

PROJECT OF AN INTERNATIONAL INSTRUMENT FOR THE PROTECTION OF THE HUMAN GENOME

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The General Conference of UNESCO, by its Resolution of 15 November 1993, invited the Director-General "to continue in 1994-1995 the preparation of an international instrument for the protection of the human genome".

This same resolution of the General Conference approved the creation of the International Bioethics Committee (IBC) by the Director-General.

This Committee, created on a decision by the Director-General, is the first institution of its kind in the world and was established on 15 September 1993. The installation of this Committee was preceded by a phase of preparatory studies by a scientific and technical orientation group, constituted in December 1992 and which met eight times between January and July 1993.

The Report of Mrs Noëlle Lenoir to the Director-General, dated 15 July 1993, concluded with the following concepts which, in my opinion, should be part of this Report: The work of the orientation group and the present report would suggest that the time has come to draft an international standard-setting instrument, based on the principles of ethical reference, ... concerning:

- the status of knowledge;
- protecting the human being;
- safeguarding the human race;
- educating, training and informing the public.

The responsibility mankind must assume today for the world of tomorrow is one of IRREVERSIBILITY. What human intervention produces, forms and recreates, dictates the future of all mankind, for as Einstein said: *«We shall have the destiny we deserve»*.

This should be the inspiration for the continuity of the work of UNESCO's International Bioethics Committee. ()

I. The Legal Commission

At the first session of the IBC, the President of the Committee announced the creation of a Legal Commission, presided by H. Ex. Mr Héctor Gros Espiell, "in order to study the conditions of the elaboration of the future international instrument for the protection of the human genome".

During the first session I presented a report on the rules of law regarding bioethical questions which can be summarized in the following manner: Mr Gros Espiell, asking what type of law should be used to deal with questions of bioethics, pointed out that without law civilized life in common was impossible. Bioethics must thus be regulated by law. Nevertheless, the boundaries between national and international law were imprecise and varied at different levels. The extension of international law was a phenomenon that went hand-in-hand with the growing realization that humankind had a common destiny. In bioethics, it would be inconceivable to establish legally binding regulations without simultaneously involving international and national law. The preparation of a future international bioethics instrument implied reference to both types of jurisprudence: national and international law.

There were several possibilities as far as the future instrument is concerned. The classical method was to start by preparing a declaration, to be subsequently adopted by the UNESCO General Conference or by the General Assembly of the United Nations; a convention or international treaty followed. The best example was the 1948 Universal Declaration of Human Rights, which was followed in 1966 by two Covenants, one in civil and political rights, the other

on economic, social and cultural rights. Those two Covenants were open for signature and ratification, and entered into force only in 1976. The process of signature and ratification was extremely slow. In view of the large number of Member States and the multiple ratifications required, it usually took 10 to 15 years for a convention to enter into force. Mr Gros Espiell therefore proposed the simultaneous approval of a declaration which would enter into force on its adoption, and a convention which, on the other hand, would become effective later in time. The declaration, which could be implemented in Member States on its adoption, could also serve as a source of law for international jurisdiction.

All dogmatism must be avoided in drafting the contents of the declaration and convention. The document should be pragmatic, and open to changes that scientific progress might impose. Both instruments must take full account of cultural and religious diversity but be based at the same time on the high universal principles that originate in human dignity.()

The fruitful debate following my report was the basis of the main guiding principles of the work of the Legal Commission of the IBC.

II. The Work of the Legal Commission

The Legal Commission, at its first meeting of 7 April 1994, gave us the occasion to examine all the possibilities concerning the drafting of an international instrument for the protection of the human genome.

Since April 1994, each of the three meetings of the Bureau of the IBC was preceded by a meeting of the Legal Commission.

At the second meeting of the Legal Commission, on 9 June 1994, the different criteria concerning the form and contents of an eventual international instrument for the protection of the human genome were established.

On the basis of these criteria and underlying principles, the President of the IBC and the Chairman of the Legal Commission have prepared a preliminary outline of an international instrument() which will be presented at the Second Session of the IBC (Paris, 20-22 September 1994).

It is thanks to the essential collaboration of Mr G. Kutukdjian, General-Secretary of the IBC, and of a group of jurists, to whom I wish to express all my gratitude, that the drafting of the preliminary outline could be carried out.

Before entering into details of the main points of this draft proposal, on its principles and its objectives, on its form and its content, I wish to point out that this instrument is inspired by ideas which formed the foundation of all the actions of the IBC and which Mrs Noëlle Lenoir expressed so well in her introductory speech at the first session: In what spirit do I see our mission ? This will be my conclusion. Two key words, it seems to me, should inspire our action: Humility, Tolerance.

Humility, as we do not know what tomorrow will bring, what science and the relations between nations have in store for us.

In a field as evolutive as genetics and as sensitive and emotional as bioethics, we of course should not adopt a peremptory point of view. We are open to the preoccupation of each and everyone throughout the world. We must aim above all for understanding from North to South, from East to West, before deciding, if necessary, to disapprove. Tolerance, even if it were not an absolute imperative, we would in any case be governed by the composition of our International Bioethics Committee, a reflection of "the divine diversity of the world". To define values in common, which will be one of our goals, should not lead to an erasing of our cultural differences which constitutes the richness of humanity. In his *Memories of an European*, the Austrian writer S. Zweig wrote in 1944: "Tolerance, far from being a sign of slackness or weakness, should be considered very highly as an ethical force".

If only we could transmit this message to future generations and to contribute within our means of action to base the progress in life sciences on Humanism, we would not have worked in vain.

III. Analysis of Various Alternatives of Form and Content of the International Instrument

The Legal Commission has studied the different possibilities for the nature and the form of the international instrument that it is to elaborate.

Since the Resolution of the General Conference does not give any precision on the type of international instrument to prepare, we can envisage all possibilities which are compatible with international law, which is why the Commission has thought of all possible formulae in all different directions.

All possible alternatives were examined during the discussions, for example, to prepare simultaneously a declaration and a convention open to signature with its adoption, a declaration and a convention a posteriori, a convention with a procedure of approval and ratification analogue to the International Labour Organisation conventions and a convention with criteria analogue to those of common law, in the case of an international private law convention.

We have finally opted for a draft declaration, but in giving to the content a special characteristic - taking into account the evolution and the actual state of practice, of jurisprudence and of doctrine - which gives to this text an immediate applicability, binding legal effect and a procedure to verify its use and its efficiency.

Naturally this option does not exclude the possibility of a future convention, which will accentuate and specify legal obligations, as well as determine and concretize responsibilities and the system of verification.

Given that rapidity is the essential temporal element in the application of this international instrument, we have therefore opted for a declaration, which by its existence as such will have effect from the moment of its adoption.

The choice for a quick implementation of the international instrument should be preferred.

In the field of the human genome, the temporal factor has a particular importance. The extreme acceleration of progress in the field of molecular biology and the considerable advances made in research devoted to the genetic "I.D. card" make it necessary for a rapid adoption of the proposed international instrument otherwise the state of law at the time of the signature of the instrument may be obsolete at the date of its enforcement.

On the other hand, the IBC has fixed 1998 as the deadline for the adoption of the international instrument, the jubilee year of the Universal Declaration of Human Rights. The next session of the General Conference, in autumn 1995, will decide on the opportunity and the form of the instrument that the IBC will have submitted beforehand to the Executive Board. On this basis, the IBC has only two years, 1996 and 1997, to make up a first draft of this instrument.

The elaboration of a draft convention at a later stage - and not simultaneously at the draft of a declaration - would have the advantage of benefiting from scientific progress which will take place after the adoption of the declaration, the premises of international law, and above all the experience of the application of the declaration, the questions and reactions which it will have provoked.

This procedure would take into account the process of drafting, of signature, of ratification and of enforcement of a convention, with all its characteristics - and which the contemporary doctrine has emphasized in comparing the content of a declaration with its later conventions (as in the case, among others, of the Universal Declaration of Human Rights, of the two International Covenants, and of the Optional Protocol to the International Covenant on Civil and

Political Rights). Since the political and legal situation today is different than the one in 1948, we have to prepare a document of declaration with special characteristics concerning the nature of the matter which is the object of this legal regulation, of the state of international law on the theme of the legal sources, of legal value of declarations adopted by international intergovernmental organizations under certain conditions.

IV. Sources taken into Account for This Work by the Legal Commission

In the Matter of the Protection of Human Rights

- Conventional Instruments

UNITED NATIONS : International Covenants on Civil and Political Rights and Economic, Social and Cultural Rights of 16 December 1966; Convention on the Elimination of All Forms of Racial Discrimination (1965); Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984); International Convention of Rights of the Child (1990); Convention on Biological Diversity (5 June 1992); UNESCO : Convention against Discrimination in Education (1960); Convention on the Protection of Cultural and Natural World Heritage (1972); Regional Organizations : European Convention on Human Rights (1950); American Convention on Human Rights (1969); African Charter of Human and Peoples' Rights (1981).

- Declarations and Recommendations

UNITED NATIONS : Universal Declaration of Human Rights (1948); Declaration on the Elimination of All Forms of Racial Discrimination (1963);

UNESCO : Declaration on the Principles of International Cultural Co-operation (1966); Declaration on Race and Racial Prejudices (1978).

In the Area of Medical Ethics

- On the International Level

- Code of Nuremberg (1947); Declaration of Helsinki (1964), revised in Tokyo (1975) then in Venice (1983), adopted by the World Medical Association; Declaration of Manila (1988) made jointly by the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS); Declaration of Inuyama (1990) adopted by the Conference of the CIOMS; Declaration of Ixtapa (1994) adopted by the Conference of the CIOMS; Declarations of Valencia relative to the Human Genome Project (1988) and concerning Ethics and the Human Genome Project (1990), from work done in workshops on international co-operation relative to the Human Genome Project, organized by UNESCO; Declaration of Moscow (1991) adopted at the "International Meeting on Bioethics and the Social Consequences of Biomedical Research" organized by UNESCO; Declaration on Gene Patenting (1992) adopted by the International Council of Scientific Unions (ICSU); Declaration of Caxambu (1992) adopted at the North-South Meeting on the human genome organized by UNESCO.

- At the Regional Level

- We can quote the Recommendation adopted by the Council of Europe on Medical Research on the Human Being (1990), on Genetic Screening and Testing (1990 and 1992) and the Draft Outline-Convention on Bioethics (1994).

In the Area of Protection of Scientists and Freedom of Research

The previously quoted texts relevant to medical ethics often refer to the principle of freedom of research. We can more specifically mention the UNESCO Recommendation concerning the Protection of Scientific Researchers (1974).

V. The Character of the International Instrument in Preparation

No international instrument related to this topic has been adopted to this date.

Nevertheless, the Resolution 1993/91 of March 1993 of the United Nations Commission for Human Rights treated the subject "Bioethics and Human Rights", and the Council of Europe elaborated a Draft Outline-Convention on Bioethics.

Nevertheless, these two texts do not have the same scope as the one called for by the General Conference of UNESCO. The resolution of the United Nations Commission for Human Rights did not treat specifically the problem of the protection of the human genome and did not try to be standard-setting. The unprecedented character of the Draft Outline-Convention of the Council of Europe, although it permits it to shed light on certain questions, obviously cannot give it the universal vocation required of the instrument prepared by the IBC.

On the other hand, the United Nations World Conference on Human Rights held in Vienna, 14-25 June 1993, did not give priority to bioethics, even if it is there that this subject made its first appearance (Part I, Paragraph 11, 3rd alinea).

On the other hand, it is important to emphasize that the texts of the previously quoted Declarations of Valence and Caxambu are very short and that these conclusions could not be considered as instruments of the declarative type in international legal practice.

UNESCO is undertaking an ambitious procedure today to adopt an international instrument on the protection of the human genome:

- the aim and principles of UNESCO make it a privileged place for the elaboration of the first international instrument with a universal vocation for the protection of the human genome and should permit it to apprehend the stakes involved;
- the essential aim of this work being the protection of human rights and dignity and the reminder that the beneficial fallout of scientific progress must be shared by all nations, the role of UNESCO prevails over that other organizations - except the United Nations - whose structure does not allow to have the same ambition or the same coherence. Past experience have shown that UNESCO could deal with questions which are more specifically in the domain of other organizations, if it is sure that it will succeed in its mission (for example, the Recommendation on the Status of Scientific Researchers of 20 November 1974).

In such a perspective, the questions of the protection of the human genome linked to medical research or to copyright should logically be raised by the international instrument, even in a subsidiary manner.

Furthermore, UNESCO has acquired a certain experience in the domain of bioethics, which it was interested in since the beginning of the 1970s. Therefore, in 1970, UNESCO organized in Madrid a symposium in collaboration with the Spanish Superior Council of Scientific Research and has since then multiplied efforts in the matter (symposiums, publications, thematic reports, etc.). In the Medium-Term Plan 1990-1995, a degree of maximum priority was given to actions by the Organization on the theme of the relationship between human rights and scientific progress.

VI. The Form and Content of the Instrument

The elaboration of an international instrument for the protection of the human genome presents many difficulties because of its complexity, since we are touching on human rights, science, technology, ethical and deontological aspects, traditions, religious and regional aspects, beliefs and customs, on scientific freedom and progress.

It is the reason for which a general and flexible text must be drafted without affecting its importance and its efficiency.

The adoption of an international instrument for the protection of the human genome, at the end of the twentieth century, should be treated with prudence - and to be compatible with conscience since the question is extremely serious - and with the certainty that science will continue to advance as well as research in genetics. We can gather from that new dimensions will open for technology, gene therapy, genetic modifications and medicine. That is why there is a need to establish general principles and to assert the ineluctable respect for dignity, freedom and human rights, while remaining flexible in order not to interfere with scientific progress but respecting ethics and the responsibilities which come with it. Therefore it is necessary to conceive of a document which can remain timely and in accordance with progress and scientific changes in the future.

The task is difficult but we are facing of a challenge which obliges us to react.

VII. Equivalent Declarations and Their Place in International Law Today

The adoption of a declaration as proposed requires determination with precision, in the actual state on the evolution of international law and the practice of States, of the value and of the significance of this type of instruments. Treaties and conventions - although this does not aim to diminish their importance - are only one of the sources possible of international law. This means, without prejudice to conventional sources, that there are other sources of international law, for example the declarations, which have a binding legal effect. This legal situation can therefore be used on the international level for the protection of the human genome.

Declarations, proclaimed by the supreme organ of an intergovernmental organization, especially in the United Nations system, if they are adopted under certain circumstances which have been specified in international practice, doctrine and jurisprudence, produce legal effect in becoming sources of international rights and obligations.

Can a declaration on the protection of the human genome have international legal effect concretely, aside from its political and ethical impact, and be able to serve as model for national legislation? Obviously yes, and this is today the case. Without prejudice to its perfecting and its implementation, it is necessary, in order to ensure its efficient application with responsibilities and adequate verification, to foresee the elaboration of a future convention.

VIII. The Content of the Declaration

What are the contents of the proposed declaration and what is the preliminary outline which has been elaborated by the Legal Commission of the IBC ? We must not forget that this is an instrument for the protection of the human genome and not a text concerning bioethics in general.

The "Preliminary Draft" contains a preamble and six parts.

A preamble is essential for a declaration. It takes stock of precedents, quotes applicable principles and determines goals, all in an applicable legal and ethical context, in consideration of the present state of international law. This means that it takes into account scientific progress and the need to solve the problem in a standard-setting way with care, equilibrium, a sense of future, respect for freedom and moral conscience. It is therefore human dignity and the future of man and humankind that are in question.

The preamble, as for the Universal Declaration of Human Rights (by which we are inspired in a certain way) is part of the text, and it is a determining factor for the interpretation of all and of each of its parts, as established by the Vienna Convention on the Right of Treaties.

The first part of the document - which consists of four articles - considers the human genome as a common heritage of humanity. As such it should be the object of special protection.

The human genome, in since it constitutes the distinctive element specific to each individual as a component of his or her uniqueness, can be transmitted as heritage and thus comes under civil law with its responsibilities. On the other hand, the human genome, as part of the gene pool of the human species as a whole and which transcends individual genetic identities, is the common heritage of humanity and came under international law. The concept of "common heritage of humanity" was in fact used in Article I, Paragraph 3, of the Declaration of the Principles of International Cultural Co-operation of 4 November 1966, in referring to the diversity of the world's cultures.

Be that as it may, according to that formula, each human being is considered to be the "depository" both of his or her genome and of the genome of the entire species, which in fact we share to an appreciable extent with other living species. Viewed in that light, the human genome, irrespective of its heritage status, can be said to create responsibilities towards oneself and specific obligations with the object of protecting the genetic diversity of humanity.

The protection of the human genome is to safeguard the integrity of the human species and, as such, the dignity of each of the members of the human family, in other words, each individual.

The genome is by nature evolutive and subject to mutations. The individual cannot be reduced to his or her genetic characteristics. Each human being has its own genetic identity which is unique. He has the right of respect for his or her dignity, whatever his or her genetic characteristics.

It is enough to point this out, in order to emphasize the human and ethical depth, the universal character, and the transcendence for the future of humanity and to assert the unique, special and full character of the human person, inseparable from the idea of dignity and rights.

The second part aims at providing a frame for the research and other interventions on the human genome in order to protect the human person.

On this subject, all discriminations based on genetic characteristics are forbidden. No research nor intervention on the human genome can be practised without the free and informed consent of the person in question. The confidentiality of genetic data should be protected.

The principle of responsibility - basis of indemnification - should be based on prejudices submitted by the individual as a result of research or intervention on the human genome.

The third part refers to the rights and obligations of researchers. We try to establish in this part a balance between the rights and obligations of researchers in order to ensure intellectual and material conditions suitable for scientific progress, but in a context of social and moral discipline, of prudence and intellectual honesty.

The fourth part refers to rights and responsibilities - guaranteed by all States - based on the principle of solidarity regarding individuals, families and populations exposed to risks because of their genetic characteristics.

The fifth part refers to the international co-operation concerning the diffusion of knowledge in the matter of scientific co-operation, and more particularly between industrialized and developing countries.

The States are committed to promote scientific teaching, while taking into account social and ethical implications of human genetics.

The States are also committed to promote training and information, in relation with the growing awareness by the State's leaders of the progress in human genetics.

The last part refers to questions which concern the applications of the declaration.

It is inspired by the Universal Declaration of Human Rights and the Declaration on Principles of International Law concerning Friendly Relations and Co-operation among States (Resolutions 2625 (XXV)), which specify the obligations of States and individuals regarding the declaration, and the duty of States to encourage its application.

Finally, the verification of the application of the declaration is entrusted to the UNESCO International Bioethics Committee which has the competence to offer recommendations.

This part is no doubt essential. If the declaration is an international instrument which has political and moral consequences and, in certain conditions, legal obligations, it is necessary to establish a system - for the moment embryonic which will develop in time - for the verification of its application and to ensure its efficiency.

IX. The Subjects of Law and Obligations deriving from the Declaration

What are the subjects of rights and obligations which emerge from this declaration?

For the instrument of the type of the declaration that we are to prepare, there may be a different answer if it were a convention.

The declaration, in view of its general character and aiming at the international community as a whole and each human being in particular, generates obligations and attributes rights to this community, to States which are part of it and to individuals, namely all human beings without exclusion and discrimination.

The reading of the draft of declaration permits finally to emphasize that certain principles, proclaimed in its first part, are at the basis of rights and obligations of all human beings.

The same applies to the second part which, moreover, for two cases (Art. 5 and 8), refers specially to candidates of recognized laws.

The third, fourth and fifth parts impose duties of different forms on the States.

Finally, the sixth part refers only to Member States of UNESCO, since it deal with a particular attribution which these latter made to the International Bioethics Committee and which concerns the verification and application of the declaration.

X. UNESCO and the Declaration

To whom is this preliminary outline of a declaration destined?

The idea of this instrument was born at UNESCO and was elaborated and drafted within the Organization. The question is therefore deliberated by the competent constitutional structures in UNESCO. According to the established tradition, the declaration should then be adopted by the General Conference. This process, perfectly compatible with the present state of international law and the current practice of UNESCO, does not object to a parallel text to be eventually adopted by the General Assembly of the United Nations, nor that a convention on this theme be elaborated and adopted by UNESCO or the United Nations.

But UNESCO should not give up its pioneer work in this field today. That is why it should open the way to the adoption of a declaration which will be the first for the protection of the human genome on an international level.

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