Presidenza del Consiglio dei Ministri

ITALIAN NATIONAL BIOETHICS COMMITTEE

ITALIAN NATIONAL COMMITTEE FOR BIOSECURITY, BIOTECHNOLOGY AND LIFE SCIENCES

GENETIC TESTING AND INSURANCE

20th October 2008

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GENETIC TESTING AND INSURANCE

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1. Reasons for the Working group's initiative

The analysis of the issue "genetic testing and insurance" entails an in depth consideration of the relationship between the acquisition, preservation, communication, knowledge of the psychological "background" and the "sensitive data"- as personal genetic data are typically deemed to be – as well as clearly defined economic activities, such as those tackled by the insurance system.

This issue has been discussed a number of times (see bibliography). The Working group, composed of the National Bioethics Committee and the Committee for Biosafety, Biotechnology and Life Sciences decided to offer a further "synthesis" in order to enable the two aforementioned Committees to express an "opinion" that will help to define Italy's position to the Council of Europe Steering Committee on Bioethics (CDBI), which requested a contribution from the delegations of the various European Council Member States on the issue at hand.

In fact, after the Seminar held in Strasbourg in December 2007, the CDBI Bureau decided to carry on analysing the issue with the contribution of each State, in order to draw up a draft "Recommendation" for the Committee of Ministers that would allow to overcome the tacit "moratorium" regime currently presiding over the relationship between the use of genetic tests and insurance activities. Consequently, the problem of the use of genetic testing by private insurance companies is a daily occurrence for the Bioethics Committees of the European Union member States. A few months ago, the Greek National Bioethics Commission expressed an opinion on this topic envisaging the adoption of a formal moratorium on the use of genetic testing by private insurance companies whilst waiting for a specific European directive to be adopted, aimed at reconciling diverse requirements: the high social value of health and the consequent importance of genetic testing for the purposes of:

a) a diagnosis, where possible a cure, and in any case a guideline for prevention, carried out with personalised methods;
b) the rights of the insured with regards to the possible risks of discrimination;
c) the rights and interests of private insurance companies based on the definition of specific risk categories and on overcoming the so-called informative asymmetry.

2. Genetic testing, information, "sensitive data" processing: brief outlines of domestic and European regulations.

Recalling, although briefly, the three arguments mentioned at the beginning does not seem necessary, in light of European and Italian national directives which represent the implementation[1] of the norms stipulated in the field of information.

a) Genetic testing

The issue of genetic testing is not a new issue amongst those posed by biomedical progress in recent years. Evidence of this is the interest shown by various national and international institutional bodies about this topic since the second half of the nineties (whilst the attention of international research bodies and independent groups of researchers towards advances in genetics date back to the first half of 70s), both in the USA, Canada, Japan as well as in several European Countries.

At the international level, we recall the UNESCO Declarations on the Human Genome (1997) and on human genetic data (2002); at the European level we recall in particular the constant focus of the Council of Europe on this issue (with the Oviedo Convention on biomedicine, submitted to the Member States for signature on April 4th 1997; the additional Protocol on genetic testing, adopted by the Organisation's Committee of Ministers on May 7th 2008, which has yet to enter into force; and in the European Union, with the European Union Charter of Fundamental Rights, which forbids any form of discrimination based, in particular, on genetic features (art.21). It is appropriate to also mention the opinion of the *European Group on Ethics in Science and New Technologies* (EGE) of July 28th 2003 on the ethical profiles of genetic testing in the workplace and the recommendations of the European Commission[2].

At the national level, two documents must be pointed out: 1) the Agreement of July 15th 2004 adopted by the Permanent Conference for Relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano containing the "Guidelines on medical genetics activities"; 2) the Guarantor's provision for the protection of personal data "Authorization n. 2/1998 to the processing of data disclosing health conditions and sexual life" and the subsequent provisions n. 2/2002, n. 2/2005 and n. 2/2007, which will be discussed later. Moreover, we draw attention to "Guidelines for genetic testing- Working Group's Report" of May 19th 1998, jointly implemented by the National Committee for Biosafety, Biotechnology and Life Sciences and by the Istituto Superiore di Sanita', and the OECD document "Genetic Testing. Policy issues for the new millennium" of the year 2000.

These two initiatives sought to harness the thriving development of an increasing activity of demand and supply of genetic testing and of laboratories destined to this purpose; an activity that has been constantly monitored by the Italian Society of Medical Genetics and by the Istituto Superiore di Sanita'.

Furthermore, we recall that both Committees taking part in the Working Group scrutinized the issue at hand: on November 19th 1999, the National Bioethics Committee

[1] National delegations were urged to provide- to the CDBI Bureau- concrete elements of information of national origin. The paragraph under consideration meets this purpose, even though it might appear pleonastic to NBC and NCBBLS members.

[2] European Commission – Directorate-General for Research - Information and Communication Unit- 25 recommendations on the ethical, legal and social implications of genetic testing. Recommendation 23. Informed consent. It recognises a patient's "right to know or not to know…In the context of genetic testing, encompassing information procedures, *counselling*, informed consent procedures and communication of test results, practices should be established to meet this need".

adopted the opinion “Bioethical guidelines for genetic testing”, which tackles in depth the complex issue of genetic testing in its various scientific, ethical and legal implications; whilst the National Committee for Biosafety, Biotechnology and Life Sciences adopted the “Guidelines on genetic testing” on May 19th 1998, considering the issue from the predominant angle of “quality” relating to the tests.

Moreover, the NBC- in its document “Biobanks and research on human biological material. Opinion of the NBC on a Recommendation of the Council of Europe and on a document by the National Committee for Biosafety and Biotechnology” of June 9th 2006, takes into account the Council of Europe Recommendation on “Protection of data and of samples of human origin”, Rec. 4(2006), is an organic follow up to the “Supplementary Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research” (Strasbourg 25/11/2005), and concerns the following “Supplementary Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for medical purposes” (approved by the Committee of Ministers in May 2008).

Lastly, the NCBBLS elaborated a reliable analysis on the development of databases, with particular focus on Italy’s potential (see document “Guidelines for the institution and accreditation of Biobanks”, published on December 19th 2005).

b) Information and protection of “sensitive data”

In the 1870-80s a clear focus towards the protection of the human being developed, as opposed to the increasing “invasiveness” into private life due to the spreading of computerized data management, databanks and registers for the most various needs.

Already back in 1971, the Council of Europe entrusted the Committee for Legal Cooperation with the task of examining aspects of civil law according to the development of new computer technologies: these studies led to the Resolution of September 26th 1973 which indicated guidelines for the protection of the private life of individuals with regards to the collection and use of electronic data in the private sector.

Subsequently, with Resolution 74-29 (of 20/12/1974) the protection of the private life of individuals was extended to cover databanks operational in the public sector.

In the period 1975-1980, a number of European States adopted national legislation on this matter. In 1975, the Parliamentary Assembly of the Council of Europe (Recommendation 866 of June 28th 1979) urged the drafting of a Convention, which was prepared and approved on September 17th 1980.

On October 24th 1995, the European Parliament and the Council of the European Community adopted directive 95/46/EC regarding the protection of individuals related to personal data processing and the protection of private life in the sector of electronic communications.

In Italy, the debate on this issue was prolonged, with significant doctrinal and political parliamentary contributions. The Convention was acknowledged with law n. 675 of December 31st 1996. By means of further several legal directives, a Legislative Decree, former statutory decree n. 127/2001 was issued, promulgating the “Personal Data Protection Code” that currently regulates the matter, issued as Legislative Decree n. 196/2003.

Significant moments in this long evolution seem to be:

1) From a doctrinal point of view, the interpretation of the concept of “privacy” no longer as the single (traditional) right to “be left alone”, but as the possibility for an “individual to be aware of, control, direct, halt the flow of information about him/her (Rodotà S., 1984), this denoting the “right to have control of our own information” (Rodotà; 1991).

2) From an operative point of view – with the aim of pursuing the effectiveness, efficiency and timeliness of the measures that might be necessary for the "prevention" of illegalities and in the removal of the obstacles hindering the exercise of the right to control our own information - highlights the institution of the Guarantor's office, which works along the general rules established by law with the aforementioned "Personal Data Protection Code". This leads, where necessary, to a dynamic interpretation of the actual record of cases.

As a result of the abovementioned measures, control of sensitive medical data, including genetic data, is also entrusted to the authorization measures set by the Guarantor, which is responsible for the protection of the "Personal Data Protection Code"[3], including medical data[4].

3. General outlines of the relationship between medicine and insurance.

a) A general preliminary note

On the basis of these records, the Working group aims at examining in depth the epistemological, ethical, legal and medical-healthcare aspects offered by genetic testing in its relation to insurance techniques with regard to life and illness risks.

These are the two sectors that can be involved in the relationship under examination: the first (life) is essentially assigned - at least in Italy - to private Organisations (better known as Insurance Companies), under the articles 1919-1927 of Section III, Book IV of the Civil Code[5]; as for the second (illness) the situation is more complex because it involves not only insurance Companies, but also several Organisations offering "supplementary" insurance policies to economically cover properties and services already supplied by the National Healthcare Services (see Battaglia 1993; Fattore 1993; Piperno 1997, etc.). These are organisations that do not fall so much within the Insurance Company "Model" as within "national insurance" models, welfare funds, cooperatives, company finances etc., in any case devoid of commercial purposes.

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[3] In words, the Code contemplates a Title V titled "Personal Data Processing in Healthcare". Title V is subdivided as follows: Chapter I identifies the general processing principles in Art. 75 "Field of application" and 76 "Healthcare providers and public healthcare bodies". Follows Chapter II "Streamlined methods of information and consent"; Chapter III "Aims of great public interest"; Chapter IV "Medical prescriptions"; Chapter V "Genetic data" including Art. 90 on genetic data processing and bone marrow donors, specifically anticipating: "1.Genetic data processing, regardless of who carries it out, is allowed only in the cases contemplated in a special authorization issued by the Guarantor, after consulting the Ministry of Health, which requests, for this aim, the opinion of the Superior Health Council."; and lastly, Chapter VI "Miscellaneous provisions".

[4] In real terms, the authorizations issued so far are the following: Authorization n.. 2/2002 to the processing of data disclosing health conditions and sexual life; Authorisation n. 5/2002 to the processing of sensitive data by various appointed categories; Authorisation n. 2/2004 to the processing of data disclosing health conditions and sexual life (GU 190 of August 14th 2004 – Ordinary Supplement 141); Authorization n.. 2/2005 to the processing of data disclosing health conditions and sexual life - December 21st 2005 (GU n.. 2 of January 3rd 2006 - Ordinary Supplement n. 1); Authorization n. 2/2007 to the processing of data disclosing health conditions and sexual life - June 28th 2007 (GU n. 196 of August 24th 2007- Ordinary Supplement n. 186); Authorization n. 5/2007 to the processing of sensitive data by various appointed categories – Deliberation n.. 28 of June 28th 2007 (GU n. 196 of August 24th 2007 - Ordinary Supplement n. 186); Authorization n.. 2/2008 to the processing of data disclosing health conditions and sexual life - June 19th 2008 (GU n. 169 of July 21st 2008 - Ordinary Supplement n. 175); Authorization n. 5/2008 to the processing of sensitive data by various appointed categories - June 19th 2008 (GU. n. 169 of July 21st 2008 - Ordinary Supplement n. 175).

[5] For in-depth knowledge, refer to "*Commentario al Codice Civile" diretto da Paolo Cendon, volume IV, art. 1655-2059, edizione UTET, Torino*.

This set of organisations is fairly common in those European countries where, in the past, a "solidaristic" notion of assistance had already been established; however while in France and Belgium, there are fully-fledged National Health Services (provided with specific codes of regulation) affecting 80% of the population in France and 60% in Belgium, in Portugal the amount falls to 7%, in Spain to 5%, and in Italy is 3.4% (1994 data by PIPERNO). In particular, in Italy, funds and company finances have seen a greater development, but always with the function of integrating the public system, of which they follow the fate and the regulations (see Article 9. of the Legislative Decree n. 229issued on June 29th 1999, "Rationalization of the National Health System, the so-called "Third Reform").

This "structural" premise to the current state of affairs in Italy concerns the issue at hand, because an eventual autonomy in regulating the knowledge of the genetic data of the insured could be discussed (as untried hypothesis) more favourably for an "absolutely voluntary mutual assistant", or for (private) insurance companies with commercial purposes, in case these models of assistance provide health services that are completely independent from the National Health Service. It could not be granted, however, to those various organisations, subsidiaries of the public health system recalled earlier.

What has been hypothesised, obviously, is valid under the legislative system in force, except for any eventual, different legal measure of a general nature.

b) Key features of Life insurance from a medical point of view

The propagation of individual insurance policies is increasing dramatically, especially the ones supplementing general welfare and healthcare systems. This rise is linked to the better guarantees offered, to cuts in the services provided by Public Healthcare, to the increase of life expectancy, etc. In recent years, "new" policies have been suggested, different from the traditional ones subdivided into "insurance in case of death", "insurance in case of life", "mixed insurance" (according to the risk: death or risk of survival to a certain date). Now the risk is also extended to the occurrence of some predefined pathologies. These are the so-called "dread disease" policies, which anticipate the liquidation of a monetary reward in the event of a "serious illness" clarified in the contract[6], while the "long term care" policies concern monetary rewards to be allocated when there's a loss of self-sufficiency, assessed according to scores that increase as autonomy decreases to the point of reaching non-self-sufficiency. Without taking into consideration the fact, and in this we have been largely preceded by the United States, that drawing up a life insurance policy acts as a guarantee that can facilitate a loan or buying a property.

According to traditional paradigms, the insurability of certain risks (and the amount of the premium) is allowed by a series of conditions: the probability that the event will occur, the extent of the event, the fact that its unfolding cannot be in any way affected by the insured; moreover, the damage must be identified as an event peculiar to a great number of people even though diversified in whether, how and when it will happen. Risk selection and classification happen through a series of parameters which enable to place the insured in a specific band that corresponds to an insurance premium; the more the assessment of the risk is accurate, the more advantageous is the premium. According to their nature, risks may be categorized as "presumed" (deduced solely from the official age of the insured[7]), "objective" (when age-based selection is perfected by analysing the circumstances that may emerge from the direct or indirect information provided by the

[6] The National Association of Insurance Companies (ANIA) considers "serious illnesses: myocardial heart attack, strokes, malignant tumours, kidney failure, organ transplant, etc. Other companies add blindness, multiple sclerosis, Alzheimer's disease, AIDS, serious mutilations, etc.

[7] Elaborated by ISTAT, they enable death and survival estimates in the upcoming years for a certain age.

insured: biological, work-related or not, environmental, inferred from the anamnestic questionnaire attached to the insurance policy, from clinical tests, from medical documentation). The insurer will be able to request further tests to be carried out by a physician trusted by the insured (usually in case of high-capital policies or in case the age of the insured at the time of taking the policy is around 60) through a medical check-up and clinical tests varying according to the different policies: from lipid determination, to glycaemia, to testing positive for hepatitis viruses; more rarely, specific investigations on the cardiovascular system, from blood pressure to ECG.

In exceptional cases and for large capitals, markers to detect neoplastic diseases, mammography tests, etc. can be requested. Cotinine (a metabolite of nicotine), an excellent screening for smokers, is not researched in our Country.

The "real" risk is the one that actually exists and that the insured conveys to the company when drawing up the contract. Jurisprudence stated the principle according to which the insurance contract is valid only if there is a correspondence between objective risk and real risk[8].

If the risk is high, the company may charge an additional premium, exclude a number of risks from the cover, reduce the contract's validity period in order to limit the possibility for the insured event to occur, or even reject the candidate from the insurance contract. Essentially, they are called standard risks, substandard risks and non-insurable risks, which correspond to specific premium bands. Reticence may cause the contract to be invalidated.

The Company can request for the insured to sign a declaration addressed to his/her physicians, releasing him from professional confidentiality with regards to pre-existing pathologies undisclosed when stipulating the contract. It goes without saying that this clause caused considerable controversy and now, after decades, tends to be dropped also due to the fact that the authorization to disclose a secret does not correspond to the physicians' obligation to reveal it. Yet, it is the beneficiary's obligation, contractually established, to provide the documents necessary to assess the damage, otherwise the benefit will not be paid.

Misrepresentation and any reticence of the contracting party relative to circumstances that, if known by the insurer, would lead to the consent not being granted, are cause for the contract to be invalidated, if the contracting party has acted fraudulently or with gross negligence (Art. 1892 c.c.)[9]. Article 1893 regarding misrepresentation and reticence without fraud or gross negligence, entitles the insurer to rescind the contract[10].

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[8] Supreme Court, May 16th 1975 n. 1917.

[9] Misrepresentation and reticence with fraud or gross negligence. The misrepresentation and reticence of the contracting party, relative to such circumstances that, if the true state of affairs had been known by the insurer, he/she would not have granted consent or not given it under the same conditions, are cause for the contract to be invalidated when the contracting party acted fraudulently or with gross negligence. The insurer loses his/her right to contest the contract if, within three months from the day he/she became aware of the statement's inaccuracy or of the reticence, he/she does not reveal to the contracting party the intention of contesting it. The insurer is entitled to the premiums relative to the outstanding insurance period at the moment of requesting the cancellation and, in any event, to the premium agreed upon for the first year. If the damage occurs before the time indicated in the previous paragraph has elapsed, the insurance company is not bound to pay the amount insured. If the insurance involves a number of people or properties, the contract is valid for those people or properties not affected by the false statement or the reticence.

[10] Misrepresentation and reticence without fraud or gross negligence. If the contracting party acted without fraud or gross negligence, the misrepresentation and the reticence are not cause for the contract to be invalidated, yet the insurer can rescind the contract, by means of a statement to be communicated to the insured within three months from the day in which he/she has known about the misrepresentation and the reticence. If the damage occurs before the moment the misrepresentation or the reticence become known to the insurer, or before he/she declared the intention to rescind the contract, the amount due is reduced in proportion to the difference between the agreed premium and the one that would have been applied if the true state of affairs had been known.

4. Concrete questions formulated by the Working group to look into the relationship between genetic testing and insurance in more depth

Given these premises and in light of the insurance practices highlighted, it seems relevant to examine a number of profiles critical to the relationship genetics/insurance.

Particularly, a number of "technical" questions have been raised which it seems appropriate to answer first:

- Are genetic data comparable to medical data, which are usually required as contractual obligation from the individuals stipulating an insurance contract?
- Which, amongst the various genetic tests for diagnostic and predictive purposes, hold particular interest in defining risk criteria, that is the explicit object of insurance, aiming at establishing whether a particular pathology will develop and in what length of time (or whether it is merely a "generic predisposition" to the manifestation of a specific pathology, or whether some tests allow a more accurate quantitative assessment and temporal prediction of the risk)?
- What sort of reliability is offered by the current techniques of variant (mutations) identification and what correlations exist between them and genetic pathologies?
- What technical and clinical reliability must be required for the correct contractual and legal use of genetic testing (actuarial reliability)?

To these technical-biological questions, we must add legal questions:

a) Should we arrive at the use of genetic testing for insurance purposes, could insurance companies request a validation system for individual tests and/or a certification system for the centres where the tests are performed)?

b) Would the legal obligations of "transparency" and "good faith" (true statement) indispensable for the drafting and definition of the insurance contract with regard to "risk" (life and disease) be applied – eventually - also in the hypothesis of requesting information on the contracting party's genetic make up?

c) Can the issue of genetic testing lead to acts of discrimination among individuals, being detrimental to their dignity or privacy and to their interests?

d) Could the refusal to insure, the requests for higher premiums, contractually ruling out "the right not to know", within an absolutely "voluntary" private contract (autonomously requested by the contracting party) be a legitimate conduct (according to contractual clauses) exercised by private insurance Companies?

5. Insurance contract and genetic data: general aspects of the problem

The questions formulated earlier led the Working group to the elaboration of the following general considerations, as premise to a more in-depth study of specific aspects which will be considered in paragraphs n. 6, 7, 8, 9 and 10.

1. The most controversial point in current evaluations regards the thesis of the comparability of genetic information and other medical data, a thesis that implies the arguments in favour of a positive judgement on the eventual request, by private insurance companies, both "*to be informed of and to take into account the results of genetic tests already carried out by policy holders",* and "*of the possibility to request that they undergo genetic testing*".

It is a very controversial idea that can, moreover, be confirmed also by the *Twenty-five recommendations on the ethical, legal and social implications of genetic testing,* drawn up in 2004 by the European Commission's group of experts. In this document we consider unfounded the idea that genetic data, *rigorously used for medical purposes* (*as is also*

prescribed by the Additional Protocol to the Oviedo Convention on genetic testing) and strictly confined to the individual's health, is different from other medical information *that may be obtained with different methods*; *nevertheless* we recommend, *in any event*, to acknowledge and take into consideration the widespread perception on the difference of these data, which is due to a variety of factors such as: the current prevalence of predictive genetic tests for rare monogenic diseases which may disclose information particularly sensitive for the patient's family, the fact that there are no cures for the majority of monogenic diseases, the fear for the potential loss of control over samples etc., *as well as the possibility to extend information to past and future genealogic line.*

In contrast, in the majority of national, European and supranational documents there is an explicit recognition of the peculiarity of this category of "sensitive" data. The arguments in favour of granting them a different legal status refer to the atypical nature of genetic information that, if it defines an individual in his/her genetic uniqueness, it also connects him/her to other individuals belonging to the same hereditary line, to the same "biological group"; and this makes even more delicate the issue of regulating access to these information and of their circulation and (S. Rodotà *Il corpo tra norma giuridica e norma sociale*, in Preta, L. (edited by), *Nuove geometrie della mente. Psicoanalisi e bioetica*, Laterza, Roma-Bari 1999).

In particular, it seems that two aspects of this peculiarity must be highlighted, with regards to the issue at hand:

a) The fact that, for a number of tests, there is a close link between knowledge and prediction, since genetic information allows an early knowledge of some aspects concerning our own biological future, either in terms of greater susceptibility compared to the norm, to develop certain diseases (or also of resistance to them), or of predestination to falling ill and premature death;

b) The fact that genetic identity is a relational identity, as personal genetic information is structurally shared in some way with other individuals belonging to the same "biological group", so that knowledge about our own genome can also entail the acquisition of information on other blood-related relatives who may not be willing to grant their consent.

Given all this, we can conclude that the identification of the specific object of hypothetic insurance interest should be restricted to the "predisposition tests", which fulfil mainly the concept of risk for the person concerned and leave (more than other tests according to the typology mentioned above) up to the insurance any uncertainty.

The "diagnosis" of an ongoing genetic disease, the "prediction" of its manifestation (see for instance, Huntington's Chorea) and also the identification of "healthy carrier" status, have certainly things in common with the life-disease insurance profile in the first two cases and with the health of the offspring on the basis of marital choices in the last. It seems however difficult that – at least in the last case - the insurer might be interested in offering risk protection contracts or to accept such a request.

Furthermore, it must be pointed out that even the (potential) interest for the condition of predisposition outlined in certain statements found in insurance literature, is not shared by the majority of geneticists. In fact, mere genetic predisposition seems to be insufficient to determine exactly the manifestation of a pathology, whereas specific physiological and environmental conditions also significantly affect the evolution of the subject's health.

Ultimately, it seems necessary to differentiate between diagnostic, predictive and susceptibility genetic testing, avoiding to reconcile to a single category different instruments with a dissimilar level of effectiveness. The risk, in the current state of scientific and technological knowledge seems to be an overestimation of the usefulness of genetic testing (think, for instance, to the importance that, according to some, these distortions increasingly have in the workplace).

2. An element of considerable and significant importance is the delicate psychological aspect linked – at the moment - to "genetic testing".

The reservations harboured by many about including genetic data in the insurance contract do not seem to derive, mostly, from a lack of understanding of the function of genes, nor from the fear of "discriminatory" social side-effects towards the so-called "virtual patients", once the specific protection currently enjoyed by the category of data under discussion is withdrawn. These reservations cannot be considered completely groundless[11], but there is another aspect – (which goes beyond the problem of the inevitability or not of higher premiums for the so-called "virtual patients", a form of discrimination towards the most vulnerable citizens) which involves instead delicate psychological profiles, of ethical and legal importance. We cannot keep from asking ourselves to what extent being aware of our own genetic predisposition to certain diseases and perceiving ourselves, and being perceived by those closest to us, as individuals "at risk", predestined to an unfavourable destiny, may affect and influence the development of our own sense of ourselves, our self-esteem and identity, constraining life choices beforehand, both society's and our own. This, in a world in which image and social acceptability are increasingly dependant on the possibility/ability to adjust to the dominant models of corporeal efficiency, health, physical and psychological "normality".

In one of his most well-known essays of the seventies, the philosopher Hans Jonas had already emphasized, as a shocking novelty in ethical theory, the emergence of a new moral "right": that of ignoring our own future, invoked in defence of the free construction and definition of the sense of self. Because what our new knowledge puts into question is the respect of *"the right of every human life to find their own path and to surprise itself*", in line with the ancient precept *"Know thyself"*, as *"the discovery of the self stemming from that precept is exactly the process of self creation, parallel to that of knowing itself through life trials; a process that "the knowledge" would in this case hinder* (H. Jonas *Philosophical Essays. From Ancient Creed to Technological Man*, University of Chicago Press 1974).

It's along these lines that, in recent years, not only the right to self-determination with regard to information, as an expression of personal freedom, but also the new "right" "not to know", have been increasingly consolidated, in our case, the right not to know information relative to our own genome, including genetic predispositions, if this lack of knowledge is considered to be a condition of the free creation of self, that is, of our own existential freedom. The request by private insurance companies of knowing personal genetic information as a prerequisite to the contract, would consequently impinge also on the right of the person involved "not to be informed" (as sanctioned by the Oviedo Convention).

3. A third aspect regards rather the concern - expressed in several documents and recommendations on the issue of the relationship between genetic testing and insurance market - of a possible negative social side-effect, in terms of "social right to health", of the eventual opening to requests by the insurance companies to be informed of the results of genetic tests already carried out.

[11] There are surveys and reports showing how people who, according to their genetic profile, can be classified as being at a higher "risk" of disease and/or premature death, have been or are more vulnerable to "discrimination" when getting into the work market and in relationships; and this I think can be the case, at first analysis, also with regards to the fruition of goods such as health and life insurance: in fact, some of them could be deemed to be uninsurable, or insurable only on condition of paying much greater higher premiums, so that it foreshadows a further decrease in opportunities for subjects genetically at risk (see L. Andrwes., D. Nelkin, *Body Bazaar*. *The Market of Human Tissue in the Biotechnology Age*, Crown Publisher, New York 2001; but also *Report On Genetic data in private insurance* attached to the document *Opinion on the use of genetic data in private insurance* drafted by the Greek National Bioethics Committee).

These requests, were they to become legitimate, could discourage the donation of biological samples aimed at researching new treatments for serious and disabling diseases and/or at reducing the number of volunteers in pharmacogenomics research, which should instead be encouraged in the name of a wider social interest: that of improving our collective health.

6. Further clarifications on the relationship between genetic testing and insurance.

As further clarification of what already discussed in paragraph 5, the profile of the relationship between genetic testing and insurance is here examined according to the perspective of the majority of human genetic experts.

a) Amongst the heterogeneous group of genetic tests, only a few seem to be at this time worthy of attention, in view of their potential use in relation to the issue of insurance techniques for the risks related to illness and life. In particular, it is possible to identify three main groups:

1. The first category regards genetic testing aimed at analysing mutations (modifications to the genetic inheritance) that intervene in a direct relationship with an illness; these are mutations which may appear already at birth (congenital diseases) or at different ages during our lifetime, always entailing a cause-effect relationship, insofar as they unavoidably give rise to pathology patterns, if the patient lives long enough (e.g. familial hypercholesterolemia, Huntington's Chorea, polycystic kidney of the adult type).

2. The second category concerns mutations characterised by a penetrance defect. This term identifies the existing relationship between the number of people who display a mutation at the clinical level and the overall number of people who carry that mutated gene. In practice the penetrance defect identifies how many people carrying a mutation are likely to fall ill during their life. For instance, it is estimated that only about 70% of the women who inherit the mutation in the BRCA1 gene, associated with a hereditary form of breast cancer, are likely to fall ill during their life. The mechanisms affecting the penetrance defect are not yet fully defined, but they seem to be linked to the genetic background, to somatic mutations that may arise during the course of a lifetime and to the effect of the environment.

3. The third category regards common mutations (the so-called polymorphisms, which have a frequency of over 1% in the general population), which, acting in addition to other common mutations and to the environment, trigger a certain multifactorial disease. Each one of these mutations confers, therefore, a susceptibility or predisposition to the illness but, individually, it usually determines only a minor component of the risk.

The first two categories of genetic testing can be assimilated to *diagnostic* tests (those carried out on a person who has or is suspected to have a genetic disease) and to *presymptomatic* testing (those carried out on people who have, in their family, a history of late on-set illnesses; therefore they are usually not "patients" but healthy individuals; a pathological outcome of the test means that this person will inevitably develop the disease at a certain time in his or her life).

The third category of genetic testing can be assimilated to *predictive* tests, those identifying susceptibility or resistance to a disease, different from what is average in the population.

b) Further consideration must be given by the general issue of family anamnesis and, specifically, to the presence or absence of precedents relative to a disease which must eventually undergo monitoring in the form of genetic testing. It is quite clear that genetic diseases or those with a significant genetic component are family-centred. Therefore, the existence of precedents in the family guides clinical, instrumental and laboratory (including genetic testing) investigations in a specific direction. In particular, the very nature of a considerable number of genetic tests allows the identification of a risk that can be quantified even many years before the illness can be recognised clinically (e.g. presymptomatic tests). On the other hand, an individual belonging to a family with Mendelian risk (i.e. 50% theoretical chance to have inherited a disease-gene, such as the polyposis of the colon) may become aware, by virtue of the results of genetic tests, if he/she will need to continue undergoing serial investigations during the course of his/her life aimed at monitoring the risk, or whether he/she will be able to avoid them, in case the test result is negative. These considerations apply both to disease-genes with complete penetrance, and to those with reduced penetrance.

c) In the event that family anamnesis is negative and the insured denies the presence of serious pathologies, at the moment it does not appear very realistic to suggest a set of screening tests relative to Mendelian disease-genes. In practice, these diseases cover a great number of rare and highly heterogeneous conditions, for which it is unrealistic to hypothesise carpet investigations capable of guiding such research, in the absence of an indicative family history.

A similar reservation regards the usefulness of researching common genetic polymorphisms and with a low individual impact on the determinism of common diseases (cardiovascular, hypertension, diabetes, etc.).

d) However, this situation could drastically change in the next 5 years. Technological development, coupled with our knowledge of the genome, indicate in fact the possibility of obtaining low-cost individual genomic analysis (about $100). It is not however clear if, to what extent and how the information gathered could be used.

In October 2007, the complete genome sequence of Craig Venter, the coordinator of the human genome sequencing project financed by private capital, was published.

Within his 23.224 genes and variable regions, including a number of polymorphisms, were identified variations conferring susceptibility to antisocial behaviour, alcoholism, coronary heart disease, hypertension, obesity, insulin-resistance, myocardial hypertrophy of the left ventricle, acute myocardial infarction, insufficiency of lipoprotein lipase, hypertriglyceridemia, stroke, Alzheimer's disease. We may wonder whether Craig Venter is a particularly unlucky person. The answer is absolutely negative. Venter's genome sequence illustrates, in effect, an "imperfect" genome shared by everyone, for the only reason of being a representative of the human species. It is in fact common knowledge that any person, randomly chosen, is heterozygote, that is, a "healthy carrier" for a considerable number of mutations (44% of Venter's genes was heterozygotic for one or more variations). A scant number of these mutations concern genes that are responsible for usually rare diseases, whereas many hundreds of thousands of variations involve genes connected to complex diseases (polymorphisms), which have a minor additive effect on their phenotype. It is difficult at this time to say what impact such an extensive

genomic analysis at the insurance level will in theory have on calculating the risks regarding illness and life.

e) Moreover, it is apparent that the idea of transferring this type of genomic analysis to the insurance field is not realistic. If genetic testing is in many ways comparable to other medical investigations, when it analyses a single Mendelian gene, which accurately measures a cause-effect relationship between a mutation and a disease, it becomes problematic when considered in the context of its intra-family ties. It is in fact common knowledge that a mutation can be transferred, on average, to half of first-degree blood relatives. If the information collected on an individual with regard to a single mutated gene can in itself become problematic for the potential traceability of that mutation amongst the relatives, the availability of genomic information would cause, in effect, unmanageable problems in terms of the potential violation of personal and family privacy.

7. Genetic testing and hypothetical obligations of the parties in insurance contracts

Resuming the examination – in order to be thorough – of the other technical-legal queries listed in paragraph 4, it seems appropriate to acknowledge that a pure and simple transposition of the information expected for regular medical data, in conformity with the principles of transparency and good faith, between insurance contracting parties, should be taken into consideration in the case of genetic tests, with particular attention to the "peculiarity" of the legal issues which could arise from this test category, if national or European regulations were to authorize their use.

In the first place, the increase of the information available to the insured would be a relevant factor for all types of health insurance, including both illness insurance and medical expenses insurance, and, although in partly a different way, life insurance.

From the point of view of bargaining dynamics, now settled through the acceptance and signing of a "questionnaire" (suggested by the insurer) by the contracting party, for common health information, the most significant aspects of the problem might involve two different situations: 1) the eventual obligation of the insured to provide the insurer with any known information about genetic tests previously carried out, and 2) the eventual obligation to undergo genetic tests upon request of the insurance companies.

Even Italian literature, as, on the other hand, most international literature, lays doubts about establishing such obligations because of the interference that the private interests involved (we refer in particular to the insurer's interests) would have on the contracting party's right to health – legally of a higher order and fundamental under the National Constitution (well-known Art. 32), and to the nature of "sensitive data", those concerning the health of the insured (in line with the Privacy Code adopted with Legislative Decree n. 196/2003), the processing of which may take place, under Art. 26, not only on the basis of a written consent by the person concerned, but also after the Guarantor's authorisation.

More specific instructions can be found, in fact, in the Guarantor's General Authorization n. 2/2002, reiterated by General Authorization n. 2/2008 (effective until December 31st 2009), in which the authorization to process data disclosing health conditions and sexual life was issued, in line with paragraph 1.2, letter e): "to physical and legal persons, enterprises, firms, associations and other bodies, only with regards to data, where necessary also related to sexual life, and to crucial operations aimed at fulfilling also pre-contractual obligations derived from a relationship with the individual concerned based on supplying him/her with goods, benefits or services". Furthermore, it made clear: "if the relationship involves credit institutions, insurance companies or securities, only data and operations necessary to provide specific goods or services requested by the person

concerned are to be considered essential". From this provision, it was inferred the non-existence, beyond the fulfilment of precise contractual obligations currently in force, of any obligation incumbent on the insured to give the insurer information about the results of genetic tests he/she underwent previously or to undergo any eventual tests upon request of the insurer.

In addition, there is no clarification for the opposite situation: that is, when it is the insured who wants to provide the insurer with "genetic health certificates"[12], in order to promote the drawing up of more favourable risk contracts: this is a hypothesis dear to the supporters of "individual autonomy", although it must be assessed also according to the interest or the social damage that this hypothesis could cause.

8. Genetic tests, insurance risk and discrimination

After outlining the situation with regards to the obligations which may arise in insurance contracts in case the use of genetic testing was allowed, it seems relevant to also take into account the discrimination profiles that could follow such a decision.

In general terms, the notion of a legal discrimination becomes relevant in all those circumstances where a different treatment of individuals in the same conditions is deemed unjustified or unfair due to specific criteria. On the basis of the notion of fairness developed by John Rawls in *A theory of justice* (1971), the following definition has been suggested: "Discrimination is the uneven treatment of individuals not justified by good reasons. These may justify a different (economic, social, moral, political) treatment only on condition that such dissimilarity does not violate a fair equality of opportunities for all the individuals concerned. A different treatment entails a 'discrimination' if it diminishes the fair equality of opportunities, namely if it makes it more difficult for certain individuals to access opportunities normally available to all under fair conditions". This "risk" is among the most feared ones, not only for premium definition purposes, but for working conditions; all having possible repercussions on the individual's health[13].

Discrimination is apparent if it diminishes the fair equality of opportunities; namely if it makes it more difficult for certain individuals to access opportunities normally available to all under fair conditions; nonetheless, the concept would not be applicable to uneven treatments which – on the basis of significant ethico-legal reasons - became necessary to offset initial individual disadvantages[14].

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[12] It is a temporary expression that should mean the absence of any evidence of serious prognostic risks, as specified in paragraph 6 of this treatise.

[13] An absurd interlink may occur: an individual refusing to undergo testing could be denied access to eventual therapies, whilst the test result could, in contrast, lead to a reduction or annulment of the insurance cover needed for the treatment (O'Neill). As reported by Rodotà, 30% of women who were offered, by a company in Ohio, a free test to assess their predisposition to breast cancer, refused for fear that their employer or insurer would find out the possibly damaging results and therefore discriminate against them when stipulating a policy. It may also happen that individuals who believe they have a low chance of developing a pathology, refuse stipulating an insurance contract causing an imbalance in the system (*free rider*).

[14] It is useful to quote a number of bibliographical references in further support of the thesis that uneven treatments are called for by the very concept of "equality", but always on the basis of significant ethico-legal reasons, generally aimed at offsetting initial disadvantages; otherwise we must talk of discrimination in the sense mentioned above.

The first reference is a "classical" text of moral philosophy dating back to the past century, which foresaw many of the issues subsequently tackled by the liberal-democratic theories of justice: Bernard Williams' essay on the idea of equality (*What is Equality?*, in *Id Problems of the self*, 1973), where it is stated that the assertion of the political-legal idea of equality implies that any difference the treatment man must be justified on the basis of a general reason, or of a principle of differentiation, but under the further condition that the reasons are morally significant and socially operative.

9. Fairness, privacy and risk distribution in genetic testing for insurance purposes.

Except for the remarks about the different typology of genetic tests, their different level of reliability and their diagnostic value - expounded in the previous paragraphs - fairness and privacy issues linked to the use of such tests in insurance may be briefly summed up as follows.

The potential insured can be split into two groups: a) those who have already undergone genetic testing, and b) those who have not. Within the first group, it is necessary to make a distinction between those who have had an outcome which reveals a "genetic condition" in the current state of knowledge (a1) and those for whom testing did not reveal any genetic anomaly linked to a certain pathology (a2). The distinction between these two groups is difficult to make in practice, both because the notion of "genetic condition" is ambiguous (it may be a single gene disorder, where testing is tantamount to a positive diagnosis, or a gene-related predisposition with different degrees of probability of developing a pathology, or a mere susceptibility to certain pathologies, hence a condition difficult to classify as pathological) and because the real confines of these conditions are unclear. Furthermore, it is possible to hypothesise that the gradual refining of genetic diagnosis techniques will progressively increase the number of people for whom such testing reveals some kind of "anomaly": expanding our knowledge on the genome increases the "conditions" identified by the relevant tests. The extreme limit of this situation is the complete mapping of every individual's genetic make-up, which would portray for each of us an individual "condition" that could only partially be assimilated to general features. The critical point is that people's genetic configuration can be linked more or less directly to pathological conditions. As this is a *continuum*, we must imagine a sort of statute fixing, in broad terms, what type of genetic profiles may be considered related to pathologies and which ones may not. A certain degree of consistency and changeability in time seems unavoidable here, as is always the case when it comes to distinguishing between health and illness.

Nevertheless, if we distinguish between "genetic condition" (group a1) and health as revealed by testing (a1), we have a fundamental distinction. Currently, a certain number of individuals hold this information about them and can decide to conceal it from the

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The second refers to the entry Equality (*Eguaglianza*; *Diritto*, in *Enciclopedia delle scienze sociali*, volume III) by the constitutionalist Alessandro Pizzorusso; it is stated that it is the same principle of substantial equality - expressed in paragraph 2c, Article 3 of the Constitution, regarded as a super-regulation in the entire constitutional text -, which requires differentiated treatments in favour of the most disadvantaged individuals, aimed at easing the effects of former oppressions and/or inequalities originated in the injustice of nature.

In this entry the term "discrimination" is used in its Latin meaning, axiologically neutral. In fact, Pizzorusso talks of a "syndicate of the reasonableness of discrimination", referring to the Constitutional Court's verdicts on fair/unfair "differentiations-discriminations" of treatment anticipated in the law.

The third refers to the essay on *Freedom and Equality* by Norberto Bobbio; in this text, social equality of opportunity is acknowledged as the core principle of the Social State, a breakthrough principle that can require differentiated treatments on condition that they serve as a tool to overcome initial inequalities, namely as an instrument of effective equality.

Behind these stances, there is the idea that the principle of equality must always take into account the many individual diversities not subordinate to subjective choices: in this case, the randomness of placing people in the distribution of "natural fundamental goods" and the fact that the most unfortunate ones, from this point of view, are faced with additional costs. A compensation for such non-selected costs should therefore be always contemplated to give people equal opportunities.

In this perspective, it is also clearer the morally significant difference between the worsening of the risk of illness, due to specific behaviours, i.e. smoking, and the worsening due instead to a particular genetic endowment (except then proving that maybe there can be a predisposition to smoking).

insurance companies when stipulating a life or health insurance contract. Therefore, this generates a state of *information asymmetry*.

At the moment insurance companies, due to the prohibition of acquiring genetic data, treat the whole population in the same way, distributing the risk in an undifferentiated manner on everybody. The availability of easily accessible tests has created a situation previously unheard of.

For those individuals diagnosed with a genetic condition, not disclosing these data means finding themselves in a "favourable" situation in the sense that they pay exactly the same as everyone else for services they know they will use with more probability and frequency. Information asymmetry plays in their favour. Nevertheless, we must take into account that these individuals are in an unfavourable condition from the point of view of their health and that their healthcare needs are greater compared to others. These individuals are in the position of being potential *free riders* of the insurance system, which they hope will cover costs that they, unlike others, are more likely to incur. For these individuals it is convenient that the risk is shared amongst the whole population, since they benefit from it. However, this advantage derives from information asymmetry and it is penalising for both insurance companies and other individuals.

However, those individuals whose tests do not reveal any pathological anomalies (group a2) know that they are paying for a service they are unlikely to use. And they know that a number of individuals, those who instead have a pathological condition and have been tested (group a1), are aware of the fact that they will use the resources available. Group a2 individuals are therefore "supporters" of a system they are less likely to benefit from. It is however possible that they are unwilling to be part of this system or that they are keen to reform it.

It is to be noted that the current situation is very different from the one where, through public healthcare, it is *compulsory* to support a system that aims at offering free medical care to the indigent and adequate services to all, as an expression of social healthcare (Art. 32 of the Constitution). The justification for public levying through healthcare taxation is profoundly different from the economic *trade-offs* regime that supports the private insurance system, which is entered into *voluntary*.

Companies spread the risk indiscriminately across the population, but for this reason they cannot offer specific cover for the peculiar issues concerning the different categories.

Therefore, this situation can generate a progressive *loss of trust* in the insurance system: the dissemination of more accurate, easy and reliable tests would lead to an increase in both the number of *free riders* and the number of those who refuse to access the system. Moreover, it is probable that this generates a progressive depletion of the resources shared by the insurance system, because the incentive to act as *free riders* is very strong indeed (services can be obtained at a lower cost, even if unfairly). Privacy protection on genetic data, if meant to also prevent the disclosure of the results of tests *previously undergone*, can set off this spiral of mistrust. Furthermore, the situation of unfairness generated by the *free riders* cannot be remedied if information asymmetry persists, namely if the genetic data already known by the individual concerned remains absolutely private.

These considerations point in favour of a specific ethical-prescriptive theory (Theory n. 1): for reasons of general fairness and in order to safeguard the fairness of the private system of insurance cover, previously undergone diagnostic tests (the argument must be formulated differently with regard to predictive ones) should be disclosed for the purpose of stipulating a life or health insurance policy.

Here, individuals have already decided to know their genetic condition and intend to use it in a way that, in this case, gives them an advantage.

On the other hand, as previously recalled individuals who have a genetic condition need more care and therefore incur higher healthcare expenses: this situation worsens if the existing difficulties are coupled with a higher insurance premium. This raises an important social issue: the proportional relationship between the covers by private insurance companies and Public Healthcare. Individuals, who have a genetic condition and are aware of it, may be willing to pay slightly higher premiums, yet if there is also an increase in other social security or other types of costs, their condition becomes objectively more and more difficult. It is here that the solidarity function of the public system must be stressed, supported and clearly distinguished from the private insurance system, *which in itself and according to its statutes belongs to the world of private enterprise even though - in those Countries with a public welfare system - it competes with the principle of social solidarity underlying such initiatives*. The loss of "fair equality of opportunity" deriving from a genetic condition cannot be counterbalanced by the private system, but by the public *welfare* system (at least if the safeguards suggested by the liberalism of fairness apply. In Nozick, Engelhardt or Charlesworth libertarian perspectives, these safeguards are excluded).

The condition of those who have not undergone any genetic testing makes up a third group of individuals (group b). With regards to them, insurance companies distribute the risk in the event of a lack of information on genetic profiles. Distribution is determined, so to speak, by nature. In this situation we are on a level that we could call "natural equity": nature's lottery distributes genetic conditions which are only taken into account in insurance premiums as general statistical data.

In this situation it may at first sight seem sensible to suggest taking a test before the contract: knowing our genetic profile, we can therefore be assigned to one of the two groups (let's say "worst-off (Wo)", namely individuals affected by genetic conditions – group b1, and "best-off (Bo), that is, "healthy" individuals – group b2) and pay in proportion to the probability of using the services. Nevertheless, the abovementioned considerations about the progressive worsening of the situation for individuals with a genetic condition make it less reasonable, for these individuals (group b1), to consent to being tested. That is, if testing is requested, it may result in having to pay lower or higher premiums, but the situation created by the genetic condition, once diagnosed, is very problematic, so that it ultimately seems more reasonable to refuse being tested. Now, as it is unacceptable to force people to behave in an unreasonable way, this means that we cannot make it compulsory to undergo testing and that the right to refuse being subjected to it remains. This corresponds to exercising "the right to not know" (more specifically: not wanting to know the results of eventual tests) and also the right of privacy (more specifically: refusing to undergo testing). More in general, the condition of no access to genetic data represents a sort of "veil of ignorance" aimed at ensuring fairness in uncertain conditions, as anticipated by Rawls' liberal theory.

Now, if these considerations are valid, it seems that we must draw the following prescriptive interpretation:

Theory n. 2: it is not reasonable to request carrying out genetic testing *ex novo* as a precondition for insurance contracts (if tests have not already been carried out) because this does not improve the condition of the individuals, who seem to be better protected if the situation of not knowing their genetic condition remains.

It follows that insurance companies would be (morally, and on the grounds of fairness) entitled to request the results of genetic tests already undergone (theory n. 1) but not to request carrying out and disclosing new tests (theory n. 2).

This situation seems to be the same as that in force in some countries (England, Switzerland, Germany, Holland), where regulations state that it is unlawful to request new

tests, that diagnostic tests already known to the individual must be disclosed, whereas predictive testing previously undergone must be disclosed at least if the capital insured exceeds a certain threshold.

Here, the protection of fairness depends essentially on the protection of *information symmetry,* which is a precondition both to mutual trust among individuals and to the functioning of the system. Where there is information asymmetry ("genetically informed" individuals *versus* "blind" companies regarding genetic data) we must re-establish fairness *at the base* of such a difference; where there is information symmetry (no-one knows anything about genetic data), the *status quo* stands as the rule.

This conclusion may be debated on many grounds. Above all, this situation appears transient and it will be largely modified by the development of genetic testing techniques, by their growing reliability and by their social dissemination (often brought about by the dynamics of a market that is already very active in this field). Secondly, if the aforementioned considerations are valid, it would seem that the situation leads to a certain "economy of information" on genetic conditions: after all, it is better not to know and therefore not to undergo tests the result of which, once obtained, should be disclosed in the event of a contract. Since if I choose to know my genetic profile I must then disclose it to the insurance company, which could apply a higher premium, it is reasonable to prefer to know nothing and rely on the nature's lottery. It is possible to object to this, insofar as the lack of information on the genetic profile may be a disadvantage to the individual concerned: for instance, when the knowledge of a certain genetic profile, maybe suggested by a health condition shared by the family, would enable carrying out preventive therapies or suitable lifestyles. If on the one hand it seems senseless to deny access to genetic information to the people concerned, extending it to third parties in a contractual situation must be adequately motivated and in particular with regards to the benefit for the individual concerned.

A fairly realistic consideration is that the dissemination of testing, already growing vertiginously, will increase further. Accordingly, information asymmetry will considerably affect the private insurance system (as the prohibition of knowing genetic data is still in place). If this situation results in generally boosting premium costs for health insurance, it is possible to argue that this is prejudicial to a system that overall helps to maintain certain fairness: in fact, to a degree the private system compensates the limitations of the public system - *as previously recalled*. It is for this reason that the issue of the relationship between public healthcare and private insurance remains delicate and complex. A*nyhow the Working group did not intend in any way to undermine any efforts in favour of purging the environment of those situations that could - together with conditions of genetic susceptibility – create circumstances of greater danger for specific individuals. On the contrary, it stresses the need to carry on with commitment any possible cleansing of the environment and protection in the workplace.*

10. Current point of view of insurance companies

Approaching the conclusion, it is worthwhile to highlight that insurance companies – today - confer crucial importance to the principle of information symmetry between insured and insurer. In fact, if this principle is violated the insurance company can suffer significant losses due to adverse selection by the insured. Individuals in poor health conditions are driven to insure themselves and act in a way that is adverse to the insurance company by not revealing specific health conditions ("*non disclosure"*) or by making false statements ("*misrepresentation")* in order to pay a lower premium or even to be granted a cover that otherwise they would not be able to obtain because non-insurable.

To offset the power that information gives the insured, the insurer needs to make a selection of the risk ("underwriting") in order to classify the risk, namely assess whether the risk is insurable and, if it is, in which risk category/class ("pool") it can be included. Otherwise, the individuals at greater risk would be inclined to take out an insurance for a higher capital, if the premium is equal, and this would lead to an increase in the overall average risk, which would cause a generalised rise in premium rates at best, or it would jeopardize the financial dependability of the insurance company, in extreme cases. Following a rate increase, those who are less in need of an insurance cover (corresponding to the so-called best risks for the insurance companies), could decide to avoid taking out an insurance, since they are not willing to pay too high a price; therefore the proportion of the "worst risks" would increase, which would exacerbate the average mortality rate of the group, setting off an unstoppable vicious spiral of premium increases.

In assessing the quality of the risk proposed, the insurer tends to gather all the information he/she feels is necessary to carry out an effective evaluation of the potential factors of deterioration so that the risk remains, although still unpredictable, within a tolerable margin of uncertainty. About this, it is important to point out that the insurer has only one chance to assess the risk and this happens at the proposal stage. Life insurance policies typically have a medium-long term duration, even a whole lifetime, and it is necessary to estimate the probability of events that can occur also in the long term on the basis of the information available when signing the contract, which then cannot be modified for all of its duration.

From the perspective of cost optimization, the risk-selection process is carried out at different levels which essentially depend on the amount insured. The higher the amount, the more accurate must be the documentation necessary to assess the risk: from a simple health questionnaire to a medical check-up, blood tests, electrocardiogram and thoracic X-ray. In fact, the insurer must fix subscription requirements so that they are *cost-effective*, namely effective and with a cost that is in proportion to the benefit. According to a number of data circulated by insurance companies, indicatively, more than 94% of individual policies are issued without a medical examination but with only a simple health questionnaire or a statement of good health. Therefore the percentage of individual policies subjected to medical examinations is lower than 6%.

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11. Conclusions

After the previous considerations, it appears impossible to draw well-grounded, definitive and shared solutions regarding an eventual use of genetic data for insurance purposes.

It seems appropriate, in any case, to attach to this report an "information file" on the rules adopted by a number of European countries.

The user (insurance candidate) does not seem willing to accept the "constraint" of having to submit genetic certificates in order to obtain a life and/or health insurance contract, but he/she would maybe not be against submitting – on his/her own free will - genetic certificates of "normality"[15] with regards to certain pathologies, if from this derives a clear financial benefit (premium reduction).

[15] See footnote 12.

Insurers invest in resources and capital to translate in probabilistic terms, useful for actuarial calculations, information deriving from medical research and they constantly update the starting point of their calculations in order to use increasingly more objective, relevant and reliable data to determine the cost of the cover. However, to this aim they consider genetic data as common medical data and, also taking into account future medical advancements and a foreseeable increase in the use of genetic testing in clinical medicine in upcoming years, today they push for their use in actuarial calculations, with the purpose of gathering experience on the "positive" contribution that such data could provide in better defining the risk. Obviously, they are not against taking precautions to protect information, as it is anticipated for "databanks".

In particular, insurance companies intend to develop specific research in order to verify the actuarial relevance of testing and review the criteria and statistical basis of risk classification, with the cooperation of geneticists and other experts to interpret the complex statistics arising from scientific studies. They state that the results of genetic testing will be taken into account only if their technical, clinical and actuarial relevance is proven.

In addition, they believe that it is particularly important to highlight the potential risks for the insurers due to the still considerable definition problems in genetics, in a condition of legislative constraints such as the current one. Experts themselves do not always agree in establishing what effectively constitutes genetic information and which genetic tests have real predictive value.

Moreover, in this situation of uncertainty, the insured could feel that they do not need to disclose pathological results of tests commonly carried out in medical practice since a number of them have a genetic component. Therefore, insurance companies hope for a review of the law in favour of the use of genetic testing and at the same time for the use of a simple, clear and shared terminology in this delicate subject.

Facing this composite scenario, the Working group makes a final consideration: behind the issue outlined by the "specific case" of the use of genetic testing for insurance purposes lie broader assumptions on the relationship between the market and "privacy" (as previously defined).

While the market system – currently also promoted in Europe - pushes for the inclusion of the knowledge of individual genetic situations in setting up premiums, in order to create markets that better respond to real situations of risk, the legal issues that burden the legal system and do not necessarily concern the market, e.g. the protection of the individual, his/her autonomy, his/her rights and also his/her different predisposition to diseases, would lead – today - to ruling out the introduction of the knowledge of the genetic status in insurance negotiations.

This is not only due to the fear of an uncontrolled disclosure of "sensitive" personal information but also to the limited contribution in terms of predictive certainty (in the current state-of-affairs) with regards to genetics and the prevailing attitude of solidarity of the European healthcare law: today, it results in a rational attitude that does not necessarily require the supplying of genetic data. However, this does not rule out further reflection founded on the solid basis of scientific research - and on the field - of the actuarial advantages that – for the entire community - are likely to arise in the future from the introduction also of some genetic data in a fair "bilateral" information process, ethically due between the counterparts.

Synthesis and Recommendations

In recent years, a very articulated international debate developed on "Genetic tests and insurance", based on the prediction that genetic testing would become, in a relatively short

time, a common practice in healthcare services. This expectation has only partially materialised, therefore the fears about the use of genetic testing by insurance companies are greatly exaggerated, at least in our Country.

However, a number of International Organizations and National Ethics Committees gather “opinions”, in the hypothesis that a European discipline might become necessary for a wider, future use of genetic testing in the insurance field.

In the complex situation described above, which is also in constant transformation, the Working Group feels that it is appropriate to recognise that - rather than a hasty and global legislative solution - *at the moment* a common practical and temporary solution should be sought, *attainable through non-legislative criteria that - operating in the spirit of mutual trust, transparency and in the context of the European debate* - on the one hand ensures that people who are genetically predisposed to certain diseases are not discriminated against when taking up an insurance policy and - on the other hand - guarantees protection to the insurance companies from the dangerous consequences of anti-selection, *which would prejudice the availability of a fair and adequate “prize money” for the large population concerned*.

The working group:

- **Waiting for a greater scientific knowledge than the one currently available,**
- **Anticipating that – in any case - it is not appropriate to penalise the dissemination of genetic testing for medical purposes for fear of negative consequences with regards to insurance,**
- **Wishing to give its contribution to the request for an opinion formulated by the Steering Committee of the Council of Europe during the meeting held in Strasbourg on the 3rd-4th December 2007,**

recommends:

- **That a moratorium regime about the use of genetic testing for insurance purposes is clearly defined in those Countries that have not yet decided upon it, waiting for the conclusions drawn by the European debate;**
- **That insurance companies set up a self-regulation code, previously approved by the competent authorities and properly publicised, on the basis of which:**
- **Insurance companies commit themselves to guaranteeing the protection of personal data in line with the modalities anticipated in current regulations;**
- **Insurance companies do not demand that the client undergoes genetic testing in order to be insured.**

***Moreover, for the sole purpose of contributing to a programme of voluntary experimental access for a fixed length of time, aimed at evaluating the practical importance that the introduction of some genetic data into the health form as a self-declaration, a form already in operation in the phase before stipulating the insurance contract, the working Group recommends that, where the self-regulation Code anticipates it,* it is not forbidden to insurance companies, upon stipulating the insurance contract, to request and have access to the results of <u>diagnostic genetic tests</u> already undergone by clients and known to them, for any amount of money insured.**

***Finally, if upon the client's request, the insured amount exceeds a certain threshold (to be decided), it should be possible for insurance companies, when stipulating the insurance contract*, to request and have access to the results of presymptomatic genetic tests already undergone by clients and the result of which is known to them.**

The Working Group also recommends that the Higher Health Council is entrusted with the evaluation of presymtomatic genetic tests and of their reliability and relevance for insurance purposes.

INFORMATION FILE

Approach in countries that have taken into account the needs of insurance companies

In these countries the situation can be sinthetised in the following points:

- insurance companies do not require undergoing predictive genetic testing
- diagnostic genetic testing already undergone must be communicated for any amount of money insured
- predictive genetic testing already undergone must be communicated starting from a certain insured amount

We briefly summarise in outline the situation in some important markets. For further details see the documents mentioned in the notes.

United Kingdom

In the United Kingdom the self-regulation code introduced in this sector is the result of a cooperation between the insurance industry, represented by the ABI (Association of British Insurers) and Government advisory bodies like the Genetics and Insurance Committee (GAIC) and the Human Genetics Commission (HGC).

The GAIC's taks is to develop technical, clinical and actuarial criteria to evaluate predictive genetic testing, their application to certain conditions and their reliability and relevance for particular types of insurance. The HGC must inform ministers about the ehtical, legal and social implications of the development of genetics and their effect on helathcare and the appropriateness of the law applied to human genetics.

In the UK is in force the "Concordat and Moratorium on Genetics and Insurance"[16] of March 2005, which is an agreement between the British Government and the ABI, the details of which can be found in an articulate and complex document. According to the general principles of this agreement, insurers can receive and take into account the results of predictive genetic testing only if such testing has been approved by the GAIC and if the cumulative insured amount per person is higher than:

- £ 500,000 for the cover in case of death
- £ 300,000 for the Dread Disease (serious illness) and disability cover in capital form and £ 30,000 per year in annuity form.

[16] *Concordat and Moratorium on Genetics and Insurance*, HM Government and Association of British Insurers, March 2005, http://www.abi.org.uk/Display/File/Child/106/Concordat_and_Moratorium.pdf

Testing must have a technical, clinical and actuarial relevance. Until now the authorisation of the GAIC has been requested and obtained only for the Huntingdon Chorea.

In the document it is stated that: "*diagnostic testing falls into the same category as other clinical technologies. The Concordat is concerned only with the far smaller number of tests used to predict future illnesses."* It is also stated that: "*The Concordat preserves the principle that, unless otherwise agreed, insurance companies should have access to all relevant information to enable them to assess the price risk fairly in the interest of all their customers. So, if a customer for life insurance knows (from medical information, family history or tests) of a specific risk to his or her health, it should in all normal circumstances be disclosed. If the risk is not disclosed, the insurance company may face more, and more costly, claims thanit was able to assume in setting the price of its insurance policies. This could potentially affect the future pricing or availability of insurance cover to all."*

As well as this, the ABI periodically publishes a "Code of Practice for Genetic Tests"[17], which regulates the insurers' use of the results of genetic tests.

Germany

In Germany[18] a moratorium similar to the UK is in force:

The restrictions regard only predictive and not diagnostic testing. The threshold is € 250,000 for capital tariffs and € 30,000 for annuities. For benefits starting from this amounts there are no restrictions on predictive testing.

In the document it is highlighted that genetic testing for the diagnosis of existing illnesses are already in common use and an indispensable tool in medicine and therefore they are not subjected to restrictions. For predictive testing however, the use of which is still unclear in the medical field, a threshold of benefit is introduced, below which these tests are not taken into consideration by the insurance company, recognising that a predictive genetic test interferes profoundly with an individual's life.

On the other hand, it is recognised that insurance companies must protect the community of insured from any abuse in obtaining a private insurance cover, if the client has unilateral information on the probability of an illness manifesting itself. There is a risk of abuse especially in the case of high amounts being insured or of high annuities. Therefore, in the case of contracts guaranteeing insurance cover exceeding the levels established in the document, insurance companies must have the same level of knowledge of the results of previous predictive genetic tests as their clients, so that they can calculate fair premiums adequate to the amount insured. Naturally, predictive genetic testing must be handled in the full respect of the regulations on sensitive data and with even more restrictive rules.

Holland

In Holland is in force a moratorium that regulates pre-symptomatic tests with a threshold of € 160,000 for capital policies and € 32,000 (for the first year) and € 22,000 (in the following years) for disability annuities.

Switzerland

[17] ABI Code of Practice for Genetic Tests, June 2008, www.abi.org.uk

[18] Voluntary formal commitment of member companies of the German Insurance Association (Gesamtverband der Deutschen Versicherungswirtschaft e. V. – GDV) 18th of July 2003

Switzerland has introduced a law similar to the moratorium in UK and Germany. The threshold for predictive testing is CHF 400,000 for capital tariffs and CHF 40,000 for disability annuities. No restrictions for diagnostic genetic testing.

Hong Kong

In Hong Kong there are no limitations but it is a general rule to take into consideration the results of tests already undergone if their reliability and relevance to the specific insurance product is proven.

Note: the threshold levels depend on the market and namely on the number of contracts and of the amounts insured. In the UK they are particularly high because the market for life insurance is very developed, unlike in Italy.

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