NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES
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OPINION ON DIRECT MARKETING OF GENETIC TESTS TO THE PUBLIC

(July, 2008)

The reflection of the National Council of Ethics for the Life Sciences (CNECV) on direct selling of genetic tests to the public, by the Council's own initiative, under the authority provided by article 1.a) of Law no. 14/90 of 9th June, was brought about by the growing marketing of this type of tests and, namely, its direct to consumer selling by public and private entities, without medical prescription and without genetic counselling.

Although, in general, it aims to cover all types of genetic tests, including their medical and non-medical applications, it deals mostly with genetic tests related to health, and, among them, in particular with those that intend to obtain or result in predictive genetic information.

Considering that,

a) genetic tests are presented today as being usable for medical or for non-medical purposes such as paternity testing, civil and criminal identification, dietary options, choice of cosmetics, athletic performance, behavioural patterns, artistic inclinations and others;

b) genetic tests can determine whether a person is a carrier of a genetic variant causing or increasing the risk for a particular disease, as well as providing the likelihood of adverse reactions to certain medicines, food and other products;

c) for each test presented for medical purposes (diagnostic, predictive, pre-natal, pre-implantation or population screening), as well as for each of the laboratory methods used to perform that same test, evidence id needed that the test is valid and useful, that it fulfils the purposes claimed, and that it can be marketed in a transparent way, without misleading the public;

d) the application of a health-related genetic test usually stems from a medical indication that takes into account the possibilities and limitations of the test, as well as the methods used for each situation;

e) the results of a genetic test often consist of complex information that is hard to interpret, and which often poses difficulties even to specialised professionals;

f) that is the case of the tests for genetic susceptibilities to common diseases of complex aetiology, where there is still little proof of their clinical utility;

g) the difficulties are, therefore, greater in defining precise medical indications for common diseases and to interpret the complex information resulting, but it is precisely those diseases that have the greatest potential for commercialisation;

h) the results of a genetic test may deeply affect life decisions and choices of an individual, of a couple or of relatives of the person tested;

i) at stake may be educational or professional choices, a decision to have a family, prenatal diagnosis and termination of pregnancy, pre-implantation genetic diagnosis, a lifestyle change or a more or less radical treatment;

j) the incorrect interpretation of the results of a test, namely due to lack of prior genetic counselling and of support and guidance after learning the results, may lead to inappropriate or even counter-indicated life-changes and behaviours, and cause psychological suffering and at the family and social level;

k) the essential safeguards to protect patients, families and the population at large, when resorting to genetic testing depend greatly on the type of test and the disease to be tested;

l) in principle, a genetic test is performed only once in a lifetime, as genetic information does not usually change from fertilisation to end of life;

m) lack of strict quality assurance may give rise to serious errors, which may have devastating, irreversible consequences for the persons tested;

n) transborder flow of samples and the proportion of genetic tests performed outside the country of origin are ever increasing;

o) given the impossibility of performing all molecular genetic tests available, public and private laboratories increasingly recur to sub-contracting, often of national or foreign laboratories that offer the best price and shortest waiting time, which may jeopardise quality;

p) sub-contracting and transborder flow are particularly common in direct marketing of genetic tests to the public;

q) direct marketing increases the danger of lack of transparency as to the methods used and their limitations, or as to the laboratory where the test was actually performed;

r) commercial interests give rise to strong advertising pressure, which may sometimes constitute deceptive publicity when claiming results and conclusions they cannot actually provide;

s) quality, transparency (including identification of the laboratory where the test was actually performed, genes and mutations tested, methods used, possibilities and limitations), as well as the test claims and the expectations they create, are aspects of eminent ethical nature;

t) the direct purchase of tests over the Internet may, given the vulnerable means used, facilitate loss of privacy and breach of confidentiality of medical and personal information, as well as of the test results;

u) the health system may become overloaded by people who, having purchased genetic tests directly (without utility or even counter-indicated), then resort to a doctor for clarification or interpretation of the results;

v) the offer of tests to the public should be accompanied by effective regulation, which, above all, should cover medical applications and predictive testing, from their development and the demonstration of validity and clinical utility to licensing of laboratories and verification of advertising and marketing;

w) the use of the Internet and trans-border flow of samples challenge effective regulation, making it necessary to reinforce educative measures for professionals, the media and the general population;

x) harmonization of legislation at the international level is essential, as is cooperation among international regulatory agencies, to enable verification of the whole process;

y) the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, of the Council of Europe), in force in Portugal since 2001, establishes in article 12 that *tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling;*

z) The Council of Europe's approval of the Additional Protocol to the Convention on Human Rights and Biomedicine, on the 7th of May, 2008, with regard to genetic tests for health purposes, which says that they should only be carried out once their clinical utility has been proven and under individualised medical supervision.

The CNECV is of the opinion that:

A. General principles applicable to all genetic tests

1. Transparency and accurateness when performing any type of genetic test are essential to ensure quality control and preserve the confidence of the public.
2. The prior information needed to take a decision to perform a genetic test should be made available in a clear, accessible form, and should include the sensibility, specificity and predictive value of the test, the scientific evidence available for that particular population and the possible implications of its results for the persons tested and their family members.
3. All genetic testing laboratories should incorporate a quality assurance system and guarantee privacy of the users and confidentiality of the information.
4. Genetic testing laboratories should be subject to appropriate licensing, certification of procedures and accreditation of the tests they perform.

B. On the regulation of genetic testing in general

5. Regulation is needed to promote transparency in genetic testing by public and private bodies, namely with regard to the laboratory where the test was actually carried out, the genes, mutations or polymorphisms tested, the methods used and their limitations.
6. Implementation of the legislation in force should be verified, so as to combat incorrect commercial and advertising practices in their relation to the public, namely regarding deceptive actions and omissions in the offer and performance of genetic tests.

7. Health authorities should require licensing of genetic testing laboratories, which should not be based merely on parameters for the general functioning of facilities and qualification of personnel, but also on verification of their quality management system and their certification and accreditation status.

C. Complementary measures

8. Effective education measures on all these issues need to be addressed to laboratories directors and other personnel, and to all those directly or indirectly involved in this activity, as well as to the public in general.
9. Cooperation with regulating bodies from other countries should be promoted, in order to harmonise quality practices and standards.

D. Health-related tests

10. Genetic tests related to health should not be offered without medical indication and personalised supervision, in respect for the principles of beneficence and non-maleficence.
11. In case the test provides or may provide predictive health-related information, it should not be conducted unless genetic counselling is made available, before and after the results.

E. Direct marketing to the public

12. Direct marketing of genetic tests to the public may induce false needs, create undue expectations and bypass the need for medical indication, and, thus, jeopardises the right to genetic counselling and information for patients and the general public, and overloads the health system.
13. When non-medical applications of genetic tests are directly marketed to the public, transparency, fair advertising and quality assurance should also be required.
14. Health-related genetic tests for diagnostic or predictive purposes should not be made available for direct marketing to the public, in respect for the fundamental ethical principles.

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This opinion was approved at the plenary session of 8th July, 2008, in which the following were present: Paula Martinho da Silva, António Vaz Carneiro, Daniel Serrão, Fernando Regateiro, Jorge Biscaia, Jorge Sequeiros, José Pedro Ramos Ascensão, Maria do Céu Patrão Neves, Fernanda Henriques, Marta Mendonça, Michel Renaud, Miguel Oliveira da Silva, Rita Amaral Cabral, Rui Nunes.