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PARLIAMENTARY ASSEMBLY

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

TWENTY-SEVENTH ORDINARY SESSION

RESOLUTION 613 (1976)[1]

ON THE RIGHTS OF THE SICK AND DYING

The Assembly,

1. Believing, for reasons set out in its Recommendation 779 (1976) on the rights of the sick; and explained in the report of its Committee on Social and Health Questions (Doc. 3699), that the true interests of the sick are not always best served by a zealous application of the most modern techniques for prolonging life;

2. Convinced that what dying patients most want is to die in peace and dignity, if possible with the comfort and support of their family and friends;

3. Concerned that unnecessary anguish may be caused by uncertainty over the most appropriate criteria for the determination of death;

4. Insisting that no other interests may be considered in establishing the moment of death than those of the dying person,

5. Invites the responsible bodies in the medical profession in the member states to examine critically the criteria upon which decisions are currently based with respect to the initiation of reanimation procedures and the placing of patients into long-term care requiring artificial means of sustaining life;

6. Invites the European Office of the World Health Organization to examine the criteria for the determination of death existing in the various European countries, in the light of current medical knowledge and techniques, and to make proposals for their harmonisation in a way which will be universally applicable not only in hospitals, but in general medical practice.

[1] *Assembly debate* on 28 January 1976 (23rd Sitting) (see Doc. 3699, report of the Committee on Social and Health Questions). *Text adopted by the Assembly* on 29 January 1976 (24th Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

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TWENTY-SEVENTH ORDINARY SESSION

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RECOMMENDATION 779 (1976)[1]

ON THE RIGHTS OF THE SICK AND DYING

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The Assembly,

1. Considering that the rapid and continuing progress of medical science creates problems, and may even pose certain threats, with respect to the fundamental human rights and the integrity of sick people;

2. Noting the tendency for improved medical technology to lead to an increasingly technical - sometimes less humane - treatment of patients;

3. Observing that sick persons may find it difficult to defend their own interests, especially when undergoing treatment in large hospitals;

4. Considering that recently it has become; generally agreed that doctors should in the first place respect the will of the sick person with respect to the treatment he or she has to undergo;

5. Being of the opinion that the right to personal dignity and integrity, to information and proper care, should be clearly defined and granted to every person;

6. Convinced that the duty of the medical profession is to serve mankind, to protect health, to treat sickness and injury, and to relieve suffering, with respect for human life and the human person, and convinced that the prolongation of life should not in itself constitute the, exclusive aim of medical practice, which must be concerned equally with the relief of suffering;

7. Considering that the doctor must make every effort to alleviate suffering, and that he has no right, even in cases which appear to him to be desperate, intentionally to hasten the natural course of death;

8. Emphasising that the prolongation of life by artificial means depends to a large extent on factors such as the availability of efficient equipment, and that doctors working in hospitals where, the technical equipment permits a particularly long prolongation of life are often in a delicate position as far as the continuation of the treatment is concerned, especially in cases where all cerebral functions of a person have irreversibly ceased;

9. Insisting that doctors shall act in accordance with science and approved medical experience, and that no doctor or other member of the medical profession may be compelled to act contrary to the dictates of his own conscience in relation to the right of the sick not to suffer unduly,

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[1] *Assembly debate* on 28 January 1976 (23rd Sitting) (see Doc. 3699, report of the Committee on Social and Health Questions). *Text adopted by the Assembly* on 29 January 1976 (24th Sitting).

10. Recommends that the Committee of Ministers invite the governments of the member states:

I. a. to take all necessary action, particularly with respect to the training of medical personnel and the organisation of medical services, to ensure that all sick persons, whether in hospital or in their own homes, receive relief of their suffering as effective as the current state of medical knowledge permits;

b. to impress upon doctors that the sick have a right to full information, if they request it, on their illness and the proposed treatment, and to take action to see that special information is given when entering hospital as regards the routine, procedures and medical equipment of the institution;

c. to ensure that all persons have the opportunity to prepare themselves psychologically to face the fact of death, and to provide the necessary assistance to this end both through the treating personnel - doctors, nurses and aids - who should be given the basic training to enable them to discuss these problem with persons approaching t the end of life, and through psychiatrists, clergymen or specialised social workers attached to hospitals;

II. to establish national commissions of enquiry, composed of representatives of all levels of the medical profession, lawyers, moral theologians, psychologists and sociologists, to establish ethical rules for the treatment of persons approaching the end of life, and to determine the medical guiding principles for the application of extraordinary measures to prolong life, thereby considering inter alia the situation which may confront members of the medical profession, such as legal sanctions, whether civil or penal, when they have refrained from effecting artificial measures to prolong the death process in the case of terminal patients whose lives cannot be saved by present-day medicine, or have taken positive measures whose primary intention was to relieve suffering in such patients and which could have a subsidiary effect on the process of dying, and to examine the question of written declarations made by legally competent persons, authorising doctors to abstain from life-prolonging measures, in particular in the case of irreversible cessation of brain function;

III. to establish, if no comparable organisations already exist, national commissions to consider complaints against medical personnel for errors or negligence in the practice of their profession, and this without prejudice to the jurisdiction of the ordinary courts;

IV. to inform the Council of Europe of their analytical findings and conclusions for the purpose of harmonising criteria regarding the rights of the sick and dying and the legal and technical means of guaranteeing their application.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

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TWENTY-NINTH ORDINARY SESSION

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RECOMMENDATION 818 (1977)[1]

ON THE SITUATION OF THE MENTALLY ILL

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The Assembly,

1. Emphasising the importance it attaches to the aims of maintaining the health, the well-being and also the personal rights of the sick on one hand, while protecting the well-being of democratic societies as a whole on the other;

2. Considering that the definition of mental illness is extremely difficult, since criteria change with time and from place to place, and since a whole new range of psychological disturbances have emerged, linked with the working rhythm, stresses, and the sociological patterns of modern life;

3. Noting that, in the thirty year period since World War II, profound changes have taken place in Europe in attitudes towards mental illness from both the medical and social points of view;

4. Aware, however, that serious lack of staff as well as insufficient or out-dated training of staff that psychiatric services are experiencing is prejudicial to proper treatment of the mentally ill;

5. Convinced that the situation of the mentally ill and, in particular, the conditions governing the internment of mental patients and their discharge from psychiatric hospitals are matters of concern to a broad section of public opinion in member countries, and that the occurrence of errors and abuses in this regard causes human tragedies in some cases;

6. Noting that several applications have been addressed to the European Commission on Human Rights concerning allegations of such error or abuse, which demonstrate how unsatisfactory or unclear the present position is, and the possible need to redefine some legal and medical guidelines;

7. Convinced that the concept of the criminally insane implies a contradiction in terms in that an insane person cannot be considered responsible for criminal actions;

8. Noting that the improved medical and psychotherapeutic technology can sometimes constitute a threat to the right of patients to their physical and psychic integrity;

9. Believing that abnormalities of behaviour in the province of morals or the law do not by themselves constitute mental disturbance;

10. Condemning the abuse of psychiatry for political purposes and for the elimination of dissidence whatever its form;

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[1] *Assembly debate* on 7 and 8 October 1977 (11th and 12th Sittings) (see Doc. 4014, report of the Committee on Social and Health Questions). *Text adopted by the Assembly* on 8 October 1977 (12th Sitting).

11. Commending the decision of the 6th World Psychiatry Congress at Hawaii condemning the abuse of psychiatry for the suppression of dissent, and welcoming the decision to establish an international code of ethics for the practice of psychiatry;

12. Welcoming the resolution on the organisation of preventive services in mental illness, adopted by the Committee of Ministers of the Council of Europe in 1976 and which covers a large variety of preventive features relating to mental health,

13. Recommends that the Committee of Ministers invite the governments of the member states:

I. i. to review their legislation and administrative rules on the confinement of the mentally ill, by redefining some basic concepts such as "dangerous", by reducing to the minimum the practice of compulsory detention for an "indeterminate period", by stopping the practice of censoring correspondence, by placing under the jurisdiction of the medical authorities all those declared by the courts to have been insane at the time of committing a crime or at the time of the trial, and by establishing procedures for the hearing of appeals against detention measures;

ii. to set up independent special mental welfare tribunals or commissions, with a duty to exercise protective functions by investigating complaints, or by intervening on their own initiative in any case, with power to discharge patients where they find that confinement is no longer necessary;

iii. to ensure that court decisions are not taken on the basis of medical reports only, but that the mental patient, like any other person, is fully given the right to be heard, and that in cases where an offence is alleged a lawyer is also present throughout the proceedings;

iv. to modify the civil capacity rules applied to the mentally ill, in order to ensure that any hospitalisation does not necessarily result in an automatic determination of legal incapacity, thus creating problems concerning property and other economic rights;

v. to implement the right to vote for those mental patients able to understand the meaning of the vote by taking the necessary steps with a view to facilitating the exercise of it, by ensuring that information on public affairs is made available, by informing the patients about the procedures, deadlines and registration, etc. and by offering material assistance to those who are physically handicapped; mental patients declared unfit to vote should have the possibility of appeal;

vi. to set up, in the Council of Europe, a working party composed of government experts and criminologists to redefine insanity and mental abnormality and to reassess the implications thereof for civil and criminal law, taking into account the latest findings of psychology and psychiatry, and experience in this field in the Council of Europe member states;

II. i. to take measures, as a long term policy, to reduce dependence on large institutions and to develop wide-spread community based services, with conditions approximating to the normal environment of individuals, provided, however, that this objective should not lead to a higher rate of early discharge from hospital before an effective network of community care is established;

ii. to seek new ways of humanising the care of the mentally ill by emphasising the humanitarian elements and the quality of the care as opposed to sophisticated technology, and by considering in this context the appropriateness, the conditions and control of utilisation of certain therapies which may leave permanent brain damage or change of personality;

iii. to take measures to stimulate and harmonise, within the Council of Europe, studies on the training and working conditions of care-giving staff in the psychiatric field, in association with international trade union organisations representing these staff, with a view to preparing a European agreement applicable to them, and, given the shortage of qualified care-giving professional staff in most member countries, to develop the psychiatric knowledge and skill of the members of other public health and social services, thus creating community-based teams working in close co-operation with professionals;

III. i. to encourage local authorities and communities to be more involved in the socio-professional rehabilitation of ex-patients by creating selective placement programmes, workshops and accommodation, and in particular by setting up information programmes aimed at modifying attitudes towards those who are, or were, mentally ill;

ii. to ensure that the registers kept in psychiatric institutions on ex-patients, or any other documentation on their case, should be considered as a strict medical professional secret and cannot be used in such a way as to constitute an unfair handicap for ex-patients entering on a new occupation.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

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THIRTY-THIRD ORDINARY SESSION

———

RECOMMENDATION 934 (1982)[1]

ON GENETIC ENGINEERING

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The Assembly,

1. Aware of public concern about the use of new scientific techniques for artificially recombining genetic material from living organisms, referred to as "genetic engineering"

2. Considering that these concerns fall into two distinct categories:

– those arising from uncertainty as to the health, safety and environmental implications of experimental research;

– those arising from the longer-term legal, social and ethical issues raised by the prospect of knowing and interfering with a person's inheritable genetic pattern;

3. Having regard, in respect of the health, safety and environmental implications of experimental research, to the following considerations:

i. the techniques of genetic engineering present an immense industrial and agricultural potential which in coming decades could help to solve world problems of food production, energy and raw materials;

ii. radical breakthroughs in scientific and medical understanding (university of the genetic code) are associated with the discovery and development of these techniques;

iii. freedom of scientific enquiry - a basic value of our societies and a condition of their adaptability to the changing world environment - carries with it duties and responsibilities, notably in regard to the health and safety of the general public and of fellow scientific workers and to the non-contamination of the environment;

iv. in the light of the then existing scientific knowledge and experience, uncertainties about the health, safety and environmental implications of experiments in genetic engineering were a legitimate cause for concern in the early 1970s-to the point of giving rise to requests, at that time, from within the scientific community, for certain types of experiment not to be made;

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[1] *Assembly debate* on 26 January 1982 (21st and 22nd Sittings) (see Docs. 4832 and 4833, reports of the Legal Affairs Committee, and of the Committee on Science and Technology). *Text adopted by the Assembly* on 26 January 1982 (22nd Sitting).

v. in the light of new scientific knowledge and experience, uncertainties in regard to experimental research have in recent years been largely clarified and resolved - to the point of allowing substantial relaxation of the control and containment measures initially instituted or envisaged;

vi. strict and comparable levels of protection should be provided in all countries for the general public and for laboratory workers against risks involved in the handling of pathogenic micro organisms in general, irrespective of whether techniques of genetic engineering are used;

4. Having regard, in respect of the legal, social and ethical issues, to the following considerations inspired by the Council of Europe's 7th Public Parliamentary Hearing (Copenhagen, 25 and 26 May 1981) on genetic engineering and human rights:

i. the rights to life and to human dignity protected by Articles 2 and 3 of the European Convention on Human Rights imply the right to inherit a genetic pattern which has not been artificially changed;

ii. this right should be made explicit in the context of the European Convention on Human Rights;

iii. the explicit recognition of this right must not impede development of the therapeutic applications of genetic engineering (gene therapy), which holds great promise for the treatment and eradication of certain diseases which are genetically transmitted;

iv. gene therapy must not be used or experimented with except with the free and informed consent of the person(s) concerned, or in cases of experiment with embryos, foetuses or minors with the free and informed consent of the parent(s) or legal guardian(s);

v. the boundaries of legitimate therapeutic application of genetic engineering techniques need to be clearly drawn, brought to the attention of research workers and experimentalists, and subjected to periodical re-appraisal;

vi. outline regulations should be drawn up to protect individuals against non-therapeutic applications of these techniques;

5. Expressing the wish that the European Science Foundation should keep under review:

a. procedures and criteria for licensing the use of products of recombinant DNA techniques in medicine, in agriculture and industry;

b. the effects of the commercialisation of recombinant DNA techniques on the funding and orientations of fundamental research in molecular biology,

6. Invites member governments:

a. to take note of the reassessments which have taken place in recent years within the scientific community concerning levels of risk from research involving recombinant DNA techniques, and to adjust, in the light of these reassessments, their systems of supervision and control;

b. to provide for the periodical reassessment of levels of risk from research involving recombinant DNA techniques within the regulatory frameworks for assessing the risks from research involving the handling of microorganisms in general:

7. Recommends that the Committee of Ministers:

a. draw up a European agreement on what constitutes legitimate application to human beings (including future generations) of the techniques of genetic engineering, align domestic regulations accordingly, and work towards similar agreements at world level;

b. provide for explicit recognition in the European Convention on Human Rights of the right to a genetic inheritance which has not been artificially interfered with, except in accordance with certain principles which are recognised as being fully compatible with respect for human rights (as, for example, in the field of therapeutic applications);

c. provide for the drawing up of a list of serious diseases which may properly, with the consent of the person concerned, be treated by gene therapy (though certain uses without consent, in line with existing practice for other forms of medical treatment, may be recognised as compatible with respect for human rights in the probability of a very serious disease being transmitted to a person's offspring);

d. lay down principles governing the preparation, storage, safeguarding and use of genetic information on individuals, with particular reference to protecting the rights to privacy of the persons concerned in accordance with the Council of Europe conventions and resolutions on data protection;

e. examine whether levels of protection of the health and safety of the general public and of laboratory workers engaged in experiments or industrial applications involving micro-organisms, including micro-organisms subject to recombinant DNA techniques, are adequate and comparable throughout Europe, and whether existing legislation and institutional machinery offer an adequate framework for their periodical verification and revision to this end;

f. ensure, by periodic reviews in liaison with the European Science Foundation, that national containment measures for recombinant DNA research and required laboratory safety practice continue to converge and to evolve (albeit by different routes) towards harmonisation in Europe, in the light of new research findings and risk evaluations;

g. examine the draft recommendation of the Council of the European Communities on the registration and notification to appropriate national and regional authorities of experiments involving recombinant DNA, with a view to the concerted implementation of its provisions in the countries of the Council of Europe;

h. examine the patentability of microorganisms genetically altered by recombinant DNA techniques.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

THIRTY-EIGHTH ORDINARY SESSION

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RECOMMENDATION 1046 (1986)[1]

ON THE USE OF HUMAN EMBRYOS AND FOETUSES FOR DIAGNOSTIC, THERAPEUTIC, SCIENTIFIC, INDUSTRIAL AND COMMERCIAL PURPOSES

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The Assembly,

1. Recalling its Recommendation 934 (1982) on genetic engineering, proposing a range of measures including in particular the recognition of the right to a genetic inheritance which should not be artificially interfered with except for therapeutic purposes;

2. Considering that recent progress in the life sciences and medicine, in particular in animal and human embryology, has opened up remarkable new scientific, diagnostic and therapeutic prospects;

3. Considering that, by the technique of fertilisation *in vitro*, man has achieved the means of intervening in and controlling human life in its earliest stages;

4. A. Considering that the exploitation of technological opportunities not only in science but also in medicine must be governed by clear ethical and social guidelines;

B. Considering that future benefits from the advance of medical science and technology must be carefully assessed in deciding when, and how, and on what grounds, to restrict the exploitation of technological opportunities;

C. Welcoming the contributions of the Council of Europe's *ad hoc* Committee of experts in the biomedical sciences, and of the European Medical Research Councils operating within the framework of the European Science Foundation;

D. Noting the statement issued by nine European Medical Research Councils following the meeting convened in London on 5 and 6 June 1986 under the auspices of the European Science Foundation;

5. Considering that, from the moment of fertilisation of the ovule, human life develops in a continuous pattern, and that it is not possible to make a clear-cut distinction during the first phases (embryonic) of its development, and that a definition of the biological status of an embryo is therefore necessary;

6. Aware that this progress has made the legal position of the embryo and foetus particularly precarious, and that their legal status is at present not defined by law;

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[1] *Assembly debate* on 19 and 24 September 1986 (13th and 18th Sittings) (see Doc. 5615, report of the Legal Affairs Committee, Doc. 5628, opinion of the Committee on Science and Technology, and Doc. 5635, opinion of the Social and Health Affairs Committee). *Text adopted by the Assembly* on 24 September 1986 (18th Sitting).

7. Aware that adequate provisions governing the use of living or dead embryos and foetuses do not at present exist;

8. Convinced that, in view of scientific progress which makes it possible to intervene in developing human life from the moment of fertilisation, it is urgent to define the extent of its legal protection;

9. Having regard to the variety of ethical opinions on the question of using the embryo or the foetus or their tissues, and to the conflicts between values which arise;

10. Considering that human embryos and foetuses must be treated in all circumstances with the respect due to human dignity, and that use of materials and tissues therefrom must be strictly limited and regulated (see appendix) to purposes which are clearly therapeutic and for which no other means exist;

11. Convinced that the use of embryos or foetuses and the removal of their tissues for diagnostic and therapeutic purposes are only justified if the principles and conditions specified in the appendix to this recommendation are observed;

12. Considering that any exclusively national regulation of the question runs the risk of being ineffective as any activity in this field could be transferred to another country which did not enforce the same regulations;

13. Stressing the need for European co-operation,

14. Recommends that the Committee of Ministers:

A. call on the governments of the member states:

i. to investigate the rumours about a trade in dead embryos and foetuses circulating in the media, and to publish the results;

ii. to limit the use of human embryos and foetuses and materials and tissues therefrom in an industrial context to purposes which are strictly therapeutic and for which no other means exist, according to the principles set out in the appendix, and to bring their legislation into line with these principles or to enact rules in accordance therewith which should *inter alia* specify the conditions in which removal and use may be undertaken for a diagnostic or therapeutic purpose;

iii. to forbid any creation of human embryos by fertilisation *in vitro* for the purposes of research during their life or after death;

iv. to forbid anything that could be considered as undesirable use or deviations of these techniques, including:

– the creation of identical human beings by cloning or any other method, whether for race selection purposes or not;

– the implantation of a human embryo in the uterus of another animal or the reverse;

– the fusion of human gametes with those of another animal (the hamster test for the study of male fertility could be regarded as an exception, under strict regulation);

– the creation of embryos from the sperm of different individuals;

– the fusion of embryos or any other operation which might produce chimeras;

– ectogenesis, or the production of an individual and autonomous human being outside the uterus of a female, that is, in a laboratory;

– the creation of children from people of the same sex;

– choice of sex by genetic manipulation for non-therapeutic purposes;

– the creation of identical twins;

– research on viable human embryos;

– experimentation on living human embryos, whether viable or not;

– the maintenance of embryos *in vitro* beyond the fourteenth day after fertilisation (having deducted any time necessary for freezing);

v. to provide appropriate sanctions to ensure the application of the rules enacted pursuant to this recommendation;

vi. to create national registers of accredited medical centres authorised to carry out such techniques and to make use of them for scientific purposes;

vii. to facilitate and encourage the creation of national multidisciplinary committees or commissions on artificial human reproduction involving scientific activities concerning genetic material, human embryos and foetuses - to guide and counsel the medical and scientific authorities, to follow and control the application of such techniques and to authorise specific projects in the absence of concrete legislation or regulation;

B. continue to study the problems relating to the use of human embryonic and foetal tissue for scientific purposes and prepare, on the basis of the points mentioned in sub-paragraphs 14.A.ii to vii, a European convention or any other suitable legal instrument which would also be open to accession by non-member countries of the Council of Europe;

15. Instructs its competent committees to prepare a report on the use of human embryos and foetuses in scientific research, taking into account the necessary balance between the principles of freedom of research and of respect for human life and other aspects of human rights.

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APPENDIX

Rules governing the use of human embryos or foetuses and the removal of their tissues for diagnostic and therapeutic purposes

A. *Diagnostic purposes*

i. No intervention for diagnostic purposes, other than those already authorised under national legislation, on the living embryo *in vitro* or *in utero* or on the foetus whether inside or outside the uterus shall be permitted, unless its object is the well-being of the child to be born and the promotion of its development.

ii. The use of a dead embryo and foetus for diagnostic purposes (confirmation of a diagnosis *in utero* or search for the cause of a spontaneous termination of pregnancy) shall be permitted.

B. *Therapeutic purposes*

i. No intervention on the living embryo *in vitro* or *in utero* or on the foetus whether inside or outside the uterus shall be permitted unless its object is the well-being of the child to be born, that is, to facilitate its development and birth.

ii. Therapy on embryos *in vitro* or *in utero* or on the foetus *in utero* shall not be permitted, unless it is for very clear and precisely diagnosed embryonic maladies, with grave or extremely bad prognosis, where no other solution is possible and therapy would offer reasonable guarantees of successful treatment of those illnesses.

iii. It shall be forbidden to keep embryos or foetuses alive artificially for the purpose of removing usable material.

iv. It would be desirable to create a list of those illnesses where therapy can be based on reliable means of diagnosis and reasonable guarantees of success. This list would be periodically updated to take account of new discoveries and scientific progress.

v. Therapy conducted on embryos and foetuses must never influence non-pathological hereditary characteristics, nor have racial selection as its aim.

vi. The use of dead embryos or foetuses must be an exceptional measure, justified in the present state of knowledge by the rare nature of the illness treated, the absence of any equally effective therapy and a manifest advantage (such as survival) for the person receiving treatment; it must comply with the following rules:

a. the decision to terminate pregnancy and the conditions of termination (date, technique, etc.) must under no circumstances be influenced by the possible or desired subsequent use of the embryo or foetus;

b. any use of the embryo or foetus must be undertaken by highly qualified teams in approved hospitals or scientific centres supervised by the public authorities; to the extent that national legislation foresees, these centres must possess multidisciplinary ethical committees;

c. total independence between the medical team terminating the pregnancy and the team which might use the embryos or foetuses for therapeutic purposes must be guaranteed;

d. embryos and foetuses may not be used without the consent of the parents or gamete donors where the latters' identity is known;

e. the use of embryos, foetuses or their tissues for profit or remuneration shall not be allowed.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

FORTIETH ORDINARY SESSION

RECOMMENDATION 1100 (1989)[1]

ON THE USE OF HUMAN EMBRYOS AND FOETUSES IN SCIENTIFIC RESEARCH

The Assembly,

1. Considering that science and technology, and especially the biomedical sciences and biotechnology, continue to advance and develop as an expression of human creativity, and that their freedom of action cannot be restricted arbitrarily, but only on the basis of, *inter alia*, professional, legal, ethical, cultural and social principles for the protection of human rights and the dignity of man as an individual and social being;

2. Noting the contents of the Council of Europe's Parliamentary Assembly Recommendation 934 (1982) and its proposal for the application of genetic engineering on the basis of respect for the genetic heritage of mankind, which shall not be interfered with in individuals save for clearly and scientifically demonstrated preventive or therapeutic purposes;

3. Noting the desirability of implementing the various parts of the Council of Europe's Parliamentary Assembly Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, in particular paragraphs 2, 3, 4.A and 4.B, as well as the necessity of ensuring:

i. that the human embryo and foetus are treated in conditions appropriate to human dignity, and

ii. that products and tissues therefrom may be used solely under strict regulation for limited scientific, diagnostic and therapeutic purposes as defined in Recommendation 1046 which cannot be attained by other methods, and having regard to the diversity of ethical views on this matter;

4. Referring to paragraph 15 of Recommendation 1046, which instructed the competent committees of the Assembly to prepare a report on the use of human embryos and foetuses in scientific research, taking into account the necessary balance between the principles of freedom of research and of respect for human life and other aspects of human rights;

5. Considering that it is customary, in the interests of progress, harmony, liberty and social justice, constantly to adapt legislation and regulations to the ethical and social values of human communities, and to scientific and technological knowledge as and when it is acquired;

6. Considering that it is appropriate to determine the legal protection to be given to the human embryo from the time that the human egg is fertilised, as foreseen in Recommendation 1046;

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[1] *Assembly debate* on 2 February 1989 (24th Sitting) (see Doc. 5943, report of the Committee on Science and Technology, Rapporteur: Mr Palacios; Doc.5989, opinion of the Social, Health and Family Affairs Committee, Rapporteur; Mrs Hubinek; and Doc. 5996, report of the Legal Affairs Committee, Rapporteur: Mr Elmquist). *Text adopted by the Assembly* on 2 February 1989 (24th Sitting).

7. Considering that the human embryo, though displaying successive phases in its development which are designated by different terms (zygote, morula, blastula, pre-implantation embryo or pre-embryo, embryo, foetus), displays also a progressive differentiation as an organism and none the less maintains a continuous biological and genetic identity;

8. Recalling the need for European co-operation and for the widest possible regulation in order to overcome the contradictions, risks and foreseeable shortcomings of exclusively national standards in these fields,

9. Recommends that the Committee of Ministers:

A. Provide a framework of principles from which national laws or regulations can be developed in as universal and uniform a manner as possible, as proposed by its Recommendations 934 (1982) and 1046 (1986) as well as by this recommendation and its appendix;

B. Invite the governments of member states:

i. to set up as a matter of urgency the national or regional multidisciplinary bodies mentioned in the above Recommendations 934 (1982) and 1046 (1986), also entrusting them with the task of informating society and the public authorities of scientific and technological advances in embryology and biological investigation and experimentation, of guiding and monitoring the potential applications thereof, evaluating results, benefits and drawbacks, notably in general terms, that is including also the dimension of human rights, human dignity and other ethical values, and authorising, provided there are appropriate regulations or delegations of authority, specific projects of scientific investigation or experimentation in these fields;

ii. to take steps to guarantee that society is informed simply, accurately and sufficiently of activities involving techniques of assisted fertilisation and related techniques, and more specifically of fertilisation *in vitro* and the use of human gametes, embryos or foetuses for scientific investigation or other purposes;

iii. to establish the requisite national mechanisms for improving knowledge of the epidemiology and incidence of human sterility and genetic or hereditary diseases with a view to their prevention and/or cure;

iv. to promote investigations aimed at:

a. improving technical procedures of assisted fertilisation, strictly as and where permitted;

b. deepening knowledge of the human cell and of its structures and its functions, and in particular of reproductive cells, of embryological development, of reproduction and heredity;

c. diagnostic (in particular prenatal) and/or therapeutic purposes, especially for diseases linked to chromosomes or genes;

d. industrial and pharmacological purposes, so as to produce medically useful substances in sufficient quantities without either the biological disadvantages or risks of infection or immunological reactions caused by the substances usually used;

v. to regulate the operations and to draw up national or regional registers of accredited and authorised centres where research or experiments are undertaken on reproductive material - be it human gametes, embryoss or foetuses, or cells, tissues or organs - and to monitor and evaluate such activities, and to require that the biomedical and scientific teams at such centres are properly qualified and authorised to perform such activities and have the necessary resources;

vi. to examine these recommendations in the light of the considerations contained in the appendix to this recommendation, and to provide for the sanctions which failure to comply therewith could entail;

C. Pursue the study and compilation of all knowledge related to human reproduction and biomedicine, and provide for joint action by all Council of Europe member states, so that, in addition to purely national action, they contribute to the framing of a common legal instrument, such as a European convention on biomedicine and human biotechnology, which would be open to non-member states also - as already proposed in Recommendations 934 (1982) and 1046 (1986);

D. Establish as a matter of urgency, as a safeguard, an international multidisciplinary body to ensure convergent approaches by the national bodies already operating or to be set up in accordance with subparagraph 9.B.i. above, and to avoid thereby the creation of "genetic havens".

APPENDIX

Scientific research and/or experimentation on human gametes, embryos and foetuses and donation of such human material

A. *On gametes*

1. Gametes may be used independently for purposes of basic or experimental investigation, subject to the provisions of the following paragraphs;

2. Investigations shall be permitted:

– on fertility, sterility and contraception;

– on phenomena of histocompatibility or immunity related to procreation;

– on the process of gametogenesis and embryonic development, for the prevention or treatment of genetic diseases;

3. The human gametes employed for investigation or experimentation shall not be used to create zygotes or embryos *in vitro* for the purpose of procreation.

B. *On live pre-implantation embryos*

4. In accordance with Recommendations 934 (1982) and 1046 (1986), investigations of viable embryos *in vitro* shall only be permitted:

– for applied purposes of a diagnostic nature or for preventive or therapeutic purposes;

– if their non-pathological genetic heritage is not interfered with.

5. In accordance with paragraph 14.A.iv, eleventh subparagraph, of Recommendation 1046, research on living embryos must be prohibited, particularly:

– if the embryo is viable;

– if it is possible to use an animal model;

– if not foreseen within the framework of projects duly presented to and authorised by the appropriate public health or scientific authority or, by delegation, to and by the relevant national multidisciplinary committee;

– if not within the time-limits laid down by the authorities mentioned above.

6. Moreover, any proposed investigation which meets the above conditions for authorisations must be excluded:

– unless it is accompanied by all the required details on the embryonic material to be used, its source, foreseen time-limits of implementation and the aims pursued;

– unless, on completion of the investigation, those responsible agree to inform the authorising body of its outcome.

7. Embryos at the pre-implantation stage which have been expelled spontaneously from the uterus shall in no circumstances be retransferred back.

C. *On dead pre-implantation embryos*

8. Investigation of and experimentation on dead embryos for scientific, diagnostic, therapeutic or other purposes shall be permitted subject to prior authorisation.

D. *On post-implantation embryos or live foetuses in utero*

9. The removal of cells, tissues or embryonic or foetal organs, or of the placenta or the membranes, if live, for investigations other than of a diagnostic character and for preventive or therapeutic purposes shall be prohibited.

10. The pregnant woman and her husband or partner must be provided beforehand with as full information as necessary:

i. on the technical operations to be performed for the removal of cells, and/or embryonic or foetal tissues, or for the removal of the membranes, the placenta and/or the amniotic fluid,

ii. on the intended purposes, and

iii. on the risks involved.

11. Persons removing embryos or foetuses or parts thereof from the uterus without clinical or legal justification or without the prior consent of the pregnant woman and, where appropriate, of her husband or partner in a stable relationship, and persons using such embryological materials in breach of the relevant legislation or regulations shall be duly penalised.

E. *On post-implantation embryos or live foetuses outside the uterus*

12. Foetuses shed prematurely and spontaneously and considered to be biologically viable may be the subject of clinical operations solely in order to promote their development and autonomous existence.

13. The performance of any operation on or the removal of cells, tissues or organs from embryos or foetuses outside the uterus shall be subject to, among other things, the parents' prior written consent.

14. Experiments on living embryos or foetuses, whether viable or not, shall be prohibited. None the less, where a state authorises certain experiments on non-viable foetuses or embryos only, these experiments may be undertaken in accordance with the terms of this recommendation and subject to prior authorisation from the health or scientific authorities or, where applicable the national multidisciplinary body.

F. *On dead embryos or foetuses*

15. Before proceeding to any intervention on dead embryos or foetuses, centres and clinics shall ascertain whether death is partial (when the embryo is clinically dead, its cells, tissues or organs may still remain alive for several hours) or total (when clinical death is matched by death of the cells).

16. The use of biological matter from dead embryos or foetuses for scientific, preventive, diagnostic, therapeutic, pharmaceutical, clinical or surgical purposes shall be permitted within the framework of the rules governing investigation, experimentation, diagnosis and therapy, in accordance with the terms of this recommendation.

G. *Applications of scientific research to the human being in the fields of health and heredity*

17. Genetic technology shall only be used for investigations on or with human or recombinant genetic material if appropriate authorisation has been obtained. Such authorisation shall be granted on the basis of the soundness of projects, full details being provided as regards their location, aims, duration and the biological material to be used; it shall be granted by the competent authorities or, by delegation, by the national multidisciplinary body.

18. Scientific research projects on genetic engineering using genetic or recombinant genetic material shall be permitted, subject to approval:

– for diagnostic purposes, as in the case of prenatal diagnosis *in vitro* or *in utero* of genetic or hereditary diseases, in order to study the biological materials obtained with a view to the treatment where possible of specific diseases or the prevention of their transmission, provided that the techniques used do not harm the embryo or the mother;

– for industrial purposes of a preventive, diagnostic or therapeutic nature, such as the pharmaceutical manufacture (by molecular or gene cloning) of substances or products for health or clinical purposes in suitable quantities, when they cannot be producted by any other method, natural or otherwise, such as hormones, blood proteins which control the immune responses, antiviral, antibacterial or anticarcinogenic agents, or the manufacture of vaccines without any extra risk of a biological, immunological or infectious nature;

– for therapeutic purposes, in particular for the selection of sex in the case of diseases linked to the sex chromosomes (particularly the X female chromosome), with a view to preventing transmission; also for the creation by surgical means of beneficial gene mosaics, by transplanting genetically and biologically healthy cells, tissues or organs from other persons to replace the diseased, damaged or defective counterparts in the person being treated. In this connection, the approval of the use of healthy recombinant DNA to replace pathological DNA causing a specific disease shall depend on the degree of scientific and technical safety which, in the opinion of the scientific and public authorities, can be achieved in the human being with the type of molecular recombination envisaged. Any form of therapy on the human germinal line shall be forbidden;

– for purposes of scientific investigation, for studying DNA sequences in the human genome - their location, functions, dynamics, interrelationships and pathology; for studying recombinant DNA within human cells (as well as in the cells of simpler organisms such as viruses and bacteria) with a view to obtaining a better understanding of the mechanisms of molecular recombination, of expression of the genetic message, of the development of cells and their components and their functional organisation; for studying the ageing processes of cells, tissues and organs; and more particularly, for studying the general or specific mechanisms governing the development of diseases;

– for any other purpose considered useful and beneficial to the individual and to humanity, and incorporated in projects already approved.

19. Investigations or acts involving genetic technology shall only be authorised at centres and establishments which have been registered, approved and authorised for such purposes, and which have the requisite specialised personnel and technical resources.

H. *Donation of human embryological material*

20. The donation of human embryological material shall be authorised solely for scientific research on diagnostic, prevention or therapeutic purposes. Its sale shall be prohibited.

21. The intentional creation and/or keeping alive of embryos or foetuses whether *in vitro* or *in utero* for any scientific research purpose, for instance to obtain genetic material, cells, tissues, or organs therefrom, shall be prohibited.

22. The donation and use of human embryological material shall be conditional on the freely given written consent of the donor parents.

23. The donation of organs shall be devoid of any commercial aspect. The purchase or sale of embryos or foetuses or parts thereof by their donor parents or other parties, and their importation or exportation, shall also be prohibited.

24. The donation and use of human embryological material for the manufacture of dangerous and exterminatory biological weapons shall be forbidden.

25. For the whole of this recommendation, "viable" embryos shall be understood to mean embryos which are free of biological characteristics likely to prevent their development; however, the non-viability of human embryos and foetuses shall be determined solely by objective biological criteria based on the embryo's intrinsic defects.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

FORTY-THIRD ORDINARY SESSION

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RECOMMENDATION 1159 (1991)[1]

ON THE HARMONISATION OF AUTOPSY RULES

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1. The Assembly considers it a necessary practice for autopsies to be carried out in all Council of Europe member states to establish the cause of death for medico-legal or other reasons or to establish the identity of the deceased.

2. As the mobility of the population increases throughout Europe and throughout the world, the adoption of uniform guidelines on the way autopsies are to be carried out and on the way autopsy reports are to be established becomes imperative.

3. This is especially so in the case of mass disasters, whether natural or not, where there may be several hundreds of victims of numerous nationalities.

4. Moreover, it is believed that autopsies should be carried out in all cases of suspicious death or where there are doubts as to the cause and that, if done systematically, they may more easily bring to light illegal executions and murders perpetrated by authoritarian regimes.

5. Internationally recognised and applied autopsy rules would therefore contribute to the fight to protect human rights, especially such human rights as the prohibition of torture and of ill-treatment, and the right to life. Here, the Assembly welcomes the fact that the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment has been ratified by twenty out of the twenty-five Council of Europe member states.

6. The Assembly therefore recommends that the Committee of Ministers:

i. promote the adoption of harmonised and internationally recognised rules on the way autopsies are to be carried out and the adoption of a standardised model protocol for autopsies;

ii. support the proposal that states world-wide formally accept and implement the obligation to carry out autopsies in all cases of suspicious death;

iii. invite the member states to apply the Interpol guidelines on disaster victim identification;

iv. invite those Council of Europe member states which have not yet done so to ratify the Council of Europe Agreement on the Transfer of Corpses;

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[1] *Text adopted by the Standing Committee*, acting on behalf of the Assembly, on 28 June 1991.
See Doc. 6332, report of the Committee on Legal Affairs and Human Rights, Rapporteur: Mr Morris, and Doc. 6374, opinion of the Social, Health and Family Affairs Committee, Rapporteur: Mr Palacios.

v. invite the five Council of Europe member states which have not yet done so to ratify the European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment;

vi. draw up international rules to facilitate the formalities proposed in sub-paragraphs 6.i, ii, iii, iv and v from the administrative (transport, crossing of borders, police, etc.) or legal points of view.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

FORTY-THIRD ORDINARY SESSION

RECOMMENDATION 1160 (1991)[1]

ON THE PREPARATION OF A CONVENTION ON BIOETHICS

1. The combined applications of biology, biochemistry and medicine, create universal problems which require solutions and have given rise to a new discipline called bioethics. The hopes raised by progress in this domain are sometimes tempered by anxiety over the most basic rights of the human person.

2. From the Council of Europe, inspired particularly by the preparatory work of the Parliamentary Assembly, have come a great many studies, colloquies and reports whose results are given in a number of recommendations to member states. An effort at co-ordination was made in 1985 with the establishment of a multidisciplinary body: the *ad hoc* Committee of Experts on Bioethics (CAHBI).

3. Furthermore, during the last decade, in certain member countries there has been a growing awareness of bioethical issues, and guidelines, laws, commissions of inquiry and ethics committees have been established in order to follow developments in this field.

4. The Assembly considers that, despite some parities which still exist in national approaches and the wide range of aspects to consider, the moment seems ripe and timely for joint European action such as the preparation of a legal instrument in order to codify existing work, which is valuable but fragmented. The Assembly already expressed its concern in 1989, in Recommendation 1100 on the use of human embryos and foetuses in scientific research.

5. Since then, there have been positive developments which the Assembly welcomes: a specific proposal by the Secretary General of the Council of Europe relating to a convention on bioethics was favourably received by the 17th Conference of European Ministers of Justice in June 1990 and, consequently, the Committee of Ministers instructed the CAHBI to examine the possibility of preparing a convention and to identify the issues involved.

6. The Assembly, which has only recently been represented in the CAHBI, encourages this work which should lead to the preparation of a convention, considering this as the culmination of over fifteen years of intense activity on the question. It currently wishes to give formal support to the principle of a convention and indicate some general guidelines as to the content and progress of work in order to coordinate national approaches, which may differ.

[1] *Text adopted by the Standing Committee*, acting on behalf of the Assembly, on 28 June 1991. See Doc. 6449, report of the Committee on Science and Technology, Rapporteur: Mr Palacios.

7. The Assembly therefore recommends that the Committee of Ministers:

i. envisage a framework convention comprising a main text with general principles and additional protocols on specific aspects. The convention should provide a flexible formula wiht regard to its form, but must not constitute the lowest common denominator as to its content. It must include human rights aspects and take into account the previous work of the Council of Europe;

ii. include in the protocols of the convention such essential issues as organ transplants and donations, medical research on the human body, including the use of embryonic structures, genetic technology and studies on the human genome, the use of genetic information in fields other than medical, and human artificial procreation;

iii. authorise and encourage the CAHBI to hold such consultations as it sees fit in preparing its draft, for example with representatives of the Third World, scientific organisations and particularly the Community institutions, as well as with specialised international governmental and non-governmental organisations;

iv. submit the draft convention to the Assembly for formal opinion before its final adoption.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

FORTY-FOURTH ORDINARY SESSION

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RECOMMENDATION 1213 (1993)[1]

ON DEVELOPMENTS IN BIOTECHNOLOGY AND THE CONSEQUENCES FOR AGRICULTURE

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1. Biotechnology which in a sense has a history as long as bread making and brewing can be defined as the use of biological organisms, systems and processes in industrial, manufacturing and service activities. The elucidation of the nature and functioning of the nucleic acids (DNA and RNA) in the 1950s has paved the way for the manipulation of the building blocks of living organisms so that cells or molecules can be altered. The gene pool available for "crossing" has been widened far beyond the limits of sexual compatibility.

2. Biotechnology's application in the agricultural sector (including forestry and fisheries) has resulted in the production of new animals which could not have been bred with traditional methods and the creation of new pest resistant and other genetically modified plants. The use of tissue culture has permitted the rapid regeneration of cells into identical full sized plants and animals (clones). Some of the new animals and plants have already been patented.

3. Biotechnology can be used to promote contrasting aims:

i. to raise agricultural outputs or reduce inputs;

ii. to make luxury products or basic necessities;

iii. to replace chemical herbicides and insecticides or target them more efficiently;

iv. to upgrade pedigree flocks and herds or expand indigenous stock in developed countries;

v. to upgrade plants for industrial use;

vi. to convert grain into biodegradable plastics or into methanol for fuel;

vii. to hasten maturity in livestock or prevent sexual maturation in locusts or in farmed salmon;

viii. to produce more nutritious and better flavoured foods or diagnose tests for bacterial contamination;

ix. to engineer crops for fertile temperature zones or for semi-arid regions;

x. to fight viral epizootic or build up populations of endangered species;

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[1] *Assembly debate* on 12 May 1993 (34th Sitting) (see Doc. 6780, report of the Committee on Agriculture, Rapporteur: Mr González Laxe). *Text adopted by the Assembly* on 13 May 1993 (36th Sitting).

xi. to reduce production of "greenhouse gases" or utilise them in food production;

xii. to clone meat animals for particular markets or form embryo banks to maintain genetic diversity.

4. The Assembly is convinced that biotechnology offers the agricultural sector (including forestry and fisheries) important new development perspectives for plant and animal breeding, for the production of food as well as non-food products (energy, pharmaceuticals, medicine).

5. Biotechnology can also be misused, for example for the production of new diseases or for the creation of animals or plants which could have unwanted negative effects on specific ecosystems. The altering of genes and cells and the manipulation of life processes of animals can also result in unnecessary suffering and thus violate animal welfare regulations.

6. The Assembly is of the opinion that the manipulation of genes and life processes must be subjected to a careful monitoring by the application of appropriate policies in order to detect inherent risks, avoid harmful aspects and promote promising developments.

7. The Assembly recalls the responsibility of developed countries towards the developing countries and, in this context, supports the respective engagements stipulated in the Biological Diversity Convention adopted at the United Nations Conference on Environment and Development in Rio de Janeiro.

8. It has taken note with satisfaction of Recommendation No. R (92) 9 of the Committee of Ministers to member states on the potential ecological impact of the contained use and deliberate release of genetically modified organisms and of the decision to organise a pan-European conference on this theme from 24 to 26 November 1993 in Strasbourg, which will bring together top-level ecologists and scientists.

9. The Assembly, recalling its Recommendation 870 (1986) on the biogenetic revolution in agriculture - a blessing or a curse - recommends that the Committee of Ministers:

i. extend its work on bioethics (that is the systematic study of human conduct towards life, examined in the light of ethical values and principles) to include issues related to the production, release, use and trade of new or modified living organisms, animals and plants or food and non-food products, and work for a European harmonisation of legislation in this field;

ii. invite the European Community and the European Patent Office to take part in this work;

iii. initiate the work by convening a European conference with representatives of all relevant professions and interest groups concerned to examine the scope and main content of European concerted action and use the experience already gained in the Council of Europe’s work on bioethics;

iv. organise, on the basis of the pan-European conference mentioned above, a second European meeting bringing together the representatives of the world of science and ecology as well as the representatives of all the professions and interest groups involved;

v. promote the setting up of national committees to analyse bioethical aspects regarding the use of biotechnology in the agricultural field, in particular with regard to field research. Such bodies could also give advice on the monitoring of new developments, on necessary policy reforms, on measures to be taken to preserve biodiversity and could be the national bodies of a European network co-operation;

vi. draw up a European convention covering bioethical aspects of biotechnology applied to the agricultural and food sector.

10. Furthermore, the Assembly asks the Committee of Ministers to call on governments of member states and the Commission of the European Communities:

i. to increase and co-ordinate European research and development in the field of biotechnology, giving priority to research of existing natural biodiversity and the sustained development and exploitation of these resources;

ii. to deploy all necessary efforts towards ratifying the Biological Diversity Convention concluded in Rio de Janeiro at the occasion of the United Nations Conference on Environment and Development;

iii. to give special emphasis to biochemical engineering and its potential applications for the pharmaceutical industry in general and for the production of new vaccines and disease-resistant plants in particular;

iv. to encourage the creation of new enterprises to exploit inventions in biotechnology and adopt a regulatory framework for their operation;

v. to pay special attention to the need for better and more information to the public through the organisation of information activities and exhibitions and through appropriate labelling;

vi. to strengthen training programmes on biotechnologies and their applications in the field of agriculture, forestry, fisheries as well as food and non-food production and processing;

vii. to accept the concept of "farmers' rights" as resulting from the United Nations Food and Agriculture Organisation's (FAO) resolution, adopted in November 1989, as well as to encourage the implementation of the project on an "International Code of Conduct for Planned Biotechnology" drawn up by the FAO;

viii. to take action to protect biodiversity and ecosystems from all possible negative influences that biotechnological inventions might cause and to use biotechnology in preserving biodiversity;

ix. to adopt a cautious policy with regard to the granting of patents for biotechnological inventions and applications so as to take due account of ethical considerations and environmental safety concerns;

x. to implement technology assessments for biotechnology inventions as a precondition for further research and development and to work for the setting up of an international biotechnology assessment office;

xi. to encourage the inclusion of bioethics in the training of specialists in the field of biotechnology and favour the development of professional ethical norms for work regarding biotechnologies and their applications - including the setting up of professional bodies at institutional, national, European and international levels;

xii. to associate the non-governmental organisations concerned with these activities.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

2ND PART OF 1994 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1235 (1994)[1]

ON PSYCHIATRY AND HUMAN RIGHTS

1. The Assembly observes that there is no overall study on legislation and practice with regard to psychiatry covering the member states of the Council of Europe.

2. It notes that on the one hand, a body of case-law has developed on the basis of the European Convention on Human Rights and that on the other, the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment has made a number of observations with regard to practices followed in the matter of psychiatric placements.

3. It notes that, in a large number of member countries, legislation on psychiatry is under review or in preparation.

4. It is aware that, in many countries, a lively debate is currently focused on problems associated with certain types of treatment such as lobotomies and electroconvulsive therapy as well as on sexual abuse in psychiatric care.

5. It recalls Recommendation No. R (83) 2 of the Committee of Ministers to member states concerning the legal protection of persons suffering from mental disorder placed as involuntary patients.

6. It considers that the time has come for the member states of the Council of Europe to adopt legal measures guaranteeing respect for human rights of psychiatric patients.

7. The Assembly therefore invites the Committee of Ministers to adopt a new recommendation based on the following rules:

i. Admission procedure and conditions:

a. compulsory admission must be resorted to in exceptional cases only and must comply with the following criteria:

- there is a serious danger to the patient or to other persons;

- an additional criterion could be that of the patient's treatment: if the absence of placement could lead to a deterioration or prevent the patient from receiving appropriate treatment;

b. in the event of compulsory admission, the decision regarding placement in a psychiatric institution must be taken by a judge and the placement period must be specified. Provision must be made for the placement decision to be regularly and automatically reviewed. Principles established in the Council of Europe's forthcoming convention on bioethics must be respected in all cases;

c. there must be legal provision for an appeal to be lodged against the decision;

d. a code of patients' rights must be brought to the attention of patients on their arrival at a psychiatric institution;

e. a code of ethics for psychiatrists should be drawn up inter alia on the basis of the Hawaii Declaration approved by the General Assembly of the World Psychiatric Association in Vienna in 1983.

ii. Treatment:

a. a distinction has to be made between handicapped and mentally ill patients;

b. lobotomies and electroconvulsive therapy may not be performed unless informed written consent has been given by the patient or a person, counsellor or guardian, chosen by the patient as his or her representative and unless the decision has been confirmed by a select committee not composed exclusively of psychiatric experts;

c. there must be an accurate and detailed recording of the treatment given to the patient;

d. there must be adequate nursing staff appropriately trained in the care of such patients;

e. patients must have free access to a "counsellor" who is independent of the institution; similarly, a "guardian" should be responsible for looking after the interests of minors;

f. an inspection system similar to that of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment should be set up.

iii. Problems and abuses in psychiatry:

a. the code of ethics must explicitly stipulate that it is forbidden for therapists to make sexual advances to patients;

b. the use of isolation cells should be strictly limited and accommodation in large dormitories should also be avoided;

c. no mechanical restraint should be used. The use of pharmaceutical means of restraint must be proportionate to the objective sought, and there must be no permanent infringement of individuals' rights to procreate;

d. scientific research in the field of mental health must not be undertaken without the patient's knowledge, or against his or her will or the will of his or her representative, and must be conducted only in the patient's interest.

iv. Situation of detained persons:

a. any person who is imprisoned should be examined by a doctor;

b. a psychiatrist and specially trained staff should be attached to each penal institution;

c. the rules set out above and the rules of ethics should be applied to detained persons and, in particular, medical confidentiality should be maintained in so far as this is compatible with the demands of detention;

d. sociotherapy programmes should be set up in certain penal institutions for detained persons suffering from personality disorders.

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1. Assembly debate on 12 April 1994 (10th Sitting) (see Doc. 7040, report of the Committee on Legal Affairs and Human Rights, Rapporteur: Mr Stoffelen; and Doc. 7048, opinion of the Social, Health and Family Affairs Committee, Rapporteur: Mr Eisma).

Text adopted by the Assembly on 12 April 1994 (10th Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

2ND PART OF 1994 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1240 (1994)[1]

ON THE PROTECTION AND PATENTABILITY OF MATERIAL OF HUMAN ORIGIN

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1. The Assembly insists that human beings are subjects - not objects - of law, that the human body is inviolable and inalienable by virtue of its relationship to a person endowed with rights, and that limits must therefore be set to how it is used.

2. The draft bioethics convention of the Council of Europe (draft convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine) establishes the principle that the human body and its parts as such - that is, as they are found in the human body - shall not give rise to any financial gain.

3. The Assembly is aware of the rapid development of genetics and the striking range of its present and potential applications. Clearly, the immense resources invested in biotechnological research entail the protection of equipment, methods and products; such protection is the only way of safeguarding the development of research.

4. Patent law - more specifically, the provisions of the 1973 European Patent Convention - plays a role to this effect. Its purpose is to confer on the patent-holder not a right of ownership but an exploitation monopoly for a given period of time.

5. The debate today on protection of innovations involving living material focuses on this purpose and the legitimate character of patent law. This is because (in particular) of the granting of patents for transgenic production techniques based on animals, and also because of current controversies surrounding the possible acceptance or refusal of patents for DNA fragments, the industrial application and functions of which are not yet known.

6. The Assembly takes the view that fundamental debate on biotechnology must not be entirely confined to patent law.

7. The provisions of the European Patent Convention - signed prior to the birth of the first test-tube baby - were drafted, necessarily, without any deep reflection on prohibitions on and limitations to the commercialisation of the human body, its parts and products, or genetic mutation processes.

8. The provisions of this convention are today inadequate, notwithstanding certain restrictions which it provides for on grounds of public policy or morality which could lead to querying certain patent awards.

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[1] *Assembly debate* on 14 April 1994 (15th Sitting) (see Doc. 7045, report of the Social, Health and Family Affairs Committee, Rapporteur: Mr Monfils; and Doc. 7068, opinion of the Committee on Science and Technology, Rapporteur: Mr Birraux). *Text adopted by the Assembly* on 14 April 1994 (15th Sitting).

9. Moreover, the convention only addresses problems inherent in the relationship between human beings and biotechnology in terms of specific cases without theoretical perspective, and in an environment where patenting is the norm and commercial considerations are omnipresent; application of rules and their monitoring are the responsibility of civil servants and technicians.

10. A proposal for a directive of the European Union (legal protection of biotechnological inventions), though limited to the perspective of patents, has the merit of clearly specifying certain prohibitions in regard to the patentability of living material. However, the approach chosen is simplistic, as much because of the European Union's substantive competence as because its action is geared to the harmonisation of the Single Market and development of Europe's competitiveness and trade. There remains, moreover, the possibility of commercialisation without patents of innovations involving living material, and the proposed directive does not provide for banning the commercialisation of non-patentable inventions.

11. In accordance with its previous Recommendations 1046 (1986), 1100 (1989) and 1160 (1991), the Assembly considers that ethical principles regarding living material should be a pre-requisite for providing scientists, in particular, with a legal framework to guide them in their work.

12. The task of deciding - in the light of social trends - on how to reconcile generally accepted moral standards, scientific research and commercial exploitation is fundamentally political; moreover, the appropriate principles are now set forth in the Council of Europe's draft bioethics convention.

13. In accordance with its Recommendations 1046 (1986), 1100 (1989) and 1160 (1991), the Assembly recommends that the Committee of Ministers:

i. adopt as soon as possible the text of the bioethics convention, refer it to the Parliamentary Assembly in good time for an opinion, and open it for signature without delay, thereby providing Europe with a reference to fundamental moral principles in the field of bioethics;

ii. initiate the immediate preparation of a protocol to the draft convention, setting limits to the application of genetic manipulation to human beings, and transmit the text to the Parliamentary Assembly for an opinion;

iii. assign the drafting of the protocol to its Steering Committee on Bioethics (CDBI), in which the Assembly should continue to be represented, with instructions to lay down a number of prohibitions, some of which may already be referred to in patent law, on inter alia:

a. processes for modifying the genetic identity of the human body for any non-therapeutic purpose contrary to human dignity;

b. techniques for cloning and producing chimeras;

as well as on such manipulations as:

c. transfer of human embryos to a different species, and vice versa;

d. amalgamation of human gametes with those of a different species;

e. production of an individualised, autonomous human being in the laboratory;

f. creation of children from persons of the same sex; and

g. sex selection for non-therapeutic purposes.

14. The Assembly also calls, in the interests of coherent development, for the European Patents Office to transmit to the Council of Europe an annual report for transmission to and debate by the Parliamentary Assembly on decisions on applications for patents relating to living material, and invites the Committee of Ministers to determine in consultation with the office the forms and procedures to be followed.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

1996 ORDINARY SESSION

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OPINION NO. 198 (1996)[1]

ON THE DRAFT 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

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1. The adoption on 7 June 1996 by the Steering Committee on Bioethics (CDBI) of a revised draft convention marked the culmination of many long years of work. In this connection, the Assembly draws particular attention to its Recommendations 934 (1982) on genetic engineering, 1046 (1986) and 1100 (1989) on the use of human embryos and foetuses, and 1160 (1991) on the preparation of a convention on bioethics, as well as its Opinion No. 184 (1995) on the first draft convention in which it recommended that the Committee of Ministers "review thoroughly" the draft text.

2. The new draft convention is more complete and better structured as a whole. The order in which its provisions are placed and the links between them are more logical than in the initial draft. The text has been more carefully worded, and the addition o new articles, for example, on organ transplantation, constitutes an improvement. On some points, such as the protection of embryos, the articles have been kept brief and are intended merely to provide the basis for future protocols.

3. The draft text is in tune with the thinking behind the Assembly's proposals, although the exact working of the individual amendments has not always been followed. A series of newly drafted provisions provides a satisfactory response to one of the Assembly's main concerns, namely the question of "consent" and, in particular, the protection of persons unable to give consent. At the same time, a further guarantee is enshrined in a new provision, based on the Assembly's amendments, concerning the role to be played by the European Court of Human Rights in interpreting the convention.

4. The Assembly believes that the new draft convention is a coherent and balanced text. It represents the maximum degree of European consensus that can be achieved at present. Once it has been adopted, the convention will serve as a universal benchmark and will encourage many states to comply with and go beyond the standards it lays down.

5. As with all texts based on compromise, it could, however, be improved in some areas. In the view of the Assembly, the draft convention provides no clear guidance on the question of the communication of results of genetic tests to third parties. This problem, which is likely to assume considerable social and economic importance in the years ahead, cannot be left unmentioned.

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[1] *Assembly debate* on 26 September 1996 (30th and 31st Sittings) (see Doc. 7622, report of the Committee on Science and Technology, rapporteur: Mr Plattner; Doc. 7664, opinion of the Social, Health and Family Affairs Committee, rapporteur: Mr Daniel; and Doc. 7654, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Schwimmer). *Text adopted by the Assembly* on 26 September 1996 (30th and 31st Sittings).

6. The Assembly therefore recommends that the Committee of Ministers :

i. amend Article 1 (Purpose and object of the draft convention by inserting a second sentence as follows:

"The Parties to this convention shall take all legislative and administrative actions necessary to give effect to and carry out the provisions of this convention within their own territories.";

ii. modify Article 2 (Primacy of the human being) of the draft convention as follows:

"The interests and welfare of the human being shall prevail over the sole interest of society or science.";

iii. amend Article 4 (Professional standards) of the draft convention by inserting a second sentence as follows:

"But persons working in the field of health and biomedical research shall have the right to exercise conscientious objection to any such interventions.";

iv. amend Article 12 (Predictive genetic tests) of the draft convention by adding the following two new paragraphs:

"2. The communication of results of genetic testing outside the health field may be allowed only in accordance with the provisions of Article 26, paragraph 1, of this convention and in accordance with national legislation on data protection.

3. Even where the person concerned has consented or is bound by contract, the results of predictive genetic tests shall be used strictly in accordance with paragraphs 1 and 2 above.";

v. amend Article 14 (Non-selection of sex) of the draft convention to read as follows:

"The use of techniques of medically assisted procreation shall not be permitted for the purpose of choosing a future child's sex.";

vi. amplify Article 16.iii (Protection of persons undergoing research) of the draft convention as follows:

"The research project has been approved by the independent multidisciplinary competent body after independent examination of its scientific merit, including the importance of the aim of the research, and ethical acceptability.";

vii. amend Article 17, paragraph 1.ii, of the draft convention to read:

"the results of the research have the potential to produce real and direct benefit to his or her health".;

viii. amend Article 18 (Research on embryos (*in vitro*) of the draft convention as follows:

"- research on embryos *in vitro* shall be permitted only in the interests of their development. It may, nevertheless, relate to the diagnosis of the most serious diseases;

ix. amend Article 20, paragraph 2.iv, of the draft convention, to read:

"The authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the judicial authorities responsible for the protection of children.";

x. amend Article 32, paragraph 6 (Amendments to the convention), of the draft convention by amplifying it as follows:

"The committee shall examine the proposal not earlier than two months after it has been forwarded y the Secretary General in accordance with paragraph 5. The committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. The Committee of Ministers shall transmit the adopted text, before approval, to the Parliamentary Assembly for opinion. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.";

xi. adopt the amended draft convention without referring it back to the CDBI and open it for signature before the end of this year, as any further delay could jeopardise the innovative nature of the text as a model for national legislators;

xii. establish a timetable for the preparation of the draft protocols on organ transplantation, medical research and the protection of embryos, instruct the CDBI also to prepare a protocol on genetics, and transmit each draft protocol to the Assembly for opinion as soon as it has been finalised.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

1997 ORDINARY SESSION

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OPINION NO. 202 (1997)[1]

ON THE DRAFT ADDITIONAL PROTOCOL TO THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE ON THE PROHIBITION OF CLONING HUMAN BEINGS

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1. The Assembly recalls its Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, in which Council of Europe member governments are called on "to forbid ... the creation of identical human beings by cloning or any other methods". This recommendation is reflected in Article 20 of the report on human artificial procreation drawn up by the *ad Hoc* Committee of Experts on Progress in the Biomedical Sciences (CAHBI, 1989), which states that "the use of techniques of artificial procreation to create identical human beings by cloning or any other method shall be prohibited".

2. The Assembly also notes, that Article 13 of the Convention on Human Rights and Biomedicine (intervention on the human genome) states that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants". Thus, this article implicitly forbids cloning of human beings.

3. Reference is also made to Article 1 of the same convention, which states that "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". Since cloning violates the dignity and integrity of human beings both as individuals and as members of the human species, this article also prohibits the cloning of human beings.

4. The Assembly has also taken note of the European Council Declaration on banning the cloning of human beings, of the resolution of the European Parliament on cloning, of the USA proposal for a cloning prohibition act of 1997, of Unesco's universal declaration on the human genome and human rights, and of the resolution of the World Health Assembly on cloning in human reproduction. All these texts take a strong stand against the cloning of human beings.

5. The Assembly welcomes the rapid reaction by the Committee of Ministers to the public uproar caused by the production of the cloned sheep "Dolly", mandating the Steering Committee on Bioethics (CDBI) in May 1997 to give an opinion on the cloning of humans.

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[1] Assembly debate on 23 September 1997 (26th Sittings). (see Doc. 7895, report of the Committee on Science and Technology (rapporteur: Mr Plattner) and doc. 7906, opinion of the Committee on Legal Affairs and Human Rights (rapporteur: Mr Schwimmer). *Text adopted by the Assembly* on 23 September 1997 (26th Sitting).

6. The Assembly appreciates the rapid response of the CDBI, which in June 1997 presented its opinion on human cloning to the Committee of Ministers. It takes note that the CDBI agreed on specific binding provisions to be adopted within the Council of Europe to prohibit any intervention seeking to create a human being genetically identical to another human being, whether living or dead ("genetically identical human beings" meaning "human beings sharing the same nuclear gene set"). It is further noted that the CDBI agreed on the elaboration of an additional protocol to the Convention on Human Rights and Biomedicine as the best way to adopt such provisions.

7. The Assembly welcomes the Committee of Minister's decision at its meeting in July 1997 seek the opinion of the Parliamentary Assembly on the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings.

8. Considering all these aspects, the Assembly recommends that the Committee of Ministers:

i. rapidly adopt the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings;

ii. invite all states that have not yet done so to sign the Convention on Human Rights and Biomedicine and therefore fulfil the precondition for signing the additional protocol on the prohibition of cloning human beings;

iii. transmit for opinion to the Parliamentary Assembly each new draft additional protocol as soon as it is finalised;

iv. call on governments of Council of Europe member as well as observer states, in line with the provisions of the draft additional protocol on the prohibition of cloning human beings, to create and implement legislation that bans any intervention seeking to create a human being genetically identical to another human being, whether living or dead ("genetically identical human beings" meaning "human beings sharing the same nuclear gene set") and to provide for severe penal sanctions to deal with any violation. The parties should, however, guarantee the protection of human beings resulting from interventions, albeit prohibited under the additional protocol to the Convention on Human Rights and Biomedicine;

v. ask the United Nations General Assembly to adopt provisions for an explicit world-wide ban on the cloning of human beings, seeking inspiration from the Council of Europe's additional protocol on the prohibition of cloning human beings;

vi. encourage member states to improve and increase information and education on biotechnological research related to human beings with a view to enhancing public support for the principles contained in the Convention on Human Rights and Biomedicine and its additional protocols;

vii. strengthen the secretariat working with the Convention on Human Rights and Biomedicine and its additional protocols to speed up the progress of work.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

FIRST PART OF 1999 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1399 (1999)[1]

ON XENOTRANSPLANTATION

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1. The advancement of transplantation technology has allowed considerable success in human-to-human organ transplants (allotransplantation) and is promising a radical breakthrough for the transplantation of animal cells, tissues, and organs into humans (xenotransplantation).

2. Whereas rejection problems and the transfer of diseases can be satisfactorily controlled in allotransplantation, these risks remain today uncontrollable for xenotransplantations. Research to solve these problems should be stepped up prior to any clinical trial.

3. The transmission of animal retroviruses and prions into humans through xenotransplants may cause diseases which, if transmitted to other humans, may cause major pandemics.

4. The health risks of xenotransplantation must therefore be weighed up against their estimated benefits and methods must be found to eliminate any such risks.

5. There are considerable scientific, medical, ethical, social and legal problems that should be answered before clinical xenotransplantations proceed. The ethical problems include the acceptability of xenotransplantations as regards both humans and animals.

6. The Assembly, noting Recommendation No. R (97) 15 of the Committee of Ministers to member states on xenotransplantation, recommends that the Committee of Ministers:

i. work for the rapid introduction in all member states of a legally-binding moratorium on all clinical xenotransplantations, and consider the feasibility of elaborating a second protocol to the Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine (European Treaty Series No.164), on xenotransplantation;

ii. take steps to make this moratorium a worldwide legal agreement;

iii. ask its European Health Committee and Steering Committee on Bioethics to work out, in co-operation with the World Health Organisation, a strategy for balancing the ethical, medical, scientific, legal, social and public health aspects of xenotransplantation, before the scientific and medical establishment is permitted to proceed with clinical trials on humans.

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[1] *Assembly debate* on 29 January 1999 (8th Sitting) (see Doc. 8166, report of the Committee on Science and Technology, rapporteur: Mr Plattner, and Doc. 8264, opinion of the Social, Health and Family Affairs Committee, rapporteur: Mr Dees). *Text adopted by the Assembly* on 29 January 1999 (8th Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

3RD PART OF 1999 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1418 (1999)[1]

ON THE PROTECTION OF THE HUMAN RIGHTS AND DIGNITY OF THE TERMINALLY ILL AND THE DYING

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1. The vocation of the Council of Europe is to protect the dignity of all human beings and the rights which stem therefrom.

2. Medical progress, which now makes it possible to cure many previously incurable or fatal diseases, the improvement of medical techniques and the development of resuscitation techniques, which make it possible to prolong a person's survival, to defer the moment of death. As a result the quality of life of the dying is often neglected, and their loneliness and suffering ignored, as is that of their families and care-givers.

3. In 1976, in its Resolution 613, the Assembly declared that it was "convinced that what dying patients most want is to die in peace and dignity, if possible with the comfort and support of their family and friends", and added in its Recommendation 779 (1976) that "the prolongation of life should not in itself constitute the exclusive aim of medical practice, which must be concerned equally with the relief of suffering".

4. Since then, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine has formed important principles and paved the way without explicitly referring to the specific requirements of the terminally ill or dying.

5. The obligation to respect and to protect the dignity of a terminally ill or dying person derives from the inviolability of human dignity in all stages of life. This respect and protection find their expression in the provision of an appropriate environment, enabling a human being to die in dignity.

6. This task has to be carried out especially for the benefit of the most vulnerable members of society, a fact demonstrated by the many experiences of suffering in the past and the present. Just as a human being begins his or her life in weakness and dependency, he or she needs protection and support when dying.

7. Fundamental rights deriving from the dignity of the terminally ill or dying person are threatened today by a variety of factors:

i. insufficient access to palliative care and good pain management;

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[1] *Assembly debate* on 25 June 1999 (24th Sitting) (see Doc. 8421, report of the Social, Health and Family Affairs Committee, rapporteur: Mrs Gatterer; and Doc. 8454, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr McNamara*). Text adopted by the Assembly* on 25 June 1999 (24th Sitting).

ii. often lacking treatment of physical suffering and a failure to take into account psychological, social and spiritual needs;

iii. artificial prolongation of the dying process by either using disproportionate medical measures or by continuing treatment without a patient's consent;

iv. the lack of continuing education and psychological support for health-care professionals working in palliative medicine;

v. insufficient care and support for relatives and friends of terminally ill or dying patients, which otherwise could alleviate human suffering in its various dimensions;

vi. patients' fear of losing their autonomy and becoming a burden to, and totally dependent upon, their relatives or institutions;

vii. the lack or inadequacy of a social as well as institutional environment in which someone may take leave of his or her relatives and friends peacefully;

viii. insufficient allocation of funds and resources for the care and support of the terminally ill or dying;

ix. the social discrimination inherent in weakness, dying and death.

8. The Assembly calls upon member states to provide in domestic law the necessary legal and social protection against these specific dangers and fears which a terminally ill or dying person may be faced with in domestic law, and in particular against:

i. dying exposed to unbearable symptoms (for example, pain, suffocation, etc.);

ii. prolongation of the dying process of a terminally ill or dying person against his or her will;

iii. dying alone and neglected;

iv. dying under the fear of being a social burden;

v. limitation of life-sustaining treatment due to economic reasons;

vi. insufficient provision of funds and resources for adequate supportive care of the terminally ill or dying.

9. The Assembly therefore recommends that the Committee of Ministers encourage the member states of the Council of Europe to respect and protect the dignity of terminally ill or dying persons in all respects:

a. by recognising and protecting a terminally ill or dying person's right to comprehensive palliative care, while taking the necessary measures:

i. to ensure that palliative care is recognised as a legal entitlement of the individual in all member states;

ii. to provide equitable access to appropriate palliative care for all terminally ill or dying persons;

iii. to ensure that relatives and friends are encouraged to accompany the terminally ill or dying and are professionally supported in their endeavours. If family and/or private networks prove to be either insufficient or overstretched, alternative or supplementary forms of professional medical care are to be provided;

iv. to provide for ambulant hospice teams and networks, to ensure that palliative care is available at home, wherever ambulant care for the terminally ill or dying may be feasible;

v. to ensure co-operation between all those involved in the care of a terminally ill or dying person;

vi. to ensure the development and implementation of quality standards for the care of the terminally ill or dying;

vii. to ensure that, unless the patient chooses otherwise, a terminally ill or dying person will receive adequate pain relief and palliative care, even if this treatment as a side-effect may contribute to the shortening of the individual's life;

viii. to ensure that health professionals are trained and guided to provide medical, nursing and psychological care for any terminally ill or dying person in co-ordinated teamwork, according to the highest standards possible;

ix. to set up and further develop centres of research, teaching and training in the fields of palliative medicine and care as well as in interdisciplinary thanatology;

x. to ensure that specialised palliative care units as well as hospices are established at least in larger hospitals, from which palliative medicine and care can evolve as an integral part of any medical treatment;

xi. to ensure that palliative medicine and care are firmly established in public awareness as an important goal of medicine;

b. by protecting the terminally ill or dying person's right to self-determination, while taking the necessary measures:

i. to give effect to a terminally ill or dying person's right to truthful and comprehensive, yet compassionately delivered information on his or her health condition while respecting an individual's wish not to be informed;

ii. to enable any terminally ill or dying person to consult doctors other than his or her usual doctor;

iii. to ensure that no terminally ill or dying person is treated against his or her will while ensuring that he or she is neither influenced nor pressured by another person. Furthermore, safeguards are to be envisaged to ensure that their wishes are not formed under economic pressure;

iv. to ensure that a currently incapacitated terminally ill or dying person's advance directive or living will refusing specific medical treatments is observed. Furthermore, to ensure that criteria of validity as to the scope of instructions given in advance, as well as the nomination of proxies and the extent of their authority are defined; and to ensure that surrogate decisions by proxies based on advance personal statements of will or assumptions of will are only to be taken if the will of the person concerned has not been expressed directly in the situation or if there is no recognisable will. In this context, there must always be a clear connection to statements that were made by the person in question close in time to the decision-making situation, more precisely at the time when he or she is dying, and in an appropriate situation without exertion of pressure or mental disability. To ensure that surrogate decisions that rely on general value judgements present in society should not be admissible and that, in case of doubt, the decision must always be for life and the prolongation of life;

v. to ensure that – notwithstanding the physician's ultimate therapeutic responsibility – the expressed wishes of a terminally ill or dying person with regard to particular forms of treatment are taken into account, provided they do not violate human dignity;

vi. to ensure that in situations where an advance directive or living will does not exist, the patient’s right to life is not infringed upon. A catalogue of treatments which under no condition may be withheld or withdrawn is to be defined;

c. by upholding the prohibition against intentionally taking the life of terminally ill or dying persons, while:

i. recognising that the right to life, especially with regard to a terminally ill or dying person, is guaranteed by the member states, in accordance with Article 2 of the European Convention on Human Rights which states that "no one shall be deprived of his life intentionally";

ii. recognising that a terminally ill or dying person’s wish to die never constitutes any legal claim to die at the hand of another person;

iii. recognising that a terminally ill or dying person’s wish to die cannot of itself constitute a legal justification to carry out actions intended to bring about death.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

4TH PART OF 1999 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1425 (1999)[1]

ON BIOTECHNOLOGY AND INTELLECTUAL PROPERTY

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1. The Assembly recalls its Recommendation 1213 (1993) on developments in biotechnology and their consequences for agriculture.

2. It is aware that the patent system, as a system for the protection of intellectual property, is an integral part of the market economy and therefore can be a driving force for innovation in many technological questions.

3. A guideline on patent legislation should help to develop criteria for granting patents continuously according to technological progress, in favour of both the interests of the claiming party and the interests of the public in regard to public order, morality and general aspects of the state economy.

4. Living organisms are able to reproduce themselves even if they are patented, and in view of this special quality of living organisms the scope of a patent is difficult to define, which makes it nearly impossible to find a balance between private and public interests.

5. The Assembly deems it necessary to oblige scientists, as well as scientific research and development units working in the field of biotechnology, to conform with the Convention on Biological Diversity (Rio de Janeiro, 1992), guaranteeing both the principle of free scientific access to worldwide genetic resources and the interests of developing countries in sharing the benefits of technological progress.

6. However, it is aware that for ethical reasons there are also severe reservations against patenting living organisms.

7. It considers that the issue of patenting living organisms should comply with the provisions of the Convention on Biological Diversity (CBD), and that greater account should be taken of the interests of developing countries in the Agreement on Trade-Related Aspects of Intellectual Property Rights (Trips Agreement) of the World Trade Organisation; it asks the World Trade Organisation to comply with the Convention on Biological Diversity.

8. The Assembly has taken note that Directive 98/44/EEC on the legal protection of biotechnological inventions of 6 July 1998 (Bio-Patenting Directive of the European Community) was challenged at the Court of Justice of the European Communities by the governments of the Netherlands and Italy, and that Norway is considering not implementing it.

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[1] *Assembly debate* on 20 September 1999 (25th Sitting) (see Doc. 8459, report of the Committee on Agriculture and Rural Development, rapporteur: Mr Wodarg; and Doc. 8532, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Vishnyakov). *Text adopted by the Assembly* on 23 September 1999 (30th Sitting).

9. The Assembly considers that monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of traditional knowledge in those countries that provide access to these resources.

10. It considers that the aim of sharing the benefits from the utilisation of genetic resources within this broader view does not necessarily require patent-holding but requires a balanced system for protecting both intellectual property and the "common heritage of mankind".

11. It also considers that the many outstanding questions regarding the patentability and the scope of protection of patents on living organisms in the agro-food sector must be solved swiftly taking into account all interests concerned, not least those of farmers and developing countries.

12. The Assembly therefore believes that neither plant-, animal- nor human-derived genes, cells, tissues or organs can be considered as inventions, nor be subject to monopolies granted by patents.

13. For these reasons the Assembly recommends that the Committee of Ministers, in co-operation with the European Union, the World Intellectual Property Organisation, the Food and Agriculture Organisation, the World Trade Organisation, Unesco and in accordance with the Convention on Biological Diversity:

i. study in detail all aspects linked to the protection of intellectual property in biotechnological innovations with a view to further improving international legislation in this field;

ii. assess and review the effects of granting patents with a broad scope as regards the progress of research and development and the free market;

iii. develop a code of conduct for scientists and scientific units working in the field of biotechnology which guarantees both free scientific access to worldwide genetic resources and benefit-sharing with developing countries;

iv. discuss a suitable alternative system of protecting intellectual property in the field of biotechnology which would fit the purposes of the Convention on Biological Diversity and meet the needs of worldwide interests both private and public;

v. encourage the ratification by those member states that have not yet done so of the Council of Europe’s 1963 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, and envisage updating the convention in the light of the conclusions of the report;

vi. consider the ethical aspects of the patentability of inventions involving biological and, in particular, human material.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

3RD PART OF 2000 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1468 (2000)[1]

ON BIOTECHNOLOGIES

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1. Biotechnology has experienced huge advances in recent decades following the elucidation of the nature and functioning of the nucleic acids (DNA and RNA) in the 1950s and later work on molecular genetics and the mapping, sequencing and interpretation of entire genomes (human and others). The discovery that DNA molecules are interchangeable among animals, plants, bacteria and other organisms and the possibility to manipulate or change their units (genes) have given biotechnology enormous scope for applications, but have also resulted in serious public concerns about the safety and ethical acceptability of some of the new inventions.

2. This new knowledge imposes choices regarding further developments and applications of biotechnology involving living matter, in particular because of possible consequences for different life forms, the earth's eco-system and humanity. A central reference for choices to be made must be the preservation of human dignity and a healthy environment.

3. It is increasingly important to include ethical considerations centred on humankind, society and the environment in deliberations regarding developments in biotechnologies, life sciences and technologies and their applications.

4. Public opinion should be more strongly involved in political decision-making as regards scientific and technological choices and scientists should be encouraged to engage more in public debate.

5. The parliamentary hearing on scientific information and the European media (Paris, 11-12 October 1999) demonstrated the important role played by the media with regard to information and awareness-raising in the field of biotechnologies.

6. This is why, as regards biotechnologies, their development and applications, especially where human and nature are concerned, the Assembly recommends that the Committee of Ministers:

i. ask the relevant steering committees to adopt the precautionary principle as a common tenet of decision-making, once its scope has been clearly defined. The Assembly welcomes in this context the agreement reached on 29 January 2000 in Montreal on an international protocol (the Cartagena Protocol on Biosafety) to the 1992 United Nations Framework Convention on Biological Diversity, regulating trade in genetically modified organisms by including the application of the precautionary principle, but regrets that the decisions made regarding traceability and labelling were not more binding;

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[1] *Assembly debate* on 29 June 2000 (23rd Sitting)(see Doc. 8738, report of the Committee on Science and Technology, rapporteur: Mr Mattéi, and Doc. 8786, opinion of the Committee on Agriculture, Rural Development and Food, rapporteur: Mr Wodarg). *Text adopted by the Assembly* on 29 June 2000 (23rd Sitting).

ii. continue to broaden its activities in the field of bioethics, as envisaged in Recommendation 1213 (1993) on developments in biotechnology and the consequences for agriculture. Due account should be taken of the findings of the Council of Europe's international conference on the ethical issues arising from the application of biotechnology (Oviedo, Spain, 16-19 May 1999), covering in particular the problems concerning the patentability of living matter and of Recommendation 1425 (1999) on biotechnology and intellectual property;

iii. ask the Steering Committee on Bioethics (CDBI) to prepare, in co-operation with other relevant organisations, for the introduction of an assessment method for ascertaining whether new technologies in medicine and biology are compatible with fundamental ethical principles, human rights and human dignity. This should take into account the decision-making procedures of individual countries and relevant international organisations as well as the different cultural, religious or social traditions or conventions in the member states. Such a method will entail the introduction of a bioethical labelling procedure based, as a minimum, on the shared principles of non-commercialisation of the human body, individual consent and legitimate use for purposes of human health;

iv. convene a group of experts to elaborate, by involving a citizens' forum, the scope and provisions of a future convention on the use of living matter. This would be with the aim of drawing up an international convention on a worldwide basis, under the auspices of organisations which are able to assume the responsibilities that go along with overseeing such a convention;

v. involve all the partners concerned in co-operation to that end, including the Parliamentary Assembly;

vi. invite the national ethics committees to participate fully in these activities;

vii. call on the member states of the European Union to request the renegotiation of Directive 98/44/EC of the European Parliament and Council of 6 July 1998 on the legal protection of biotechnological inventions, in particular Article 5, paragraph 2 thereof. The time thus gained, with immediate effect, would permit the necessary public discussion and the finding of an appropriate solution in conformity with the Council of Europe 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 (European Treaty Series No. 164). In this connection, those member governments which have already brought appeals against Directive 98/44/EC before the Court of Justice of the European Communities should be supported.

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

2ND PART OF 2001 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1512 (2001)[1]

ON PROTECTION OF THE HUMAN GENOME BY THE COUNCIL OF EUROPE

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1. The Council of Europe's Parliamentary Assembly notes that the human genome international research project, in view of the numerous and unimaginable consequences that it might have for medicine and for the animal and plant world, conjures up scenarios for all humanity that raise numerous ethical questions, while holding out the promise of enormous improvements in the quality of life.

2. The protection of human dignity should be the guiding principle for the handling of the Human Genome Project.

3. The genetic age will dawn with the completion of the project: diagnosis will become objective, and it will be possible to identify the presence of genetic disorders or a genetic predisposition to illnesses at an early stage. In many cases, gene therapy will become possible, and this will basically give rise to a form of genetic engineering designed, for instance, to avoid the development of a tumour in an individual found to be at risk. It might also be applied to other illnesses, such as hypertension, diabetes, Alzheimer's disease, osteoporosis, certain psychiatric disorders, etc.

4. At the same time, the Assembly is aware of the enormous ethical implications of further research on the human genome, including some of a negative nature. These include questions regarding the cloning of cells, the conditions ruling genetic testing and the divulging and use of obtained information.

5.In this connection, the Assembly is fully aware of the now well-known fact that laboratories, with their associated databanks, are already actively at work on DNA separation in certain European countries and enjoy the financial support of prominent pharmaceutical companies.

6. The Assembly is also aware that substantial economic interests are at stake in the Human Genome Project, by virtue of the very fact that it might hold out incalculable opportunities for preventing illness and improving treatment, as it involves many public and private research centres to which considerable financial resources will be allocated.

7. The Assembly is of the opinion that the results of this grandiose research effort – in which the United States has the lead over Europe – must be made available to all, genetic information being a common human heritage, as set out in Article 1 of the Universal Declaration on the Human Genome and Human Rights, adopted at Unesco in Paris on 11 November 1997. The Assembly in particular refers in this context to the Council of Europe 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 (ETS No. 164) as well as its own Recommendations 1425 (1999) on biotechnology and intellectual property and 1468 (2000) on biotechnologies.

8. In particular, the Assembly is aware that the prospects opened up by the discoveries associated with the Human Genome Project pose a whole series of ethical problems, essentially concerning such fundamental issues as the use of genetic information for preventive purposes and possibly a presumed right, at a later stage, to take preventive action when certain genetic information is obtained. However, a crucial question will be the assessment of who will have which rights to use the information: the case of insurance companies, employers, parents, schools, etc.

9. The Assembly calls, *inter alia*, through the establishment of a Euroforum on Human Genetics, for the widest possible participation by citizens in the discussion on the human genome through the involvement of the European media and suitable and accurate information by the Council of Europe.

10. The Assembly expresses the wish that the scope of action of the above-mentioned authority should not be confined to Europe, but that it may become part of a world authority under the aegis of the United Nations. To this end, the Assembly advocates that the necessary contacts be established with the appropriate bodies within the UN and Unesco as soon as possible.

11. In view of the above, the Assembly recommends that the Committee of Ministers:

i. invite every Council of Europe member state concerned to set up, under its own domestic legislation, a national authority having the express task of monitoring, informing and advising on the compliance of research on the human genome with universally recognised ethical and moral principles of respect for life and human dignity;

ii. set up, at European level as well, and more specifically in the context of the Council of Europe, a body or authority to fulfil on a permanent basis the task of monitoring the development of the Human Genome Project research process, ensuring respect for ethical principles in the context of research on the human genome, assessing the effects of such research also regarding health risks, and giving thorough consideration to all the ethical aspects of the project, and consider in this context the role of the Steering Committee on Bioethics (CDBI);

iii. ensure that these bodies for monitoring research on the human genome will familiarise the European public with
new possibilities for progress in genetics in terms of information and technology and serve also to promote campaigns to inform and educate the public, in particular the health professions;

iv. make sure that consultation of the European authority be mandatory, and that it formulate an opinion when conventions are drafted on this subject in the context of the Council of Europe and codes of ethics produced; such a body should also have free access to important information on genetics and be able to carry out its own inspections of public and private European research institutes;

v. ask member states to sign, ratify and implement the Convention on Human Rights and Biomedicine;

vi. ask all Council of Europe member states to strive to change the basis of patent law in international fora, as far as the ownership of human being tissue and genes is concerned, into law pertaining to the common heritage of mankind.

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1. *Assembly debate* on 25 April 2001 (13th Sitting) (see Doc. 8901, report of the Committee on Culture, Science and Education, rapporteur: Mr Martelli).
Text adopted by the Assembly on 25 April 2001 (13th Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

3RD PART OF 2003 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1611 (2003)[1]

ON TRAFFICKING IN ORGANS IN EUROPE

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1. Rapid progress in medical science and technology has transformed organ transplantation, and kidney transplantation in particular, into a routine medical procedure practised in hospitals across the world. Five-year survival rates for most organ transplantation programmes are reaching the level of 70%, thereby rapidly increasing the demand for organ donation.

2. Medical research demonstrates that renal transplantation increases the life expectancy of patients. The supply of organs from cadaveric, but particularly from living, donors is very limited and strictly controlled in Europe. There are currently 120 000 patients on chronic dialysis treatment and nearly 40 000 patients waiting for a kidney transplant in western Europe alone. Some 15% to 30% of patients die on waiting lists, as a result of chronic shortage of organs. The waiting time for transplantation, currently about three years, will reach almost ten years by the year 2010.

3. International criminal organisations have identified this lucrative opportunity caused by the "gap" between organ supply and demand, putting more pressure on people in extreme poverty to resort to selling their organs.

4. Worldwide, the issue of organ trafficking is not new. In the 1980s experts began to notice what was to become known as "transplant tourism" when prosperous Asians began travelling to India and other parts of Southeast Asia to receive organs from poor donors. Since then other routes have opened up, such as to Brazil and the Philippines. Allegations have been made against China of commercial use of organs from executed prisoners. Organ sale continues in India despite new laws, which make the practice illegal in most regions.

5. While current estimations show that organ trafficking remains on a relatively modest scale in Europe, the issue is nevertheless of serious concern, since it is very likely that further progress in medical science will continue to increase the gap between the supply of, and demand for, organs.

6. As a result of poverty, young people in some parts of eastern Europe have sold one of their kidneys for sums of US$2 500 to US$3 000, while recipients are said to pay between US$100 000 and US$200 000 per transplant. It is a matter of grave concern that following illegal transplants the donor's state of health generally worsens in the medium term, due to the absence of any kind of medical follow-up, hard physical work and an unhealthy lifestyle connected to inadequate nutrition and a high consumption of alcohol. Most illegal donors will thus be forced in time to live on dialysis treatment or await, in turn, a kidney transplant.

7. This situation raises a number of ethical questions: Should the poor provide for the health of the rich? Should the price of alleviating poverty be human health? Should poverty compromise human dignity and health? And in terms of medical ethics, should help to recipients be counterbalanced by neglect of, and harm to, donors?

8. The Parliamentary Assembly therefore disapproves of recent trends in some western European countries towards less restrictive laws, which would allow greater scope for unrelated living donation.

9. Trafficking in organs – like trafficking in human beings or drugs – is demand driven. Combating this type of crime should not remain the sole responsibility of countries in eastern Europe. Examples of measures to be taken by all member states in order to minimise the risk of organ trafficking in Europe include reducing demand, promoting organ donation more effectively, maintaining strict legislation in regard to living unrelated donors, guaranteeing the transparency of national registers and waiting lists, establishing the legal responsibility of the medical profession for tracking irregularities and sharing information.

10. The Assembly therefore recalls Committee of Ministers' Recommendation No. R (97) 16 on liver transplantation from living related donors, and Recommendation Rec(2001)5 on the management of organ transplant waiting lists and waiting times, and welcomes Recommendation Rec(2003)12 on organ donor registers.

11. The principle according to which the human body and its parts shall not, as such, give rise to financial gain is part of the legal *acquis* of the Council of Europe. This principle, already present in Resolution (78) 29 of the Committee of Ministers and confirmed, in particular, by the final declaration of the 3rd Conference of European Health Ministers, which was held in Paris in 1987, was enacted by Article 21 of the Convention on Human Rights and Biomedicine (ETS No. 164). The principle was reiterated in its Additional Protocol on Transplantation of Organs and Tissues of Human Origin (ETS No. 186), opened for signature in January 2002.

12. While the prohibition of organ trafficking is legally established in the Council of Europe member states, most countries still have legislative loopholes in this domain. Criminal responsibility in organ trafficking is rarely clearly specified in national criminal codes. Criminal responsibility should include brokers, intermediaries, hospital/nursing staff and medical laboratory technicians involved in the illegal transplant procedure. Medical staff who encourage and provide information on "transplant tourism" should also be liable to prosecution. The medical staff involved in follow-up care of patients who have purchased organs should be accountable if they fail to alert the health authorities of the situation.

13. Organ trafficking, like most criminal activities, is difficult to prove. But it should not be left to the media alone to investigate. Member states have a common responsibility to deal openly with this problem nationally, but also – through multilateral co-operation at European level – bringing together ministries of health, the interior and justice.

14. In the light of the above, the Assembly recommends that the Committee of Ministers:

i. invite all member states:

a. to sign and ratify the Convention on Human Rights and Biomedicine, and its Additional Protocol on Transplantation of Organs and Tissues of Human Origin;

b. to sign and ratify the United Nations Convention against Transnational Organised Crime and its Protocol to Prevent, Suppress and Punish the Trafficking of Persons, especially Women and Children, and the Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography, as trafficking in organs is closely linked to trafficking in people;

c. to recognise their common responsibility in minimising the risk of organ trafficking by strengthening existing mechanisms of co-operation at the Council of Europe level by the Committee on the Organisation Aspects of Co-operation in Organ Transplantation (SP-CTO) and stepping up funding for assistance activities in this area, which is crucial in helping to put efficient transplant systems in place;

d. to adopt and apply the recommendations in the World Medical Association's (WMA) Statement on Human Organ and Tissue Donation and Transplantation, adopted by the 52nd WMA General Assembly in Edinburgh, Scotland, in October 2000;

ii. urge the member states to intensify their co-operation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively. Stepping up the funding of the two agencies in this domain is equally crucial since they are both running on extremely low budgetary and staff levels in this field;

iii. invite the so-called "donor countries":

a. to improve primary prevention through awareness-raising and peer education, particularly in rural areas, in partnership with NGOs, the media, and relevant international agencies;

b. to undertake measures to improve primary health care;

c. to take steps to identify illegal donors and provide for their medical follow-up;

d. to strengthen existing transplant systems, with the assistance of the Council of Europe,;

e. with legal support from the competent services of the Council of Europe, toamend, where necessary, their criminal codes, in order to ensure that those responsible for organ trafficking are adequately punished, including sanctions for medical staff involved in transplanting organs obtained through illegal trafficking;

*f.*to restrict the donation of organs and tissues from prisoners and other individuals in custody, as they are not in a position to give informed consent freely and can be subject to coercion, with the exception of donations for members of their immediate family;

g. to undertake effective measures to combat trafficking in general;

h. to provide special facilities at border crossings with a view to identifying potential victims;

i. to implement national anti-corruption programmes;

j. to implement national poverty reduction strategies and create conditions for investment;

iv. invite the so-called "demand countries":

a. to maintain strict laws in regard to transplantation from unrelated living donors;

b. to deny national medical insurance reimbursements for illegal transplants abroad;

c. to deny national insurance payments for follow-up care of illicit transplants, except where such a refusal would endanger the life or health of patients unable to cover the cost of vital treatment themselves;

d. to improve donor awareness by organising national campaigns and by actively supporting the regular organisation of the European Day for Organ Donation and Transplantation;

e. to take appropriate measures to encourage individuals to indicate, by means of statements of "consent", their wish to donate their organs after their death, in order to increase the availability of organs and tissues obtained *post mortem*;

f. to ensure strict control and transparency of organ registers and waiting lists, and establish clear responsibilities for tracking irregularities;

g. to harmonise data and strengthen co-operation mechanisms for the allocation of organs in donation procedures;

h. to take steps to track down “broker” advertising (through newspapers, agencies, etc.);

i. to co-operate and provide expertise to “donor” countries in connection with trafficking in human beings and organs;

j. to ensure the flow of case-related information and provide necessary support to Interpol and Europol in this domain;

v. instruct the relevant bodies of the Council of Europe:

a. to develop, in co-operation with relevant organisations, a European strategy for combating trafficking in organs and to consider, in the framework of the drafting of the future convention on trafficking in human beings, the inclusion of an additional protocol covering trafficking in organs and tissues of human origin;

b. to advise and assist member states on organisational measures necessary for putting in place an efficient transplant system to minimise the risk of organ trafficking;

c. to provide legal assistance in drafting specific amendments to national criminal codes;

d. wherever applicable, to widen their existing activities to include organ trafficking;

vi. use its influence, in terms of more specific regional co-operation in South-eastern Europe, to broaden the activities of the Stability Pact Task Force on Trafficking in Human Beings (Working Table III) to cover the issue of trafficking in organs;

vii. call on all member states to demonstrate European solidarity towards the countries in eastern Europe which are most affected by the vicious cycle of poverty and to assist them, in co-operation with the international financing institutions and the international donor community, in developing measures to reduce poverty and create a secure business environment for investment.

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[1]. *Assembly debate* on 25 June 2003 (21st Sitting) (see Doc. 9822, report of the Social, Health and Family Affairs Committee, rapporteur: Mrs Vermot-Mangold; and Doc. 9845, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Dees).

Text adopted by the Assembly on 25 June 2003 (21st Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

4TH PART OF 2003 PARLIAMENTARY ASSEMBLY SESSION

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RESOLUTION 1352 (2003) [1]

HUMAN STEM CELL RESEARCH

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1. The Parliamentary Assembly recalls its previous work on bioethics and, in particular, its Opinions N° 198 (1996) on the draft convention on human rights and biomedicine and N° 202 (1997) on the draft additional protocol to that convention on the prohibition of cloning human beings.

2. It notes that the aim of stem cell research is to add new tools for the development of treatments of several diseases that, up to now, have been incurable or not effectively curable.

3. Human stem cells may be derived from a growing number of tissues and fluids from humans of any age and are not limited to embryonic sources.

4. Any therapeutic use of stem cells that is not derived from the patient has to surmount the barrier of rejection (which might be avoided through cloning techniques).

5. The harvesting of embryonic stem cells for the time being necessitates the destruction of human embryos.

6. Furthermore, the use of xenotechnologies for growing human stem cells – for example feeder cells of animal origin or chimera cloning – increases the risk of transmission of new and dangerous infectious diseases (TSE, HIV, Sars).

7. The Assembly points out that a number of embryonic human stem cell lines suitable for scientific research are already available worldwide.

8. It recalls that Article 18 of the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) expressly states that "where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo". The details of this regulation should be the subject of an additional protocol to be prepared by the Steering Committee on Bioethics (CDBI).

9. The same article expressly prohibits the creation of human embryos for research purposes.

10. The destruction of human beings for research purposes is against the right to life of all humans and against the moral ban on any instrumentalisation of humans.

11. Therefore the Assembly calls on member states:

i. to promote stem cell research as long as it respects the life of human beings in all states of their development;

ii. to encourage scientific techniques that are not socially and ethically divisive in order to advance the use of cell pluripotency and develop new methods in regenerative medicine;

iii. to sign and ratify the Oviedo Convention to make effective the prohibition of the production of human embryos for research;

iv. to promote common European basic research programmes in the field of adult stem cells;

v. to ensure that, in countries where it is allowed, any research on stem cells involving the destruction of human embryos is duly authorised and monitored by the appropriate national bodies;

vi. to respect the decision of countries not to take part in international research programmes which are against ethical values enshrined in national legislation and not to expect such countries to contribute either directly or indirectly to such research;

vii. to give priority to the ethical aspects of research over those of a purely utilitarian and financial nature;

viii. to promote the establishment of bodies where scientists and representatives from civil society can discuss different kinds of projects on human stem cell research with a view to strengthening transparency and democratic accountability.

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1. Assembly debate on 2 October 2003 (33rd Sitting) (see Doc. 9902 report of the Committee on Culture, Science and Education, rapporteur: Mr Wodarg; and Doc. 9942 opinion of the Social, Health and Family Affairs Committee, rapporteur: Mr Høie).

Text adopted by the Assembly on 2 October 2003 (33rd Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

2ND PART OF 2004 PARLIAMENTARY ASSEMBLY SESSION

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OPINION NO. 252 (2004)[1]

ON THE DRAFT ADDITIONAL PROTOCOL TO THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE ON BIOMEDICAL RESEARCH

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1. The draft additional protocol to the Convention on Human Rights and Biomedicine on biomedical research is the third in the series of additional protocols to the convention, after those on the Prohibition of Cloning Human Beings (1997) and on Transplantation of Organs and Tissues of Human Origin (2001). The Parliamentary Assembly welcomes this further enrichment of the convention.

2. Freedom of research is necessary for the progress of knowledge. It is part of freedom of thought and freedom of expression, and should therefore be recognised as a human right.

3. The development of knowledge in the field of biomedicine, with a view to saving lives, treating disease and improving quality of life, depends on research, including research on human beings.

4. Such research, however, has both cultural and ethical implications. It must respect the dignity and identity of human beings and guarantee to those who participate in it respect for their integrity and all their other rights and fundamental freedoms.

5. The aim of the draft additional protocol to the Convention on Human Rights and Biomedicine is to increase the effectiveness of the protection of human dignity. It does so without imposing unnecessary barriers to the freedom of research.

6. While understanding the difficulty of agreeing a text which states general principles without entering into details of legislation, the Assembly wishes to draw attention to the fact that a number of points are left open to the interpretation of the member states, which are future parties to the protocol.

7. The Assembly welcomes the separation between the approval of research on the basis of scientific merit (Articles 7 and 8) and the review of its ethical acceptability (Articles 9 to 12). However, the definition of "ethical acceptability" (Articles 7, 9.1, 9.2 and 11.1) remains unclear and vague.

8. While the draft protocol focuses in Chapter III on the independence of the ethics committee (Article 10), it does not specify in any way its multidisciplinary composition (Article 9.2). Yet multidisciplinarity is both a fundamental element of an ethics committee and a strong feature which reinforces the committee's independence.

9. The Assembly also insists on the protection of persons not able to consent, and in particular persons in emergency clinical situations (Article 19.2.ii and sub-paragraph xiii in the appendix to the draft protocol) and therefore recalls Article 6.1 stating that "research shall not involve risks and burdens to the human being disproportionate to its potential benefits".

10. Article 27 (duty of care) states that "if research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them". Yet the question arises as to who will assess the "relevance" of such information. Any given information or data may only become relevant in the light of new scientific discoveries, while before it may not have been considered relevant. An example of this would be advances in the diagnosis of genetic diseases. The Assembly believes that this issue merits further debate.

11. The Assembly welcomes Article 29 which clearly resolves the problem of research initiated in countries with strict jurisdiction but completed in other states with less stringent rules. The provision of this article requires member states, parties to the protocol, to ensure that the same ethical criteria be respected for the part of the research undertaken outside their jurisdiction.

12. The Assembly is in favour of the draft protocol and in consequence recommends that the Committee of Ministers open it for signature as soon as possible. It urges all states signatories and parties to the Convention on Human Rights and Biomedicine to sign it on the day of its opening.

13. The Assembly regrets that twenty-eight out of the forty-five member states of the Council of Europe have not yet ratified or acceded to the Bioethics Convention and urges them to do so as soon as possible. In addition, it would encourage Observer states also to adhere to the principles of the convention and its additional protocols.

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1. *Assembly debate* on 30 April 2004 (16th Sitting) (see Doc. 10121, report of the Committee on Culture, Science and Education, rapporteur: Ms Westerlund Panke; and Doc. 10126, opinion of the Social, Health and Family Affairs Committee, rapporteur: Mr Evin).

Text adopted by the Assembly on 30 April 2004 (16th Sitting).

PARLIAMENTARY ASSEMBLY
OF THE
COUNCIL OF EUROPE

4TH PART OF 2005 PARLIAMENTARY ASSEMBLY SESSION

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RECOMMENDATION 1726 (2005) [1]

SERIOUS HUMAN RIGHTS VIOLATIONS IN LIBYA – INHUMAN TREATMENT OF BULGARIAN MEDICAL STAFF

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1. Five nurses of Bulgarian nationality – Kristiana Vulcheva, Nassya Nenova, Valentina Siropoulo, Valya Chervenyachka and Snejana Dimitrova – were arrested by the Libyan police on 9 February 1999. They are accused of deliberately causing an epidemic by injecting some 426 children at the Al-Fateh Hospital in Benghazi with the Aids virus. Charged with premeditated murder for having deliberately contaminated the children with the Aids virus, they were sentenced to death on 6 May 2004, together with a Palestinian doctor, Dr Ashraf al-Hajuj. The Committee of Ministers and the Parliamentary Assembly severely condemned this verdict which is contrary to the fundamental values they uphold. The Libyan Supreme Court, with which an appeal has been lodged on points of law, will deliver its judgment on 15 November 2005.

2. The Parliamentary Assembly is deeply concerned about the fate of the five Bulgarian nurses and the Palestinian doctor, who have spent over six and a half years in Libyan prisons. It categorically condemns the barbaric way in which they were treated in the first few months after their arrest and the torture and ill-treatment to which they were subjected. It considers that there is no proof of their guilt and that they are being used as scapegoats for a dilapidated Libyan health system. The Assembly is shocked by the attitude of hatred towards them in public opinion, fuelled by certain sections of the Libyan leadership and media which have stirred up public resentment against these five women and this man.

3. The Assembly notes the following:

3.1. distinguished specialists, testifying under oath at their trial, exonerated the nurses and the doctor, showing clearly that the infection had broken out in 1997 at Al-Fateh Paediatric Hospital in Benghazi, in other words over a year before the Bulgarians had come to work there, and that it continued after their arrest; they concluded that there had been a series of accidental nosocomial infections owing to the failure to comply with standards of hygiene, to neglect and to bad medical practices;

3.2. one of the nurses never even worked at the Benghazi paediatric hospital;

3.3. the experts proved that the storage conditions of the bottles of blood plasma used as prosecution evidence were such as to preclude any conclusive biological analysis;

3.4. the numerous breaches of Libyan law (torture, procedural irregularities, etc.) also militate in favour of the nurses' innocence.

4. The Assembly thus concludes that the Bulgarian nurses and the Palestinian doctor should be regarded as completely innocent.

5. The Libyan authorities, sheltering behind the independence of their country's judicial system, take note of the judgments handed down by the Libyan courts, in which the nurses were found guilty and convicted of the crimes of poisoning and homicide, while the Libyans accused of torture were

acquitted for lack of evidence. They consider that the payment by Bulgaria of compensation to the families and the provision of free care for the contaminated children in European hospitals are essential prerequisites for any progress on the nurses' case. The Bulgarian authorities have categorically rejected all of Libya's financial demands, refusing to buy the release of the nurses by paying compensation to the Libyan victims, as this would be tantamount to recognising the nurses' guilt and, beyond that, the Bulgarian State's responsibility.

6. The matter before the Assembly, which is a source of tension in Libya's relations with western countries, is complex. But however complex it may be, it first of all involves two painful tragedies: the plight of some 426 Libyan children contaminated with the Aids virus, 51 of whom have died so far, and the ordeal of five Bulgarian nurses and a Palestinian doctor, who are innocent.

7. The Assembly expresses its compassion for the Libyan children contaminated with the Aids virus and its sympathy with their families. It welcomes the efforts by the European Union and certain states, foremost among them Italy, which have made it possible to bring under control the epidemic that had broken out in the country eight years previously. It strongly supports the Action Plan launched by the European Commission in November 2004 in view of co-ordinating the humanitarian assistance to the infected children.

8. The sick children are now getting treatment. The death sentence passed on five women who are clearly innocent of the crimes of which they are accused in no way relieves the suffering of the children and their families. Libya has nothing to gain by adding a second tragedy to the first.

9. Notwithstanding the efforts over the last year to reintegrate Libya into the international community, the lifting by the United States of the main economic and trade sanctions, the lifting by the European Union in October 2004 of the arms embargo, the signing of agreements on compensation for the victims of terrorist attacks and the willingness displayed by the Libyan authorities to open up and move closer to Europe, as reflected in the visit by Colonel Gaddafi to Brussels in April 2004, no favourable outcome has yet been found to the nurses' and the Palestinian doctor's plight.

10. The Assembly reaffirms its complete opposition to capital punishment, which has no place in the penal systems of modern, civilised societies. The death penalty, even applied to persons found guilty of the most heinous crimes, is a serious violation of universally recognised human rights. The Assembly firmly condemns the execution by Libya on 15 July 2005 of two Turkish nationals who had been sentenced to death. It calls on the Libyan authorities to act swiftly to abolish capital punishment and immediately place a moratorium on executions.

11. The Assembly asks the Committee of Ministers to:

11.1. call solemnly on the Libyan authorities to:

11.1.1. show goodwill and, in a spirit of constructive dialogue, settle the case of the Bulgarian medical team as quickly as possible and in full conformity with the internationally recognised legal norms by which Libya is bound;

11.1.2. release the nurses and the Palestinian doctor or, failing that, implement the judicial procedures through the Supreme Court to guarantee a fair trial so that their innocence is recognised and they be acquitted;

11.1.3. secure full respect for the rights of the defence and, to this end, take scrupulous care to ensure that the duly appointed international lawyers are able to provide their clients with effective assistance, guarantee them regular access to their clients, access to the files and ensure that visas are issued to them in good time;

11.1.4. speedily conduct a serious and thorough investigation into the allegations of torture and ill-treatment of the five nurses and the Palestinian doctor;

11.1.5. adhere to the universally recognised fundamental values of protection of human rights and preservation of human dignity and in particular act swiftly to abolish capital punishment and immediately place a moratorium on executions;

11.1.6. sign and ratify the United Nations optional Protocol to the Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment;

11.1.7. allow Dr Zdravko Georgiev, a Bulgarian doctor and the husband of one of the nurses, to leave Libya;

11.2. call on the member states to:

11.2.1. resolutely support the European Union's action plan, which is an act of solidarity with the contaminated Libyan children, through financial or material contributions, in order to guarantee the rapid provision of humanitarian assistance in Libya;

11.2.2. establish a clear link between the continuation of the process of Libya's reintegration into the international community and the satisfactory resolution of the Bulgarian nurses' and the Palestinian doctor's fate;

11.2.3. take action in all bilateral negotiations with Libya, including trade negotiations, to facilitate a speedy settlement of the fate of the Bulgarian nurses and the Palestinian doctor;

11.3. encourage the Bulgarian Government to continue its dialogue with the Libyan authorities and urge the newly-created Bulgarian NGO to speed up its work with the victims' families.

12. In consideration of the decision to be taken by the Libyan Supreme Court on 15 November 2005, in particular, the Assembly asks the President of the Assembly to send a delegation to Libya to meet with the Libyan head of state and to follow the court proceedings. It considers it useful that its Committee on Legal Affairs and Human Rights continues to follow the development of this issue and report to the Assembly in due time when necessary.

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1. *Assembly debate* on 6 October 2005 (31st Sitting) (see Doc. 10677, report of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Lloyd).

Text adopted by the Assembly on 6 October 2005 (31st Sitting).

PART B

MINISTERIAL CONFERENCES

EUROPEAN MINISTERIAL CONFERENCE ON HUMAN RIGHTS (VIENNA, 19-20 MARCH 1985)

RESOLUTION NO. 3
ON HUMAN RIGHTS AND SCIENTIFIC PROGRESS IN THE FIELDS OF BIOLOGY, MEDICINE AND BIOCHEMISTRY

The Ministers taking part in the European Ministerial Conference on Human Rights, held in Vienna on 19 and 20 March 1985;

Having examined the report submitted by the French delegation on the "protection of human beings and their physical and intellectual integrity in the context of the progress being made in the fields of biology, medicine and biochemistry", as well as the contributions made by other delegations;

Considering that recent developments in the fields of biology, medicine and biochemistry concerning notably techniques of artificial human procreation, tests on human beings, genetic diagnosis, organ transplantation, modification of the genetic heritage and treatment of mental illness, are capable of bringing definite benefits for mankind but may also involve risks for the rights and freedoms of individuals and for society as a whole;

Convinced of the need to evaluate such developments in particular from the standpoint of the protection and promotion of human rights and fundamental freedoms;

Reaffirming in this regard the essential importance of the principle of human dignity;

Reiterating their devotion to the spiritual and moral values which are the common heritage of the people of their countries;

Emphasising the desirability of an international approach to the issues involved, whilst taking into account the specific situation of each country;

Note that there is a growing awareness in different disciples of the important human rights issues raised by recent developments in the fields of biology, medicine and biochemistry;

Welcome the results already achieved and the work in progress within the Council of Europe and its member States, concerning the ethnical and legal problems associated with the above-mentioned developments;

Consider that, faced with these developments, it is important in future work to bear in mind the relevant provisions of the European Convention on Human Rights;

Consider furthermore that thought should be given to the possible recognition, content and conditions of application of certain principles in the fields covered by the report of the French delegation, which deals in particular with procreation, knowledge of one's biological origins, freedom over one's own body and respect for one's genetic make-up;

Recommend that the Council of Europe become the European focal point for work at national level in the areas covered by this Resolution and, in particular:

a) a clearing-house for relevant information, opinions and proposals;

b) a forum for discussion and, if appropriate, joint action at international level;

Recommend that the Committee of Ministers of the Council of Europe, having regard to the above considerations, takes appropriate action to intensify the Council's work in relation to the problems posed, in particular from the standpoint of human rights, both at international level and in the context of national practices and legislation, by progress in the fields of biology, medicine and biochemistry.

17TH CONFERENCE OF EUROPEAN MINISTERS OF JUSTICE (ISTANBUL, 5-7 JUNE 1990)

RESOLUTION NO. 3
on bioethics

The Ministers attending the Seventeenth Conference of European Ministers of Justice (Istanbul, 1990),

Reaffirming their commitment to the principles of respect for human rights, human dignity and the rule of law;

Having examined the "Proposal for a Convention for protection of the human person with regard to biomedical science" submitted by the Secretary General;

Considering that the most fundamental rights of human beings are likely to be affected by the development of biomedical sciences and that it is therefore desirable to promote as much as possible the harmonisation of national laws in this field;

Recalling that, at their informal Conference in Edinburgh in 1985, it had already been recognised that the impairment of the effectiveness of national laws in this area could be prevented by the conclusion of international agreements;

Considering that the universality of the rights of the human person makes it necessary for States to protect these rights in their international context;

Considering that an initiative of the Council of Europe in this sense could stimulate international co-operation in the field of the biomedical sciences;

Referring to Recommendations 934 (1982), 1046 (1986) and 1100 (1989) of the Parliamentary Assembly, which ask the Committee of Ministers to initiate joint action by the member States in the bioethics field,

Recommend that the Committee of Ministers:

I. instruct the *ad hoc* Committee of Experts on Bioethics (CAHBI):

a. to identify as soon as possible the questions to be dealt with as a matter of priority;

b. to examine the possibility of preparing a framework convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences;

II. ensure that the necessary resources are provided for completion of this activity with all due urgency.

PART C

REPORT ON HUMAN ARTIFICIAL PROCREATION

Principles set out in the report of the ad hoc committee of experts on progress in the biomedical sciences (CAHBI, published in 1989)

Principles

I. Scope and definitions

The principles set out hereafter shall apply to the techniques of human artificial procreation, in particular to artificial insemination, to the methods involving the removal of ova such as *in vitro* fertilisation, as well as methods that involve donation of semen, ova or embryos and to acts and procedures on embryos made possible by these techniques.

For the purpose of the application of these principles:

a. artificial insemination means the introduction of sperm into a woman's genital tract by any means other than sexual intercourse;

b. *in vitro* fertilisation means the fusion of an instrumentally removed human ovum with a spermatozoon induced in a culture vessel;

c. embryo means the result of the fusion of human gametes at all stages of development before the foetal stage;

d. donor means a person, other than the surrogate mother, who provides his/her gametes or an embryo for the benefit of another person;

e. surrogate mother means a woman who carries a child for another person and has agreed before pregnancy that the child should be handed over after birth to that person;

II. General conditions for the use of artificial procreation techniques

Principle 1

1. The techniques of human artificial procreation may (subject to the circumstances covered by paragraph 1 of Principle 7 below) be used for the benefit of a heterosexual couple when appropriate conditions exist for ensuring the well-being of the future child and only when:

a. - other methods of treatment of infertility have failed or are not appropriate in the particular case or offer no prospect of success; or

- a serious risk exists of transmitting to the child a grave hereditary disease; or

- there is a serious risk that a child would suffer from some other disease which would result in his early death or severe handicap; and

b. - there is a reasonable chance of success and there is no significant risk of adversely affecting the health of the mother or the child.

2. The techniques of human artificial procreation must not be used for obtaining particular characteristics in the future child, in particular for the purpose of selecting the sex of the child except where, in conformity with sub-paragraph a. of the preceding paragraph, a serious hereditary disease linked with the sex is to be avoided.

Principle 2

Any act required by artificial procreation techniques and procedures carried out on embryos and manipulations connected therewith must be performed under the responsibility of a physician and within an establishment authorised by the competent authority of the state or an authority set up by the state for that purpose.

Principle 3

No person may be compelled or required to take a direct part in the performance of acts mentioned in the present principles to which he/she has an objection on the grounds of conscience.

Principle 4

1. The techniques of artificial procreation may be used only if the persons concerned have given their free informed consent, explicitly and in writing, in accordance with national requirements.

2. Before obtaining such consent, the physician and the establishment using the techniques of artificial procreation must ensure that the persons concerned are given appropriate information and counselling about the possible medical, legal, social and, where relevant, genetic implications of this treatment, particularly, those which might affect the interests of the child to be born.

Principle 5

The physician and the establishment using the techniques of artificial procreation shall make appropriate inquiries and investigations in order to diagnose and to reduce the risk of transmission of a hereditary or infectious disease, or any other factor which may present a danger to the health of the woman or the future child.

Principle 6

The physician and the establishment using the techniques of artificial procreation must keep records of any information needed in order to fulfil or prove that they have fulfilled the obligations imposed upon them under these principles.

III. Storage of gametes and embryos

Principle 7

1. A single person who is at risk of infertility or of another hazard that may impair his or her future procreative capacity may deposit his/her gametes for his or her own personal future use, provided that at the time of the artificial procreation all the requirements set out in these principles are fulfilled.

2. Where a person who has deposited his/her gametes for his/her own future use dies during the storage period or cannot be traced on the expiry of that period, the deposited gametes shall not be used for artificial procreation.

3. Gametes shall not be stored for a period longer than that fixed by national legislation or any other appropriate means.

4. Artificial procreation with the semen of the deceased husband or companion shall not be allowed.

Principle 8

1. Only the minimum number of ova shall be fertilised as is strictly necessary to ensure the success of the procreation.

2. Embryos shall not be stored for a period longer than that fixed by national legislation or any other appropriate means.

3. The destination of embryos stored for the use of a couple for procreation but not used by them may be decided upon only with the consent of both members of the couple.

IV. Donation of gametes and embryos

Principle 9

1. No profit shall be allowed for donations of ova, sperm, embryos or any element collected from them. Only loss of earnings as well as travelling and other expenses directly caused by the donation may be refunded to the donor.

2. A person or a public or private body which is authorised to offer gametes for the purpose of artificial procreation or research shall not gain any profit from such offer.

3. Donations of gametes for artificial procreation shall not be subject to any discriminatory conditions. The donor can, at any moment before their use, require that his/her gametes shall not be used for the initially intended purpose and give instructions about the use which should be made of them.

Principle 10

The number of children born from the gametes of any one of the donor shall be limited by national legislation or any other appropriate means.

Principle 11

1. In principle, *in vitro* fertilisation shall be effected using gametes of the members of the couple. The same rule shall apply to any other procedure that involves ova or *in vitro* or embryos *in vitro*. However, in exceptional cases defined by the member states, the use of gametes of donors may be permitted.

2. The donation of embryos not used by a couple to another couple for the purpose of artificial procreation may be allowed in exceptional cases by member states.

Principle 12

The transfer of an embryo from the uterus of one woman to the uterus of another shall not be allowed.

Principle 13

1. The physician and the staff of the establishment using the techniques of artificial procreation shall maintain the anonymity of the donor and, subject to the requirements of the national law in legal proceedings, shall keep secret the identity of the members of the couple as well as the fact of artificial procreation. Where it is necessary in the interests of the child's health or for the purpose of genetic counselling, information on the genetic characteristics of the donor can be given.

2. However, national law may provide that the child, at an appropriate age, may have access to information relating to the manner of his or her conception or even to the identity of the donor.

V. Determination of maternity and paternity

Principle 14

1. The woman who gave birth to the child is considered in law as the mother.

2. In case of utilisation of sperm of a donor:

a. the mother's husband is considered as the legitimate father and, if he has consented to the artificial procreation, he may not contest the legitimacy of the child on the grounds of artificial procreation;

b. if the couple is not married, the mother's companion who gave his consent cannot oppose the establishment of parental responsibilities in relation to the child, unless he proves that the child was not born as a result of artificial procreation.

3. Where the gametes donation is made through the intermediacy of an authorised establishment, no filial relationship may be established between the donor of the gametes and the child conceived as a result of artificial procreation. No proceedings for maintenance may be brought against a donor or by a donor against a child.

VI. Surrogate motherhood

Principle 15

1. No physician or establishment may use the techniques of artificial procreation for the conception of a child carried by a surrogate mother.

2. Any contract or agreement between surrogate mother and the person or couple for whom she carried the child shall be unenforceable.

3. Any action by an intermediary for the benefit of persons concerned with surrogate motherhood as well as any advertising relating thereto shall be prohibited.

4. However, states may, in exceptional cases fixed by their national law, provide, while duly respecting paragraph 2 of this principle, that a physician or an establishment may proceed to the fertilisation of a surrogate mother by artificial procreation techniques, provided that:

a. the surrogate mother obtains no material benefit from the operation;

b. the surrogate mother has the choice at birth of keeping the child.

VII. Acts and procedures carried out on embryos

Principle 16

The fertilisation of ova *in vitro* and the obtaining of embryos by lavage shall not be permitted for research purposes.

Principle 17

1. No act or procedure shall be permitted on any embryo *in vitro* other than those intended for the benefit of the embryo and for observational studies which do no harm to the embryo.

2. When a state allows, in addition, investigative and experimental procedures other than those mentioned in the preceding paragraph for a preventive, diagnostic or therapeutic purpose for grave diseases of embryos, it shall require that the following conditions be fulfilled:

a. the purpose cannot be achieved by any other method; and

b. the embryo shall not be used after fourteen days from fertilisation, any period of storage by freezing or by any other means not included; and

c. the consent of the couple has been given according to paragraph 3 of Principle 8 and, if the embryo has resulted from fertilisation *in vitro* using donor's gametes, their consent shall also be required; and

d. a properly constituted multidisciplinary ethical committee has given its approval.

3. The splitting of the cells of an embryo may be allowed by member states only in order to use a part of it for diagnostic purpose if it is designed to establish a serious illness or anomaly in the future child and if conditions b, c and d mentioned in paragraph 2 above are satisfied.

Principle 18

The introduction into a woman's uterus of a human embryo which has been subjected to any act or procedure other than those mentioned in paragraphs 1 and 3 of the preceding principle shall be prohibited.

Principle 19

Once it has been implanted, an embryo resulting from fertilisation *in vitro* shall not undergo experimentation *in utero*.

Principle 20

The use of the techniques of artificial procreation to create identical human beings by cloning or any other method shall be prohibited.

Principle 21

1. The placing of an human embryo in the uterus of another species or vice versa shall be prohibited.

2. The fusion of a human gamete with the gamete of another species shall also be prohibited. The same shall apply to the fusion of embryos or other procedure likely to produce a chimera.

3. However, member states may allow the fusion of human and animal gametes for investigation aimed at diagnosing infertility, provided that the development of any resulting hybrid cells ends at the two-cell stage.