



Presidenza del Consiglio dei Ministri
NATIONAL BIOETHICS COMMITTEE

**OPINION ON THE DRAFT
PROTOCOL ON HUMAN GENETICS**

6th of March 2002

After examining the text of the "Draft Protocol on Human Genetics" (CDBI-CO-GT4/RAP.8), produced in the wake of the eighth meeting (6-8 March 2002), the NBC congratulated the Drafting Group for the work carried out, and expressed the opinion that in general terms the text is sufficient for effective legislation on the use of genetic testing as part of the protection of human health.

The NBC believes that it is important to reiterate what has already been expressed elsewhere, namely that every genetic test ordered and carried out in relation to a health condition (either current or potential) should be accompanied by genetic counselling (i.e. a process involving consultation and assistance).

The consultation and assistance provided may, in terms of quality and duration, be in accordance with the gravity of the problem in question and the availability of skilled personnel: in any case, health services should make every effort to prepare staff adequately.

The NBC considers the direct sale of diagnostic kits to the public for self-administration of genetic tests inconceivable, owing to the nature of the situations involved, which may be considered to be against the interests of the patients themselves (application of the principle of precaution).

On the basis of these considerations, the NBC considers that it appropriate to adopt hypothesis B as described in Article 15 of the Draft Protocol in question.

While acknowledging the importance of a Community framework for genetic testing as regards its role in insurance and in the workplace, the NBC poses the question of whether it is advisable at present to subordinate the text on the application of genetic testing to issues more closely related to the protection of health. It is of course clear that the analysis of the Working Group, which is to continue to reflect on the matters discussed, will form the basis of a subsequent protocol.

It does seem, however, to be appropriate, to establish a protocol for review on certain aspects of medical applications, taking into consideration, albeit in broad terms:

- Pharmacogenetic tests
- Testing for verification of mutations caused to the genome and of possible damage from environmental pollutants
- Gene therapy protocols, with (possible) indications for somatic therapy.