Stellungnahme zur öffentlichen Anhörung am 16. Oktober 2000
“Folgen der genetischen Diagnostik”

Stefano Rodotà

1. In EC Directive 95/46 as well as in all national laws of EU Member States concerning personal data protection, a distinction is drawn between “ordinary” and “sensitive” personal data – the latter being granted enhanced protection. Sensitive data are meant as any data disclosing racial or ethnic origin, religious or philosophical beliefs, political opinions, membership of trade unions, political parties or associations, sex life and health. The enhanced protection applying to these data is largely related to the fact that the use of such information may result into social discrimination and/or stigma in respect of the relevant data subjects.

2. The data concerning health are granted special protection among sensitive data, with particular regard to genetic data – indeed, the latter can be regarded as the personal data with the highest degree of protection. This is related to a few features of genetic data that make them different from any other personal data. Indeed, genetic data

- constitute a link between generations, are a common feature of all the individuals belonging to the same biologic line and are therefore, the only personal data that are shared by different individuals on account of their very structure, and
- have a “predictive” aptitude, meaning that their use allows foreseeing an individual’s biological future with variable approximation.

3. In the past few years, international instruments and national legislation recognized the specificity of genetic data exactly in the light of their peculiar features and granted them a different legal status as compared with other personal data. This is why strict rules have been set out in respect of the collection, use and storage of genetic data.
For instance, under Article 12 of Council of Europe Convention on Human Rights and Biomedicine predictive genetic tests are permitted, in principle, “only for health purposes or for scientific research linked to health purposes”. This provisions should be seen in connection with Article 11 of the above Convention, stating that “any form of discrimination against a person on grounds of his or her genetic heritage is prohibited”.
There is an interesting comparison to be made between the legal framework applying to the Council of Europe Convention and that of the Universal Declaration on the Human Genome and Human Rights. Article 6 of the latter states that “no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect to infringe human rights, fundamental freedoms and human dignity”; article 7 further provides that “genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law”. This comparison shows that the protection enshrined in the Convention is stronger that that provided for by the Universal Declaration - for three main reasons. There is an absolute ban on discrimination in the Convention, whereas in the Universal Declaration this ban only applies in case of a breach of specific, though wide-ranging, values; the collection of genetic data is regarded as legitimate by the Convention exclusively with a view to a specific purpose, whereas this issue is not addressed in the Universal Declaration; according

to the Universal Declaration, limitations on privacy protection may be set by the law without any reference to the relevant criteria, which are conversely mentioned in Article 26 of the Convention. In this regard, it should be pointed out that the latter article is framed after Article 8.2 of the European Convention of Human Rights; however, in the article of the Biomedicine Convention the interests related to national security, moral and economic welfare of the country are not included among those possibly justifying a limitation on privacy – which implies that purely economic interests can never justify the reduced protection of genetic data.

4. In analyzing laws and bills in this sector, there are a few legal rules that can be identified as regards genetic data: absolute ban on the collection of genetic data for purposes other than health care and research; lawfulness of genetic testing exclusively in specific cases and/or for specific purposes; lawfulness of genetic testing exclusively with the data subject's consent; prohibitions to use the data; rules applying to access to the data and use of the data for purposes other than the original ones. The background values for these rules can be found basically in fundamental human rights; the approach used for ensuring protection is mostly based on stringent privacy rules.

However, the emphasis on privacy protection is often not enough to eliminate the risks related to data collection – especially whenever there is an actual possibility of discriminatory utilization, which can only be ruled out by providing for a ban on performance of genetic tests. Indeed, the equality issue best summarizes the ethical, social and legal issues in connection with genetic testing. Genetics allows highlighting the ultimate diversity of each person, which strongly argues against any type of racism and promotes the development of a mass individual society. However, this unrelenting revelation of diversity can also be exploited to distinguish, discriminate against, exclude access to opportunities and services for any person showing certain characteristics – by leading to the establishment of genetic normality parameters. Thus, it is fundamental to identify those cases in which not even the data subject's consent can make data collection and/or utilization lawful if the latter can negatively affect human dignity.

These are no groundless concerns, as shown above all by the debate on employment and insurance contracts. Moreover, that there is ground for concern was shown most recently by President Clinton's Executive Order no. 13145 of 8th February 2000 "To Prohibit Discrimination in Federal Employment Based on Genetic Information". Given these premises, the increasing availability of genetic testing and the widespread collection of genetic data require that an assessment be made of the overall legal status of these data. Who is entitled to be in the possession of these data, access them and make them available to others?

In view of the fact that this type of information is shared by various individuals because of its very structure, one should refrain from an individualistic approach in addressing a few regulatory issues applying to genetic data – especially as regards access within a biological group. This item is not taken into consideration either in the European Biomedicine Convention or in the Universal Declaration on Human Genome and Human Rights; indeed, the arrangements applying to data protection would appear to be based on an individualistic approach. A totally different perspective can be found in other instruments which pay greater attention to the current significance of genetic information – see Council of Europe

Recommendation no. R (97) 5, Clinton's Executive Order and the Statement on DNA Sampling by the Hugo Ethics Committee.

Under the Recommendation, genetic data are those data that, irrespective of their type, "concern the hereditary characteristics of an individual or concern the pattern of inheritance of such characteristics within a related group of individuals" . In the Executive Order, the "protected genetic information" also includes that "about the occurrence of a disease or medical condition or disorder in family members of the individual" (sec. 2 (e) C). The Hugo Ethics Committee recommended that "special consideration should be made for access by immediate relatives"- in fact, the latter are given special relevance, since the destruction of collected genetic data is made conditional upon their having no interest in accessing the data.

Based on this concept, in 1999 the Italian Data Protection Commission (Garante per la protezione dei dati personali) granted a lady the authorization to access her father's genetic data against the latter's will. The lady had applied for access to the data in order to take a reproductive decision by assessing the risks of transmission of a genetic disease which had affected her father. The application was granted on the ground that the lady's right to health – meaning bodily and mental health as per the WHO definition - was to override her father's right to privacy. However, this conclusion could only be reached on account of the peculiar nature of genetic data, which are transmitted from one generation to the other and therefore represent a common heritage for different individuals (the Council of Europe Recommendation was expressly referred to in the decision by the Commission).

5. The main issues requiring specific legal rules can be listed as follows:

- purposes of data collection: to be limited to the protection of data subjects' health or else extended to the fight against crime, medical prevention, economic activities;
- reproductive decisions: possibility of using genetic data in order to prevent disease transmission;
- access to data: exclusively available to data subjects; available to their immediate relatives; available to other entities (public bodies, businesses, insurance companies);
- arrangements for genetic tests and setting up of genetic data banks.

Stefano Rodotà is professor of law, Rome "La Sapienza" University.

President of the Italian Data Protection Commission. President of the European Union Group on Data Protection. Member of the European Union Group on Ethics in Science and New Technologies.

Visiting Fellow, All Souls' College, Oxford; Visiting Scholar, Stanford Faculty of Law, USA. Lectures and seminars in many universities in Europe, USA, Canada, Central and Latin America. Books and essays also translated into English, French, Spanish.

Member of the Italian Chamber of Deputies (1979-1994), of the Parliamentary Assembly of the Council of Europe (1983-1994), of the European Parliament (1987). Vice-President of the Italian Chamber of Deputies (1992).

Member of the Convention drafting the Charter of Fundamental Rights of the European Union (1999-2000).