Ethical and legal implications of interventions on 'unpatients': therapeutic v. non-therapeutic treatments

Silvia Salardi*

ABSTRACT: Advances in modern medicine and technology represent the factual premise to deal with the question of legitimateness and justification of non-strictly therapeutic interventions on a 'quite new' class of individuals termed in the 1990s 'unpatients'. Main aim of this paper is to identify the major ethical and legal aspects concerning this topic today, in order to define the borders of the map traced with regard to the ethical and legal debate some decades ago. A close examination of the ethical dilemmas of non-strictly therapeutic interventions will highlight characteristic perspectives and specificity of treatments administered to unpatients. To some of these peculiarities legal regulation has already provided answers, whereas with regard to other aspects a balance among different principles at stake is needed along with mechanisms set to safeguard their implementation.

KEYWORDS: unpatients; non-therapeutic treatments; medical ethics; enhancement; definition of illness

SUMMARY: 1. Introduction – 2. Developments in modern medicine as premise for the debate on non-therapeutic interventions – 3. Therapeutic v. non-therapeutic treatments: patients v. unpatients – 4. Ethical dilemmas of non-therapeutic medical interventions on unpatients – 5. The legal response: a critical analysis.

1. Introduction

Ethical questions concerning implications of non-strictly therapeutic interventions challenge today's scenario of modern medicine from a political, legal, social, individual, cultural, and clinical viewpoint.

Non-strictly therapeutic interventions may have either 'aesthetic', 'enhancing', or 'preventive' purposes. The distinction between the two last mentioned purposes – enhancing and preventive – is, however, not easy. In particular, when it comes to treatments for future diseases with uncertain destiny with regard to their manifestation. Indeed, some preventive measures may also have an indirect enhancing result: consider, for instance, the paradigmatic case of vaccines. But today, advances in science and medicine have broadened the horizons of potential interventions with preventive and enhancing goals, i.e. gene therapy. In this quite recent scenario, non-strictly interventions, intended broadly as preventive measures, may be referred to a particular 'new' class of individuals known as

* *PHD, senior researcher at the Università degli Studi di Milano-Bicocca, lecturer in Bioethics at the 'Università degli Studi dell'Insubria' in Como, lecturer in the Master on Bioethics and Biolaw for the Clinical Praxis Università Milano-Bicocca.*

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'unpatients', namely neither patients nor healthy individuals, as they carry a gene mutation which may lead to the future manifestation of a given disease, but with a different probability depending on the disease the gene mutation refers to and on the gene-environment interplay.

Main aim of the paper is to identify the major ethical and legal aspects with regard to non-strictly therapeutic interventions on this category of individuals, in order to define the borders of the map traced with regard to the ethical and legal debate some decades ago, when the term 'unpatients' was coined[1].

To analyse the questions arising in this field, the first step needed is to frame the context of the discussion about non-therapeutic interventions, so that it will be possible to distinguish non-therapeutic treatments that could have an ethical-rational justification and those which are not justifiable. Indeed, the debate for or against the ethical suitability of some non-therapeutic interventions presupposes a wide availability of treatments and interventions which are strictly connected with the extraordinary advances in modern medicine and technology, occurred in the second half of the XX century. These advances prompted relevant changes in medical ethics[2], and more in general in the social and individual perception of the role medicine plays in enhancing health in modern Western societies.

The second step will focus closer on the ethical dilemmas of non-therapeutic medical interventions with the intent to highlight characteristic perspectives and specificity of treatments administered to unpatients.

Finally, a closer examination of the current legal framework regarding non-therapeutic – strictly speaking- interventions on 'unpatients' – will show how much has been done *de jure condito*, and how much is still to be done *de jure condendo* to give ethical dilemmas solutions useful for individuals' life in the moment in which they live.

2. Developments in modern medicine as premise for the debate on non-therapeutic interventions

From the earliest ages of medicine, therapeutic expectations have guided the activity of physicians along with scientific curiosity. In the Hippocratic theory, diagnosis and prognosis played a relevant role, in particular prognosis, i.e. the physician's ability of predicting the likely outcome of the disease. In Hippocrates's view, many factors – environmental, psychological, social – ought to be taken into account to understand diseases, to heal patients, and to take preventive measures.

After the 'therapeutic revolution'[3], and the following 'biological revolution', the old Hippocratic teachings still play a role, but in a new way. Scientific advances occurred over time and the following great availability of technological devices, biomedical treatments[4], and drugs[5] changed the course of human life deeply. What were once considered fatal conditions can be, in many cases, easily healed

[1] A.R. JONSEN, S.J. DURFY, W. BURKE, A.G. MOTULSKY, *The Advent of the Unpatients*, in *Nature Med.*, 2, 6, 1996, 622-624.

[2] T.L. BEAUCHAMP, J.F. CHILDRESS, *Principles of Biomedical Ethics*, sixth edition, New York, 2009.

[3] J. BERNARD, *La Bioéthique*, Paris, 1994.

[4] Surgical interventions, diagnostic techniques, imaging etc.

[5] F. BRINDEL, *Les médicaments qui on changé la vie*, Lausanne, 1985.

or recovered today[6]. The 'therapeutic revolution' concerned medicine with regard to advances in treatments, clinical therapeutic trials, epidemiology, clinical research, and prevention of diseases.

The 'biological revolution', which followed later, contributed to give humankind 'mastery on reproduction, on genetics, and on the nervous system'[7]. From that moment on, prediction became a key word in modern medicine. Predictive medicine as part of preventive medicine opened up the possibility to define the probability that a pathological event occurs in individuals who do not give clinical signs of the disease.

And in time, the concept of preventive measures has gained, indeed, relevance in parallel with scientific advances in different sectors, for instance in genetics and neurosciences. As opportunities in these last scientific fields expanded, the concept of disease underwent a radical change.

This occurred since early identification of 'molecular diseases'[8] has become a real option in biomedicine, as it gives the power to analyse the microscopic entities of our body, not only to diagnose a disease in its early stages, but to predict its future coming.

In particular, advances in the different fields of genetics have created great expectations with regard to the possibility of intervening to prevent developing future genetic diseases. Consider the Human Genome Project (HGP), which was welcomed as the event that could have limited or even eliminated – in the short period – the 'natural dependence' of human beings from pathological conditions. And, indeed, after its completion in April 2003, which gave human kind the ability to read our complete genetic blueprint, genetic testing boomed.

Genetic testing allows the identification of changes in chromosomes, genes, or proteins. Results from genetic testing help to confirm or to rule out a suspected genetic condition or to predict a person's future chance of developing or of passing on a genetic disorder.

The term 'prediction' marked, therefore, genetic advances from their beginning. The ability of predicting becomes a key element in the debate about prevention. The more accurate prediction is, the more precise preventive measures can be elaborated. Therefore, the concepts of prediction and prevention are interdependent. This interdependence gains importance for some ethical issues in this topic. In particular, the 'accuracy', that is exactness and correctness, of results from genetic testing is useful to avoid pernicious effects on the individual perception of one's own genetic make-up[9] and when decisions concerning public resource allocation are made: To whom should be granted access to genetic testing? According to which criteria?

These are just two of the main questions arising when the concept of 'accuracy' is considered. And these questions are strictly connected with other considerations: on the one hand, the possibility of accessing genetic testing on the part of all individuals or, on the other hand, only on the part of those

[6] Let us think of what has been medically possible after the discovery of the HELA cell lines. See on the story of Henrietta Lakcs, R. SKLOOT, *The immortal life of Henrietta Lacks*, New York, 2010.

[7] J. BERNARD, *De la biologie à l'éthique les comités d'éthique de biologie*, in *European Review*, 1, 2, 1993, 151.

[8] Expression used in the paper by L. PAULINGS, H.A. ITANO, S.J. SINGER, I.C. WELLS, *Sickle Cell Anemia, A Molecular Disease*, in *Science*, 110, 1949, 543-548.

[9] 'Guilt phenomenon' and search in one's genome for the answer to the question Who Am I? are just some of the problematic issues connected with information about individual's genetic make up. On this topic see P. ROCHE, G. ANNAS, *DNA Testing, Banking and Genetic Privacy*, in *Engl. J. Med.*, 355, 6, 2006, 545-546; M. CUCINATO, *Il vissuto psicologico di fronte alla predizione genetica*, in C. BRESCIANI (ed.), *Genetica e medicina predittiva, verso un nuovo modello di medicina?*, Milano, 2000; S. SALARDI, *Test genetici tra determinismo e libertà*, Torino, 2010.

whose risk to develop a future genetic disorder may be predicted with some precision (familial history, for instance), and among these individuals a further selection criterion could be the availability of therapeutic tools for the identified genetic disorder.
These have been some of the considerations taken into account, already in past years, in the debate about access to genetic testing and availability of therapeutic treatments. Some of these considerations have become part of legal solutions, which will be analysed in the last paragraph.
To draw some intermediate conclusions at this point of our discussion, we can underline that the huge advances in medicine and in empirical sciences have created the framework in which the debate on non-strictly therapeutic interventions can take place. Indeed, the availability of biomedical instruments, technological devices, and drugs makes it possible to intervene both in case of ongoing pathologies or even in absence of symptoms, but in presence of a susceptibility or predisposition.
Scientific advances represent, therefore, the factual premise for any ethical-legal discussion, unknown to our ancestors, about interventions of non-strictly therapeutic nature. While discussing this issue, we should keep in mind the challenge, hiding beyond this «ambiguous progress based on probability calculation, and statistics, that is to say based on a slippery slope»[10], which is to dominate these scientific advances and not be taken their hostage.

3. Therapeutic v. non-therapeutic treatments: patients v. unpatients

But what can be considered non-therapeutic interventions? And to what extent are these interventions legitimate and justifiable, for instance, in terms of public funding, of creating categories of individuals with particular rights or even dispensed from given duties?
To answer these questions, we ought to start with the distinction between therapy and enhancement[11]. Therapy can be generally and broadly defined as a set of medical, pharmacological, surgical, and technological measures and treatments aiming at recovering the health status, that is to say the normal functions of the body. Instead, the term enhancement refers to a set of measures which aim at increasing abilities and improving bodily functions for given purposes. Why this distinction?
This distinction was introduced for economic and allocative reasons. Insisting on a diagnosis of disease is justified by the fact that insurance companies and/or public health care systems need to protect themselves against expensive and sometimes bizarre requests.
Taking into account this distinction appears relevant in the discussion about interventions on unpatients, that is the new class of individuals who are found to carry a gene mutation, i.e. a susceptibility to a certain genetic disorder.
Indeed, the two broad definitions of therapy and enhancement do not help to decide which category better fits the unpatients. Preventive measures, where possible for this group of individuals, range from simply changing life-style to surgical interventions, which may turn out to be very invasive and very expensive for public health care systems and insurance companies. In-between these two ex-

[10] G. ISRAEL, *Etica e Tecnologia nella Pratica Medica*, in *Atti del Convegno Clinica e Tecnologia nella Medicina Contemporanea*, Napoli, 2012, 25-26, English translation of the sentence by Silvia Salardi.
[11] Comitato Nazionale per la Bioetica, *Neuroscienze e potenziamento cognitivo farmacologico: profili bioetici*, March 2013.

treme solutions, there are preventive measures focused on constant controls and instrumental investigations, which could, on the one hand, strongly influence individuals' lives, and on the other hand, cause huge economic costs to society. Therefore, deciding if treatments concerning unpatients are therapeutic or enhancing is a relevant question. For instance, John Harris[12] questioned that to alter susceptibility to diseases like poliomyelitis or smallpox by using preventive vaccination can be easily defined as therapy, rather than enhancement[13]. So what about other preventive measures like surgery or gene therapy?

Would it be possible to draw a conventional line between therapy and enhancement, or is there a *continuum* between them that does not justify any kind of exclusion from the access to technology and to medical treatments?

To try to answer these questions we can focus on the well-known definition of health by the World Health Organization (WHO), 1947[14]. This definition had the merit of overcoming a strictly biologist perspective of health as absence of pathology and tried to shape the notion of health by introducing subjective factors and social conditions which influence individuals' well-being and quality of life[15]. Critics of this definition point(ed) at the utopian identification[16] of health with "…a state of *complete* physical, mental, and social well-being and not merely the absence of disease or infirmity". And critics are right to argue that a *complete well-being* is far from being achievable despite the encouraging progress in science, medicine, and technology. However, the relevant aspect of the definition, at least for the purposes of this paper, is the reference to psychological status along with physical ones.

The psychological factors may play a relevant role in defining criteria to decide about the availability of non-strictly therapeutic tools with regard to unpatients. With the advent of DNA analysis, various impacts on individuals and society have been discussed and investigated. From the individual's viewpoint, one of the major impact is of psychological nature. Psychological consequences on individuals, who undergo genetic testing, is well-documented in literature[17]. And it has often been underlined that there is a huge gap between people's perception of advances in genetics and the real state-of-

[12] J. HARRIS, *Enhancing evolution. The Ethical Case for Making better People*, Princeton, 2007.

[13] Another example of borderline interventions between therapy and enhancement is represented by medical and surgical treatments to realign gender and sex of transsexuals. Consider, for instance, using hormones for female breast enhancement. Are these practices therapeutic or enhancing? In this case, however, arguing in favour of one or the other solution cannot ignore the fundamental right to sexual identity. The Italian Constitutional Court stated in its historic decision n. 161/1985 that there is, indeed, a fundamental right to sexual identity. In its decision n. 252/2006, the Constitutional Court highlights that interventions to realign gender and sex are admitted in the Italian constitutional order, though they contradict Article 5 of the Italian Civil Code prohibiting interventions aimed at a permanent limitation of someone's physical integrity.

[14] «Health is a complete physical, mental and social well-being and not merely the absence of disease or infirmity».

[15] P. BORSELLINO, *Bioetica tra autonomia e diritto*, Milano, 1999, 145. See also of the same author *Bioetica tra 'morali' e diritto,* Milano, 2009.

[16] See for instance D. CALLAHN, *The WHO Definition of Health*, in *Hasting Center Studies*, vol. I, 3, 1973,77-87.

[17] D. NELKIN, S. LINDEE, *The DNA Mystique: The Gene as Cultural Icon*, New York, 1995; C.M. CONDIT, *How the public understands genetics:non-deterministic and non-discriminatory interpretations of the "blueprint" metaphor*, in *Public Understanding of Science*, 8, 1999, 169-180; B. BATES, A. TEMPLETON, P.J. ACHTER, T.M. HARRIS, C. CONDIT, *What does "a Gene for Heart Disease" mean? A focus group study of public understandings of genetic risk factors,* in *American Journal of Medical Genetics*, 119, 2003, 156-161; P. ROCHE, G. ANNAS, *op.cit.*

the-art in this field. In popular culture, indeed, it is deeply rooted the perception of genetic as an 'ultimate' context, where we find answers to fundamental questions like *Who Am I?*[18] This perception is strictly connected with individual's attitude of 'taking genetic advances on trust', that is without necessity of proof or of closer examination.

With the words of Nelkin and Lendee «the images and narratives of the gene in popular culture reflect and convey a message we will call genetic essentialism. Genetic essentialism reduces the self to a molecular entity, equating human beings, in all their social, historical, and moral complexity, with their genes»[19].

And as clinical genetics is concerned to a large extent with conveying information about probabilities, that is why genetic counselling has become part of genetic testing. What we termed previously 'slippery slope' with regard to conveying information about genetic testing has to be kept in mind when the question concerns conveying information to unpatients, because information about probability may be misunderstood in two relevant ways. First, statistics, on which probabilities are based, are often used in a mechanic way: it is often forgotten that the correctness of their results depends on how good and adequate the samples' selection is, and that their aim is to give a global indicator not referred to a single, peculiar case.

Secondly, misunderstandings may be on the part of the (un)patients, due to the individual's risk perception. This varies from individual to individual and from the way information is conveyed. Some individuals are 'risk lovers', other are 'risk adverse' or 'risk neutral'; the way in which the information is presented may influence risk's perception[20]; risks' presentation in the media may affect the way they are perceived by the public[21]; and individuals may be concerned more with the nature of the risk than its probability.

If these are the alternatives concerning the psychological perception of genetic testing results, non-therapeutic interventions could be justified in so far they contribute to maintain a status of health, which may be primarily psychological and then physical. But as it occurs in case of therapeutic treatments, also in case of non-strictly therapeutic measures the main decision if to undergo or not genetic testing to find out one's susceptibility to a genetic disorder ought to be made by the individual whose life is at stake. In case of non-strictly therapeutic interventions, rules concerning the right to know, not to know, or to delegate knowledge should be, if possible, even stricter than in other circumstances because the psychological impact on individual's course of life is not foreseeable in advance.

So in line with these considerations, it could follow that practically everyone could ask for genetic testing and consequently for non-strictly therapeutic interventions, in particular preventive measures

[18] P. ROCHE, G. ANNAS, *op.cit.*

[19] D. NELKIN, S. LINDEE, *op.cit*.

[20] A. TVERSKY, D. KAHNEMAN, *The framing of decisions and the psychology of choice*, in *Science,* 211, 1981, 453-458; S. SHILOH, M. SAGI, *Effect of framing on the perception of genetic recurrence risks*, in *American Journal of Medical Genetics*, 33, 1989, 130-135.

[21] See on the point, for instance, Nuffield Council on Bioethics, *Genetics and Human Behaviour*, *the Ethical Context*, London, 2002. Besides individual perception of risks on a strict scientific point of view, heterogeneity of human population requires different aspects to be taken into account to define individual risk, see, for instance, N. RISH, E. BURCHARD, E. ZIV, H. TANG, *Categorization of Humans in Biomedical Research: Genes, Race, and Race*, in *Genomebiology*, 3, 7, 2002.

like surgery if he/she is found with a predisposition to a genetic disorder. If we consider the subjective conditions in the normative definition of health as relevant factors, then there would be a *continuum* between therapeutic and non-therapeutic treatments, and it would not be easy to justify any kind of exclusion from the access to technology and to medical treatments: non-strictly therapeutic treatments for unpatients would be justified by their contribution to maintain a healthy status avoiding future diseases.

However, the (un)patients' subjective, central role in evaluations concerning the right to access resources, which are unfortunately limited, needs to be integrated with further aspects, which will inevitably restrict the proposed option.

In this sense, to build a framework of criteria useful to identify priorities, we ought to take into account the appropriateness, that is the pertinence of technological devices and advances to the objectives they aim at, based on the reasonable evidence of efficacy[22]. This criterion is not new, but the compelling need to practice evidence-based medicine has been neither overcome[23] nor fulfilled. This criterion, which, taken seriously, could help distinguishing among non-strictly therapeutic treatments those whose offer should be mandatory, is also suitable to contrast attempts to affirm hierarchical priorities by economic groups with their own interests in medicine and in its developments.

4. Ethical dilemmas of non-therapeutic medical interventions on unpatients

Despite the considerations made in the previous paragraph, specific dilemmas concern non-therapeutic medical interventions on unpatients, which is useful to highlight separately, though briefly, before analysing the legal framework on this topic. We can start with the general consideration concerning individuals affected by a disease to underline differences with unpatients.

In modern Western societies, the state of being affected by a severe and/or chronic disease produces relevant impacts on society and on the individual. Indeed, besides the understandable individual expectation of receiving, in these cases, care and access to therapies, there are important effects in terms of rights and responsibilities, which ought to be taken into consideration.

With regard to rights, when an individual is diagnosed with a severe and/or chronic disease or disorder, he/she may gain access to free services from the health care system: drugs, preventive services etc. So, being and being declared seriously ill may produce legal rights, in particular social rights, and dispense an individual from some social established duties. These opportunities are legally regulated in many legal orders nowadays. But what about the unpatients?

May non-strictly therapeutic interventions on unpatients with a preventive goal, like for instance those necessary to avoid the future, uncertain development of a pathology, justify expanding social rights and limiting responsibilities?

Consider, for instance, an individual diagnosed with an 'innate risk' to develop a future disease, for instance a common disease, whose risk of development could be reduced if exposure to given substances, radiations, and so on could be avoided. We could ask to what extent individuals with this

[22] P. BORSELLINO, *Bioetica tra autonomia e diritto*, *cit*.

[23] D. SARGENT, *What constitutes reasonable evidence of efficacy and effectiveness to guide oncology treatment decisions?*, in *The Onchologist*, 1, 2010, pp. 19-23.

susceptibility may be authorised and legitimated to ask for a job which does not expose them to risks.

If we take, for instance, common diseases into account, we could further investigate the legitimateness of requests from an individual diagnosed with susceptibility to – let us say – heart disease, in terms of sparing time for preventive activities: jogging, fitness etc. And while waiting and watching for any sign of the disease, the unpatients will undergo preventive controls, measures, organising their lives around prescribed activities useful to postpone the risk of becoming ill.

We could then ask if this new way of living, which could be very harsh depending on individuals' characteristics and their emotive status, could represent a pre-condition to evaluate the possibility of delivering free preventive services to unpatients.

These ethical dilemmas need to be seriously considered today, as they are no more hypothesis or conjectures. When the term 'unpatients' was introduced in 1996, it was wisely and in advance underlined that «the ability to test for susceptibility for future disease has the potential to sweep into the world of medicine millions who experience no pain or discomfort or limitation»[24]. Nowadays, the potentiality has become reality. Millions of people in Western countries undergo genetic testing of different kind to know their genetic make-up. Results of *predictive* genetic testing concern therefore a large amount of individuals, and we should decide if this quantitative factor could be considered a good starting point to reconsider access to health care services under facilitated conditions. However, the question is not limited to quantity, but also to the characteristics of the 'innate risk' and the possibility to weight it with regard to other social, economic, and political needs.

A look at the legal solutions and their potential development in some already traced directions could be useful to try to give some answers to the ethical questions arisen in the previous paragraphs.

Indeed, switching from the ethical debate to legal solutions represents a decisive turning point to evaluate which values and interests have gained the status of rights, and consequently which model of society is identified and approved through legal choices.

5. The legal response: a critical analysis

A first aspect to be evaluated concerns what is termed *right to health*. Previous considerations made about the concept of *health* led us to broaden theoretically, on the one hand, the possibility to access preventive measures in case of predictive positive testing, but, on the other hand, it was also underlined the need for balancing this *open* access with some criteria which may help to reasonably manage the peculiarity of predictive medicine. It was stated, first of all, that the criterion of appropriateness is useful to overcome the problem of allocation of insufficient economic resources. Moreover, we highlighted that peculiarities of predictive medicine, in particular with regard to legitimateness of requests concerning implementation of preventive controls and preventive measures, do play a role in the debate around non-strictly therapeutic interventions on unpatients.

A first step of our analysis will restrict the concept of health to the use in the expression *right to health*. And as *health* has already been considered, the focus will be on the concept of *right.*

[24] A.R. JONSEN, S.J. DURFY, W. BURKE, A.G. MOTULSKY, *op.cit.*

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As far as the *right to health* is concerned, the expression *right* could be used in two ways. The first one refers to a technical-legal use of the expression[25], meaning rights attributed to individuals by legal norms of a positive legal order, including rights corresponding to principles positively anchored, for instance, in national constitutions or in international treaties, conventions etc. The second use of the term *right* reminds us of social and individual demands, claims, and expectations, which are widespread at the social level, but which are not translated in legal norms yet. Regarding this second use, the term *right* is, in many cases and to some extent, already part of social programs, principles, and interpretive criteria, and it helps fostering their transposition into legally binding rules.

For the purposes of this paper, the term *right to health* is used in a technical-legal sense.

So, the evaluation will focus only on existing rules and on those which could be formulated respecting values and principles already existing in the current legal framework.

The *right to health* is anchored in relevant international and national legally binding documents. And over time, shifts in meanings and interpretations shaped this right in a new way adding important content and nuances.

Consider, for instance, Article 32 of the Italian Constitution, which states «The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person». This Article was originally interpreted as a typical social right. But, over the course of decades, it has been reinterpreted in the light of right to *liberty* both in the negative and positive sense. In the negative sense, it guarantees that third parties could not improperly interfere in the individual's private sphere. In the positive sense, it guarantees the implementation of self-determination, that is active individuals' participation to decision-making process regarding his/her lives.

Both interpretations of Article 32, as social right and right to liberty, contribute to underline that all individuals, organisations, and institutions have the duty to behave in such a way that health is preserved[26]. Following these considerations, access to preventive controls, measures, and so on, on the part of the unpatients could be considered mandatory. However, the peculiarities of predictive genetic information as well as the relevant and potentially dangerous impacts on individuals and society of an *open* access to genetic testing represent unavoidable aspects to be taken into account to further frame the legal regulation in this field.

And, indeed, if we analyse the existing legal rules and the principles inspiring them in genetic testing, we find evident traces of attempts to balance all the aforementioned aspects. A preliminary consideration on the legal regulation concerning genetic testing is of a general evaluative kind. Indeed, from the point of view of values' and principles' implementation, we can look at the international and national rules as a coherent *corpus* in this topic, with the aim of protecting self-determination, dignity, freedom, integrity, and equity.

[25] U. SCARPELLI, *Diritti positivi, diritti naturali: un'analisi semiotica*, in *Diritti umani e civiltà giuridica,* Perugia, 1992.

[26] P. BORSELLINO, *Bioetica tra autonomia e diritto*, *cit.*, 144-145.

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In dealing with scientific (genetic) advances Law is inspired, in general, by a principle which guides (or at least should guide) clinical practice and scientific research, namely that any decision concerning administration of treatments on the part of the physician is based and is in accordance with scientific standards which have been accepted and shared by the international scientific community. No imposition on this appreciation on the part of the physician ought to be imposed by Law, if so, this would cause a violation of the physician's professional autonomy. Furthermore, some legislations[27] clearly state on this point that an independent, multidisciplinary committee established by law has the duty to control the current state-of-the-art as far as scientific progress is concerned.

Giving relevance to this aspect means to try directing legal regulation of scientific advances, in particular in genetics, towards a non-ideological use[28]. Indeed, if it is true that medicine cannot give certain answers, and if it is true that science itself is not able to find definitive answers, but only answers based on probabilities, it cannot follow that everything is uncertain. Using scientific advances as the cognitive basis for further evaluations is useful both to avoid common misunderstandings about the way things work on a biological and genetic level and to implement legislation when deemed necessary.

To apply this criterion with regard to unpatients when deciding if to intervene with non-strictly therapeutic treatments has important effects on the ability of individuals to form through adequate information his/her own awareness and making them less hostage of scientific advances and of groups with particular economic interests. Indeed, correct information based first of all on the most recent evidences enables unpatients to recognise if undergoing genetic testing, in particular of predictive nature, coincides with a true, personal need or is, instead, externally driven and manipulated.

And legal international and national regulation on the topic of information is absolutely clear and coherent: Information ought to be clear, appropriate, and balanced about purposes, uses and storage of information derived by biological samples, and it must be anticipated by an informed consent[29]. This regulation states at the legal level the implementation of self-determination with regard to direct and active control on one's information. Moreover, rules on genetic testing prescribe 'genetic counselling' as mandatory, in particular for predictive genetic testing[30], to be delivered by expert physicians.

So, if information appears as the main tool guaranteed by Law in this topic to implement self-determination, dignity, integrity etc. and to permit to evaluate on the part of the individual the need of undergoing predictive genetic testing, it also connects strictly both with appropriateness as previ-

[27] German Law, Gendiagnostikgesetz (GenDG 2009), Swiss Federal Act on Human Genetic Analysis (2007), Austrian Gene Technology Act, Gentechnikgesetz (GTG, 1994).

[28] Refusing for instance reductionist or deterministic views of human beings. On the point see S. SALARDI, *op.cit.*

[29] Declaration of Helsinky (amended 2013); Unesco International Declaration on Human Genetic Data 2003; European Charter of Human Rights (2001); Convention on Human Rights and Biomedicine (1997); Directive 2002/98/EC; Directive 2004/23/EC; Recc. (2006) 4 of the Council of Europe; Italian Constitution Articles 32, 13, 21, 2; General Authorisations issued for the Processing of Sensitive Data from the Italian Data Protection Authority; National statutes on genetic testing (Austria, Germany, Switzerland) just to mention a few. On this topic, see S. SOINI, *Genetic Testing Legislation in Western Europe-a Fluctuating Regulatory Target*, in *J Community Genet*, 2012, 3, 143-153.

[30] German Law on Genetic Testing, Swiss Federal Act on Human Genetic Analysis, Austrian Gene Technology Act.

ously defined and with the evaluation on the part of experts about effective utility of a predictive test for a given individual.

And indeed, with regard to this last aspect, the legal regulation in this field states that genetic testing is never mandatory, and it prescribes that biological samples and genetic data of an individual ought to be used for third-parties of the same biological group only with the express consent of the interested person and only in those cases in which this use aims at protecting *health* of the third-party enabling him/her to put preventive or therapeutic measures into practice as well as to make aware reproductive choices[31]. Furthermore, at the European and national level there is a strong opposition to *direct to consumer genetic testing*, that is genetic testing offered via Web, opposition based primarily on the impossibility to control the appropriateness and quality of the centres and laboratories undertaking this activity, but also on the principle of utility for individuals to undergo such procedures[32].

This last criterion adds a new element to our considerations: if predictive genetic testing should be undertaken on the account of the effective evaluation of utility for individuals, then not any request on the part of individuals concerning implementation of preventive controls and measures ought to be accepted. Indeed, requests of undergoing predictive genetic testing, in particular for common diseases, funded by the national health care systems, may be selected based on the family history, and therefore on empirical evidence.

In conclusion, the current legal framework on genetic testing is inspired by values like self-determination, dignity, responsibility, freedom, and equality. Norms at different levels have translated these values in principles and in specific legally binding rules. A look at this legal scenario shows that the answer to the question concerning the legitimateness of non-strictly therapeutic interventions on unpatients needs to be analysed taking into account various criteria, and only an adequate balance among them can lead to a reasonable management of all the interests at stake. A prerequisite for a reasonable solution in the balancing operation is to use Law free from ideological influences[33].

Predictive genetic tests have a great potentiality in improving human life, and therefore to some extent non-strictly therapeutic interventions should be granted by public health care systems. But as

[31] See, for instance, Article 3 of the Authorisation No. 8/2013 for the Processing of Genetic Data of the Italian Data Protection Authority; similar provisions are contained in the mentioned German Law, in Norvegian Biothecnological Act (2003), in the Spanish Act on Biomedical Investigations (2007).

[32] See for instance the Report *Direct-to-consumer genetic testing for health related purposes in the European Union: the view from ESAC and FEAM,* 2012.

[33] In this sense the Congress of the United States makes the following considerations in the preamble of the Genetic Information Non Discrimination Act 2008: «Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress. New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun. Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments. These advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment. […] Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies».

predictive medicine is still far from finding definitive and certain solutions for humanity, and there is no evidence this will occur soon or necessarily, the following criteria appear unavoidable in the balancing operation: 'accuracy', that is exactness and correctness, of results from genetic testing, appropriateness, that is the pertinence of technological devices and advances to the objectives they aim at, based on the reasonable evidence of efficacy, and effective utility of a predictive test for individuals.

When these criteria are fulfilled, then it becomes possible to reason about the legitimateness of requests on the part of unpatients to 'new' rights and to 'less' responsibility.

De jure condendo, proposals of legislations should, therefore, focus more on these aspects. Without losing their flexibility useful to remain in line with the scientific advances, legal rules on genetic testing should try to balance, clearer than it appears to be in the current case, the principles of self-determination, dignity, equity, and freedom with the application of the above-mentioned criteria and, consequently, to set mechanisms to safeguard their implementation, taking into account the scientific and social evolution in this relevant, but ethically problematic field.

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