



Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

BIOETHICAL GUIDELINES FOR GENETIC TESTING

(19th November 1999)

abstract

The opinion examines the issue of genetic testing which is of particular complexity owing to the broad spectrum of its fields of application and the rapid developments in genetics and molecular biology techniques.

The term “genetic testing” defines a “series of tests aimed at: a) prenatal or postnatal identification of genetic abnormalities in an individual’s DNA, believed to be responsible for serious disease in individuals already with symptoms, or with late onset, that is, demonstrating genetic “susceptibility” and /or with a predisposition to the onset of complex multifactorial disease; b) the typing of DNA regions contained both in the cell nucleus and in the mitochondria, in order to determine the traits that identify each individual, or group of individuals, on the basis of their genetic constitution.”

The first part of the document outlines the state of the art pointing out several general concepts on DNA and the key technologies for its manipulation and describes the different types (diagnostic or symptomatic testing; presymptomatic or preclinical testing; prognostic testing; “susceptibility” or predispositional testing; heterozygote identification testing; and forensic genetic testing) and the various applications of genetic testing in the field of the promotion of health (with particular regard to hereditary diseases, testing and genetic screening in the medical field, and genetic testing on gametes and the pre-implanted embryo), but spanning also in different fields from those concerning the health of the individual or community, with regard to the predisposition to deviant behaviour or to the social sector (including work activities, insurance, and its application for identification purposes). The second part of the document examines the state of the art in Italy for genetic testing, with regard to the operative structures on national territory and the current reference regulations. Lastly, the third part examines the various bioethical problems, first, in general terms and then in specific topic form.

On account of the complexity of the issue the CNB does not adopt general ethical conclusions but draws attention to some important ethical objectives on the subject of genetic testing and screening; genetic counselling; predictive testing; complex behavioural characters; genetic testing in the workplace; the filing of DNA profiles for individual identification. In addition, it provides several specific recommendations on the subject of the Human Genome Project; genetic testing in oncology, genetic testing on minors, genetic testing and work activities; genetic testing and insurance with reference to the problem of genetic discrimination. It is of significance to note that, the document is concluded with its making reference to several principles of the Convention of Human Rights and Biomedicine of the Council of Europe (on the subject of private life and the right to be informed; non discrimination; and predictive genetic testing) and to the Universal Declaration on the Human Genome and Human Rights by UNESCO, whose adoption on an international scale took place at the same time as the completion of this opinion.