposes (medical or other, labour or insurance contracts, judicial proceedings, etc.), therapeutic purposes, educational publications;
- Indefinite consent (physical, sensorial or psychical disabilities, dementia, paraplegia, assisted elderly, intensive care, etc);
- Final consent (life-will, etc.).
- And so, in such scenarios, privacy is at risk of being violated by the social environment or by technology and biotechnology and, therefore, their use calls for accurate assessment of the interests at stake (*biotechnology looting*, they call it).

* * * *

Some remarks and suggestions (in italics) to the wording of the Declaration we are discussing:

- The Preamble makes no reference to the biological "samples" needed for the collection of genetic data, as opposed to Articles 3b, 5b, 7b, 11 and 17. In my opinion, this may be misleading;
- There is no reference either to the issue of "autonomy". I suggest the word is added to "Reaffirming:... protection of privacy and *autonomy*,..";
- The ultimate destination of the samples is not established, the exception being those to be used for judicial purposes (art. 22);
- The word "handicapped" (article 7b) is quite disturbing as it fails to differentiate physical, sensorial or psychological disabilities. In order to avoid justifiable protests by the physically and sensorialy disabled - as occurred on drawing the early rough drafts of the Bioethics Convention of Asturias – I suggest the use of "*persons not able to consent"*, as it also encompasses the underage and others (prisoners, etc.).

ARTICLE 3

To paragraph b, at the end, the following wording is suggested:

"… for persons or groups, *more particularly the indigenous groups or cultural ethnics,* and for this reason ..."

ARTICLE 4

The following wording is proposed:

"... medical and other scientific or *anthropological* research…"]

From Article 4 it stems that the collection of "samples" and the production of human genetic data pursue USEFUL and APPLICABLE aims, in part related to the provision of medical care and treatment. It follows that research and application require INVESTMENT, but investments are also aimed at getting economic benefit in turn and, consequently, it is by means of patent rights that investors can neutralize the financial risks involved.

It seems convenient to recall that:

- The Universal Declaration on the Human Genome and Human Rights of UNESCO, Article 1, sets forth that "in a symbolic sense, it [the human genome] is the heritage of humanity". And in Article 4 "the human genome in its natural state shall not give rise to financial gains".
- The Bioethics Declaration 2000, SIBI (section 8) makes clear that "the human genome is the heritage of all humanity and is not patentable as such".

- The Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions sets forth amongst other things:

  "(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

  …

  (37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or morality must also be stressed in this Directive;

  Article 2

  1. For the purposes of this Directive "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

  Article 3

  1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

  2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

  Article 5

  1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

  2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

  3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

Note: There seem to be contradictory interpretations in these texts, about which this Public Hearings gathering ought to give their opinion and, if possible, have that opinion express in the declaration under discussion here.

ARTICLE 5

I suggest the following addition to the heading: *"Procedures, public debate and ethics committees"*.

With regard to paragraph a), in Article 5, I must say the underlying intention is praiseworthy as the need for on-going public debate is inexcusable. However, reality is far from yielding the objective and is not very effective.

As regards paragraph b), notwithstanding the significance of those committees, the truth is that from country to country there are contradictory standpoints on specific issues to be reviewed by the ethics committees and set forth herein.

I therefore suggest that in the final draft of the document, that a public-spirited pact for the rational use of biotechnology be encouraged. UNESCO could easily take the lead in that regard so as to secure greater support.

ARTICLE 7

As regards paragraph a) my suggestion is that it should be set forth whether or not the consent is to be provided in writing, should the answer be not, then the requirements for the consent to be valid (eye-witness, etc.), different from those already set forth in the Declaration (parents, family, judicial bodies, etc.) ought to be listed. See Articles 13 b), 16 and 17 .

And as regards paragraph b):

- about taking of biological samples, see below;
- the term "handicapped" must be replaced by "persons not able to consent";
- the declaration must include in its wording reference to "the opinion of children must be taken into account in accordance with their intellectual maturity".

ARTICLE 10

It should be added (in a new paragraph b,) whether or not a person who knows that he/she is affected with a genetic disease must disclose his/her condition where the genetic defect is likely to be passed onto his/her children, even though this information is not offered for other purposes (to the occasional sexual partner, for instance).

ARTICLE 11

As regards the first paragraph, once the request for the collection of samples is made on the basis of a judicial decision, who can have access to the genetic data and how can they be used? Will both the counsel for the defence and the prosecution lawyer have access to these data on equal basis?

To complete the final sentence of the paragraph, it should be clearly determined who or what centre or service can carry out parentage testing in regard to the production of genetic data on the basis of competence and characteristics and in agreement with that set forth in Articles 13 and 15.

For parentage testing purposes, samples can be retrieved, for instance, from the mouth's mucose tissue. DNA will then be isolated with the aid of enzymes. Results offer 99% reliability. In the United States of America, parentage testing is not performed at public health centres, however, there are private centres that are engaged in parentage testing and their results are widely accepted by the courts. Even TV-broadcasting companies have had them performed live and cost-free!

ARTICLE 13

As regards paragraph a), legislation may differ from country to country (it is often the case). Therefore, in the present declaration, UNESCO should encourage States to make an effort to harmonize legislation in this field and to study the convenience of punishing non-compliance with the confidentiality requirement.

As regards paragraph b), it should be established whether or not informed consent is to be provided in writing. Genetic data must be kept codified and secret; to that end, the creation of data registers should be encouraged to safeguard confidentiality in agreement with national legislation.

ARTICLE 16

Again, the issue of informed consent in writing or not?

ARTICLE 17

I suggest the following wording for the heading: *"Collection and Storage"*.
I propose "stored" samples as opposed to "archived".

Informed consent, in writing or not?

Otherwise, Article 17 is complex in its interpretation because even though the underlying spirit is very positive, one can not fail to observe that in regard to the free circulation of data, Genetic data might be used under the excuse of "important reasons of public health" in the absence of informed consent. And even if the genetic data are unlinked to an identifiable person (as regards the provisions under article 5b), there is no reason to think that it is ethically or legally acceptable to use them in the absence of rigorous requirements as to their use because:

i) The person or persons from whom samples have been obtained as well as the resulting genetic information, will remain being the "donors" whether or not they are identifiable as such and in spite of the fact that their genetic data might be significant for public health purposes.

ii) What is to be the ultimate destination of samples other than their destruction, as set forth in Article 22?

iii) To whom belong the remaining samples and under what reasons?

iv) Can they be patented for industrial purposes (medical, pharmaceutical, proteomics, diagnostics, etc.) and commercial purposes? And should that be the case, who can patent them?

v) Should that be the case, and aside from the provisions set forth in Article 20, will the donor of samples benefit in any way of the patent rights?

ARTICLE 21

The whole paragraph should make reference not only to genetic data but also to samples, in agreement with the aims of the declaration and as has been argued so far in this presentation.

ARTICLE 22

As regards the last part of paragraph a), how long can the genetic data pertaining to individuals found guilty of a crime be conserved? Indefinitely? Even if that person has completed prison-sentence, rehabilitated and returned to society?
In the event that these questions are answered affirmatively, my proposal is that the samples and the genetic data obtained from them be destroyed.
As regards availability of genetic data by virtue of judicial proceedings, please go back to remarks on Article 11.

ARTICLE 23

The second half of paragraph b) should be reworded taking into account my remarks on Article 22 and with regard to the fact that genetic data conserved for diagnostic purposes might be the same as those used for civil proceedings purposes.

ARTICLE 24

I suggest the last line to be reworded as follows:
"… of education, training, public information and *public debate."*

* * * * *

Ladies and Gentlemen,

To finish I wish to add that there is no such thing as "a risk society", in the words of Ulrïch Beck, as if risk were inherent to society, a sort of unforgivable or irremediable sentence. Rather, there is "a humanity subject or exposed to risk", which implies that there are causal agents responsible for that risk – be it intended or accidental – which must be made known so that the risks associated with those agents can be prevented or annihilated.

The present declaration drafted by the IBC along with the contributions presented at this Public Hearings Day should suffice to accomplish the aims pursued, even in spite of the difficulties arising from the different approaches to the issues and despite the fact that some countries have already made legislation on these issues.

REFERENCES

In addition to what the Declaration on the Human Genome and Human Rights (UNESCO, 1997) sets forth to the effect, the following documents may prove useful:

- Universal Declaration on Human Rights (UN, 1948);
- Convention on the Protection of Human Rights and Fundamental Freedoms (1950)
- Convention on the Protection of Persons with regard to the Processing of Personal Data (Council of Europe, 28 of January, 1981);
- Convention on Human Rights and Biomedicine, or Bioethics Convention of Asturias (adopted by the Council of Ministers of the Council of Europe on 19.11.96 and open to signature in April 1997);
- Directive 98/44/EC on the legal protection of biotechnological inventions, of the European Parliament and Council of 6 July 1998;
- Bioethics Declaration of Gijón (June 2002);
- Declaration of Helsinki of the World Medical Association "Ethical principles for medical research and experimentation on human beings" (adopted by the 18th World Medical Association Assembly, Finland, June 1964 and amended by the 52nd General Assembly, Edimburgh, Scotland, October 2002);
- Declaration “Universal Commitment to the Dignity of the Human Being”, 2002;
- Declaration “On HIV-AIDS”, 2002.

(The latter two were approved by acclamation at the II World Conference on Bioethics, Gijón-Spain, 4.10.2002)

KATI MYLLYMAKI
President
WORLD MEDICAL ASSOCIATION (WMM)

The World Medical Association (WMA) is an independent confederation of free medical associations representing physicians all over the world. WMA was founded in 1947 when physicians gathered together to discuss human rights insults inflicted by physicians during the Second World War. WMA has 80 member associations representing 10 million physicians around the world. The aim of the WMA is to serve humanity and to achieve the highest international standards in medical education, medical science, medical art and medical ethics and health care for all people of the world. The most widely known WMA document is the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

We are grateful for the opportunity to comment on the Revised Outline of the International Declaration on Human Genetic Data (22 January 2003). As we have not yet held our own decision making meetings (Medical Ethics Committee) my comments are based on our earlier decisions: declarations, resolutions and statements.

Applicable WMA documents are the Declaration of Helsinki (1964, 2002), Statement on Genetic Counselling and Genetic Engineering (1987), Declaration on the Human Genome Project (1992), Declaration of Lisbon on the Rights of the Patient (1981, 1995), Resolution on Cloning (1997) and the most recent ones: Declaration on Medical Ethics and Advanced Medical Technology (2002) and Declaration on Ethical Considerations Regarding Health Databases (2002). These documents are available on our website (www.wma.net).

The Declaration of Helsinki concerns ethical principles for medical research involving human subjects – not just randomised clinical pharmaceutical trials. The last revision of Helsinki (2000) defined the scope of the Declaration as "medical research involving human subjects includes research on identifiable human material or identifiable data". It was acknowledged that medicine and medical research have changed rapidly and the important issues of informed consent, confidentiality and risks and burdens have a new importance to our patients as well as to healthy volunteers in research. We congratulate the International Bioethics Committee (IBC) for addressing these problems in the new version of the document.

WMA decided upon a statement on Genetic counselling and genetic engineering in Madrid, 1987 and addressed the possibilities of modern technology to screen and evaluate prospective parents for genetic disease before conception and in utero. The basic difficulty about abortion is described. "Physicians engaged in genetic counselling are ethically obligated to provide prospective parents with the basis for an informed decision for childbearing. Where a genetic defect is found in the foetus, the prospective parents may, or may not, request an abortion. Physicians, for personal moral reasons may, or may not, oppose the provision of contraception, sterilization or abortion as part of the genetic counselling services. Whether they advocate or oppose providing such services, physicians should avoid the imposition of their personal moral values and the substitution of their own moral judgment for that of the prospective parents. Physicians who consider contraception, sterilization and abortion to be in conflict with their moral values and conscience may choose not to provide genetic services. However, in appropriate circumstances, the physician is nevertheless obligated to alert prospective parents that a potential genetic problem does exist, and that the patient should seek medical genetic counselling from a qualified specialist".

With regard to genetic engineering research, this document refers to the Declaration of Helsinki especially about informed, voluntary and written consent. WMA says that appropriate guidance must be provided by the scientific community, medicine, industry, government and the public to regulate research in genetic engineering.

The WMA Declaration on Human Genome Project was given in Marbella 1992. This Declaration deals with evaluation of risk versus advantage. It emphasizes strongly the respect of a person as a human being, respect of autonomy and respect of privacy. This document clearly states that information should not be passed on to a third party without consent. "Even if family members of the patient may be at risk, medical secrecy has to be kept unless there is a serious harm and this harm could be avoided by disclosing the information".

The Declaration of Lisbon on the Rights of the Patient (1981, amended 1995) is one of the key documents of WMA. It states that "the patient has the right to be fully informed about his/her health status including the medical facts about his/her condition The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life. All identifiable data must be protected. Human substances from which identifiable data can be derived must be likewise protected. The patient's dignity and right to privacy shall be respected at all times in medical care and teaching, as shall his/her culture and values".

In Paris 1997 WMA gave a resolution on cloning : "WMA calls on doctors engaged in research and other researchers to abstain voluntarily from participating in the cloning of human beings until the scientific, ethical and legal issues have been fully considered by doctors and scientists, and any necessary controls put in place."

Last year in Washington medical ethics and advanced medical technology was discussed. In the accepted declaration it is said that "efforts must be made to ensure the provision of comprehensive medical education as a way to deepen the understanding that at the heart of medicine is a love for all humanity".

In 2002 also a Declaration on Ethical Considerations Regarding Health Databases was accepted. The background for this Declaration was the so-called Icelandic Database which aroused great concern about confidentiality of patient records combined with genealogical data. This document is the latest one by WMA and it addresses the very same problems as the IBC document (it is available on Internet, www.wma.net).

JEAN MICHAUD,
Membre du Comité consultatif national d'éthique français

ASSOCIATION MONDIALE DES AMIS DE L'ENFANCE (AMADE)

DONNEES GENETIQUES ET ENFANCE

Ce sujet ne relève pas directement des objectifs de l'Association mondiale des amis de l'enfance (AMADE). Il comporte en effet un aspect scientifique sur lequel il ne revient pas à notre organisation de se prononcer. Mais la génétique touche à l'origine et à l'avenir de l'enfant dont même sous cet angle nous ne saurions nous désintéresser. Il n'est que de reprendre quelques points de nos statuts pour comprendre que nous pouvons avoir notre mot à dire, en la matière, et nous vous remercions de nous le permettre. En particulier l'article 3 de nos statuts énonce : « l'association a pour but de prendre ou de faire prendre toutes initiatives ou dispositions de faire assurer le bien être physique, moral ou spirituel de l'enfance dans le monde, sans aucune distinction de race, de nationalité ou de religion et dans un esprit de totale indépendance ». Ajoutons que parmi les objectifs figurent le souci de susciter, soutenir et entreprendre des programmes d'aide à l'enfance particulièrement dans les pays en voie de développement et d'encourager, soutenir les recherches et les études faites dans tous les domaines intéressant l'enfance. On trouve dans ces textes les éléments qui, au regard de l'enfance, doivent orienter la technique des données génétiques : participer au bien-être physique grâce à une prévision devenue possible et au soutien de la recherche, ne pas admettre les avancées scientifiques en tant que facteur de discrimination. Pour preuve de l'intérêt porté par l'AMADE à la santé de l'enfant, il faut citer le colloque international co-organisé par notre association et l'UNESCO au mois d'avril 2000. Il était intitulé : « Bioéthique et Droits de l'enfant ». D'éminentes personnalités venant du monde entier y ont pris part ; il en est résulté une déclaration dans laquelle j'aurai à puiser par la suite.

Ainsi ces données génétiques qui constituent un progrès considérable en matière de santé posent des problèmes particuliers pour l'enfance. Leur application n'est pas nécessairement bénéfique. Elles peuvent servir l'enfant, elles peuvent aussi lui nuire.

Ce caractère ambivalent est un des traits majeurs des avancées que connaît notre temps en biologie. Il en résulte l'impérieuse nécessité d'une réflexion éthique. Mais au préalable, il convient de cherche à définir ce qu'est l'enfance. Où commence-t-elle, où finit-elle ? La notion englobe-t-elle aussi l'embryon ? Faut-il la faire coïncider avec la minorité ? C'est la position adoptée par la Convention internationale relative aux droits de l'enfant, adoptée par l'Organisation des Nations Unies le 20 novembre 1989 dans son article 1.

La réalité vécue ne s'accommode pas toujours des barrières juridiques. Il faut relativiser la notion d'enfance, en fonction de l'âge certes, mais aussi du degré de maturité variable selon les individus.

On peut examiner le problème de l'étude des caractéristiques génétiques chez l'enfant sous deux angles : la santé, l'identité.

S'agissant de la santé, il est une première considération à retenir : on ne saurait envisager le test génétique de routine. Cette technique doit répondre à des situations particulières, fondées sur une analyse des données médicales et familiales. L'objectif à atteindre n'est pas unique : la maladie peut-elle survenir chez le sujet examiné ? à quelle échéance ? Y a-t-il un traitement possible ? Il s'agit de déterminer la nature de la maladie, la date présumée de son apparition, les possibilités de traitement. A cet égard, le Comité consultatif national d'éthique français avait adopté en 1991 une position qu'on ne peut que reprendre : « les parents peuvent demander l'analyse d'un génotype de leur enfant, seulement si la maladie liée à ce génotype peut se déclarer avant 18 ans ou peut bénéficier de mesures préventives instaurées avant 18 ans ». On pense à la maladie de Huntington qui peut faire l'objet d'un dépistage pré-symptomatique. Elle apparaît entre 30 et 40 ans et on ne lui connaît aucun traitement. Il faudrait en pareil cas où il est décidé de faire pratiquer le test, pour ceux

qui ont la charge de représenter l'enfant, affronter un cruel dilemme. N'y a-t-il pas alors obligation de révéler le résultat positif à l'enfant devenu en âge de comprendre. Ceci revient à provoquer chez lui une angoisse insupportable. Si au contraire le résultat est dissimulé, on ne le met pas en mesure de bénéficier d'un éventuel traitement qui serait découvert avant que l'affection ne se révèle. Au surplus on le priverait d'une information d'intérêt capital pour sa descendance. En revanche la détection d'une affection éventuelle curable, peut permettre la mise en place d'un traitement de nature à en empêcher son apparition ou à la combattre. C'est une chance à donner à l'enfant. On doit envisager aussi la découverte, par examen génétique, de risques pouvant affecter la future descendance du sujet examiné. A ce stade, se pose principalement la question de l'information.

En effet, dans ces diverses situations, il convient de réfléchir sur la personne même de l'enfant, hors de son entourage. Le principe général est celui du consentement libre et éclairé pour l'exécution d'un acte, tel l'analyse génétique portant sur le corps. Il faut dissocier en l'espèce les deux adjectifs. Il n'est en effet pas question de liberté, pour le tout jeune enfant jusqu'à l'âge ou commence la compréhension. Mais l'information, « le caractère éclairé », doit se préciser au fil du temps. La « Déclaration de Monaco : Réflexions sur la bioéthique et les droits de l'enfant », précise à ce sujet, et je cite : « l'enfant doit être associé aux décisions qui le concernent, tant sur le plan de la santé que sur celui de son éducation, de plus en plus et de mieux en mieux au fur et à mesure de l'affirmation de son autonomie. Il appartient aux parents de se conformer l'un et l'autre à cette exigence ». Cette déclaration a clôturé les travaux du Colloque de Monaco. A cette occasion ont été définis quelques-uns des points forts qui traduisent la position de l'AMADE vis à vis de l'enfance.

L'information devient de plus en plus nécessaire s'agissant de la future descendance de l'intéressé qui serait porteur d'une mutation révélée par une analyse qu'il n'a pu connaître. Son information passe à l'évidence par celle de ses parents, ou de ses tuteurs, qui devront être tenus au fait de notions d'accès parfois difficile. Il s'agit pour les uns et les autres de la prise de conscience de sérieuses responsabilités. Il est au moins un droit que l'enfant va être définitivement empêché d'exercer : celui de ne pas savoir, qui prend place désormais parmi les droits de l'homme. Lorsque cet enfant sera en âge de comprendre, il sera pour lui trop tard pour refuser l'information. La technique se sera exercée et ses résultats seront connus. Néanmoins ceci ne doit pas servir d'argument pour abandonner la recherche sur le jeune enfant. Il faut cependant y voir un élément supplémentaire en faveur du renforcement de sa protection.

Il convient de souligner ici le rôle déterminant des parents ou des autorités de tutelle à qui revient la tâche de consentir à l'exécution de la recherche génétique. Mieux que de consentement, il faudrait parler d'autorisation. Cette substitution nécessaire des parents à leur enfant devient problématique en cas de dissension entre eux ou simplement de positions contraires. Il y a lieu alors de saisir l'autorité judiciaire. Mais ce recours qui s'impose lorsqu'il s'agit de soins dont on ne peut se dispenser, ne va pas de soi pour une technique qui offre un choix. La question vaut d'être posée.

L'investigation génétique peut avoir pour suite l'utilisation de la technique du diagnostic prénatal. Les résultats ne sont pas sans risques pour l'enfant à naître. Sans doute la détection d'une grave affection peut-elle déterminer une décision d'interruption de grossesse dans le cadre légal. Mais l'annonce d'une maladie de moindre gravité et curable peut susciter la tentation, là aussi, de l'avortement médical. C'est un danger contre lequel il faut protéger le fœtus menacé.

L'intérêt de l'enfant est d'abord celui qui est relatif à sa santé quant à l'utilisation des données génétiques. Il vient d'en être question. Un autre intérêt est d'ordre social. Il est celui de l'identité. Il faut citer à cet endroit la Convention internationale relative aux droits de l'enfant, adoptée par l'Organisation des Nations Unies le 20 novembre 1989 et qui reconnaît à celui-ci le droit de connaître ses parents dans la mesure du possible et d'être élevé par eux. Les données génétiques peuvent contribuer à l'exercice de ce droit. L'AMADE n'a pas pris de position précise à ce sujet. Elle se réfère dans la déclaration précitée à l'information que les parents peuvent devoir délivrer en fonction de l'intérêt de l'enfant. Mais une marge d'incertitude subsiste sur l'interprétation de la Convention internationale. Si l'exercice de ce droit de l'enfant ne doit pas être entravé, existe-t-il corrélativement, un devoir de prêter concours à cet exercice ?

Dans la Déclaration finale du Colloque de Monaco figure cette disposition : « l'utilisation des données de la génétique et de la médicine fœtale, doit respecter le principe de non discrimination et ne doit pas viser à réduire ou à éliminer la diversité humaine ou les aléas inhérents à la vie ». Ce texte montre bien que le progrès scientifique peut comporter deux faces, l'une claire, l'autre sombre. Il faut savoir les discerner surtout lorsque sont en cause les êtres les plus fragiles. On pense d'abord aux enfants dans leur ensemble et ensuite aux plus exposés d'entre eux qui vivent dans les pays en développement. Ce sont ceux-ci qui par le truchement des AMADE nationales font l'objet de l'attention la plus soutenue de notre organisation.

Je voudrais traduire et résumer les soucis de l'AMADE au regard de ce progrès capital qu'apporte la génétique.

En premier lieu, il s'agit de l'enfant vis à vis du monde extérieur. Il ne faut pas que la connaissance de ce qu'il sera, acquise par les moyens de la biologie, conduise à l'élimination accentuée de celui dont on ne veut pas ou à la recherche affinée de l'être exactement tel qu'il est souhaité. Le danger de discrimination, répétons-le, apparaît alors comme constituant une injustice majeure contre ceux qu'on écarte et un défi aux droits de l'homme : discrimination individuelle d'abord qui peut devenir collective et ouvrir ainsi les voies de l'eugénisme.

En second lieu, il s'agit de l'enfant vis à vis de lui-même. La connaissance de ce qu'il sera, et de ceux des dangers qui menacent sa santé, et qui sont irrémédiables, serait pour lui facteur d'angoisse et par suite atteinte à sa liberté. Ses actions risqueraient d'être dictées non pas vraiment par ce qu'il veut, mais par ce qu'on lui a appris sur lui-même. A ces dangers, le texte qui nous est soumis doit contribuer à apporter des parades apaisantes.

Je voudrais, fort de la permission qui m'en est donnée, compléter mon exposé par trois remarques sur l'Esquisse révisée de la déclaration internationale sur les données génétiques humaines :

1. Le préambule de ce document est de haute tenue. Il rend compte des fondements du texte et de l'esprit qui s'en dégage. Cependant nous considérons qu'il pourrait être encore amélioré par l'introduction d'un mot, celui d'enfant, ou d'enfance qu'on n'y trouve pas. C'est en effet à partir du tout début de la vie que se situe nombre de problèmes soulevés par la génétique alors que la technique va peut être peser notablement et souvent profitablement sur la vie que le sujet va mener alors qu'il est encore loin de pouvoir en accepter le principe et en prendre la mesure. Certes on comprend bien, à la lecture de ce préambule que l'enfant est concerné. Mais nous aimerions qu'en plus il y soit cité par exemple dans le « considérant » commençant par : « reconnaissant le statut spécial des données génétiques humaines » ;
2. La seconde remarque a trait à l'article 7b relatif au consentement qui n'a pu être donné d'emblée pour une raison tenant à l'incapacité. Ce texte retient l'alternative : consentement libre et éclairé ou décision de justice. Il y manque semble-t-il, entre les deux, le recours à l'autorité parentale ou de tutelle.
3. L'article 22 mériterait une clarification. En effet il y est question, successivement d'une enquête criminelle, puis d'une enquête en matière de délit, enfin de personnes reconnues coupable d'un crime. Il serait préférable d'utiliser le terme général d'infractions.

FRANCIS CRAWLEY[1] & CAROLINE TROUET

EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE

The European Forum for Good Clinical Practice (EFGCP) wishes to thank Mr. Koïchiro Matsuura, Director-General of UNESCO, for the invitation to provide public commentary on the Revised Outline of the International Declaration on Human Genetic Data at the Public Hearing Day on 28 February 2003 in Monaco. The EFGCP shares with UNESCO the interest in promoting the *Universal Declaration of Human Rights*, and it recognises the role of the United Nations institutions in providing instruments that facilitate the responsibility of States for the implementation and assurance of human rights throughout society.

It is especially appropriate that this Public Hearing be held on the 50th anniversary of the discovery of deoxyribonucleic acid (DNA). The cardboard model of the DNA double helix James Watson assembled in his Cambridge University office on 28 February 1953 became the first building block for the human genome project, resulting in an enormous gateway into human genetic data (HGD), the meaning and consequences of which we are only beginning to appreciate.

This very recent and powerful ability of science to arrive at an increasingly defined and accurate description of human biology through HGD offers great promise in the fight against disease and the goal of "health for all". At the same time, HGD poses substantial threats to the identity of persons and/or groups or communities when used without regard to the dignity of persons and communities. The proposal of an international declaration on human genetic data has the potential to contribute substantially to the promotion and protection of human rights with regard to the use of HGD. The EFGCP welcomes an open and public debate on the potential need for such an international instrument, as well as the eventual scope and content of such a declaration.

EFGCP Recommendations Regarding General Principles for Human Genetic Data

Based on an analysis of the scope and content of the Revised Outline of the International Declaration on Human Genetic Data, and taking into consideration the opinions and proposals in this area by Member States as well as by other international organisations, the EFGCP recommends the following principles be considered in the further development of this international instrument.

1. The aim of such an international instrument on HGD should be to promote and safeguard the dignity and the rights of persons and communities, having regard to the *Universal Declaration of Human Rights* (10 December 1948) and taking into consideration the *Universal Declaration on the Human Genome and Human Rights* (1997) and the *Convention on the Rights of the Child*. Further reference should be made to the World Medical Association's *Declaration of Helsinki* (1964-2000) with regard to health (biomedical) research.
2. A clear definition of human genetic data (HGD) needs to be made alongside a clear definition of human biological material (HBM). HGD and HBM should be clearly distinguished from one another.
3. The declaration should clearly state that genetic data is "biological data" whose meaning with regard to human dignity as well as personal and community identity is limited to that which can be derived from biological material.
4. The declaration should provide clear argument for the special consideration provided here to HGD vis-à-vis other forms and origins of data regarding persons and/or groups and communities.

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5. The scope of the declaration should be more clearly defined. Firstly, a decision needs to be made regarding a full inclusion of HBM considerations or a focus limited to HGD. Secondly, HGD (and perhaps HBM) should be considered in all aspects regarding their use in health, health-related research, civil matters (e.g., employment, insurance, criminal procedures), military uses, and matters of state security; or the declaration should be limited to considerations of HGD in only health and health-related research.

6. The prior, free, and informed consent for the use of HBM and HGD should be guaranteed. Any use of HBM or HGD without prior and free informed consent should be made the subject of open public debate, including international partners, and subject to prior review by an ethics committee.

7. The question of the 'ownership' of HGD (and HBM) should be discussed and considered in relation to questions of "guardianship" and "usership".

EFGCP Specific Recommendations

Based on the principles provided above, and with the guidance of the Questionnaire provided by UNESCO, the EFGCP provides the following specific comments on the Revised Outline of the International Declaration on Human Genetic Data. The recommendations provided here do not address the details of the Revised Outline, but rather are intended to provide guidance for implementing the principles.

- The aim of an international declaration on human genetic data should be to promote and safeguard the dignity and the rights of persons and communities, having regard to the *Universal Declaration of Human Rights* (10 December 1948).

- The distinction between human genetic data (HGD) and human biological material (HBM) (from which genetic data may be derived) is not clear in the Revised Outline. Further clarification is also required regarding the scope of the declaration. Considerations regarding the use of HGD in health, health-related research, civil matters (e.g., employment, insurance, criminal procedures), military uses, and matters of state security should be clarified.

- The Preamble should stress that genetic data is "biological data" whose meaning with regard to human dignity as well as personal and community identity is limited to that which can be derived from biological material. The Preamble should also point towards the distinction between HGD and HBM.

- The World Medical Association's *Declaration of Helsinki* should be highlighted with reference to health-related (biomedical) research. The United Nations *Convention on the Rights of the Child* should be referred to regarding children.

- In Article 1, the definition of HGD as "heritable characteristics of individuals obtained by DNA analysis" is lacks precision and threatens confusion. The potential confusion is more explicit in the Brief Presentation of the Revised Outline of the International Declaration on Human Genetic Data, which accompanies the Revised Outline: "the genetic heritage is characteristic of each individual" (page 3). A more precise definition would be as follows: "Human genetic data is information derived from human biological material regarding fundamental biological characteristics of persons and/or groups or communities". The terms "heritable" and "heritage" are inappropriate here; the genetic characteristics of a person may result from fabrication, deliberate or otherwise.

- The concepts of "heritable" and "heritage" (also as presented in Article 1 of the Universal Declaration on the Human Genome and Human Rights) have connotations that go beyond the biological and threatens the stigmatisation of persons and communities.

- It may be appropriate for an international declaration to address HBM ('samples' or otherwise). This would change considerably the present Revised Outline. It is also possible to address only HGD, but a clear distinction between HGD and HBM would need to be made regardless of the final scope of the declaration.

- Article 2 should more clearly express that neither a person's and/or group's or community's identity nor individuality may be determined by strictly biological (genetic) characteristics.

- In Article 4, the purposes for the collection, processing, use, and storage of HGD in HGD in health, health-related research, civil matters (e.g., employment, insurance, criminal procedures), military uses, and matters of state security should be clarified. The phrase "other scientific research" does not contribute to clarity (as it is written in the Revised Outline its meaning is limited to 'judicial purposes').

- In Article 5:b), it is not clear to which ethics committees the Revised Outline refers. Currently, most Member States do not have ethics committees that perform such a function and it is not clear which ethics committees States would attribute such a remit. The phrase "the review of these questions shall be based on the principles set forth in this Declaration" should be rewritten as "the review of these questions shall take into consideration the principles set forth in this Declaration and other international instruments, as appropriate". It is inappropriate to restrict the freedom of ethics committees or to consider that any principle is universally and directly applicable in its written form.

- Consent of family members, groups, and/or communities may at times be required and should be fully considered throughout the declaration.

- In Article 11, add to the end of the first sentence the following: "consistent with human rights and the principles of this Declaration". Rewrite the end of the second sentence as follows: "the best interest of the child, having regard to the interests and rights of the parents and other family members".

- Regarding Article 13:b), many UN Member States do not have national legislation indicating in which cases HGD may be disclosed or made accessible. Requiring such legislation in advance of any disclosure or accessibility may be unrealistic and hinder person and/or group and community rights.

- The term "third party" should be defined.

- Confidentiality should be specified with regard to third parties, explicitly including employers, insurance companies, educational institutions, research organisations, governments, military agencies, and national security agencies.

- In Article 16, the phrase "or it is decided by law" is inappropriate. This declaration should provide a standard for implementing into law human rights with regard to HGD. It should not sanction in advance deviations from the principles of this declaration.

- Regarding Article 17, research and public health purposes do not justify the use of HBM to generate HGD without free informed consent, linked or not linked. Any use of HBM or HGD without prior and free informed consent should be made the subject of open public debate, including international partners, and subject to prior review by an ethics committee.

- In Article 18, it is advisable to add at the end the following: "The circulation of HGD shall be subject to review by an ethics committee".

- In Article 19, the last sentence is better rewritten as follows: "Such regulation should guarantee the rights of persons regarding their HGD based on this Declaration".

- In Article 20, priority should be given to those persons and/or groups or communities that have contributed their HGD to the research.

- In Article 21, the distinction between HGD and HBM is particularly important with regard to the management and monitoring of HGD. The question of "ownership" should be discussed in a separate article and considered in relation to 'guardianship' and "usership".

- In Article 22, clear guidance is needed regarding the duration for maintaining HGD (and HBM) as well as the destruction of HGD (and HBM).

- In Article 23, it should be made clear that prior and free informed consent is required for cross-linking HGD.

- Article 25 should precede Article 24.

- The declaration should provide further argument for the priority given to HGD over other personal data.
- The declaration should take into consideration the World Medical Association's *Declaration on Ethical Considerations Regarding Health Databases* (2002).

Conclusion

The EFGCP shares with UNESCO a commitment to the highest standards of ethics in health research and practice. These standards can only be achieved through partnership between international agencies, non-governmental agencies, researchers, patients, and institutions as well as funders and industry. This Public Hearing Day demonstrates the importance of the ongoing development of such partnerships based on shared ethical principles.

In the areas of science's and society's engagement with human genetic data and human biological materials, it is essential that globally and locally we find means to advance health while promoting and protecting.

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FEDERATION INTERNATIONALE DES FEMMES DIPLOMEES DES UNIVERSITES (FIFDU)

Je remercie au nom de la Fédération internationale des femmes diplômées des universités (FIFDU) toutes les personnes qui ont œuvré pour la réussite de cette journée qui traite des multiples impacts dus à l'évolution rapide de la technologie, qui semble appartenir au monde du fantasme beaucoup plus qu'à la réalité.

La FIFDU comporte plus de 170 000 femmes diplômées reparties en 72 associations appartenant à différents pays, parmi lesquelles je cite l'Association libanaise des femmes universitaires (ALU), dont je suis membre. C'est une organisation bénévole de femmes instruites au service des problèmes relatifs à la femme dans tous les domaines et pays - je citerai entre autre la culture, l'atteinte à la dignité, la violence et l'indépendance matérielle de la femme.

C'est en tant que membre de cette fédération que mon intervention se propose de présenter les opinions et les visées et non pas en tant que chercheur en génie génétique que je suis.

Dans le cadre de ses multiples activités, la FIFDU a organisé son 26e congrès à Graz (en Autriche) le 20-25 août 1998, où deux résolutions traitant de la bioéthique ont été adoptées. En résumé elles portent sur les questions suivantes:

- la nécessité de financer les commissions qui s'occupent de questions sociales et éthiques relatives à l'application des avancées génétiques.
- la nécessité d'informer le public et de prendre en considération les moeurs et cultures des groupes éthniques au sein des populations.
- ce congrès a souligné aussi la nécessité d'éviter la discrimination et le racisme génétique.

En ce qui concerne plus spécifiquement l'Esquisse révisée de la déclaration internationale sur les données génétiques humaines du 22 janvier 2003, dans les dispositions générales, on parle de la collecte du matériel génétique, de la confidentialité, de la fiabilité, des finalités de l'utilisation et des modifications éventuelles, de la destruction du matériel et du flux-trans frontière. Je m'arrête sur les articles 4 « Finalités » et 5 « Procédures » et plus particulièrement sur le terme « se doit » et je demande : comment parviendra-t-on à l'application ?

Pour avoir la réponse il faut connaître le problème, et connaître le problème c'est déjà la moitié de la solution trouvée.

Voici ce que je propose. Faire un rapide survol sur quelques apports de la génétique dans l'amélioration de la vie quotidienne en insistant sur les points qui préoccupent la FIFDU. Ensuite j'exprimerai les attentes propres à la FIFDU de ces rencontres fructueuses et riches.

A. Quelques applications de la génétique

a. Nature des données génétiques

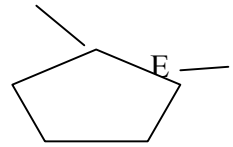
Dans chaque cellule il y a un mètre environ d'un ruban ou chaîne d'ADN**.** Au cours de la division cellulaire, ce ruban se coupe en morceaux ou chromosomes dont le nombre est constant. Ce nombre définit l'espèce.

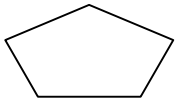
L'aspect et le nombre de chromosomes constituent le caryotype. Un diagramme montre les chromosomes numérotés. Toute erreur sous ou surnuméraire entraîne des anomalies dont la trisomie du chromosome 21 (mongolisme) est l'anomalie la plus fréquente.

Les chromosomes peuvent se heurter accidentellement et échanger une partie de leurs bras, c'est un crossing-over ou enjambement. Il entraîne des combinaisons, donc des caractères nouveaux.

En 1960 la biologie moléculaire commence ses travaux. L'analyse de l'ADN prend une nouvelle allure, on apprend que l'ADN est une combinaison de glucide de dérivé phosphate et de base azotée A, T, C, G.

L'unité==nucleotide =





= OSe

O = phosphate

E = base, selon qu'il y a deux ou trois ponts disulfures de liaisons on a A et T C et G.

Le ruban est donc une suite de nucléotide où la seule variante se trouve au niveau de la base azotée A , T, C, G . Notre ADN provenant de deux parents, on a deux brins anti-parallèles (pour des convenabilités spatiales). Ces deux brins s'enroulent autour de protéines isolantes appelées histones : c'est la double hélice.

L'ordre de succession ATCG constitue un code génétique dont l'unité s'appelle gène. Elle est constituée par 3 bases au moins. Pour chaque caractère on a deux gènes identiques ou allèles (venant du père et de la mère).

Les copies des ADN sont appelées ARN. Elles œuvrent pour l'expression des caractères codés. Toute modification au niveau de cet ordre est une mutation. Elle peut être spontanée ou provoquée par l'homme, elle est toujours héréditaire. Lorsqu'un changement s'opère au niveau de l'ARN, on a une élition c'est-à-dire la fixation surnuméraire d'une base entraînant un décalage de toutes les autres, qui se doit d'être répétitive pour être transmise.

Le séquençage représente une technique de lecture (avec usage de déceleur radio-actif) afin de déterminer l'ordre de succession de bases et les modifications possibles. L'interprétation de cette lecture constitue les données génétiques qui définissent l'individu, elles peuvent entraîner sa discrimination au sein d'une population si une anomalie (maladie) est dévoilée. Les données génétiques peuvent encore prévoir la possibilité de l'apparition future de maladie.

b. <u>Le clonage (principe)</u>

On se demande comment des cellules à code identique fonctionnent différemment : l'une produit le lait, l'autre une hormone. En effet, il existe pour tout caractère un ensemble de gènes appelé « opéron » qui obéit à une série de blocages et de déblocages influençables par de multiples facteurs plus au moins connus. Au bout de quelques années, on a compris que la chaleur perturbe l'ordre de succession et que entre 65º et 85º température de fusion, l'ADN peut présenter des réarrangements c'est à dire des mutations.

Quand à la brebis Dolly, elle est le résultat d'une procédure différente. C'est un zygote normal auquel on a retiré l'ADN et remplacé par l'ADN d'une cellule mammaire d'un autre individu. C'est ce qu'on appelle clonage c'est à dire culture de cellules in vitro en vue de conférer à ces cellules des potentialités nouvelles à usage ultérieur.

c. <u>La thérapie génique</u>

Elle a débuté vers 1980-1990. Elle peut apporter des solutions à plus de 4 500 maladies héréditaires. En effet, si dans un organisme un gène est déficient, on y introduit des cellules fœtales correctrices. Le gène déficient n'est pas touché mais on a inoculé un gène de remplacement capable de fonctions similaires. Pourquoi fœtales ? Parce que les signes de vieillissements précoces peuvent être évités par l'utilisation de cellules juvéniles.

Si beaucoup de maladies ont trouvé une solution (par exemple le diabète, la mucoviscidose, l'hématochromatose, le cancer, la leucémie, le sida, etc.), il existe encore d'autres maladies à maîtriser.

La technique améliorée consiste à découper l'ADN contenant un gène d'intérêt (= vecteur de clonage) et à le recoller à l'ADN d'une cellule dont le gène correspondant est déficient, en obtenant ainsi des organismes transgéniques. On a même pu asservir des bactéries à la production de protéines à usage thérapeutique (enzyme, hormone, molécule immunitaire) et des protéines à usage industriel (insecticide, arômes artificiels, viscose et même synthèse d'eau et dépollution). On a pu « humaniser » des gènes, c'est-à-dire chez un organisme récepteur, le gène murin (animal) est remplacé par un gène humain (fabrication d'organes).

Ces travaux ont induit la nécessité d'une banque de gènes, qui garantissent la conservation de l'ADN des espèces non encore modifiées. Toutefois, le problème qui se pose actuellement est le manque de réglementation de ces banques de gènes.

d. Critique

Il faut mentionner que des remaniements peuvent interférer et modifier la thérapie. Le gène d'intérêt peut se perdre au bout de quelques générations ou bien répondre différemment aux stimulus. Des gains de nouveaux gènes peuvent avoir lieu et camoufler le gène d'intérêt. Les dérapages techniques au niveau du protocole à suivre peuvent survenir. Il n'y a pas de risque zéro et on n'a pas toujours rigoureusement des conditions identiques.

Quelquefois, la mutation survient et elle est inapparente. D'autres fois, des substances tératogènes peuvent provoquer des ralentissements des divisions ce qui a pour résultat l'apparition des caractères anormaux à différents niveaux.

> Exemple : l'apoptose ou mort cellulaire programmée est à l'origine de la modélisation des caractères. Si l'apoptose n'a pas lieu au niveau de la main de l'embryon, le futur bébé n'aura pas de doigts. Si l'apoptose se fait à un niveau différent (parce qu'elle est tardive) on a des doigts déformés.

On constate de ce résumé qu'il y a beaucoup d'apports par le génie génétique, mais les risques sont omniprésents et on se demande que faire des « erreurs ». Peut-on disposer d'eux ? Où se situe alors la dignité humaine?

Un autre sujet de préoccupation est l'impact évolutif sur les équilibres écologiques dans 20-30 ans dû à une éventuelle pratique systématique du clonage ? Les écosystèmes seront-ils identiques ?

B. Réflexions bioéthiques

Je laisse le côté religieux pour d'autres débats où des personnes plus compétentes peuvent intervenir.

Le côté économique quoique important (des millions sont en jeu) ne m'intéresse pas. D'autres développeront cette question plus tard, notamment en ce qui concerne la relation assureur – assuré.

Si actuellement beaucoup de médicaments sont désignés superflus, donc non remboursés par la sécurité sociale déficitaire, qui payera demain les énormes factures de la thérapie génique ? L'assureur en déficit? Ou l'assuré? Si l'assuré est démuni, doit-il renoncer à ces soins avantageux ? Que signifierait alors l'adage « tous les hommes sont égaux en droits et en devoirs »? Concernant plus précisément l'Esquisse, aucune disposition ne préconise le droit des démunis à ces avantages technologiques.

Ces soins n'améliorent pas seulement la qualité de vie, mais ils assureront aussi la prolongation de la vie. Une autre question se pose. Qui payera les retraites interminables ? A quel âge doit-on s'arrêter de travailler ? Quelles seront les opportunités de travail pour les jeunes? Un nouveau statut social s'annonce : il faut l'organiser, le gérer ensuite.

Je ne parlerai pas du droit à la confidentialité et des tests génétiques en criminalité, les juristes le feront certainement.

Quand à la femme, elle a un rôle primordial puisque c'est elle qui fournit les ovocytes et l'Esquisse révisée traite longuement de la nécessité d'un consentement qui doit être impérativement libre et éclairé. Or, combien de femmes accepteront de se soumettre à des épreuves hors d'un projet personnel? Dans les pays en développement les cultures locales et certaines traditions relèguent la femme au deuxième plan. Comment éclairer ces femmes ? Je crains que les femmes du tiers monde ne soient les fournisseurs d'ovocytes pour quelques dollars dérisoires. Que faire pour empêcher ces abus?

En ce qui concerne les personnes handicapés et l'autorisation parentale ou tutrice préalable : ne doit-on pas ajouter un adjectif qualificatif supplémentaire à coté de handicapé? En effet on doit préciser les handicapés sensoriels et culturels. Dans le deuxième cas l'autorisation familiale sera-t-elle suffisante pour protéger les illettrés?

En ce qui concerne l'enfance, et le droit de l'enfant à naître, on en parle très peu, pourquoi? Voici quelques réflexions à ce sujet. L'état civil reflète l'appartenance d'un individu à une civilisation, à une ethnie. En cas de clonage humain, lieu et date de naissance seront-ils mentionnés ? Ou remplacés par laboratoire tel, tube numéro X ? Doit-on omettre ces désignations ? Si oui, pourquoi est-il nécessaire de mentionner sur l'étiquette des produits alimentaires leur nature transgénique? Si non, quelle sera l'appellation de l'enfant ? « Enfant cloné » ou « transgénique », ou enfant tout court.

Aujourd'hui la loi protège les enfants adoptés et elle rend obligatoire l'information en ce qui concerne les origines de l'enfant. Dans le cas du clonage, quelle sera l'attitude de l'enfant vis à vis de sa mère virtuelle, alias l'ADN original connu ou inconnu? Quelle sera son attitude vis à vis de sa mère éducative ?

A l'école les enfants seront de trois catégories : ceux bi-parentaux, ceux monoparentaux (clonage à partir d'un homme et d'une femme) et ceux a-parentaux à partir d'un gamète ou d'un ADN inconnu. On peut se demander : quelles seraient leurs relations mutuelles ? La violence scolaire ne va-t-elle pas empirer ? Les enfants ne vont-ils pas se targuer d'apostrophes discriminatoires ? Y aura-t-il une classe classique ? Ou bien pour éviter ce qui précède l'enfant aura un apprentissage à domicile sur ordinateur avec absence de toute initiation à la sociabilité ?

Quand aux performances culturelles ou manuelles, elles sont toujours précédées du terme 'doué', autrement dit on admet qu'elles sont héréditairement transmises. Si on admet que le clonage sera systématique dans 15-20 ans, on peut se demander si nous aurons une société comparable à celle des abeilles autrement dit sexiste, avec élimination systématique du sexe jugé indésirable. Y aura-t-il une descendance modifiée c'est à dire des individus différemment constitués en vue d'activités robotiques ? En d'autres termes, on nous fait naître pour devenir ouvrier, mécanicien ou chimiste. Où se trouve alors l'identité de l'individu parmi une multitude d'exemplaires similaires ? Irons-nous un jour jusqu'à la réclamation du « droit à la différence » alors que nous réclamons aujourd'hui le « droit à la liberté » ?

Malheureusement l'Esquisse révisée concentre son attention sur la procréation assistée et les tests génétiques propres à l'identification des maladies et de la criminalité. Je souhaite que les précédentes réflexions puissent trouver quelque part une place plus ou moins importante.

En ce qui concerne le changement de finalité je souligne que parfois lorsque les travaux en biotechnologies sont détournés de leurs finalités, ils sont bien payés et ces pratiques sont hélas très discrètes. Que faire pour les dévoiler ou, mieux, les supprimer ? A quelle distance peut-on arrêter la cupidité humaine ? Que propose-t-on aux pauvres qui veulent à tout prix accéder aux profits de la science même au prix de la criminalité ?

Dans la Déclaration universelle sur le génome humain et les droits de l'homme, l'accent a été mis sur la régulation, et non la législation, probablement par honnêteté pour ne pas tomber dans le piège des mots. Que doit-on choisir aujourd'hui comme facteur de prohibition? La loi se doit d'être protectrice de la dignité humaine. Il y a donc un besoin urgent d'une législation détaillée qui mentionne les délits probables et la manière de dévoiler les actes frauduleux et de suggérer les peines correspondant à la violation de « l'intérêt scientifique » souvent mentionné dans le texte. Je me demande comment définir ce terme alors qu'il peut englober beaucoup de controverses indéfinissables.

A l'avenir si l'individu devient propriété de l'Etat quelle sera la place des sentiments ? Le concept d'abnégation ? Quelle sera la relation sociale des individus ? L'attitude vis-à-vis de la mort sera-t-elle la même qu'aujourd'hui? Pourquoi l'Etat accepterait-il de dépenser des fortunes pour remplacer des organes dans un corps défectueux ? Ne serait-il pas plus simple de prélever son ADN, de cloner un individu tout neuf et « jeter » l'ancien ? Le privilège de la réparation sera-t-il réservé aux personnes exceptionnelles ou au pouvoir ?

Conclusion

Toutes ces réflexions laissent peut-être à penser que nous sommes contre le clonage ? Non, on ne peut arrêter la science et nous avons montré les côtés largement utiles ainsi que les aléas et, si je n'ai pas spécifié d'articles à corriger, c'est que je suis incapable de le faire et je ne veux pas le faire.

La FIFDU cherche à vous apporter quelques réflexions globales dont j'espère vous tiendrez probablement compte.

Pour terminer, je dirai : qu'avons-nous fait pour préparer l'humanité à cette nouvelle forme de société où la mondialisation va mettre sous la même enseigne des cultures diversifiées et divergentes, lesquelles disparaîtront progressivement ? Joignons nos efforts, arrêtons-nous de nous demander, êtes-vous pour ou contre le clonage ? La question se doit d'être : comment pensez-vous préparer l'humanité à cette nouvelle forme de vie ? Comment protéger la femme, l'enfant ?

L'éthique était autrefois une recherche facultative et personnelle, aujourd'hui elle se doit d'être impérative avec une initiation de la jeunesse à l'école ou l'université. En effet les débats éthiques englobent actuellement toutes les sciences. Oeuvrons pour la mise en œuvre d'un programme d'éthique au niveau scolaire qui permettrait à l'humanité d'évoluer mentalement en harmonie avec le progrès. Je rappelle ici une citation de Boileau : « Science sans conscience n'est qu'une ruine de l'âme ». Dans ce cas, nous serons comme Saint Exupéry à la recherche de nouveaux horizons utopiques.

Prenons à l'avance des mesures. En 1980 le futur c'était l'an 2000. Les chercheurs étaient partis de zéro et le progrès fut énorme. Le demain de l'an 2003 c'est peut être l'an 2020 ou 2030 et, vu ce que nous avons, je prévois que le progrès sera effrayant.

J'espère avoir été utile pour la déclaration que vous préparez en vous apportant ces quelques réflexions des femmes de la FIFDU.

KLAUS LACHWITZ
CHAIR OF THE TASK FORCE FOR HUMAN RIGHTS
INCLUSION INTERNATIONAL

Distinguished Members of the International Bioethics Committee,
Ladies and Gentlemen,

It is an honour for me to be here today and to speak in the name of Inclusion International. It is one of the largest international human rights organisations, representing more than 200 member associations in 115 countries and lobbying for 60 million intellectually disabled people and their families.

We call ourselves a human rights NGO because we fight for self-determination of persons with intellectual disabilities and against abuse, degrading treatment and discrimination.

The debate on the "pros" and "cons" of an international declaration on genetic data is of utmost importance for an organization like ours that tries to promote and defend the rights of people who belong to the most vulnerable groups in our societies. They are, in many parts of the world, totally neglected and incarcerated in big institutions without any self-determination or privacy.

Many of these people are uneducated and, due to their specific disability, unable to understand what the background and aim of the storage and use of genetic data.

It goes without saying that such a group of persons needs protection from those who would use human genetic data for discriminatory purposes or in a way that may lead to the stigmatisation of individuals with intellectual disability. The same is true for family members, particular if the intellectual disability is the outcome of hereditary disease.

We are, therefore, very grateful that Article 6 of the UNESCO 1997 Universal Declaration on the Human Genome and Human Rights reads: "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect on infringing human rights, fundamental freedoms and human dignity."

And we very much welcome Article 24, which prescribes that consultations with parties concerned, such as vulnerable groups, should be organised.

We are satisfied that the1997 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 states that:

1. "Any form of discrimination on grounds of genetic heritage is prohibited"(Art. IV.11);
2. The respect for private life and the right to know and not to know information about one's health must be warranted/guaranteed (Art.III.10);
3. Intervention in the health field, including research, requires free consent which can be given only with knowledge of the purpose and nature, the consequences and risks (Art. II.5).

More precisely, the 1991 UN-Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care state: "Informal consent is consent obtained freely, without threats or improper inducements, after appropriate disclosure to the patient of adequate and understandable information in a form and language understood by the patient…" (Principle 9).

Finally, I want to refer to the new Charter of Fundamental Rights of the European Union, which contains the Right to Integrity of a person and states that in the field of medicine and biology "the prohibition of eugenic practices, in particular those aiming at the selection of persons, must be respected" (Chapter I, article 3).

This provision in the Fundamental Charter reflects the experience that disability, in the history of humankind, was for a long time, and in many parts of the world still is, treated as a negative characteristic to be eliminated from humanity.

We fight for change. We take the view that disability represents an element of the diversity of the human existence: A person with intellectual disability, e.g. a person with Down Syndrome, might need more time than a so-called non-disabled person to understand what is happening in everyday life and what he or she has to do to master the challenges of life, but emotionally, for instance, we can learn a lot from them as they do not hide their feelings, they like to communicate, they are open-minded and they treat other people with respect and dignity.

There is no reason to "prevent" persons with an intellectual disability.

We fight for acceptance and for the right to be different, because the human standard we have reached is the result of an evolutionary development that, so far, is characterised by the fact that nobody has tried to change the structure of human genes or has succeeded in creating a "perfect human being".

Diversity is the explanation of our human existence and we believe that the right to be different is one of the most important human rights that should be included in international human rights instruments.

I think this short description of our background and motivation is necessary to understand and accept our reservations against any attempts to undermine the status of persons with disabilities in our societies.

The process of collecting and storing genetic data in itself does presuppose any negative or positive judgement about a person. But we all know that new forms of discrimination would arise if insurance companies or employers, for instance, could use genetic data as a basis for denying insurance coverage or rejecting an applicant for a job.

We therefore need limits and we accept that the Revised Outline of the International Declaration of Human Genetic Data respects the view that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms, and respect for human dignity.

Nevertheless, the Revised Outline contains too many loopholes and leaves too much room for interpretation.

There is no clear position on how to balance the right of a person not to be screened, tested or examined with the interest of genetic researchers to make use of genetic data for the benefit of society.

We miss the clear statement that there is a "primacy of the human being" and we refer to Article 3 of the Working Document on the Application of Genetics for Health Purposes published by the Steering Committee on Bioethics (CDBI) of the Council of Europe on 7 February 2003, which reads: "In the application of genetics covered by this protocol, the interests and welfare of the human being shall prevail over the sole interest of society or science."

Another controversial topic we want to mention is Article 7 of the Revised Outline of the International Declaration of Human Genetic Data, which states that "prior free informed and expressed consent shall be required for the collection of human genetic data, either through invasive or non-invasive procedures and whether public or private institutions carry them out". What will happen if a person is unable to consent due to his or her intellectual disability or to mental illness?

The Revised Outline refers to the possibility that in such cases a legally authorised third party might decide instead of the person concerned on the basis of national regulations by regarding the "best interest" of such a person. This regulation is far too weak and can be misused quite easily.

As the collection of genetic data can affect the integrity and the right of self-determination, we, again, want to refer to the European Convention on Human Rights and Biomedicine (1997) which, at least in principle, states that an intervention in the integrity of a person can be accepted only, if it produces a direct benefit to the health of the person or if the intervention is necessary to protect the (equal) rights of a third party.

For many years national laws and judgements in countries like Germany, Sweden, China, etc. told us that it is in the best interest of a woman with intellectual disability to be sterilized (so-called involuntary sterilization) and new euthanasia laws in the Netherlands, Belgium and Switzerland try to convince people that, under certain circumstances, it is in the best interest of a person to die.

We do not accept these dangerous phrases!

Either a society should be able to prove that a person with intellectual disability can give his or her consent to genetic screening or testing by really knowing what is going on and by receiving all information required in an understandable way (e.g. in an easy to read language) or the collection of human genetic data of such a person should be prohibited, if it is not for the direct benefit of the person.

I summarize: We are not a fundamentalist, but a pluralist, international umbrella organisation representing the views of many associations in different parts of the world. We are not against research and progress in the field of biomedicine, but we are acting as a watchdog as far as the collection, storage and use of human genetic data is concerned. All too often we have seen persons with intellectual disability, especially those living in institutions, used as subjects of research and teaching in ways that have been discriminatory, degrading and even dangerous!

Thank you for giving us the opportunity to present our views today.

GENOVEVA KEYEUX
Institute of Genetics
UNIVERSIDAD NACIONAL DE COLOMBIA

Distinguished Chairperson Mrs Questiaux,
Members of the Drafting Group,
Ladies and Gentlemen,

As a molecular geneticist working in a developing country, where for the past 15 years I have been involved in population studies (both in basic research and health-related), I feel particularly pleased to present some views about the signification of the meaning and use of genetic data in a cultural context such as the Latin American. May I remind those of you who are not familiar with our continental diversity that in some of these countries, such as Colombia, Amerindians, Europeans and Africans have mixed together and left their genetic makeup and their culture, leading to a quite complex human identity.

Genetic studies in diverse populations have taught us not only about human evolution and relatedness – phylogenetics – but also about health and disease behaviour, especially in the case of worldwide distributed genetic diseases when they are put into the context of environment and genetic background of populations. This is to say that the behaviour, not only of multifactorial or complex diseases, but also of some monogenic traits, can be quite different, depending on the background genome. This, in turn, is reflected as particular proteome expression patterns, conferring different phenotypes to individuals. Therefore, genetic determinism is not completely clear even when one deals with a single-gene expression.

In a context of generalized scientific illiteracy, strong cultural and religious beliefs, the aim of my presentation is to stress the issues about genetic data that could be misunderstood in developing countries. In my presentation, I will consider three main topics genetic data linked to predisposition and genetic diseases; genetic data, law and minority rights; and genetic data and international cooperation. I will focus in each case on particular situations identified in Latin America or, on a broader scale, in developing countries.

Genetic data linked to predisposition

One of the problems of handling data about an individual's genetic predisposition to a disease is that these data are to be treated as no-certainties, as opposed to data from a non-predisposed individual, where one becomes almost confident that the individual will not develop the disease. When genetics says "probable", it entails that chance, which can be translated as "environment" and "stochastic biophysical and biochemical influences", is a strong element moulding its manifestation. Twin studies are the best examples to illustrate this: in the best cases you have 40-60% concordance in the expression of complex diseases (e.g. Insulin-dependent diabetes mellitus IDDM), or even some monogenic diseases (e.g. cystic fibrosis (CF)). This concept is basic when one has to argue with third parties, whose reasoning is based on "certainties" of acquiring a particular health condition, provided the situation is considered at long-term. That is to say, there is no clear distinction between determinism and probability linked to an individual's genetic information. How can we assess the qualitative and quantitative difference between a potential risk versus a likely danger? Is the "genetic" risk a heavier burden for individuals, groups of individuals or society as a whole than the risk associated to life style and behaviour? Is it legitimate to base grave decisions that affect life, liberty and fulfilment of individuals on uncertainties called genetic risk? Even in the case of a Mendelian disorder like CF, it is difficult to foresee the diagnostic value of the genotype (*a priori* information), when the phenotype associated with a given mutation can be dissimilar, from mild to severe, depending on yet unidentified modifier genes and environment (*a posteriori* information).

At present, we do not even know if the problem of the manifestation of complex diseases or traits, for which it has been postulated that an exhaustive analysis of genetic markers would provide insight as to whether individuals or whole populations are prone or not to develop theses diseases, is a *qualitative* matter – which markers are present or not – or a *quantitative* trait. Recent investigations on gene expression in the brain of chimpanzees and humans show that the difference is more a quantitative variation in the expression of the same genes in both species. This suggests that genetic data might not be relevant in the way we think today and that differences in behaviour, diseases, skills, talents, etc. might better be explained at the transcriptome level than at the genome level.

Whilst I do not doubt that it might be partially valid for some wealthy countries, in developing countries, where fierce neo-liberal economies rule the social and economic interests and where there is a more or less total ignorance of the scientific facts, there is an urgent need for a clear definition of what predisposition means, what the limits of genetic data-linked probabilities are and, especially, what guarantees there are for a patient to benefit from being tested for such predisposing markers through preventative treatments, regular medical check-ups, etc. It should be warranted by all possible means, that at-risk individuals are not excluded from health and social security systems inspired by free market economic models. It is no secret that due to their high debts to the International Monetary Fund (IMF) and the World Bank, developing countries have to reduce their fiscal deficit. They do this by lowering investment in social programmes, especially health and education. Health is expensive and the present health providers prefer to cover ready-to-cure illnesses rather than possibly life-long treatments. The point regarding genetic data is critical: under binding economic models they are expected to direct the design of schemes of preventive medicine, whereas in neo-liberal economies they can be used to exclude all the "expensive" treatments, as it already happens without having to test for genetic markers (AIDS, cancer, cardiovascular diseases). This is also reflected in the fact that there are no public policies for screening of common genetic disorders. Such policies should go hand-in-hand with public support for families with these problems. In developing countries, living conditions, which depend on better food, housing, sanitary conditions, education, are the problems that should be focused on, much more than the genetic make-up of individuals.

On the other hand, some genetic data can be powerful predictors that can be ultimately used to fashion preventive measures – health and environmental – thereby preventing the development, or at least reducing the severity, of common diseases, such as cardiovascular diseases, Alzheimer, cancer, etc. But we must also consider the expectations raised by such modern bio-medical tools in developing countries, when the cure, or at least the triggering factors, have not even been discovered. We have some examples from other fields that should open our eyes to this problem. Experimental vaccines or pharmaceutical treatments to cure infectious diseases affecting thousands of, generally low-income, peoples have been publicized before the effectiveness of these treatments was fully established and validated. This has led to the withdrawal of preventive sanitary measures that had proven to be effective, at least in reducing the levels of infection.

Genetic data linked to inherited diseases

Special care should be taken to protect women from abusive disclosure of information in the case of X-linked genetic data. Carrier status for sex-linked diseases or anticipation disorders transmitted to a next generation through female meiosis can lead to stigmatisation against women, especially in countries with a sexist culture and poor education level of the population. In many Latin American countries, genetic diseases or congenital malformations, no matter if autosomal or X-linked, are actually perceived as a problem transmitted by the mother. The man's role in reproduction and inheritance is poorly understood, beyond the fact that it is linked to sperm. This leaves women alone with the duty of raising children with severe genetic diseases or malformations. Even the gender of a future child is in many social classes still the "job" of women. Therefore, special care must be taken to raise awareness of the special significance for a women's future and to avoid disastrous reactions when informing other family members of an inherited sex-linked disorder.

Genetic data and international cooperation

In developing countries, particularly in Latin America, there is an increasing asymmetry in the availability of genetic services: while almost every country has already, or is in the process of building, facilities for human identification, there are few laboratories for molecular diagnostic testing. Where they exist, their capacity is limited to a small number of tests. For several reasons that are beyond the scope of the present topic, it seems that it would be more urgent to provide genetic data for human identification than for diagnosis and prevention of genetic diseases. At the level of international cooperation, efforts to provide insight into the benefits of public policies of disease testing, train expert personnel and provide facilities should be equal to or stronger than the efforts to train people to use expensive machines to furnish genetic data on individuals, when the purpose is linked to criminality, war, terrorism and paternity trials. These efforts would lead to the improvement of health problems and reduction of a heavy burden for families that remains unattended by the public health systems. At the same time, the acknowledgement of paternity could better be addressed, in the long term, by social work and public campaigns, rather than by coercive measures bound to legal prosecution.

Genetic data, law and minority's rights

One detrimental consequence for minorities and ethnic groups, when there is no clear delimiting and control of the access and use of genetic data, has been debated for many years. The core of the debate is whether genetics will be used to sustain the idea of racial differences between human groups, thus conferring support to value judgments that would nourish any form of discrimination. Although, from the scientific point of view, it is increasingly evident that there is no way to draw clear-cut compartments in the human species based on genetic data, it is also true that a few markers are specific to some populations. Their presence in an individual's genome echoes the footprint left by a forebear from that particular human group in his pedigree. Particularly, this is the case with mitochondrial and Y-chromosome markers transmitted through matrilineal and male lineages, respectively, and some autosomal regions. Due to the absence of recombination in these genes or regions (mtDNA can be considered to be an extra chromosome that is transmitted only by the ovum during reproduction), they have accumulated mutations that have co-evolved with the dispersal of human groups (2). Consequently, as these human groups were separated by thousands of years of geographical isolation, the two chromosomes show population-specific differences, which happen to be also continent-specific. Besides these two genomic regions, some autosomal markers are also known to exist in particular populations. Nevertheless, the presence of any one of these markers in an individual only reflects a small proportion of the total genome diversity, which as a whole belongs to no particular population, or, in other words, is present in every population.

We have detected two types of problems linked to this popularly accepted idea of the existence of "ethnic genomes". I will explain these with concrete examples. In the case of Colombia, we and others have shown that the fair-skinned dominant population (about 90%), still bears 78-85% mtDNA markers inherited from a female ancestor who was a native Amerindian (3,4). The interesting point about this is that they do not recognize themselves as "indios", but rather as "white" or "descendants from Spaniards", and in fact most surnames, customs, traditions, religions, etc. were transmitted through the European male lineage since the very early times of the discovery of America. What would happen if the dominant, wealthy social class would claim legal rights on the Resguardos, which are Indian Reservations, and, on the basis of a genetic marker inherited from a distant Amerindian ancestor, dispute the legal right that the Amerindian communities have to the communal ownership of these territories, after having been expelled from the rest of their lands? As pointed out earlier, it must be clear that genetic data from particular human groups is collected, some population-related markers, if present in an individual, only represent a tiny part of his genetic background. These markers cannot in any case show that this person belongs, biologically speaking, to a particular population or group. What makes a person belong to a specific ethnic group is his/her culture, his/her traditions.

On the other hand, it must also be clear that genetic data from any individual or group do not contain and cannot be converted into marketable values. As a consequence of the upheaval raised by the patents issued in the frame of the Human Genome Project, many native American groups have seen in their genomes the last "Eldorado" (5). In Latin America, particularly Colombia, there has been a great debate about biodiversity and intellectual property on genetic material, which at many levels of society has included human genes or the genome from Amerindian communities. The communities themselves have claimed the right to benefit from royalties issued from their genomes. This very sad misunderstanding about the real significance of genome studies – the possibility of understanding human history and disease/environment relationships – must be prevented now through clear statements about the worth of genetic data, making clear that these are certainly not marketable values.

There is another risk, which should be avoided because it results in strong discrimination against minorities in every society if genetic data are misused. Education, professional training, the whole accomplishment of a person's life could be strongly limited or even distorted if one day genetic data were to be used to sort out who is "fit" for a specific occupation and if education, training, employment, etc. is offered only to these genetically "fit" individuals. We have already seen enough examples of people trying to establish a direct relationship between genes and intelligence. Imagine what could happen if we had to witness the discovery of genetic markers associated with aptitudes for sport, arts, science, etc in a population, but not found in another population. We could foresee that governments would easily find arguments to select the appropriate recipients to receive the economical benefits for developing those skills, based on scientific findings of loose links between the individual's genetic make-up and his capabilities. In a world of growing inequities between wealthy and poor people, scientists should really insist that social, psychological and nutritional conditions, as well as educational opportunities, are the strongest factors that will allow developing any potentials of individuals.

Lastly, in societies where ethnic belonging results in different treatment of civil rights before the law, especially in the case of women, the use of a few genetic markers to ascertain in a more "scientific" way a particular ethnic belonging could lead to social discrimination. Particular care should be taken so that genetic data is not used to apply racist labels to individuals.

Conclusions and specific recommendations

May I respectfully make some concluding remarks and recommendations to the excellent draft presented by the Drafting Group. The main concern I could express regarding the *Revised Outline of the International Declaration on Human Genetic Data* is the somewhat deterministic character given to human genetic data. We should in no way deny the importance of genetic data in the identification of predispositions to disease, personality traits, skills or clumsiness, which not only can affect an individual's life, but also the lives of his or her relatives and descendants. I want to stress that perception of this determinism can have diverse interpretations, according to the cultural and educational background of the persons involved. Genetic data should not be converted into almighty "political icons" in the sense of A. Mauron (6), for even in the case of human fingerprints, there are intra-individual inconsistencies (presence of heteroplasmies of the mitochondrial DNA molecules in different tissues) or inter-individual variations (mutation in one locus of one offspring or another member of the same family).

The *International Declaration on Human Genetic Data* should clearly state somewhere (in the Preamble) that, genetic data are <u>relative</u> and not <u>absolute</u> data about an individual's genetic performance in life, whose ultimate expression is intimately connected with environment in the broadest sense (the proteome considered as the inner environment, together with the external milieu). Similarly, in the *Universal Declaration on the Human Genome and Human Rights*, it should be also stressed that human identity cannot be reduced to the genetic makeup of a person.

In Article 20, along with preventing the misuse of genetic data, the *International Declaration on Human Genetic Data* should foster pro-active attitudes in the face of genetic data, such as those issued by the Human Genome Organization (HUGO) in its meeting from 1999:

*improvement of choices for at-risk individuals;

*adaptation of drug therapies to the genetic constitution of individuals;

*where suitable, presymptomatic targeting of therapies.

This is especially urgent in the face of the health burden stemming from genetically determined diseases in developing countries, where little attention is paid to the benefits of early diagnosis.

A clear distinction should also be made regarding the significance of genetic data, according to their use: in the case of research of gene-gene or gene-environment relationships, genetic data from particular human groups should be regarded as determining factors or elements in the investigation seeking to understand the course of diseases, but in the case of being used by third parties as predictors, it must be clear that they are only probabilistic information about a given person.

REFERENCES

1.- Enard W, Khaitovich P, Klose J et al. 2002. Intra- and interspecific variation in primate gene expression patterns. Science 296: 340-343

2.- Rosenbergh N, Pritchard JK, Weber JL et al. 2002. Genetic structure of human populations. Science 5602: 2381-2385

3.- Rodas C, Gelvez N, Keyeux G. 2003. Mitochondrial DNA studies show asymmetrical Amerindian admixture in Afro-Colombian and Mestizo populations. Hum Biol 75: 13-30

4.- Carvajal-Carmona LG, Soto ID, Pineda N, et al. 2000. Strong Amerind/White sex bias and a possible Sephardic contribution among the founders of a population in Northwest Colombia. Am J Hum Genet 67: 1287-1295

5.- Chee HL, El-Hamamsy L. Fleming J, Fujiki N, Keyeux G, Macer D. 1996. Bioethics and human population genetics research. Report from the subcommittee on population genetics. International Bioethics Committee of UNESCO. Proceedings of the Third Session Vol I. p 43-72

6.- Mauron A. 1998. The human genome: metaphysical object and political icon. In: Bioethics in Asia. Fujiki & Macer, Edit. Eubios Bioetnics Institute, Japan p: 35-40