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HUMAN GENETICS PROGRAMME  
DIVISION OF NONCOMMUNICABLE DISEASES

Geneva, 15-16 December 1997

**STATEMENT OF**  
**WHO EXPERT ADVISORY GROUP**  
**ON**  
**ETHICAL ISSUES IN MEDICAL GENETICS**

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A meeting of WHO experts in genetics was convened in Geneva, Switzerland, from 15 to 16 December 1997, to review proposed international guidelines on ethical issues in medical genetics and genetic services. An executive summary and full text of the proposed Guidelines will be made available to medical geneticists, genetic counsellors, other health care professionals and interested parties, upon request to the WHO Human Genetics Programme.

The meeting of experts also considered pertinent ethical issues that arise from current research advances in medical genetics, particularly from the international human genome project. The present statement, intended for policy-makers and the general public, highlights the key points of agreement by the group on the issues that it believes should receive urgent attention from WHO and the international community.

The experts felt that the time is ripe for a clear Declaration dealing with the new ethical issues that arise from advances in genetics and reproductive technologies. The following recommendations are meant to initiate discussions with a view to formulating such a Declaration. The recommendations should assist decision-makers at national and international levels to recognize the great potential of advances in human genetics for public health, and to develop policies and practices which will ensure that these new technologies are accessible to all and at the same time are applied with due regard to ethics and justice worldwide.

The advances in human genetics that have occurred during the past 20 years have revolutionized our knowledge of the role played by inheritance in health and disease. It is clear that our DNA determines not only the emergence of catastrophic single-gene disorders, which affect millions of persons worldwide, but also interacts with environments to predispose individuals to cancer, allergy, hypertension, heart disease, diabetes, psychiatric disorders and even to some infectious diseases.

When used properly, this knowledge will be extremely important in helping to achieve better health for people in all countries. However, these advances will only be acceptable if their application is carried out ethically and with due regard to autonomy, justice, education and the beliefs and laws of each nation and community. Genetics teaches that there is no such thing as a "superior" or "inferior" genome; humankind depends for its richness, and indeed its survival, on the interaction of its complex genetic diversity with the environment. With these important concepts in mind, the experts recommend the following to WHO:

#### GENERAL ETHICAL CONSIDERATIONS:

- The medical application of genetic knowledge must be carried out with due regard for the general principles of medical ethics: doing good to the individual and family, not doing harm, offering autonomy of choice in the context of adequate knowledge, and facilitating personal and social justice.
- Ethical considerations of autonomy and justice imply that all applications are carried out in the context of an effective genetics service, including counselling, bearing in mind the stage of economic development and the social traditions of each country.

#### THE PROPER USE OF GENETIC DATA:

- Since we inherit our genes from our parents, pass them on to our children, and share them with our close and distant relatives, every genetic diagnosis, test and procedure involves many people.

- It is ethically imperative that genetic data should only be used to the advantage of members of a family or ethnic group, and never to stigmatize or discriminate against them.
- No law or regulation should permit genetic data to be used to the disadvantage of individuals because of their genetic inheritance.

#### VOLUNTARY USE OF GENETIC SCREENING AND TESTING:

- There should be no compulsory genetic testing of adult individuals or populations.
- Every test shall be offered in such a way that individuals and families are free to accept or refuse according to their wishes and moral beliefs.
- Children shall only be tested when it is for the purpose of better medical care, as in the case of newborn screening for a genetic disorder amenable to treatment.

#### GENETIC SCREENING AND TESTING:

- This should be available as an effective aid to public health planning in any country.
- With a view to eventual appropriate extension within national or regional prevention and treatment programmes, pilot programmes of testing for genetic susceptibility to common diseases such as heart disease and cancer should be based on the ethical principles outlined here. These should form part of public health programmes in both developing and industrialized countries.
- To facilitate equitable access for all to genetic services, WHO should seek consensus on a list of useful gene tests -- comparable to the WHO list of essential drugs -- that comprise essential medical procedures and technology, to be made available to all completely free from patent constraints.
- WHO should promote community education programmes in all countries to raise the level of knowledge of genetics, and should encourage the organization of regional workshops to create expertise in diagnostic and therapeutic approaches, particularly by encouraging collaboration between developing and developed countries.

#### GENETIC TESTING IN PREGNANCY:

- This should be offered to those who request it for relevant medical conditions, but there must be no pressure on couples to accept such testing, nor to use the results of the test to compel either continuing or terminating a pregnancy with an affected fetus. Social and medical support should be available to couples making either choice.
- The ethical beliefs of individuals and the traditions, resources and legal positions of countries differ, but where choices are possible, the ultimate decision on issues of genetics in the context of reproduction rests with those being tested, not with physicians or the government.
- Gene analysis during pregnancy should be confined to testing for medical disorders, and should not include the analysis of normal genetic variation, nor should it be undertaken with a view to fetal sex selection.

- As non-invasive procedures such as ultrasound are used more widely, it is important that health care professionals as well as those being screened should be aware of the possibility that screening may reveal fetal conditions of a wide range of severity. In such cases, genetic counselling should be offered within the contexts of local options, traditions and beliefs.

**REPRODUCTIVE CLONING IN HUMANS** (the use of a genome from an individual to create a new but genetically identical individual via nuclear or cell transfer):

- The potential use of reproductive cloning in humans has aroused fears in the public and has been outlawed by many international bodies. The Meeting of Experts agreed that reproductive cloning in humans would run counter to current international ethical standards. It was further agreed that WHO and many other international bodies are correct in rejecting any intentional step towards human cloning as unsafe and ethically unacceptable.
- Reproductive cloning should not be confused with cell cloning or gene cloning, both of which are of great clinical value in the diagnosis and treatment of disease.

**EQUITABLE ACCESS:**

- Justice demands equitable access to services of high quality for all who are at risk of genetic disease or who could benefit from the prevention of pathology, to the extent possible depending on the economic development of a country. At present, genetic services are well developed only in a small number of countries.
- Genetic services for the prevention, diagnosis and treatment of disease should be available to all, and should be provided first to those whose needs are greatest.
- It is recommended that appropriate strategies be developed in all countries to offer training in clinical genetics and genetic counselling to all health professionals, particularly those working in public health and primary care.

**GENETIC SAMPLES FROM INDIVIDUALS AND FAMILIES:**

- Genetic samples from individuals and families must be handled with respect, should be taken only after consent is obtained and should be used only as stated in the consent document.

**CONFIDENTIALITY OF GENETIC DATA:**

- Genetic data should be treated as highly confidential at all times.
- Such data should only be used to improve ways in which an individual or family deals with the prevention or treatment of a genetic condition. Data relevant to health care should be collected and kept by medical geneticists as secure confidential files, stored separately from such population data as will be required for public health planning.
- Genetic data on individuals should not be given out to insurance companies, employers, schools or governments, other than after obtaining the full informed consent of the person tested. Where necessary, confidentiality and non-discriminatory use of data may be protected by law.

### GENETIC COUNSELLING:

- Counselling entails the provision to individuals and their families of accurate, full and unbiased information, within a professional and caring relationship. Such counselling should offer guidance but should allow those being counselled to arrive at their own choices both before and after genetic procedures.
- Genetic counselling should be available widely, and should be as non-directive as possible, bearing in mind the nature of the condition and the education and culture of those being counselled.
- Genetic counselling is particularly important when pre-symptomatic or predictive tests for severe conditions are being offered, since the results often lead to critical choices for the persons tested and their relatives.

### PATENTING:

- Patenting forms part of the normal process of product development, in genetics as in other medical fields, but the Meeting of Experts is concerned that it has the potential to impede international collaboration, especially between developed and developing countries, to the ultimate detriment of health care for those with genetic disorders.
- Patents on gene sequences should be granted only in the context of inventions of methods or procedures of proven utility.
- If genetic information that results in a patent stems from a family or ethnic group with a particular variant or disease, there is an obligation in justice that the donors should receive some benefit in return.

### SOMATIC CELL GENE THERAPY:

- This form of therapy for those with a specific medical condition is ethically comparable to any other therapy. Research in this promising area should be encouraged, provided that there is neither the intention nor the possibility of altering the genes passed on to children.
- Germ cell gene therapy should not be permitted in the foreseeable future.

### EDUCATION IN GENETICS:

- There is at present little or no education or training in genetics, whether intended for health care professionals or the general population.
- Yet genetics is playing an increasingly important part in medical practice, and in some countries the public is alarmed about possible abuse of this new knowledge. It is important that education about genetic principles relevant to human health should be emphasized appropriately for all people in all cultures.
- Education is a two-way process, and geneticists and other health care professionals have much to learn from support and advocacy groups representing those with genetic disorders.

- Support and advocacy groups are an integral part of genetic services, and should be guaranteed a voice in policy and education.

The experts agreed that there are many variations of experience and belief in different countries and cultures, but would argue strongly that the principles outlined here can apply to all of humankind. For this, it is essential that education in ethics should be included in the professional training of all health personnel, as well as that of educators and other decision-makers with an interest in health policy.

The practice of medical genetics must remain highly ethical, with a full commitment to public transparency and justice. This is imperative to ensure that scientific advances can be deployed without discrimination and in ways that will permit more equitable access to health for all.

The experts urged WHO and its constituents to consider these issues as a matter of priority, to facilitate global consultation and consensus on them, and to ensure that ethical guidelines be adopted nationally and internationally so as to safeguard and promote the public good.

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