



*Presidenza del Consiglio dei Ministri*

## **NATIONAL BIOETHICS COMMITTEE**

### **GENE THERAPY**

(15<sup>th</sup> February 1991)

#### *abstract*

The opinion on gene therapy is made up of two separate but closely coordinated reports, entitled *Gene therapy. Technical-scientific report and Characteristics of gene therapy in immunodeficiency diseases from adenosine-deaminasis (ADA deficit)*. The NBC considered it opportune to approve a third document, *General conclusions and opinions of the Committee on gene therapy*, which, on the basis of the scientific notions analytically set out in the above mentioned documents, is aimed at formulating summaries and guidelines in a language that is more easily comprehended by public opinion.

Gene therapy is defined as the introduction of a gene into organisms or human cells, for the purposes of preventing and/or treating a pathological condition. This therapy can aim at correcting genetic defects in cells of the germinal line with effects on the offspring (germinal gene therapy), or can eliminate or reduce molecular effects at the level of somatic cells, with limited effects for the person undergoing it (somatic gene therapy).

Germinal gene therapy presents considerable technical-scientific difficulties and, in the NBC's opinion, is justifiable from the ethical-juridical point of view only if it presents therapeutic features on the basis of the principle of the intangibility of the genetic patrimony of the person. Nonetheless, it is necessary to carefully assess the risks of these practices, since all the corrective interventions carried out on the germinal line with extraneous genetic material, of the same or different species, lead to a modification of the structure and the very organization of the subject's genoma, with unforeseeable consequences in the development of the person and their progeny.

The practicality of somatic gene therapy is on the other hand less problematic, insofar as it is not very unlike other forms of therapeutic intervention and is subject only to the general criteria of any medical assistance, for which reason it must be founded on verified scientific suppositions, precise indications and on the absence of contraindications; it can be carried out in the absence of certainly more efficient alternative therapies and only with the patient's informed consent. Should the therapy be of an experimental nature, there must be a very detailed assessment of the risks to the patient.