OPINION OF THE GROUP OF ADVISERS
ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY
TO THE EUROPEAN COMMISSION

No 4 **13.12.1994**

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THE ETHICAL IMPLICATIONS OF GENE THERAPY

Reference: Commission request for an opinion dated 23 September 1993

Rapporteur: Prof. Luis Archer

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The Group of Advisers on the Ethical Implications of Biotechnology of the European Commission:

- Having regard to the request of the Commission of 23 September 1993 for an Opinion on gene therapy;

- Having regard to the Treaty of European Union and in particular articles 129, 129A adn Article F.2 of the Common Provisions;

- Having regard to the European Regulations in particular the Council Directives on genetically modified (micro) organisms 90/219/EEC and 90/220/EEC and relevant product legislation;

- Taking account of the statements expressed by the European institutions, the Council of Europe, the UNESCO and other international or national ethics committees;

- Having heard the report on "Ethical Aspects of Gene Therapy" by the rapporteur Prof. Luis Archer;

considering that:

1.1 Scientists generally agree that somatic gene therapy is one of the most promising ways of allowing to alleviate, to cure or to prevent a growing number of genetic as well as acquired diseases, including cancer and even perhaps AIDS. Somatic gene therapy has indeed recently entered the clinical setting as a highly experimental therapeutic procedure. An important and long lasting research effort is still required before routinely performed medical applications can be envisaged.

1.2 As somatic gene therapy is highly experimental, the ethical principles to be respected are at the very least all those applying to good clinical practice concerning research involving human subjects (namely, informed consent of the patients with special care for children and incapacited persons, review of research protocols by an independant and multidisciplinary body, such as an ethics committee, proportionality of risks and benefits, confidentiality, etc…). In this respect, there is, concerning gene therapy, a tendency in many countries to reinforce the initial action of local committees by national supervisory bodies.

1.3 Specific regulations concerning genetically modified organisms (directives 90/219/EEC and 90/220/EEC as well as product legislation) have been adopted to fulfill safety requirements. These regulations do apply to certain research and development aspects relevant to gene therapy, but not to clinical trials in the context of gene therapy.

1.4 At its present stage, gene therapy focusses on serious diseases for which there is no other effective available treatment. In the future, therapeutic indications may be widened.

1.5 Somatic gene therapy has not only short tem, but also individual and social long term consequences. Its cost is at present high but could become much lower in the future. In this respect, I should also be in mind that rare diseases are of little interest for pharmaceutical industry compared to more frequent diseases. Both these points raise the problem of equal access to treatment.

1.6 As somatic gene therapy applications are in the long term bound to be quite important, the use of new therapeutical products will be of great interest for the development of European Union biotechnological industry. Public control of the production and distribution processes is already exercised in some European countries and will be influenced by the recently established European Agency for the Evaluation of Medicinal Products.

1.7 Germ line gene therapy, which implies the attempt to cure or prevent tansmission to future generations of gene defects resulting in serious diseases, raises considerable and controversial ethical problems. Although many discussions are already going on in various fora, the scientific basis and the technical feasibility of germ line gene therapy are far from being established. The possible transmission of the modification to future generations raises specific philosophical questions. Therefore, no proposal for clinical experimentation of germ line gene therapy on humans is at present even contemplated.

1.8 There are high expectations raised by the propsect of treating or preventing serious and widespread diseases. The public has often either too high expectations or needless concerns.

The Group Submits to the European Commission the following opinion:

2.1 Somatic gene therapy should be encouraged at different necessary levels (basic research, clinical trials, biotechnology), by supporting research actions (especially at European level by means of the Community Research Programmes in Biomedicine and Health, involving also research on bioethics), organizing training and exchange programmes for researchers and students, and by any other appropriate means.

2.2 The ethical evaluation of somatic gene therapy protocols requires processes assuring quality, transparency and efficiency of this evaluation without introducing any unnecessary delays to the treatment of patients. In addition to local review systems, a national supervisory body is important to evaluate as thoroughly as possible this experimental technology.

The harmonization and partial standardization of all European evaluation processes could be helpful especially for research carried out at European level.

2.3 To consider the specific problems linked to the use of genetically modified orgnisms in the context of gene therapy implies a national or even European control of clinical trials. Relevant regulations for this purpose could be elaborated at a European level.

2.4 Because of its present risk assessment, somatic gene therapy should be restricted to serious diseases for which there is no other effective available treatment. The widening to other possible therapeutical indications could be considered, indication by indication, with an evaluation of the medical as well as ethical aspects.

2.5 Appropriate measures should be taken to assure equal access to gene therapy within the European Union. In addition, according to this equal access principle, a special status could be attributed at European level to orphan drugs and diseases as already done within the Biomedical and Health Research Programme of the European Commission.

2.6 To guarantee transparency and to fulfill the objectives of the European construction by involving the citizens, special regulations should provide for evaluation at European level of the risks and results of gene therapy technology. The conclusions of this evaluation must be regularly published to allow public scrutiny and encourage public debate.

2.7 Because of the important controversial and unprecedent questions raised by germline therapy, and considering the actual stae of the art, germ line gene therapy on humans is not at the present time ethically acceptable.

2.8 It is vital importance that, simultaneously, public information and education are promoted, so that the public gains an objective and correct picture of the possibilities and limitations of gene therapy and related developments. The issue of gene therapy requires a didactic as well as a democratic approach, involving a close participation of European citizens.

In accordance with its terms of reference, the Group of Advisers on the Ethical Implications of Biotechnology hereby presents this Opinion to the European Commission.

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