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e le Scienze della Vita**

## **GENETIC TESTING AND INSURANCE**

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**Prof. Adriano Bompiani**, Presidente onorario del Comitato Nazionale di Bioetica (cordinatore)

**Prof. Bruno Dallapiccola**, Ordinario di Genetica, Università La Sapienza di Roma

**Prof. Luca Marini**, Docente di Diritto Internazionale Università La Sapienza di Roma, vice-presidente del Comitato Nazionale di Bioetica

**Prof. Monica Toraldo di Francia**, Docente di Bioetica, Dipartimento di Filosofia, Università di Firenze

**Prof. Giancarlo Umani Ronchi**, Ordinario di Medicina Legale, Università La Sapienza di Roma

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**Prof. Giuliano D'Agnolo**, Dipartimento di Biologia cellulare e Neuroscienze, Istituto superiore di sanità, vice-presidente del Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita

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**Prof. Roberto Mordacci**, Professore di Filosofia Morale, Facoltà di Filosofia, Università Vita-Salute San Raffaele, Milano

**Prof. Angelo Santoliquido**, Docente Università Cattolica del Sacro Cuore, Roma

**Prof. Emilio Tosi**, Professore di Diritto Privato e Diritto dell'Informatica, Università di Milano Bicocca

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**Dr. Ivano Giacomelli**, Consiglio Nazionale Consumatori e Utenti

**Dott.ssa Patrizia Marocco**,

### **Per la struttura di supporto**

**Dott.ssa. Agnese Camilli** (coordinatore)

## GENETIC TESTING AND INSURANCE

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### **1. Purpose of the Working group’s initiative**

The analysis carried out on the issue “genetic testing and insurance” entails an indepth consideration of relations between acquisition, storage, communication, knowledge of the psychological “background” and “sensitive data”- as personal genetic data are deemed to be - moreover, well-structured economic activities, such as the ones dealt with by the insurance system.

This issue has been covered a significant number of times (see bibliography). The Working group composed of the National Bioethics Committee and the Committee for Biosecurity, Biotechnology and Life Science decided to provide a further “synthesis”, to enable the two aforementioned Committees to give an “opinion” that may help to define Italy’s stance within the Steering Committee on Bioethics of the Council of Europe (CDBI) following the latter’s request for a contribution from the delegations of the several European States on the issue at hand.

Consequently, after the Seminar held in Strasbourg in December 2007, the Bureau of CDBI was determined to go on with the issue analysis by virtue of the effort of the single States in order to draw up a draft “Recommendation” addressed to the Committee of Ministers that would allow to overcome the tacit “moratorium” regime currently underlying the relationship between the use of genetic tests and insurance activities. Accordingly, the problem of the use of genetic testing by private insurance companies is a daily issue faced by the Bioethics Committees within the Member States of the European Union. A few months ago, the National Bioethics Commission of Greece gave its advice on the topic envisaging the adoption of a formal moratorium on the use of genetic tests by private insurance companies while waiting for the adoption of a European specific discipline aimed

at reconciling diverse requirements: the high social value of health as well as the related significance of genetic testing with the purpose of:

- a) a diagnosis, a treatment if possible, and in any case a guideline towards prevention, carried out through custom-made modalities;
- b) the rights of the insured party with respect to possible risks of discrimination;
- c) the rights and interests of private insurance companies based on the definition of specific risk classes and on the overcoming of the so-called informative asymmetry.

## **2. Genetic testing, information, “sensitive data” processing: brief outlines related to the domestic and European regulations.**

Briefly recalling the three main issues in summary form proves useful in light of the European and Italian national discipline which embodies the implementation<sup>1</sup> of the norms stipulated in the field of information.

### **a) Genetic testing**

Genetic testing does not disclose a new issue among the ones stemming from biomedical progress in recent years. Evidence thereof may be seen in the interest shown by various institutional bodies at national and international levels ever since the second half of the nineties (while the attention of international research organisms and independent groups of researchers towards advances in genetics date back to the first half of 70s), in the USA, Canada, Japan as well as in several European Countries.

At the international level, it is worthwhile recalling the UNESCO Declarations on the Human Genome (1997) and on human genetic data (2002); particularly, at the European level, the steady attention the Council of Europe has given to the issue should be borne in mind (with the Oviedo Convention on biomedicine, submitted to the Member States for signature on April 4<sup>th</sup> 1997; the supplementary Protocol on genetic testing adopted by the Organisation’s Committee of Ministers on May 7<sup>th</sup> 2008, which has yet to enter into force; and at the EU level with the Charter of Fundamental Rights of the European Union which forbids any form of discrimination and especially on the ground of genetic features (art.21). It is appropriate to mention the opinion of the *European Group on Ethics in Science and New Technologies* (EGE) of July 28<sup>th</sup> 2003 on the ethical profiles obtained by

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<sup>1</sup> National delegations were urged to provide- to the CDBI Bureau- tangible informative elements of national source. The section under consideration matches this purpose, even though it might appear unnecessary to the members of the NBC (National Bioethics Committee) and to the NCBLS (National Committee for Biosecurity, Biotechnology and Life Science).

genetic testing at work as well as by the recommendations of the European Commission<sup>2</sup>.

At the national level, two documents must be pointed out: 1) the agreement of July 15<sup>th</sup> 2004 adopted by the Permanent Conference for Relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano containing “Guidelines on medical genetics activities”; 2) the Guarantor’s provision for the protection of personal data “Consent n. 2/1998 to the treatment of relevant data to disclose health status and sexual life” as well as the following provisions n. 2/2002, n. 2/2005 and n. 2/2007 that will be discussed later on.

Moreover, it is worth indicating the “Guidelines for genetic tests- Relation by the Working Group” of May 19<sup>th</sup> 1998, jointly implemented by the National Committee for Biosecurity, Biotechnology and Life Science and by the Superior Institute of Health, as well as 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 the increasing demand and supply activity with regard to genetic testing and to the establishment of ad hoc laboratories; this activity has been constantly monitored by the Italian Society of Medical Genetics and by the Superior Institute of Health.

Furthermore, it is necessary to recall that both Committees taking part in the Working Group scrutinized the issue at hand: on November 19<sup>th</sup> 1999, the National Bioethics Committee adopted the opinion “Bioethical orientation for genetic testing”, which tackles in depth the complex issue of genetic testing as regards its various scientific, ethical and legal implications; while the National Committee for Biosecurity, Biotechnology and Life Science adopted the “Guidelines on genetic testing” on May 19<sup>th</sup> 1998, considering the issue from the predominant angle of “quality” related to tests.

Moreover, the NBC- in its document “Biobanks and research on human biological materials. The opinion of NBC on a recommendation of the Council of Europe and on a document drafted by the National Committee for Biosecurity and Biotechnology” of June 9<sup>th</sup> 2006, takes into account the Recommendation of the Council of Europe on “Protection of data and of samples of human origin”, Rec. 4(2006), follows up systematically 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” (implemented by the Committee of Ministers in May 2008). Lastly, the NCBLS worked out a solid analysis on Database development, attaching major consideration to Italy’s potential (see document “Guidelines for Biobank Establishment and Certification”, released on December 19<sup>th</sup> 2005).

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<sup>2</sup> European Commission – Research Directorate-General- Information and Communication Unity- 25 recommendations on ethical, legal and social effects of genetic testing. Recommendation 23. Informed consent. It is acknowledged to the patient “ the right to be informed or not...concerning genetic tests, it shall be recommended to establish within this purpose, other than the procedures related to the conveyance of information, counselling, informed consent procedures and the test outcome communication, also specific action in the latter’s case”.

## b) **Information and protection of “sensitive data”**

The 70-80s of the previous century witnessed the heightening of direct attention on person-related protection with regard to the increasing “invasiveness” into the personal life of individuals as a result of the divulgation and circulation of data stemming from computerized data management, databases and records for various needs.

Already back in 1971, the Council of Europe had entrusted the Committee on 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 26<sup>th</sup> 1973 which specified lines of action aimed at protecting the private life of individuals with respect to the collection and use of electronic data within the private sector.

Successively, the private life protection for individuals was extended to cover databases operational within the public sector according to Resolution 74-29 (of 20/12/1974).

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 28<sup>th</sup> 1979) urged the drafting of a Convention which was prepared and then approved on September 17<sup>th</sup> 1980.

On October 24<sup>th</sup> 1995, the European Parliament and the Council of the European Community adopted directive 95/46/EC regarding the protection of individuals related to the treatment of personal data and private life protection within the field of electronic communications.

In Italy, the debate turned out to be lengthy due to significant doctrinal and political parliamentary contributions. The law of December 31<sup>st</sup> 1996, n. 675 embodied the aforementioned Convention.

By means of several legal instruments following the latter, a Decree-Law, former statutory decree n. 127/2001 was issued promulgating the “Personal Data Protection Code” that currently regulates the matter enacted under the Statutory Decree n. 196/2003.

Significant data related to this long evolution arise:

- 1) on a doctrinal basis, the interpretation of the concept of “privacy” not anymore as the single (traditional) right to “be left alone”, but as the opportunity given to an “individual to be aware of, control, direct, halt the information flow concerning him/her (Rodotà S., 1984), this denoting the “right to preserve control of one’s information” (Rodotà; 1991).
- 2) on an operative basis – aiming at effectiveness, efficiency and the timeliness of provisions necessary to achieve tort “prevention” and to

remove the obstacles hindering the assertion of the right to control one's information- the incumbency is held by the Office of the Guarantor that relies on the text of general rules established under the law throughout the aforementioned "Personal Data Protection Code". This leads, where necessary, to a dynamic interpretation of the actual record of cases. Also the surveillance of sensitive medical data, including genetic data, falls within the discipline for authorization set by the Guarantor, as a result of the provisions referred to earlier.

The Guarantor is responsible for the defence of the "Personal Data Protection Code"<sup>3</sup>, including therein medical data<sup>4</sup>.

### **3. General sketch of the medicine-insurance relations.**

#### **a) A preliminary and general note**

Relying on the foregoing records, the Working group aims at examining thoroughly the epistemological, ethical, legal and medical-aid aspects that come along with genetic testing whenever the latter relates to the issue of insurance techniques with regard to life and health risks.

The two sectors concerning the relationship submitted to examination are the following: the former (life) is basically assigned- at least in Italy- to private bodies (better known as Insurance Companies), under the articles 1919-1927 of Section III, Book IV of the Civil Code<sup>5</sup>; as for the latter (health) the situation becomes far more complex due to the involvement of several Organisations aside from insurance companies, which provide "supplementary" insurance policies to economically cover properties and services already supplied by the National

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<sup>3</sup> The Code phrasing provides for a Title V called "Personal Data Treatment in the Healthcare sector". Title V contains as follows: Chapter I identifies the general principles related to the treatment and embodied in Art. 75 "Applicatory field" and in 76 "Healthcare providers and public healthcare bodies".

Follows Chapter II "Streamlined modalities related to information and consent"; Chapter III "Goals of great public interest"; Chapter IV "Medical prescriptions"; Chapter V "Genetic data" providing for Art. 90 on genetic data treatment and bone marrow donors specifically including: "1. Genetic data treatment, aside from who carries out the activity, shall be allowed exclusively in the cases agreed upon by a special authorization issued by the Guarantor once the Ministry of Health has been informed. For the mentioned reason, the latter receives the opinion of the Superior Health Council."; at last, Chapter VI "Miscellaneous provisions".

<sup>4</sup> In real terms, the authorizations hitherto issued are the following: Authorization No. 2/2002 to the treatment of relevant data to disclose health status and sexual life (Official Journal 190 of August 24<sup>th</sup> – Ordinary Supplement 141); Authorization No. 2/2005 to the treatment of relevant data to disclose health status and sexual life- December 21<sup>st</sup> 2005 (Official Journal No. 2 of January 3<sup>rd</sup> 2006- Ordinary Supplement n. 1); Authorization n. 2/2007 to the treatment of relevant data to disclose health status and sexual life- June 28<sup>th</sup> 2007 (Official Journal No. 196 of August 24<sup>th</sup> 2007- Ordinary Supplement n. 186); Authorization n. 5/2007 to the treatment of sensitive data by holders of various categories- Decision No. 28 of June 28<sup>th</sup> 2007 (Official Journal No. 196 of August 24<sup>th</sup> 2007- Ordinary Supplement n. 186); Authorization No. 2/2008 to the treatment of relevant data to disclose health status and sexual life- June 19<sup>th</sup> 2008 (Official Gazette n. 169 of July 21<sup>st</sup> 2008- Ordinary Supplement n. 175); Authorization n.5/2008 to the treatment of sensitive data by holders of various categories- June 19<sup>th</sup> 2008 (Official Journal No. 169 of July 21<sup>st</sup> 2008- Ordinary Supplement n. 175).

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

Healthcare Services (see Battaglia 1993; Fattore 1993; Piperno 1997, etc.). These organisations do not fall so much within the Insurance Company “Model” as within the “national insurance” models, welfare funds, cooperative societies, corporate funds etc., in any case lacking trade purposes.

This set of organisations is fairly common to those European countries which had previously witnessed the establishment of a “solidarity-based” conception of assistance; however while in France and Belgium, there are fully-fledged National Health Services (provided with specific regulation codes) affecting 80% of the population in France and 60% in Belgium, the share falls to 7% in Portugal, to 5% in Spain, thus, it is equal to 3.4% in Italy (data collected by PIPERNO in 1994). Especially in Italy, funds and enterprise funds have seen a greater boost but always in terms of supplementary functions of the public system they are bound to as for its objectives and discipline (see Article 9. of the Decree-Law issued on June 29<sup>th</sup> 1999 n. 229, “Rationalization of the National Health System, the so-called “Third Reform”).

This “structural” preamble to the current state of affairs in Italy concerns the issue at hand, due to the fact that a possible independent regulation with regard to the disclosure of the insuring party’s genetic data may be examined (uncertain hypothesis) in the case of “mutual assistance on an absolutely voluntary basis” or of (private) insurance companies with trade purposes, in the event of providing health services through assistance models fully independent from the National Health Service.

On the contrary, this may not be the case of those subsidiary bodies of the public health system recalled earlier.

The assumptions made are clearly valid under the legislative system in force, except for any different general legal provision.

## **b) Key features of Life insurances from the medical point of view**

The divulgation of individual insurance policies is increasing dramatically, especially the ones supplementing basic health and social security systems. This rise is linked to better guarantees provided, to the cut in benefits issued by the Public Health Service, to the extension of life expectancy, etc. In recent years, “new” policies were put forward compared with the former ones subdivided into “insurance in case of death”, “insurance in case of survival”, “endowment insurance” (according to the risk: death or survival at a given maturity date). Currently, the risk is also extended to the occurrence of certain diseases. This involves the so-called “dread disease” policies which provide economic benefits in the event of a “severe disease” enshrined in the contract<sup>6</sup>, while “long term care” policies concern economic benefits to be allocated whenever a loss of self-sufficiency occurs. The latter is assessed according to scores which go up as

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<sup>6</sup> The National Association of Insurance Companies (ANIA) considers the following as “severe diseases”: infarction of the myocardium, strokes, malignant tumours, kidney failure, organ transplant, etc. Other companies add blindness, multiple sclerosis, Alzheimer’s disease, AIDS, serious mutilations, etc.

independence drops to the point of reaching a non self-sufficiency status. It goes without saying that drawing up a life insurance policy acts as a guarantee yielding the chance of a loan or of property purchase and the United States came greatly before us in achieving this stage.

According to traditional paradigms, the insurability of certain risks (as well as the premium amount) is established by a number of conditions: the possibility of the circumstance to occur, the extent of the latter, the fact that the unfolding event cannot be under any circumstance affected by the insured party; moreover, damage must be identified as an event peculiar to a great deal of people even though it may appear different regarding conditions, modalities and timing.

Risk selection and classification are produced by a series of criteria which enable to place the insured party in a specific insurance premium bracket; the more the risk assessment is accurate, the better will be the premium's profitability for the insureds.

According to their nature, risks may be categorized as "presumed" (deduced solely from the insured party's personal age<sup>7</sup>), "objective" (when age-based selection is improved by analysis of contingencies which may occur following direct or indirect information provided by the insured party: biological, job-related or beyond, environmental, drawn by a set of anamnestic questions attached to the insurance policy. Thus, by clinical tests, medical documentation). The insurance company is entitled to request for the insured party to undergo further testing through his/her trusted physician (it usually applies to cases with high-capital insurance policies or when the estimated starting age is roughly 60). This would include a medical check-up and clinical tests varying according to the different policies: from lipid determination, to glycaemia and seropositivity for hepatitis viruses; on the contrary, specific investigation on the cardiovascular system, blood pressure or ECG is seldom asked for.

Markers to detect neoplastic diseases, mammography tests, etc. may be requested in extraordinary cases and whenever considerable sums of money are at stake. No research whatsoever is carried out in our Country on Cotinine (a metabolite of nicotine) which proves to be an excellent screening for smokers.

The "real" risk is the actual one the insured party confers upon the company when drawing up the contract. The case-law claimed the principle according to which the insurance contract is valid solely whether there is a likeness between objective risk and real risk<sup>8</sup>.

If the risk is high, the company may charge an additional premium, leave out a number of risks from the coverage, reduce the contract validity period in a way that it limits the chance of the insured event to occur, or even exclude the candidate from the insurance contract. Basically, one deals with standard risks, substandard risks and non- insurable risks matching specific premium categories. Reticence may lead to contract invalidity.

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<sup>7</sup> Worked out by ISTAT, they enable death and survival evaluations in the upcoming years for a certain age.

<sup>8</sup> Supreme Court, May 16th 1975 No. 1917.

The Company may request the insuring party to sign a declaration addressed to the latter's physicians in discharge of professional confidentiality and regarding previous diseases not disclosed when stipulating the contract. Let alone the many disputes sparked off by such a provision which tends to be dropped in recent decades also due to the fact that the authorization to disclose a secret does not necessarily correspond to the obligation for physicians to reveal it. Yet, according to contractual provisions, it falls within the beneficiary's obligations to provide the relevant documents for claim assessment, under penalty of non-payment of the claim.

Intentional false statements and reluctance of the contracting party to disclose certain events that, if known by the insurance company, it would have avoided granting its consent, may lead to contract quashing. This occurs whenever the contracting party acts upon fraudulent misrepresentation or gross negligence (Art. 1892 c.c.)<sup>9</sup>. Article 1893 regarding intentional false statements and reluctance without fraudulent misrepresentation or gross negligence, entitles the insurance company to withdraw from the contract<sup>10</sup>.

#### **4. Tangible issues put forward by the Working group to analyse genetic testing-insurance relations in depth.**

Given the preliminary remarks and in light of the insurance procedures pointed out earlier, it turns out to be crucial to examine a number of profiles essential to the understanding of the genetic-insurance relationship.

Particularly, a number of "technical" questions have been raised to which it would be appropriate to provide an initial answer:

- Is genetic data comparable with medical data that is regularly required from the individuals applying for an insurance contract in accordance with contractual obligations?

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<sup>9</sup> Intentional false statements and reluctance with fraudulent misrepresentation or gross negligence. The intentional false statements and the reluctance of the contracting party related to circumstances insofar as the insurance company would not have granted its consent or at least not under the same conditions if it had been acquainted with the actual status quo, lead to contract invalidation whenever it is proved that the contracting party has acted with fraudulent misrepresentation or gross negligence. The insurer loses his/her right to challenge the contract if, within three months starting from the day he/she became aware of the falseness of the statement or of the reluctance, he/she does not reveal to the contracting party the intention of lodging an appeal. The insurance company is entitled to a refund of insurance premiums related to the outstanding insurance period at the moment of the cancellation request and, in any event, of the agreed premium for the first year. In case of claim prior to the running time limit established by the aforementioned paragraph, the insurance company is not bound to pay the insured capital. Whether the insurance involves a group of people or properties, the contract assumes validity for those people or properties to which the intentional false statement or the reluctance is not referred to.

<sup>10</sup> Intentional false statements and reluctance without fraudulent misrepresentation or gross negligence. If the contracting party acted without fraudulent misrepresentation or gross negligence, the intentional false statements and the reluctance are not to lead to contract quashing, yet the insurance company may back down on the mentioned contract, by means of a statement to be transmitted to the insured party within three months time from the day the former has been acquainted with the intentional false statement and the reluctance. In case of claim prior to the moment the insurer was informed of the intentional false statement or the reluctance, or earlier than the latter's declared will to withdraw from the contract, the due amount is curtailed in proportion to the mismatch between the agreed premium and the one that would have been applied if the actual status quo would had been known.

- Which genetic tests among the ones having medical diagnostic and predictive purposes hold considerable interest as to the definition of risk criteria, namely the clear subject matter of insurance, aiming at stating whether a particular disease will develop and when (or is it merely about “generic proneness” to the appearance of a specific disease, or do a few of them enable a risk quantitative and temporal analysis)?
- What sort of reliability is offered by the current variant (mutations) identification techniques and what mutual relationship is in place between mutations and genetic diseases?
- What technical and clinical reliability must be required to derive a contractarian and legal use of genetic tests (actuarial reliability)?

In addition to technical-biological questions, there are the following legal issues:

- a) In the event of using genetic tests for insurance purposes, may insurance companies request a validation system to be set for individual tests and/or a certification system for the centres where tests are performed?
- b) Are 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 health) to be applied – if needed- also in case of requesting information on the applicant’s genetic apparatus?
- c) May the subject of genetic testing lead to acts of discrimination among individuals, being detrimental to their dignity or privacy as well as to their personal interests?
- d) May Insurance denials, requests for higher premiums, contractually ruling out “the right not to know”, all within an exclusively “voluntary” private contract (deliberately requested by the policy holder) fall under a legitimate conduct (related to contract provisions) exerted by private insurance Companies?

## **5. Insurance contract and genetic data: general features related to the problem**

The questions earlier devised led the Working group to the elaboration of the following general considerations preliminary to a further in-depth treatment of specific aspects which will be taken into account in paragraphs No. 6, 7, 8, 9 and 10.

1. The main controversial issue concerning ordinary evaluations focuses on the theory of putting genetic information and other medical-based data on the same footing. This assumption implies a judgement favourable to possible requests by private insurance companies both “*to be informed and to keep track of the results*”

*related to genetic tests applicants have already undergone*”, as well as *“the possibility to require that the latter should take genetic tests”*.

It is a much debated question that may, moreover, be confirmed by the Twenty-five recommendations regarding the ethical, legal and social impact of genetic testing drawn up in 2004 by the Expert Group of the European Commission. This document deems as not well-grounded the view according to which genetic data, strictly used for medical purposes (as established, on the other hand, by the Additional Protocol to the Oviedo Convention on genetic testing) and exclusively bound to the individual’s health, is to be considered different from any other medical information that may be obtained through diverse methodologies; nevertheless it recommends, in any event, to acknowledge and take into consideration the wide-spread perception on the difference of the abovementioned data stemming from several elements such as: the current prevalence of predictive tests for rare single-gene diseases which may disclose particularly sensitive information related to the patient’s family, the fact that there are no treatments for most single-gene diseases, the fear for a potential loss of control over samples etc., as well as the possibility to extend information to past and future line breeding.

On the contrary, a great number of national, European and super-national documents clearly recognize the peculiarity of such a category known as “sensitive” data. The issues supporting the latter’s differential legal status rely upon the atypical origin of genetic information that, if on one side defines an individual according to his/her genetic uniqueness, on the other it relates the latter to other individuals belonging to the same hereditary line, to the same “biological group”; This makes the matters pertaining to the regulation of access to information and of their divulgation and use more sensitive (S. Rodotà *Il corpo tra norma giuridica e norma sociale*, in Preta, L. (a cura di), *Nuove geometrie della mente. Psicoanalisi e bioetica*, Laterza, Roma-Bari 1999).

In particular, it is worthwhile pointing out two aspects of this peculiarity essential to our issue at hand:

- a) The fact that, a number of tests provide for knowledge and prediction being tightly interwoven, since genetic information allows one to become ahead of time acquainted with several aspects linked to one’s biological future, either in terms of greater susceptibility comparing to the average, to develop certain diseases (or even of resistance to the latter), or of predestination to fall ill and of premature death;
- b) The fact that genetic identity is a relational identity, as personal genetic information is structurally shared with other individuals belonging to the same “biological group”, hence having knowledge about one’s genome may also entail the collection of information on other kinsmen who may not be willing to grant their consent.

That being stated, it is possible to conclude that the specific object identification of the assumable insurance interest should be restricted to the “predisposition tests”, which fulfil mainly the concept of risk for the person concerned, the hazard

remaining (more than other tests according to the category mentioned above) up to the insurance.

The “diagnosis” of a genetic disease underway, the “prediction” on the appearance of the latter (see for instance, Huntington’s Chorea) and also the identification of “healthy carrier” status shall undoubtedly be coupled with the life-health insurance profile as for the first two cases and with the health of the offspring according to marital decisions in the last one. Although, at least concerning the latter, it looks as if it is complex to find the insurer interested in offering risk protection contracts or to agree to the request.

Furthermore, it is necessary to point out that the very (potential) interest in the predisposition status envisaged in certain assumptions contained in the insurance literature is not shared by scores of genetists. Accordingly, the mere genetic proneness proves to be insufficient to determine exactly the outbreak of a disease, whereas specific physiological and environmental conditions also significantly affect the evolution of the person’s health.

Ultimately, it is crucial to make a distinction between diagnostic, predictive and susceptibility genetic tests, avoiding to reconcile to a single category different instruments provided with a dissimilar effectiveness degree. The risk currently emerging from scientific and technological knowledge turns out to be the excessive and distorted use of genetic testing (recall for instance, the significance that such distortions ever more embody within job environments).

2. Sensitive psychological aspects currently linked to “genetic tests” represent a far remarkable and not negligible element.

Perplexities harboured by many about including genetic data in the insurance contract do not seem to essentially derive from a lack of understanding as for the gene function, nor from the fear of “discriminatory” social spillovers detrimental to the so-called “virtual sick individuals”, once the mentioned data category were to lose the specific protection it currently benefits from. These doubts may not be considered as groundless<sup>11</sup>, although there is a further aspect which goes beyond the fact that this shall or shall not lead to unavoidably higher premiums for the so-called “virtual sick individuals”. On the contrary, a form of discrimination against more vulnerable citizens regards sensitive psychological profiles of ethical and legal importance. We cannot keep from asking ourselves to what extent being aware of one’s genetic proneness to certain diseases as well as perceiving ourselves and being perceived by the people surrounding us as individuals “at risk”, or doomed to an unfavourable destiny, may affect and influence the

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<sup>11</sup> There are surveys and reports showing how people falling under the classification of individuals with higher disease and/or premature death “risk”, according to a genetic-based profile, were or are more vulnerable to “discrimination” acts when getting into the job market as well as for relationships; and this may also be the case, at first analysis, for the enjoyment of commodities such as health and life insurance: as a matter of fact, a share of the latter could be deemed non-insurable, or insurable insofar as they are bound to the payment of much higher premiums, therefore heralding a further decrease in the opportunities of genetically at risk subjects (see L. Andrwe., 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 National Bioethics Committee of Greece).

development related to the sense of one's self-worth, to one's self-esteem and identity, constraining beforehand one's life choices, within our current societies. This occurs in a world where impression and social acceptance certainties are ever more linked to the adjustment chance/ability with regard to prominent models of corporeal, health, physical "normality" as well as mental efficiency.

The philosopher Hans Jonas, in one of his well-known essays of the seventies, had already emphasized as an outbreking news for ethical theory the fact that an innovative moral "right" was coming to the fore, namely the one to ignore one's future invoked to uphold the free building and definition of the sense of oneself. What the ground-breaking knowledge questions is the very respect of "*the right of every human life to find one's path as well as to be a discovery for itself*", in line with the ancient rule "*Know thyself*", given the fact that "*the discovery of the Self stemming from that rule is tantamount to the self's creation process, coupled with its knowledge through life trials; such a process would be hampered by previous "knowledge in this case"*" (H. Jonas *Philosophical Essays. From Ancient Creed to Technological Man*, University of Chicago Press 1974).

In the wake of what was stated above, in recent years the establishment of the right to self-determination with regard to information has been in flux, as an expression of personal freedom. Nevertheless, this is combined with a new "right", that is, "not to know". Within our context, it applies to the right not to know information related to one's genome, including genetic predispositions, whenever that non-knowledge is estimated as a condition for free self-education, or rather for one's existential freedom. The request to be acquainted with personal genetic information by private insurance companies, as a pre-condition to the contract, would consequently impinge on the right of the person involved "not to be informed" (as confirmed by the Oviedo Convention).

3. A third aspect regards rather the concern- expressed in several documents and recommendations on the relationship between genetic testing and insurance market- of a possible negative social spin-off, within the framework of the "social right to health", deriving from a probable openness to the requests by the insurance companies to be informed of the outcomes of the genetic tests previously taken.

If the requests were to become legitimate, they could daunt biological sample donations aimed at the treatment of serious and disabling disease research and/or at making the number of volunteers in pharmacogenomics research fall; they should instead be encouraged on behalf of a wider social interest: namely public health improvement.

## **6. Further explanations on genetic testing-insurance relations**

In order to provide further explanations pertaining to what was dealt with in paragraph 5, the profile of genetic testing-insurance relations will be considered as follows, according to the view of human genetic experts.

a) Within the heterogeneous group of genetic tests, only a few prove to be currently attention-worthy, considering their potential use with respect to the issue of insurance techniques for risks related to health and life. In particular, it is possible to identify three main groups:

1. The first category deals with the genetic tests aimed at analysing mutations (mutations related to genetic pool) that intervene in a direct relationship with a disease; these include mutations which may appear early at birth time (congenital diseases) or in a broad range of ages throughout lifetime, nevertheless, always entailing a cause-effect relationship, insofar as they would unavoidably give rise to disease patterns if the patient were to lead a long enough life (e.g. familial hypercholesterolemia, Huntington's Chorea, polycystic kidney of the adult type).

2. The second category concerns mutations featuring an incomplete penetrance. This term embodies the existing relationship between the number of people who developed a mutation at the clinical level and the overall share of those carrying a mutation related to that gene. More specifically, the incomplete penetrance identifies how many people are likely to be affected by a disease during their life. For instance, only roughly 70% of the women inheriting a mutation in the BRCA1 gene associated with an hereditary form of breast cancer, are likely to fall ill during their life. The mechanisms underlying incomplete penetrance are not yet well-known, although, they seem to be linked to the genetic background, the somatic mutations which may arise throughout life and to the environment effect.

3. The third category regards common mutations (the so-called polymorphisms, the great number of which occur in over 1% of the general population) that, acting in addition to other common mutations and to the environment, trigger a certain multifactorial disease. Each mutation confers, therefore, disease susceptibility or proneness but, individually, it usually represents solely a risk minor element.

The first two categories of genetic testing embody *diagnostic* (the ones a person undergoes whenever he or she is or is suspected of being affected by a genetic disease) and *presymptomatic* (the ones a person undergoes in the event of late disease occurrence in the family records; they are usually not "patients" but healthy individuals; a pathological outcome of the test means that the person involved will inevitably develop the disease at a certain time in his or her life) testing.

The third category of genetic testing embraces *predictive* tests, namely those identifying a disease susceptibility or resistance different from the average population.

- b) The issue related to family case history deserves further consideration and, specifically, to the existence/absence of records pertaining to diseases which would need to be put through a possible monitoring in the form of genetic testing. There is enough evidence to state that genetic diseases or the ones carrying a significant genetic component are family-centred. Therefore, the existence of a family case history enables to put clinical, instrumental and laboratory (including genetic testing) surveys on a specific track. In particular, the very nature of a considerable number of genetic tests allows risk identification, likely to be quantized even many years prior to clinical recognition (e.g. presymptomatic diseases). On the other hand, an individual belonging to a family with Mendelian risk (i.e. 50% chance in theory to have inherited a disease-gene, such as polyposis coli) may become aware, by virtue of the genetic test outcome, of his or her need to pursue undergoing serial surveys aimed at risk monitoring throughout lifetime, or whether it is possible to refrain from the latter, in case of a negative test outcome. These remarks apply both to disease-genes showing a complete penetrance and to those having a reduced penetrance.
- c) In the event of a negative result stemming from the family case history and whenever the insured party denies the occurrence of serious diseases, it appears to be currently unrealistic to suggest undergoing a set of screening tests related to mendelian disease-genes. In practice, these diseases cover a great number of rare and highly heterogeneous conditions for which it is unlikely to foresee area surveys capable of directing such research, if lacking a preliminary family case history.

A similar doubt is expressed with regard to the benefit arising from research on common and single genetic polymorphisms having a low impact on common disease control (cardiovascular diseases, hypertension, diabetes, etc.).

- d) However, this background may go through significant change in the forthcoming 5 years. As a matter of fact, technological development coupled with genome knowledge, indicate the possibility to obtain low-cost single genomic tests (roughly 100 dollars). Yet our understanding of how and to what extent the gathered information could be used remains blurry.
- In October 2007, Craig Venter's complete genome sequence was released. The latter is the supervisor of the human genome sequencing project financed by private capital.
- Within his 23.224 genes and variable regions, including a number of polymorphisms, variations were identified as conferring susceptibility to antisocial conduct, alcoholism, coronary heart disease, hypertension, obesity, insulin-resistance, myocard hypertrophy of the left ventricle, acute myocardial infarction, deficit in lipoprotein lipase, hypertriglyceridemia, stroke,

Alzheimer's disease. One may ask oneself whether Craig Venter is a tremendously unlucky person. The answer is absolutely negative. Actually, Venter's genome sequence illustrates an "imperfect" genome shared by everyone, merely due to the fact of being a representative of the human species. It is common knowledge that any person, taken on a random basis, is a heterozygote, namely "healthy carrier" for a considerable range of mutations (44% of Venter's genes proved to be heterozygotic for one or more variations). A scant number of these mutations concern genes that are responsible for customarily rare diseases, whereas many hundreds of thousands of variations involve genes connected to complex diseases (polymorphisms), having a minor additive effect on their phenotype. It is challenging to currently devise the specific impact that such a wide-ranging genomic analysis will cause at the insurance level, as for life and health risk assessment.

- e) Moreover, it is apparent that it would not be realistic to convey this type of genomic analysis to the insurance field. If on one hand, genetic testing may be for many reasons equated with other medical investigation whenever it carries out analysis on a Mendelian single gene, the latter accurately assessing a cause-effect relationship elapsing between a mutation and a disease, on the other hand, they disclose problems in the event of being considered within the context of family ties. Thus, it is common knowledge that a mutation is likely to be transferred, in average, to half of first-degree kinships. If the information collected on an individual with regard to a single mutated gene may hinder in itself the potential traceability of such mutation within families, the genomic information available would actually cause problems not easy to sort out as for their potential breach of personal and family privacy.

## **7. Genetic testing and hypothetical duties of the parties in insurance contracts**

In order to resume and complement the analysis pertaining to other technical-legal based queries, listed in paragraph 4, it seems appropriate to acknowledge that a mere transposition of the report provided for regular medical data in conformity with transparency and good faith principles should be considered between insurance contracting parties in the case of genetic tests, notably in relation with the peculiarity of the legal issues which are likely to arise from this test category, whenever a national or European provision were to authorize their use.

In the first place, the increase in available information for the insured party would turn out to be a remarkable element for all types of insurance on the individual, including both health and medical-expense insurance, as well as life insurance although, regarding the latter, in a partly different way.

Concerning bargaining dynamics which are currently settled through the acceptance and signing of a "questionnaire" (suggested by the insurer) by the contracting party, as for common health information, the most significant aspects

related to the problem may focus on two different situations: 1) the possible duty on the insured party's side to provide the insurer with the information he or she holds on genetic tests previously carried out, and 2) the feasible duty to undergo genetic tests following insurance company requests.

Even Italian literature, aligned with a great deal of the international one, lays doubts about the establishment of such obligations given that the interference of private interests at stake (notably, one refers to the insurer's interests) would reverberate on the right to health of the contracting party- occupying a higher legal rank, besides being fundamental both under the National Constitution (well-known Art. 32) and to the nature of "sensitive data", namely the ones concerning the health of the insured party (according to the Privacy Code adopted under Decree-law no. 196/2003), whose treatment may take place, under Art. 26, not only on the grounds of written consent by the necessary person, but also subject to the Guarantor's authority.

More specific instructions are, therefore, drawn by the General Authorization no. 2/2002 of the Guarantor, reiterated in General Authorization no. 2/2008 (effective until December 31<sup>st</sup> 2009), issuing the Authorization on the treatment of eligible data to disclose health status and sexual life, according to paragraph 1.2, lett. e): "to physical and legal persons, enterprises, corporations, associations and to other bodies, this being restricted to data, thus, whenever it is deemed necessary, also embracing data related to sexual life and to crucial operations aimed at fulfilling obligations including precontractual ones stemming from the supply relationship with the individual concerned of commodities, benefits or services". Furthermore, it made clear: Whether the relationship involves credit institutions, insurance companies or securities, only data and processes needed to provide specific goods or services requested by the person concerned are to be considered essential". Following the abovementioned provision, it was inferred the non-existence of any obligation incumbent on the insured party beyond the fulfilment of fixed contractual obligations currently effective, as to granting the insurer access to the information related to outcomes of the genetic tests he or she previously underwent or to undertake feasible testing subsequent to the insurer's request.

In addition, there is no specification as for the inverted situation: namely if the insuring party is willing to provide suitable "genetic health certificates"<sup>12</sup> to foster the drawing up of risk contracts being more favourable to the latter: this possibility is dear to the supporters of "the person's autonomy", although it must be assessed according to the interest or the social-based damage emerging from such a possibility.

## **8. Genetic tests, insurance risk and discrimination**

After outlining the situation on the grounds of obligations which may arise from the insurance contract whenever the use of genetic testing is granted, it is crucial

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<sup>12</sup> It is a temporary expression that should stand for the absence of important prognostic risk ratios, in line with what is mentioned by paragraph 6 of this treatise.

as well to take into account the discrimination profiles that are likely to follow such a decision.

Generally speaking, the notion of discrimination on legal grounds comes to the fore in all those circumstances where a different treatment provided among individuals under the same conditions is deemed unfair or inequitable due to specific criteria. Drawing from the notion of fairness developed by John Rawls in *A theory of justice* (1971), one may imply the following definition: “discrimination is an unfair treatment of individuals not substantiated by good reasons. The latter may justify (economic, social, moral, political) treatment dissimilarities solely under the condition that such a dissimilarity were not to violate the fair equality of opportunities granted to all the individuals concerned. A different treatment entails a 'discrimination' if it diminishes the fair equality of opportunities, namely if, for certain individuals, it hinders access to opportunities normally provided to all under fair conditions”. This “risk” falls within the most feared ones, not only as for premium definition purposes, but for the classification of working conditions; all having possible impacts on the individual’s health<sup>13</sup>.

Discrimination is apparent if it diminishes the fair equality of opportunities; namely if it hinders access to opportunities normally provided to all under fair conditions; nonetheless, the concept would not be applied to unfair treatments which- according to significant ethical and legal reasons- were estimated as necessary to offset initial individual disadvantages<sup>14</sup>.

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<sup>13</sup> An absurd cross bond may occur: an individual refusing to undergo testing could be denied access to possible therapeutic means, whereas the test outcome could, in turn, lead to a reduction or annulment of the insurance coverage useful to the treatment (O’Neill). As reported by Rodotà, 30% of women to whom was offered for free by a company in Ohio, a test to assess one’s proneness to breast cancer, refused because worried that a possible detrimental outcome may be disclosed to the employer or insurers, therefore, being discriminated whenever drawing up an insurance policy. It may also be the case that individuals deeming to have low chances of being affected by diseases, decline to take out an insurance contract causing a system unbalance (*free rider*).

<sup>14</sup> It is worthwhile mentioning a number of bibliographical references meant to further support the argument according to which unequal treatments are called for by the very concept of “equality” based on significant ethical and legal reasons, generally aimed at counterbalancing initial disadvantages; otherwise one must refer to discrimination under the aforementioned meaning.

The first reference is a “classical” text of moral philosophy dating back to the past century which has foreseen a significant number of issues being dealt with later on by the liberal democratic-oriented 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 a political and legal idea of equality implies a validation of any difference in individual-reserved treatment on the basis of a general reason, or of a principle of differentiation, although under the further condition of the existence of morally significant and socially effective reasons.

The second one refers to the word Equality ( *Eguaglianza*; *Diritto*, in *Enciclopedia delle scienze sociali*, vol III), expressed by the constitutionalist Alessandro Pizzorusso; it is stated that the mere principle of substantial equality, enshrined in paragraph 2., Article 3 of the Constitution and regarded as super legislation of the entire constitutional text-, requires differentiated treatments in favour of the most underprivileged individuals, aimed at easing the effects of former oppressions and/or inequalities actually rooted in the unfairness of nature.

Within this entry the word “discrimination” is used under the latin meaning, axiologically neutral.

As a matter of fact, Pizzorusso mentions the concept of “control of discrimination reasonableness” when referring to the Constitutional Court’s verdicts on fair/unfair based “differentiations-discriminations” of treatment provided by legislation.

The third one refers to the essay on *Freedom and Equality* by Norberto Bobbio; within the text, social equality of opportunity is acknowledged as the core principle of the Social State, a breakthrough principle requiring differentiated treatments only if they serve as a useful tool to overcome initial inequalities, namely as an instrument of substantial equality.

## 9. Fairness, privacy and risk sharing in insurance genetic testing

Except for remarks on the different types of genetic tests, their dissimilar extent 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 parties may be split into two groups: a) the ones having already undergone genetic testing, and b) the ones who have not. Within the first group, it is necessary to make a distinction between those disclosing an outcome which portrays a “genetic condition” at the current state of knowledge (a1) and those for whom testing did not reveal any genetic anomaly linked to a certain disease (a2). The distinction between these two groups is difficult to formulate in concrete terms, both due to the ambiguity lying behind the notion of “genetic condition” (it may deal with a single gene disorder, where testing is tantamount to a certain diagnosis, or with a gene-related predisposition leading to different probability levels to develop a disorder, or with a mere susceptibility to specific diseases, hence a condition unlikely to be classified as pathological) and to the fact that real boundaries related to these conditions are fuzzy. Furthermore, it is possible to assume that the gradual refining of genetic diagnosis techniques will lead to an ever-more extensive area embracing those revealing, through such testing, an “anomaly” of a specific type: expanding our knowledge on genome enables an increase in the number of “conditions” identified by relevant testing. The extreme threshold of this situation is set by the complete map of hereditary information referring to every individual which would depict, for each one, an individual “condition” only partially restored to general features. The thorny point concerns the fact that the genetic pattern of individuals may be more or less directly linked to pathological conditions. Being a *continuum*, one must visualize a sort of provision fixing, in broad terms, what type of genetic profiles may be deemed as related to diseases and which ones cannot be considered as such. As always when it comes to the distinction between health and illness, a certain extent of conventionality and mutability is unavoidable.

Nevertheless, if one marks a distinction, anyway, between “genetic condition” (group a1) and health disclosed through testing (a2), it is possible to obtain a crucial difference. Currently, a certain number of individuals hold this self-related information and may decide to conceal it from the insurance companies whenever

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Behind these stances, there is the idea according to which the principle of fairness must always take into account numerous individual diversities not subordinate to subjective choices: in this case, the arbitrariness of collocation with reference to people in providing “natural fundamental goods” and the fact that, following this standpoint, the most unfortunate ones are faced with additional costs. Accordingly, a compensation for such non-selected costs should be guaranteed in any circumstance to ensure people are given equal opportunities. In this framework, the morally significant difference between the aggravated disease risk, due to specific behaviours, i.e., smoking, and, as an alternative, the aggravation stemming from a peculiar genetic endowment (barring the fact that it is given evidence about a possible predisposition also related to smoking) is even greatly straightforward.

drawing up a life or health contract. Therefore, this generates a state of *information asymmetry*.

At their current state, insurance companies, owing to the prohibition on the acquisition of genetic information, treat individuals on a common basis distributing the risk in an undifferentiated manner for all.

Having easily available tests, gave rise to a situation not existing beforehand.

For those individuals diagnosed with a genetic condition, a lack of disclosure of such data implies the creation of a “favourable” status, namely they pay exactly as any other for services they will benefit from with greater chance and frequency. Information asymmetry is on their side. Nevertheless, one must take into account the fact that the mentioned individuals experience an adverse health condition, hence their need for treatment is greater compared to others. The status of these individuals is, thus, the one of potential *free riders* of a system, that is, the insurance companies, from which they hope to see granted a cost cover they are more likely to stand differently from others. For these individuals, sharing the risk comprehensively among the population turns out to be suitable, since they draw a benefit from it. Although, this benefit is achieved by information asymmetry while proving to be prejudicial both to the insurance companies and other individuals.

However, the individuals for whom testing does not show pathological anomalies (group a2) are aware of paying for a service they will unlikely benefit from. At the same time, they know that a number of individuals, the ones who, on the contrary, have undergone testing (group a1) are mindful of the fact they will benefit from the resources available. Accordingly, the individuals under group a2 are the “supporters” of a system they benefit from to a lesser extent. There is likelihood that the latter are unwilling to access such a system or that they are keen to reform it.

It is to be noted that the current state of affairs is far different from the one where, through public health, one contributes *mandatorily* to fuel a system aiming at guaranteeing free medical care to the indigent and adequate services to all, as an expression of the social safeguard of health (Art. 32 of the Constitution). The reason for public tax burden with regard to public health deeply differs from the economic system of *trade-offs* underlying the private insurance system, which is endowed with *voluntary* support.

Companies allocate the risk indiscriminately across the population, as a result, they cannot provide a specific insurance cover for peculiar issues concerning diversified categories.

Therefore, this condition may induce an increasing loss of trust in the insurance system: the divulcation of more accurate, easy and reliable tests would lead to an enhanced number of *free riders* and of those that deny their access to the system. Moreover, this may yield a progressive depletion of the resources shared by the insurance system due to the fact that the incentive to act as *free riders* is very strong indeed (one is provided with services at a lower cost, even if unfairly). Privacy protection on genetic data, whether it also prevents the disclosure of outcomes related to *earlier undergone* tests, it may set off this spiral of mistrust.

Furthermore, the unfairness condition brought about by the *free riders* is not redeemable if the information asymmetry were to continue, namely if the genetic information already held by the concerned individual remains utterly impossible to reveal.

**These remarks lead to a favourable stance with regard to a specific ethical-prescriptive theory (Theory no. 1): for reasons of general fairness and in order to safeguard the fairness of the private insurance system, the earlier undergone diagnostic tests (the argument is to be alternatively formulated with regard to predictive ones) should be disclosed with the purpose of drawing up a life or health insurance policy.**

Individuals have hereby decided to be acquainted with their genetic condition, while envisaging a use that, in this case, grants them a profit.

On the other hand, as previously recalled, the individuals displaying a genetic condition are in greater need for treatment, thus, entailing more significant health expenditures: this situation may deteriorate if the existing difficulties are coupled with a higher insurance premium.

This gives rise to a crucial social issue: the proportion relationship between private insurance covers and Public Health. Individuals having a genetic condition and being aware of it, may show a willingness to pay slightly higher premiums, yet if this is matched with a surge in additional social security or any other costs, their condition becomes ever more complex. Within this context, the solidarity function of the public system is to be stressed once again, as well as upheld and clearly differentiated from the private insurance system, *which belongs in itself and according to its relevant statutes to the private business category even though- in those Countries endowed with a public welfare system- it competes with the principle of social solidarity underlying such initiatives*. The loss of “fair equality of opportunity” stemming from the genetic condition cannot be counterbalanced by the private system but by the welfare public system (if the protections suggested by fairness liberalism apply. In the libertarian visions of Nozick, Engelhardt or Charlesworth, these protections are left out).

The condition of those not having undergone genetic testing makes out a third group of individuals (group b). With regard to the latter, insurance companies distribute their risk in the event of a lack of information on genetic profiles. It is possible to state that such a distribution is established according to nature. This framework sets us on a level which can be defined as “natural equity”: the nature-based lottery gives out genetic conditions that are considered by insurance premiums insofar as mere general statistical data.

In such a context, it may at first sight seem sensible to suggest taking a test before contract stipulation: once being aware of one’s genetic profile, individuals are likely to 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 their chance to benefit from the services. Nevertheless, the above-mentioned remarks clearing out the progressive deterioration of the situation experienced by individuals with a genetic

condition, make it less sensible for such individuals (group b1) to consent to testing. Or, even better, whether testing is required, it may result in paying higher or lower premiums, although, once disclosing the diagnosis of a genetic condition, one witnesses the arising of a particularly knotty situation, therefore it seems, ultimately, more reasonable to reject testing. Then, due to the fact that it would be inadmissible to compel people to act in an irrational way, it is unconceivable to oblige the latter to undergo testing, while retaining the right of refusal to go through it. Such a conduct matches the exertion of “the right not to know” (in details: the willingness to ignore the results of possible tests) jointly with the right of privacy (in details: refusal to undergo testing). Overall, the condition of denied access to genetic data represents a sort of “veil of ignorance” aimed at ensuring fairness under doubtful conditions, as foreseen by Rawls’ liberal theory.

Accordingly, if such remarks are to be deemed worthy of consideration, one must draw the following prescriptive interpretation:

**Theory no. 2: it is not sensible to require that an individual submit to genetic testing for the first time as a precondition for insurance contracts (whenever genetic tests have not been taken already) since it does not improve the status of individuals, that seem to be better protected if the condition of ignorance on their genetic condition is to linger.**

As a consequence, insurance companies would be (morally, and on the grounds of fairness) entitled to request the outcomes of previously undergone genetic tests (theory no. 1) but not to require the carrying out and the disclosure of new tests (theory no. 2).

This situation seems to be echoed by the one in place throughout a number of countries (England, Switzerland, Germany, Holland), where regulations provide that it is unlawful to require new predictive testing, that the diagnostic tests the individual concerned is aware of shall be disclosed, whereas earlier undergone predictive testing are to be revealed at least in the case of an insured capital exceeding a certain threshold.

In the current context, the protection of fairness is basically tied to the safeguard of *information symmetry* which is a precondition both to mutual trust among individuals and to the system functioning. In the event of an information asymmetry (“genetically informed” individuals versus “blind” companies regarding genetic data), fairness ought to be restored out of such a difference; where there is information symmetry (everyone ignores genetic data), the *status quo* stands as the rule.

This conclusion may be debated on many grounds. Above all, the mentioned situation is likely to be provisional and will go through modification to a large extent, due to the development of genetic testing techniques, their mounting reliability and to the social divulgation (often brought about by the trends of a market already pro-active at this regard) of such tests. Secondly, if the aforementioned considerations are to be deemed consistent, the situation is likely to tend towards a certain “information saving” on genetic conditions: after all, it is

better to ignore, therefore, not undergoing tests which would entail, once it is obtained, their outcome disclosure in the event of a contract. Since in case one decides to be informed of his/her genetic profile, one should disclose it to the company that may charge a higher premium to the latter, it is sensible to prefer to totally ignore it and rely on the nature-based lottery. It is possible to object to such a consideration, insofar as the loss of information on genetic profile may become detrimental to the very individual: for instance, whenever being aware of a certain genetic profile, maybe hinted by a peculiar family health condition, would enable to carry out preventive treatments or suitable lifestyles. If on one side it seems senseless to deny access to genetic information to the people involved, extending it to third parties in a contractual situation must be duly justified, in particular, referring clearly to the benefit of the individual concerned.

It is fairly realistic to state that test diffusion, which is already experiencing a skyrocketing growth, will see a further increase. Accordingly, information asymmetry will considerably affect the insurance private system (the prohibition to be aware of genetic information still being in place). If this situation results in generally boosting premium costs for health insurances, it is possible to argue that it is prejudicial to a system that comprehensively promotes a certain fairness preservation: as a matter of fact, the private system supports public system limitations to a certain extent, *as previously recalled*. For this reason, the issue involving the relationship between public health and private insurances remains sensitive and complex. *Under all circumstances, the Working group did not intend in any way to sap whichever efforts acting in favour of an environment decontamination of those situations- associated with genetic susceptibility conditions- which are likely to generate conditions of greater danger for specific individuals. On the contrary, it points out the need to strive on with any possible environment decontamination and the safeguard of workplaces.*

## **10. Current point of view of insurance companies**

In light of the approaching conclusion standing ahead, it is worthwhile stressing that, today, insurance companies confer crucial importance to the principle of information symmetry between the insured party and the insurer. As a matter of fact, in the eventuality of a breach of such a principle, the insurance company may suffer significant losses due to an adverse selection by the insured party. Individuals experiencing adverse health conditions are driven by the need to insure themselves and act in a way that is adverse to the insurance company without disclosing specific health conditions or throughout a misrepresentation meant to pay a lower premium or even to see granted a cover that otherwise they would not obtain, as not insurable.

Against the power of the insuring party arising from information, the insurer needs to perform underwriting in order to formulate a risk classification, namely assess whether the risk is insurable and, if the answer is positive, in what risk pool/category it may be included. Otherwise, the individuals at greater risk would

be inclined to take out an insurance for a higher capital amount, premium being equal, and this would induce an increase in the overall average risk while leading, at best, to a comprehensive rise in premium rates or, at worst, to jeopardizing the very financial soundness of the insurance company. Following a rate increase, those that consider themselves to be less in need of an insurance coverage (therefore being identified as 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; this would lead to a rise in the “worse risks” proportion which is likely to further exacerbate the average portfolio mortality while setting off an unrestrainable vicious spiral of premium increases.

In performing the quality assessment of the offered risk, the insurer tends to gather every possible information that they consider necessary to carry out an effective assessment of potential deterioration factors in such a way that, even if unpredictable, the risk maintains a tolerable degree of uncertainty. At this regard, it is essential to point out that the insurer has one only chance to assess the risk and this happens at the proposal stage. Life insurance policies typically offer an average long-term duration, also providing a lifetime coverage, therefore, one must estimate the probability of occurrence of events also in the long-run on the basis of the information available when signing the contract, which is no longer alterable throughout its validity period.

From the perspective of cost optimization, the risk-selection process is undertaken on different levels basically depending on the insured amount. Higher is the amount and greater will have to be the accuracy of the necessary documents to assess the risk: ranging from a simple health survey to a medical check-up, blood testing, electrocardiogram and chest X-ray. As a matter of fact, the insurer must fix subscription requirements in a *cost-effective* manner, namely being effective while determining a cost proportioned to the benefits. According to a number of data diffused by insurance companies, roughly more than 94% of individual policies are issued without any medical report but exclusively based on a mere health survey or on a good health statement. The share of individual policies going through medical examination is, therefore, lower than 6%.

## **11. Conclusions**

Following previous considerations, it appears impossible to draw final, well-grounded and shared solutions regarding a feasible use of genetic data for insurance purposes.

Anyway, it is worthwhile attaching to this report an “information document” on the rules adopted across a number of European countries.

The user (candidate for an insurance) does not seem willing to accept a “constraint” concerning the submission of genetic certificates in order to have granted a life and/or health insurance contract, but he/she would unlikely show reluctance to give out –on his/her own initiative- genetic certificates disclosing a

“normality”<sup>15</sup> condition related to certain diseases, whenever a clear benefit is to arise in financial terms (premium reduction).

Insurers invest in resources and capital to transpose in probabilistic terms useful to perform actuarial calculus, information retrieved throughout medical research while constantly updating their calculus basis so to avail of ever more objective, relevant and reliable data to determine the coverage cost. Although, to this aim, they consider genetic data as common medical data and, given also future advancement in the medical field, as well as a foreseeable increase in the use of genetic data within clinical medicine in the upcoming years, today they urge for their very use in such actuarial calculus, with the purpose of gathering experience related to the “positive” contribution that such data could provide to better define the risk. Of course, they are not reticent about taking precaution measures meant to safeguard information, exactly as provided for “databases”.

In particular, insurance companies envision research development for specific purposes in order to verify the actuarial relevance of testing and review the criteria and statistical foundations for risk classification, in union with the cooperation of geneticists and other peers so the interpret the complex statistics arising from scientific studies. Such statistics single out the fact that genetic testing results are taken into account only if their technical, clinical and actuarial relevance will be ascertained.

In addition, they consider crucial to point out the potential risks for the insurers that are likely to stem from the persistent and significant definition problems in the genetic field, in a condition of legislative constraints such as the current one. The very peers do not always agree on what concretely forms genetic information and which genetic tests are endowed with a real predictive value.

Moreover, in this uncertain condition, also the insured parties may decide not to disclose pathological results obtained through common testing carried out in medical practice since some of them have a genetic component. Therefore, insurance companies hope that the provision will be reviewed in favour of the use of genetic testing, as well as contemporarily adopting a simple, straightforward and shared terminology for this sensitive subject.

Against this composite background, the Working group makes a final remark: behind the issue outlined by “the specific case” represented by the use of genetic testing for insurance purposes lie broader assumptions on the relationship between the market and “privacy” (as previously mentioned).

While the market system- upheld also at the European level- would induce to embrace the awareness of individuals’ genetic situation within premium modulation aiming at creating markets being capable of better responding to real situations of risk, law-related issues that are incumbent upon a legal system and which do not necessarily concern the market, as for instance, individual protection, autonomy, rights as well as his/her different proneness condition to

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<sup>15</sup> See footnote 12.

diseases, are likely to lead, today, to ruling out the introduction of awareness related to genetic status within insurance bargaining.

The reason for this, is not uniquely the fear for an uncontrolled divulgence of “sensitive” personal data but also the limited degree of genetic predictive certainty (following the current state-of-art) and the prevailing solidarity attitude of the European health law: today, it results in a rational attitude not necessarily requiring genetic data provision. However, this does not rule out a further consideration on the grounds of a solid basis for scientific research- and concretely- on the actuarial benefits for the community at large which are likely to arise in the future from the introduction of a number of genetic data throughout a fair “bilateral” information process, morally adequate among counterparts.

## 12. Synthesis and Recommendations

“Genetic tests and insurance” triggered an in-depth international debate in recent years, hinging upon the assumption that genetic testing would shortly become a common practice in healthcare services.

This anticipation proved to be only partially feasible, thus, the fears arising from the use of genetic tests on the insurance side outbalance the status quo, at least in our Country.

However, a number of International Organizations and National Ethics Committees gather “advice” to put forward the opportunity of having a suitable shared discipline at a European level enabling, in the future, a broader use of genetic tests in the insurance field.

**Following the aforementioned complex situation as well as its constant transformation, the Working Group contends that - better than a hasty and global legislative response- it would be relevant, at the moment, to seek a tangible and temporary shared solution attainable through non-legislative criteria that- performing on the basis of mutual trust and transparency within the European debate- on the one hand may prevent people genetically prone to certain diseases from being discriminated whenever underwriting an insurance policy, moreover- on the other hand- may guarantee protection to the insurance companies from the dangerous consequences deriving from anti-selection that risks to prejudice the supply of fair and adequate “prize money” for the large population concerned.**

**The working group:**

- **While waiting to avail oneself of a broader scientific knowledge comparing to the one currently at hand,**
- **Provided that – under any circumstance- it shall not be appropriate to curb genetic testing diffusion for medical reasons fearing a negative outcome on the insurance side.**

- **Wishing to give its contribution embodied in an opinion as requested by the Steering Committee of the Council of Europe during the meeting held in Strasbourg on 3-4 December 2007,**

**recommends:**

- **That a moratorium regime shall be made clear as to the use of genetic testing within the insurance field in those Countries that have not yet decided upon it, waiting for the end of the European debate;**
- **That insurance companies shall be provided with a self-regulation procedure, endorsed beforehand by the competent authorities and properly disseminated according to which:**
- **Companies commit themselves to guaranteeing the protection of personal data under the formalities enshrined in the regulations in force;**
- **Insurance companies do not demand that the client should undergo genetic testing in order to have an insurance granted.**

**Moreover, given the sole target residing upon joining a voluntary experimental programme of a pre-established time length, directed to the practical importance evaluation stemming from the introduction of a number of genetic data into the health form designed as a self-declaration, the aforesaid form being already working prior to the drawing up of the insurance contract, the Group recommends that, whether provided by the self-regulation procedure, it shall not be forbidden to the companies, when agreeing upon the insurance contract, to request and get hold of results relevant to diagnostic genetic tests previously taken by clients, thus, the latter being aware of such a step, for any insured amount.**

**Ultimately if, upon request of the client, the insured amount is to exceed a certain threshold (the extent to be set), it should be possible for companies, when drawing up the insurance contract, to request and get hold of results relevant to presymptomatic genetic tests previously taken by clients, the latter being aware of the result.**

**The Working Group likewise recommends that also the Superior Institute of Health be entrusted with presymptomatic genetic test evaluation as well as its reliability and significance for insurance purposes.**