HUMAN HEALTH AND VULNERABILITY IN THE ERA OF THE ANTHROPOCENE AND OF THE TRANSHUMANISM

SALUD HUMANA Y VULNERABILIDAD EN LA ERA DEL ANTROPOCENO Y DEL TRANSHUMANISMO

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Abstract: The era of the Anthropocene poses unprecedented challenges and affects human health, concerning above all socially and economically vulnerable groups. This study suggests a human rights-based approach and assesses the solutions adopted in the framework of the European Union and of the Council of Europe for ensuring a better and more equitable access to healthcare, by also taking into consideration the jurisprudence of the Court of Justice of the European Union and of the European Court of Human Rights. From this perspective, some human rights-based solutions are advanced in light of the opportunities offered by biotechnology, pharmacogenetics or pharmacogenomics, gene therapy and regenerative medicine in a reality where transhumanism, as a result of the application of the advanced scientific achievements, is no longer a remote possibility.

Resumen: La época del Antropoceno conlleva desafíos sin precedentes e interesa la salud humana, afectando sobre todo los grupos social y economicamente vulnerables y requiriendo soluciones adecuadas y equitativas a todos los niveles de gobernanza. El presente estudio sugiere un enfoque basado en los derechos humanos y analiza las soluciones adoptadas en el contexto de la Unión Europea y del Consejo de Europa para garantizar un mejor y más justo acceso a la asistencia sanitaria, tomando además en consideración la jurisprudencia del Tribunal de Justicia de la Unión Europea y del Tribunal Europeo de los Derechos Humanos. Por ende, se proponen unas soluciones basadas en los derechos humanos a la luz de las oportunidades que la biotecnología, la farmacogenética o farmacogenómica, la terapia génica y la medicina regenerativa ofrecen en una realidad en la que el transhumanismo, como resultado de las más avanzadas aplicaciones científicas no parece más una posibilidad remota.

Key words: Vulnerability – Human Rights approach - Transhumanism

Palabras clave: Vulnerabilidad – Enfoques basados en derechos humanos - Transhumanismo
1. INTRODUCTION

In 2016, the Working Group on the Anthropocene has suggested that the mid-20th Century be adopted as the moment that marked the transition of the Earth from the geological Age of the Holocene into the geological Era of the Anthropocene.

The notion of “Anthropocene” was advanced by biologist Eugene F. Stoermer and popularized by the Dutch Chemist and Nobel Prize winner Paul Crutzen in 2000. This conception refers to the era where “the many geologically significant conditions and processes are profoundly altered by human activities”. Although the earliest events that triggered the process that led up to the Anthropocene date back even to the development of early agricultural society, about 5000 to 8000 years ago, and some imprint in geological strata was left since about 1800 at the times of the Industrial Revolution, it was in the mid-20th Century that the so-called “Great Acceleration” took place.

Among the human activities responsible for speeding up the advent of the Anthropocene, we can mention, for instance, methane production by cattle, fishing, wasteful use of nitrogen and phosphorus in fertilisers, the use of fossil fuels and plastics and, in general, overexploitation of resources.

The consequences are massive and often overwhelming: primarily, climate change and, among the various aftermaths, flooding, sea level rise, ocean acidification, loss of biodiversity, large scale species extinction, which are all capable of impacting human

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health from many viewpoints. For example, due to water pollution, to reduced crop yields and to the deterioration of the quality of food given the loss of micronutrient caused by the use of carbon dioxide fertilization, which alter food quality.\(^3\) Again, climate change can be a determining factor for the spread of epidemics, as the Zika virus outbreak has recently demonstrated, and natural catastrophes can be a major challenge for disaster health management systems.\(^4\)

The adverse effects on human health can even come to affect the genetic dimension from an epigenetic perspective,\(^5\) by triggering gene expression and thus determining the onset of several genetic diseases and by causing epigenetic mutations. The epigenetic consequences of the impact of Anthropocene on human health can be quite wide in time, as they can be transmitted to future generations both intergenerationally – as they can affect the child during pregnancy - and transgenerationally.

The Report issued by the Rockefeller Foundation/Lancet Commission on Planetary Health\(^6\) in 2015 clearly described how human health directly depends on the state of the natural systems and, among its recommendations, also called for developing adequate research capacity in this respect.

It goes without saying that the Anthropocene requires appropriate States’ rethinking of their policies and allocation of resources not only as far as it concerns research, which plays a basic role in order to identify and assess specific health risks posed by the peculiar effects of the Anthropocene, but as far as it regards the elaboration of wide

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scale preventive and therapeutic strategies and accessibility of health care. Clearly, it is not an easy task, especially considering the global financial crisis which has affected our world since the late 2000 and the adoption of austerity measures that it has brought about, besides the skyrocketing growth of world population and its stronger impact on health budget.\(^7\)

Under this premise, the purpose of this paper is taking into account how the diagnostic and therapeutic means made available by scientific progress, putting particular emphasis to the most advanced ones as genome editing, human therapeutic cloning, pharmacogenetics or pharmacogenomics, regenerative medicine may help to tackle the challenges that characterize the era of the Anthropocene and the threats it poses to human health, consistently with the principles of international biolaw.

The starting point of this reflection is assessing whether advanced biotechnologies and bioengineering, as the most evolutionary horizon of science, may help to face with the unprecedented challenges that the new geological era is posing. In particular, the view that inspired this reflection is whether the Anthropocene may ease the affirmation of the views supported by transhumanism.

In this regard, it should be primarily stressed that the conception of transhumanism has evolved and has assumed more specific and peculiar shades in light of scientific progress since Julian Huxley elaborated it in 1927.\(^8\)

Transhumanism was intended as the possibility for man and mankind to express the highest potentiality of human nature, as the full realization of the potential of human nature, for human nature; a process to be intended individually, but for the whole human species, for the whole mankind, through the “energetic exploration” of science and

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\(^8\) HUXLEY, J., “Transhumanism”, Journal of Humanistic Psychology, n° 8 (1), 1968, pp. 73-76.
the possibilities that it offers. Transhumanism, in the view of Huxley, is intended as a new existence where the human being, individually and collectively, with regard to the mankind, is free from the suffering that affect him. There is a logic of solidarity that cannot be overlooked, and which can inspire an ethical and human rights-based response to the challenges posed by the adverse effects of the advent of the Anthropocene on human health, with special regard to the socially and economically vulnerable people. In fact, socially and economically precarious conditions of life expose to higher risks of exclusion from the enjoyment of healthcare, even basic health services. This is so because several gaps can be found in the social protection they can enjoy, especially social health protection, which is due to a number of reasons. For example, in the context of our analysis, gaps in statutory coverage, financial protection and specific eligibility criteria, coupled with limited scope of benefits are factors of basic importance. This is why this study focuses on making accessibility to healthcare viable, through the adoption of a human rights-based approach as the suitable way for pursuing this purpose, and for including not only basic healthcare but also the advanced therapeutic achievements of scientific progress.

This is all the more true since the means made available by scientific progress are now capable of making the transcendence of the human nature a reality, through a number of achievements that can affect the human being from several viewpoints, first of all genetically. After the sequencing of the human genome, we have entered the post-genomic era. Genetics is not merely intended in relation to inheritance of genetic traits, but it deeply surveys the molecular processes related to inheritance and has come to


assume the dimensions of the genetics of populations. The ethical issues related to human germline and somatic alterations and to human therapeutic cloning have assumed primary importance in the bioethical discourse, as well as human cloning that has raised a complicated debate at the global level at the United Nations and at the UNESCO that has highlighted the difficulty to reconcile different views. Genetic therapy, pharmacogenetics or pharmacogenomics and regenerative medicine have lightened huge hope worldwide and now offer innovative therapeutic means that imply some manipulation of the human body.

That being said, we should then question: is the time ripe for the “neuro-bio-info-nano machine” without setting aside human rights, equality and social justice? This study aims to provide a response to this query in relation to the two major European realities, the European Union and the Council of Europe, for assessing how a similar approach might find justification and implementation in their respective frameworks, through reference to international law and the core conception of the right to health and access to health from an evolutionary view point, expanding on the possible evolutionary horizons of the right to science.

2. A NEW ERA, MAYBE A NEW MAN BETWEEN ETHICS, RIGHTS AND STATE POLICY

Since its theorization, the Anthropocene has increasingly gained ground in the international debate in different fields of knowledge.

When the various approaches to the Anthropocene and in particular to climate change as one of its major implications, are taken into consideration, it can be quite soon observed that bioethics has so far dedicated very poor attention to these issues.

Some calls were made in scholarship advocating the need that bioethics join the scientific debate.

As some scholars have highlighted, the reluctancy of bioethicist to engage in the reflection on Anthropocene is largely due to the influence of their traditional matters of interest (abortion, euthanasia, informed consent, access to health care too, for example) and to their usual operational field, which basically entails cooperation with health facilities, services and professionals. Usually the questions related to Anthropocene and, in general, to environment, are seen as distant concerns.

However, since the manifold impact of the Anthropocene on health care implies necessarily a rethinking of State policies and budget management, a bioethical approach might help. As new challenges keep on emerging, it is necessary to cope with them by adopting new solutions, as for example the innovative means offered by biomedical progress. Action has to be promptly taken: the adoption of a renewed approach cannot be delayed as population is likely to be widely and transversally affected, to the particular detriment of socially and economically vulnerable subjects. Therefore, policies should be reconsidered in order to address society comprehensively and through enhancement of the protection of social rights, especially the right to health and accessibility of health care, and in order to cope with the related strong risks of discrimination of the most socially and economically vulnerable members of society.

In his study “Just Health Care”, Professor. Norman Daniels highlighted three criteria of allocation of resources in public health and priority setting, namely:

1) the market; 2) rights; 3) needs.

The choice is particularly delicate when one considers the recent austerity policies and cuts to public spending due to the financial crisis the world’s been facing.

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The privatization of health care in a growing number of countries and, in some cases, the effects of the adoption of a health insurance system are two major issues as well.\(^\text{15}\)

The principles of bioethics seem to be capable of offering some precious guidance for shaping health policies and priority setting.

Reference goes to dignity, autonomy, information, justice, solidarity, universality, vulnerability, non-maleficence and beneficence.\(^\text{16}\)

Dignity is defined in international law as “inherent” in the human being, a basic and inalienable feature of human essence. Although sometimes in scholarship, it was argued that it may end up being a void concept, as for instance Ruth Macklin,\(^\text{17}\) and that in practice other principles would structure its content, as autonomy, actually the fundamental role of human dignity is clearly recognized, along with its unifying nature as an inherent value of the individual and of the human species. It is especially from this transcendental viewpoint that human dignity can provides us guidance when assessing whether the new era of the Anthropocene may lead also the ascent of what we could call “a new man”, to whom we should question how much of the “original” human nature is left.

Human dignity as a feature of our species is of basic importance when we consider how far we can reach through manipulation of the human being, either through alterations of the human genome with regard to the human germline or through the incorporation into the body of 3D-printed tissues and organs thanks to the advances of bioengineering and regenerative medicine.

Human dignity, in this regard, arguably provides important guidance in two senses: on the one hand for assessing the admissibility of specific practices and interventions on

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\(^{17}\) MACKLIN, R., “Dignity is a useless concept”, British Medical Journal, nº 327, 2003, p. 1419.
the human beings, helping to clarify which of them can be helpful but, at the same time, respectful of the dignity and, we could also say, the integrity of the human being. On the other hand, human dignity provides guidance for the recognition and affirmation of a renewed understanding of human rights related to transhumanism. Indeed, in this regard, the issue is whether human rights and, especially, the conception of health and of the highest attainable standards of health protected under international law are capable of embracing access to the new tools made available by the scientific progress and, if so, to which extent. Could we someday invoke not just advanced therapeutic opportunities or could we enjoy the benefits of enhancing treatments? Of course, enhancement itself would require better definition, and human dignity can be very helpful of course, surely through further contextualization in relation of the specific scientific and legal circumstances as well. What is more, as is further analysed with regard to the evolutionary understanding of the core conception of health affirmed in international law in paragraph 5, human dignity as an inherent feature of the human species underlies the protection the human nature of the future generations from any dramatic and irreversible intervention that scientific achievements might allow to make, in order to promote the ethics of post-humanism.

Along with human dignity, the bioethical and biolegal principles may help to define a feasible approach aimed at tackling the issues considered above: in particular, autonomy is of basic importance, along with the respect of information and, thus, of informed consent, to preserve the physical and mental integrity of the human being and its choice to embrace or not any possibility of evolving his nature. We could possibly call it a choice to remain human or, otherwise, to enjoy as far as possible, the benefits of scientific progress and its capacity to improve the human condition. Of course, this may be feasible only through adequate cooperation with physicians and effective implementation in advanced medical and scientific practice of beneficence and non-maleficence, by pursuing the benefit of the patient and that good produced by an immediate treatment is higher than the harm that might be caused for the patient. In this respect, the “rights” perspective theorized by Professor Daniels can be helpful also to prevent any dangerous drift towards a market perspective, that might cause the
commodification of the patient. For example, one the most common hazard is that patients are exploited for experimentation: they might be captivated by promising experimentation of advanced treatments without adequate respect for their rights and for bioethical principles, by taking advantage of their socio-economic vulnerability. In this regard, the adverse effects of the advent of the era of the Anthropocene might exacerbate these risks, as to the deterioration of health conditions, for example epigenetically and surely conditions of socio-economic vulnerability would worsen such situation.

The principles of universality, solidarity and justice may help to frame the social dimension of the question and provide guidance for appropriate allocation of resources and ensure accessibility to advanced health care, even when it encompasses such resources and means as those made available by biotechnology and regenerative medicine. Since the impact of the Anthropocene and its adverse effects on human health cannot be overlooked and may affect some areas more than others, particular exposure to the adverse environmental conditions of the new geological era might be included among the standards for allocation of new treatments among the population. In this regard, it is fundamental to be realistic: science is promising and sometimes even prodigious; but it goes without saying that it is expensive, and appropriate rethinking of State budget is necessary for ensuring equitable allocation and access, that should be especially ensured to the most vulnerable if we want to ensure social justice. In this regard, a combination of the standards of rights and need, as classified by Professor Daniels, would provide adequate framing and justification.

When we focus on the European reality, two major regional frameworks provide the interesting landscape for analysis of feasibility of a similar approach. The next paragraphs respectively focus on the European Union and on the Council of Europe in order to assess how and whether a bioethical approach to advanced scientific progress, pushed to the horizons of transhumanism, might be advanced as a means for tackling the challenges that Anthropocene poses to the health of people in Europe. In this regard, in both frameworks, the first step of the analysis is to assess how accessibility to health
is understood and protected in the two systems, especially in relation to socio-economical vulnerability, in order to further assess the role of scientific progress in each context and the possibility of a human rights-based and ethics consistent transhumanistic approach.

3. THE VIABILITY OF A TRANSHUMANISTIC APPROACH IN THE LEGAL ORDER OF THE EUROPEAN UNION

The assessment of the possible horizons of transhumanism in the Anthropocene in the European Union (EU) requires primary framing of healthcare and environmental issues, their framing within the EU legal order and the capacity of the EU Treaties to offer some justification to biolegal questions. Indeed, strictly speaking, biolaw falls outside the purview of the EU.\(^{18}\) Therefore, from a regional perspective, it helps to understand why, whilst bioethics is a thriving reality for the Council of Europe, dealing with this field has been a major challenge for the European Union, primarily, because no specific legal bases are provided in its legal framework.

Nevertheless, the EU has been capable of developing an important approach to bioethics and to biolaw, by relying on several suitable legal bases that, as anticipated, can be found in the architecture of the Treaties,\(^ {19}\) namely: Article 114 of the Treaty on the Functioning of the European Union (TFEU) on internal market; Article 168 TFUE on public health; Articles 179 and the following provisions of Title XIX, Part III of the TFEU on Research and technological development; Article 208 of the TFEU on development cooperation.

These provisions have allowed the EU to adopt some remarkable acts, which have concurred to improve and harmonize the regional approach to bioethical issues of basic

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importance. Noteworthy examples are Directive 98/44/EC\textsuperscript{20} on the Legal Protection of biotechnological inventions and Directive 2004/23/EC\textsuperscript{21} on setting standards of quality and safety for the donation, procurement, testing, processing of human tissues and cells.

When the focus is set on the competence of the EU with regard to health care, the reference legal basis is primarily Article 168 of the TFEU, whose wording eloquently recalls the principle of subsidiarity, which appears consistent with the nature of the EU competence in relation to “the protection and improvement of human health”. In fact, in the post-Lisbon framework, this area was incorporated in Article 6 sub (a) of the TFEU, which concerns the activities of the Member States in relation to which the Union is competent to carry out actions of support, coordination or supplement with regard to their European dimension. This area of EU competence is characterized by the exclusion of the harmonization of laws according to Article 2(5) of the TFEU.

It means that Member States play a predominant role in this field, which is particularly a sensitive area and implies delicate issues of politics and budget management. It clearly results from Article 168(7) of the TFEU where it provides that “Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them”.

The EU human rights framework reflects this delicate balance.

Indeed, in this sense, Article 35 of the Charter of Fundamental Rights of the European Union (CFR)\textsuperscript{22} on health care, which embodies principles and programmatic


requirements, provides that “[e]veryone has the right of access to preventive health care
and the right to benefit from medical treatment under the conditions established by
national laws and practices”.

However, it is arguable that some integration between health and environment
capable of giving adequate consideration to the impact of Anthropocene is a feasible
route at the EU level, according to paragraph 2 of Article 35 of the CFR, where it
requires the integration of health policy in “the definition and implementation of all
Union policies and activities” by ensuring “a high level of health protection”. The
interrelationship between environment and health can also be found in the Treaties
framework in Article 191 of TFEU, where it provides that “protecting human health” is
one of the objectives pursued by Union policy on the environment.

So far, in practice, the interaction between internal market and health has been a
more thriving sector for ensuring access to health care.

Directive 2011/24/EU,23 renowned as EU Patients’ Rights Directive, adopted on the
basis of Articles 114 and 168 TFEU, is a significant example of the promotion of
mobility and access to cross-border safe and high-quality health care in the EU, and of
cooperation between Member States.

According to the Directive, patients are entitled to several rights, primarily the
reimbursement of actual costs faced. Again, the right to accountability and the right to
transparency enrich the protection ensured by the Directive which, in this sense, goes
beyond the views affirmed in the case law of the European Court of Justice (ECJ), that
had prompted the adoption of this act, from Kohll to Watts case.24 It is noteworthy that

22 European Union: Council of the European Union, Charter of Fundamental Rights of the European
application of patients’ rights in cross-border healthcare, available at https://eur-lex.europa.eu/legal-
24 C-158/96 Raymond Kohll v Union des caisses de maladie (Kohll) [1998] ECR I-1931; Case C-372/04
The Queen, ex parte Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health
[2006] ECR I-4325; Case C-120/95 Nicolas Decker v Caisse de maladie des employés privés (Decker)
[1998] ECR I-1831. In particular, in these cases, the Court applied the freedom to provide services to
the Directive applies to all types of curative health care, including those provided privately, outside of public health system. In this respect, it is arguably indicative of the fact that the EU’s criteria in relation to resource allocation according to Professor Daniels’ classification is “rights”.

That being said, it should be considered whether this framework might prospectively allow a bioethical and a biolegal evolution capable of incorporating scientific progress to the point of welcoming transhumanism.

In this regard, some primary considerations should be made in light of the EU’s legal framework from a comprehensive viewpoint. First of all, consistently with the Union’s approach to healthcare and to resource allocation informed to “rights”, the primary reference is the Charter of Fundamental Rights of the European Union (CFR) which offers some reference and some guidance to frame the feasibility of the incorporation of advanced biomedical results and technologies within the EU health policy.

The relevant provision is enshrined in Article 3 of the Charter, which provides the biolegal founding views of the EU and helps to outline the borders of the practices allowed. In particular, Article 3 poses some main principles, namely informed consent, the prohibition of making the human body and its parts a source of financial gain and, which appear to be particularly helpful for our reflection, the prohibition of cloning for reproductive purposes and the prohibition of eugenic practices, “in particular those aiming at the selection of persons”.

Few considerations have to be made about the CFR, to understand the importance of the statements it contains from several viewpoints: first of all, because the CFR, in the post-Lisbon system, is a primary source of EU law. Therefore, it inspires and informs EU legal order and outlines its bioethical frame, thus EU acts have to be adopted in compliance with its provisions.

Secondly but not less importantly, Article 3 of the CFR of basic importance for the understanding of the concept and the scope of human dignity in EU law: as the prohibition of human reproductive cloning is enshrined in this provision and not in Article 2, on the right to life, in scholarship it was authoritatively held that the conception of human dignity embraced by the CFR refers to the born person.25

The consequences from a perspective of transhumanism are remarkable: indeed, it may be argued that the EU approach to bioethics does not forbid human germline interventions, which is one of the most significant and discussed intervention that might be made for helping human nature to express all its potential, to recall Julian Huxley’s view. We could argue that it is not prohibited by the principle of human dignity.

A similar conclusion may be held relying directly on the text of Article 3 of the Charter as, when explicitly banning eugenics practices, it only makes reference to the selection of persons, whilst no reference is made to human germline modifications. It goes without saying that the issue should be considered more in depth to specifically outline the feasibility of such interventions from an ethical viewpoint, in particular whether we should consider admissible both kinds of human germline alterations, that is merely therapeutic modifications or also the enhancing ones. Of course, this would require careful debate in the political sphere and, despite the important achievements made, primarily the CRISPR technique,26 the consequences of these interventions are still being tested and assessed by researchers, in both short and long term, basically the immunotoxicity and the genotoxicity. However, it is remarkable that in 2015 the United Kingdom, still as a Member State of the EU, adopted the Regulation on mitochondrial

replacement therapy (MRT),\textsuperscript{27} which allows replacing the mother’s mitochondrial DNA with that of a donor in case she may transmit a mitochondrial disorder to the child.

Indirectly, some confirmation of the feasibility of therapeutic interventions may be sought in the prohibition of human cloning only for reproductive purposes. This statement seems to indirectly allow human cloning for therapeutic purposes and it appears all the more relevant since in the last years the international community, both in the UN and the UNESCO framework has dedicated huge efforts for the adoption of targeted instruments, that led to the UN Declaration on Human Cloning in 2005,\textsuperscript{28} which posed a blanket ban on both kinds of cloning. It split the international community, as consensus exists only on the prohibition of human reproductive cloning, as is dealt with more in depth in paragraph 6.\textsuperscript{29}

However, it cannot be overlooked that the Biotechnology Directive, that addresses patentability of biotechnological inventions, seems to adopt a different view and to consider contrary to \textit{ordre public} and morality both human germline alterations and human cloning, without making any distinction among therapeutic and reproductive purposes with regard to the latter. The ban is set in relation to patentability of inventions relying on such practices, consistently with the scope of the Directive. This entails that, beyond the scope of application of this act, a cautious approach would be recommendable from a general viewpoint.

\textsuperscript{27} In practice, MRTs allow replacing the mother’s mitochondrial DNA with the one from a woman donor.
\textsuperscript{29} Ibid.
This is clearly an important element that would suggest a careful consideration of the possible EU’s approach to transhumanism and its incorporation from a healthcare perspective, as a response to the Anthropocene. However, in light of the considerations made above, some room for political debate and thorough assessment of these issues cannot be excluded, especially as scientific progress is promising and, for example, somatic genetic therapy has achieved some important results in the last years. This might induce to mitigate the strict approach adopted in 1998 in the wake of the sequencing of the human genome, when concerns and instances of protection of the human genome were particularly strong. However, the fact that the Biotechnology Directive rules out the patentability of the human body, “at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene”.

What may be inferred from the analysis of the EU framework is that feasibility of transhumanistic interventions, especially in the sense on which we are focusing here, and, in particular, which practices may be viable requires very careful consideration. It would be desirable that some further clarification came as to such practices as human germline alterations, in particular the therapeutic modifications, and human therapeutic cloning, especially because scientific progress is making important steps ahead and the possibility to really help humanity to express its potential at its best, in terms of health and wellbeing, is becoming a real opportunity and not just an optimistic wish. However, such practices as pharmacogenetics or pharmacogenomics and accessibility to regenerative medicine, for example, are not precluded by the framework analysed. Nevertheless, subsequently it is assessed whether and to which extent their use might be considered as a part of health policies of the EU in line with the provision enshrined in Article 35 of the CFR, to be translated also into an approach to the Anthropocene’s adverse impact on human health. It could also be a way of U of “protecting human health” as part of the Union policy on environment according to Article 191 of TFEU.
4. TRANSHUMANISM AT THE COUNCIL OF EUROPE BETWEEN THE ECHR AND THE OVIEDO CONVENTION SYSTEM

Through the decades, the Council of Europe (COE) has devoted growing attention to bioethics, focusing on various thematic areas, namely biomedical research, cloning and issues related to human embryo and the foetus, end of life, genetics, transplantation, biobanks and psychiatry. The soft law landscape offers many examples of the commitment of the COE in this field and, in particular, with regard to equal access to health care. Recommendation 2020(2013)30 and Resolution 1946(2013)31 are emblematic in this respect.

What is more, the COE has been capable to provide the propitious framework for the adoption of some international binding instruments in the field of bioethics: the first step was the European Convention on Human Rights and Biomedicine (hereinafter “the Oviedo Convention”)32 that was followed by its Additional Protocols, which respectively deal with the prohibition of cloning human beings, the transplantation of organs and tissues of human origin, biomedical research and genetic testing for health purposes, and then, in 2011, followed the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (the “Medicrime Convention”).33

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31 Council of Europe, Parliamentary Assembly, Resolution 1946(2013) on Equal Access to Healthcare, available at http://semantic-pace.net/tools/pdf.aspx?doc=aHR0cDovL2Fzc2VtYmx5LmNvZS5pbmRvbnJlZG1sLjhhbSZWYvWDJILURXLWV4dHlUYYx5luZ2ZpbGVpZD0xOTkMSZsYW5nPUVO&xsl=aHR0cDovL3NlbWFudGljcy5jcmwvSGFjZS5uZXQvWHNsdC90QZGYvWFJlZi1XRC1BVC1YTUwyUERGLnhzbA==&xsltparams=ZmlsZWlkPTE5OTkx accessed 13 September 2018.
33 Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. Reference, opening of the Treaty 28/10/2011, entry into force 01/01/2016, CETS
Similarly, environment, climate change and sustainable development have been at the top of its Agenda: since the COE Environment Programme was launched in 1961, various treaties were adopted in its framework as, for example, the European Landscape Convention, Convention on the Conservation of European Wildlife and Natural Habitats, and the Framework Convention on the value of Cultural Heritage for Society.

However, so far, the COE has not tackled the Anthropocene nor its impact on human health and the duties of States arising from it. Again, the efforts to introduce the right to a healthy environment in the system of the European Convention on Human Rights (ECHR) through an additional protocol, were never successful.

Nevertheless, some interesting indications on the possible evolution of the COE’s approach to health in the Anthropocene can be indirectly found in the jurisprudence of the European Court of Human Rights (ECtHR) in the field of environment, health rights and biolaw, as closer analysis shows.

Indeed, the ECtHR has proven capable of providing interesting responses when environmental issues were raised before it through the “incorporation of environmental values” within the scope of application of the European Convention on Human Rights (ECHR), provided that an interrelation with a right protected under the Convention
existed. In particular, the right to life and the right to private and family life, respectively enshrined in Articles 2 and 8 of the ECHR, and the right to property provided in Article 1 of the First Additional Protocol to the ECHR, have offered suitable legal bases. A paradigmatic example is offered by the case law of the Strasbourg Court on States’ duties in relation to natural disasters, which were connected to the adverse effects of climate change in the Budayeva and Kolyadenko v. Russia judgments. In these cases, the Court elaborated a pattern hinged on the standards of foreseeability, gravity and mitigability of the threat posed by a natural disaster, as means for assessing and affirming State duty to adopt positive measures to protect the population affected from the risks connected.

In a similar fashion, although the ECHR does not expressly provide the right to health nor to access to health care, the ECtHR has been capable of providing interesting responses to health rights by relying on Article 2 and on Article 3 of the Convention, which prohibits torture and inhuman and degrading treatment. In this regard, the Court has elaborated a settled approach especially with respect to the right to access to health care.

In particular, the Strasbourg Court has developed the view that the denial of access to life-saving emergency treatment amounts to a breach of the substantive limb of Article 2 of the ECHR. In the case of Mehmet Şentürk en Bekir Şentür v. Turkey, v. Turkey, various Turkish hospitals refused to admit for treatment a heavily pregnant mother, who subsequently died while travelling in search for the emergency treatment


needed. The court held that “the authorities of a Contracting State put an individual’s life at risk through the denial of health care they have undertaken to make available to the population in general” and found a breach of Article 2 of the Convention, since States have positive obligations to set up a “regulatory structure […] requiring that hospitals, private or public, take appropriate steps to ensure that patients’ lives are protected”. In the case, instead, health care system was inadequate and under-resourced.

A similar pattern was adopted, for example, also in the cases of Asiye Genç v. Turkey, Elena Cojocaru v. Romania and Aydoğan v. Turkey and was taken up again recently in the Lopes de Sousa Fernandes v. Portugal. This suggests that an enhanced approach has been adopted in Strasbourg in comparison with the Court’s view in the Cyprus v. Turkey judgment, where the it did not go any further than saying that “more than an issue may arise” under Article 2 where treatment was systemically denied to individuals.

In the Aleksanyan v. Russia judgment, the Court held that the denial of access to appropriate health care and treatment constituted an inhuman and degrading treatment.
since it “undermined [the applicant’s] dignity and entailed particularly acute hardship, causing suffering beyond that inevitably associated with a prison sentence and the illnesses he suffered from”. In a similar vein, it is of particular importance that, in the same line of jurisprudence, the Court almost recognized the right to ensure continuing access to palliative care under Article 3 of the Convention in the case of D. v the United Kingdom.  

Again, the ECtHR has developed an important case law in the field of bioethics, which encompasses a wide array of issues, ranging from euthanasia and reproductive rights to human embryos. For our purposes, it is particularly interesting that the Court had chance to assess the issue of accessing to a given medical treatment in the field of bioethics and biolaw when abortion rights were at stake. Article 8 of the ECHR, which guarantees the right to respect for private and family life, has offered the suitable legal basis for assessing the issue of accessibility to given health treatments made available by biomedical progress. In particular, the Court has recognized the right to timely access to amniocentesis and the right to access to abortion services under the procedural limb of Article 8 of the Convention, occasionally in conjunction with Article 3 of the ECHR.  

A significant example is offered by the R.R. v. Poland judgment. In the Costa and Pavan v. Italy case, the Strasbourg Court recognized that the applicants’ exclusion from medically assisted reproduction amounted to a disproportionate interference with their right to respect for private and family life. Whilst in both R.R. and Costa and Pavan...
judgments, the Oviedo Convention was taken into account as relevant law, in the *Glass v. the United Kingdom* case the Court used the Oviedo Convention to assess whether “the regulatory framework in place in the United Kingdom is in any way inconsistent with the standards [it] lay down […] in the area of consent”. This statement is all the more interesting when one considers that the United Kingdom has not even signed the Oviedo Convention and that, notwithstanding this, the Convention’s standards were applied as parameters to assess the consistency of domestic regulations with its bioethical and human rights-based standards.

What emerges from these considerations is that the ECtHR has proven capable of tackling States’ duties in relation to environmental hazards and, specifically, to affirm the duty to ensure adequate protection to human life and health with regard to mitigable, foreseeable and serious risks. As those that the Anthropocene poses, we could argue, and which are likely to affect society in a transversal and massive way, especially the most vulnerable subjects including from an economic and social viewpoint. What is more, accessibility to healthcare was affirmed by the ECtHR as a right protected under the ECHR through remarkable interpretive efforts, and also in relation to several biorets. However, so far, the Court has not had the chance to address issues related to transhumanism, for example human cloning, to which one the Additional Protocols of the Oviedo Convention is dedicated. When we focus on the legal framework of the

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COE, it appears that some justification can be found in relation to somatic genome editing, since Article 13 of the Oviedo Convention provides that any “intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes”. Otherwise, subsequently Article 13 prohibits human germline alterations where it allows genome editing “only if its aim is not to introduce any modification in the genome of any descendants”. In this regard, Paragraph 91 of the Explanatory Report of the Oviedo Convention further specifies the prohibition with regard to the gametes, where it states that that “in particular genetic modifications of spermatozoa or ova for fertilisation are not allowed”. The objective to protect future generations from any distorted use of biology and medicine was a serious concern when the Oviedo Convention was adopted, back in 1997 as emerges clearly from the Preamble, where it recalls “the need to respect the human being both as an individual and as a member of the human species”. However, it should also be considered that now more than twenty years have passed since the Oviedo Convention was drafted and that the context of its adoption was peculiar. If, on the one hand, that historical moment had raised great expectations on a promising scientific future thanks to the great achievements related to the sequencing of the human genome for treating genetic diseases, on the other hand scientific progress was not advanced as it is today. Despite some techniques and their effects in the short and the long term still require to be ascertained fully, the benefits they can bring are undeniable. In this regard, it is significant that the Council of Europe itself has issued its Recommendation 2115(2017) on “The use of new genetic technologies on human beings”, in which it has warned...

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about the “potential abuse for enhancement or eugenic purposes” of the genetic engineering techniques. Recommendation 2115(2017) also recalls the risks related to human germline alterations in particular, as still some scientific uncertainty as to their results exists but also recognizes that some techniques, as the mitochondrial replacement therapy (MRT) are practiced, and cited in this regard the experience of the United Kingdom. More in detail, it has acknowledged that “[d]eliberate germ-line editing in human beings would cross a line viewed as ethically inviolable”51 but, at the same time, it has also recalled that, according to Articles 32 and 28 of the Oviedo Convention, this treaty can be amended pursuant to the procedure provided therein by the twenty-nine States Parties, considered that “the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation”.52 This statement seems to help to suggest a different consideration of the moratorium that the COE invokes in relation to human germline alterations; possibly, we could argue that this ban might be reconsidered when the results achieved by scientific progress become more stable and certain, especially their positive impact on human health of present and future generations. This may be particularly true with regard to those applications capable of helping human nature to express its potential, as the transhumanistic view wished.

The COE has adopted an express statement on human cloning as well, in the Additional Protocol to the Oviedo Convention dedicated to this question. Article 1 therein contains a blanket ban on human cloning, which possibly should deserve some reconsideration in relation to human therapeutic cloning in light of the international practice. It is relevant in this regard that in Oregon, in the United States of America, important results were achieved for treating successfully a child affected by a serious
genetic disorder.\textsuperscript{53} Therefore, despite we still have to wait for the scientific applications considered to ascertain their impact on human health, especially with respect to human germline modifications, these techniques are promising and some reconsideration someday may become duly and, possibly, also desirable. This is why it seems important to anticipate that moment and to provide human rights consistent responses the soonest, which also seems in line with the statement contained in the Explanatory Report of the Oviedo Convention that “the developments in medicine and biology […] should be used only for the benefit of present and future generations and not be diverted in ways that run counter to their proper objective”, as scientific progress has to serve always the “benefits of progress to the whole of mankind”.\textsuperscript{54}

Given the delicate nature of these applications, we should not let law lag behind science, to describe this with the words of Professor García San José.\textsuperscript{55}

5. THE EMERGENCE OF AN INTERNATIONALLY SHARED CORE CONCEPTION OF THE RIGHT TO HEALTH

5.1 An overview of the universal and regional landscape

Definition of the more specific content of the right to health in the framework of the EU and of the COE for the prospective approach to the era of the Anthropocene cannot prescind from the landscape of international law.


In this respect, as authoritatively highlighted in scholarship, an *opinio iuris* has emerged at the international level, as closer analysis of conventional international law shows.

At the global level, under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), “[e]very human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity” since “[h]ealth is a fundamental human right indispensable for the exercise of other human rights”, as the Committee on Economic, Social and Cultural Rights has clarified in General Comment No. 14 on “The Right to the Highest Attainable Standard of Health”. Practical enforcement is defined by the “4-A scheme”, that hinges on availability, accessibility, acceptability and adaptability - which turns into quality when health is at stake. Substantially, it requires that health services, goods and facilities, be made available in sufficient quantity and be made accessible without discrimination, physically, economically and informationally.

At the regional level, the Inter-American Court of Human Rights, in connection with human dignity and the conception of dignified life, the Court has affirmed the right to access to the highest attainable standards of health, including health care and assistance, treatment and medication, without any discrimination. The decisions of the Court in the cases of the *Yakye Axa Indigenous Community v. Paraguay*, *Ximenes-Lopes v. Brazil*, *Albán Cornejo et al. v. Ecuador* and *Ver-Vera et al. v. Ecuador* are some paradigmatic examples. What is more, the Court had the chance to apply this view in

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57 Inter-American Court of Human Rights [IACtHR], Case of the *Yakye Axa Indigenous Community v. Paraguay*, Merits, Reparations and Costs, IACHR Series C No .125, IHRL 1509 (IACHR 2005), Judgment of 17 June 2005.

58 Inter-American Court of Human Rights [IACtHR], Case of *Ximenes-Lopes v. Brazil*, Merits, Reparations and Costs, IACHR Series C No. 149, IHRL 1533 (IACHR 2006), Judgment of 4 July 2006.

59 Inter-American Court of Human Rights, Case of *Albán-Cornejo et al. v. Ecuador*, Interpretation of the Judgment on the Merits, Reparations and Costs, IACHR Series C No. 171, Judgment of 5 August 5, 2008

60 Inter-American Court of Human Rights [IACtHR], Case of *Ver-Vera et al. v. Ecuador*, Preliminary Objection, Merits, Reparations and Costs, Series C No. 226, Judgement of 19 May 2011.
the field of bioethics in the case of Artavia Murillo et al. v. Costa Rica, 61 where it held that the prohibition of in-vitro fertilization set by Costa Rica breached the right to privacy, the right to personal liberty, the right to physical, mental and moral integrity and the right to found a family protected under the ACHR and recognized the right to access to given biomedical techniques, namely in-vitro fertilization, under the ACHR, by establishing that the rights to private life and to personal integrity are also directly and immediately linked to health care.

With reference to the allocation of resources, Article 2 of the ICESCR and Article 26 of the American Convention on Human Rights provide the “progressive realization” clause, which otherwise is not contemplated by the African Charter on Human and Peoples’ Rights that, in its Article 16 enshrines the “right to enjoy the best attainable state of physical and mental health”. Moreover, the African Commission on Human and Peoples’ Rights has provided an important reading of the right to health in connection of environmental degradation due to oil activities in the Social and Economic Rights Action Center (SERAC) and the Center for Economic and Social Rights (CESR) v. Nigeria. 62

This conception of the right to health echoes the Constitution of the World Health Organization (WHO), 63 that defines “the highest attainable standard of health as a fundamental right of every human being”, and the UNESCO Universal Declaration on

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Bioethics and Human Rights. The latter is a particularly interesting reference, especially for two reasons. First, because in its Part II it enshrines some substantial principles of bioethics, among which access to healthcare and essential medicines (Article 14) by connecting “social responsibility and health”. Then, but not less important, because although non-binding it has the nature of a legal instrument, since it was adopted in the framework of an intergovernmental organization and therefore it enhances the view that an *opinio iuris* has progressively emerged as to a generalized, shared conception of the right to health.

### 5.2 Some considerations on the core conception of the right to health

That being said, we should question whether this core conception of health and in particular the application of the notion of highest attainable standards may be considered from an evolutionary viewpoint, that is, in particular, whether its scope should be considered in a flexible and farsighted way, capable of incorporating the advances of scientific progress and the purposeful reflections elaborated in the philosophical debate.

Besides the capacity of the international jurisprudence considered above to provide an advanced reading of States’ duties under the right to health, four our purposes it is indicative that the Committee of Economic, Social and Cultural Rights has expressly clarified in its General Comment n. 14(2000)\textsuperscript{65} that the right to health has not to be intended as the right to be healthy but it entails, along with other components, the creation of appropriate environmental conditions. In this regard, an interconnection emerges between human health and environmental conditions, among which those impacted by the Anthropocene may be included. In order to further clarify the scope of the right to health and theorize how it may be intended in relation to advanced scientific

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techniques as a means for coping with the adverse impact of the Anthropocene, it would be helpful to rely further on the interpretive guidance provided the Human Rights Committee. Despite the General Comment No. 14(2000) does not expressly recall scientific progress, it contains some interesting reference with regard to the standard of quality, where it requires that “health facilities, goods and services must also be scientifically and medically appropriate and of good quality”.

We could argue that advanced therapeutic means made available by scientific progress maybe encompassed in the notion of quality. What is more, it is indicative that Paragraph 13 of General Comment 14(2000) clarifies that the specific measures contemplated at Paragraph 12.2, concerning the right to maternal, child and reproductive health, the right to healthy natural and workplace environments and the right to prevention, treatment and control of diseases are not exhaustive and other measures, as those suggested, may be considered for implementing the right to health and ensuring the enjoyment of the highest attainable standards of health.

Moreover, some additional confirmation may be sought in the more recent General Comment No. 22(2016), on the right to sexual and reproductive health. Indeed, this reference provides more specific and explicit guidance with regard to the standard of “quality”. In particular, it is significant that at Paragraph 21 it provides that “[t]he failure or refusal to incorporate technological advances and innovations in the provision of sexual and reproductive health services, such as medication for abortion, assisted reproductive technologies and advances in the treatment of HIV and AIDS, jeopardizes the quality of care”. According to a comprehensive consideration of both General Comments considered and since sexual and reproductive health is encompassed in the core conception of the right to health emerged in international law, we could argue that

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66 Ibid, para. 12(d).
access to the advanced techniques made available by scientific progress represents a component of the right to health and to the enjoyment of its highest attainable standards.

6. SOME REFLECTIONS ON THE POSSIBLE UNDERSTANDING OF TRANSHUMANISTIC INTERVENTIONS ON THE HUMAN BODY

However, we should question more specifically which advanced techniques could be included in this notion and which purposes could be consistently pursued.

The conception of transhumanism, in fact, is quite wide, as well the interventions and transformations that could be made on the human body from this perspective, including for coping with the adverse impact of the Anthropocene. Therefore, some guidance to define which interventions may be feasible should be sought, from a wide viewpoint, in the conception of genetic identity and genetic integrity, which helps to clarify how the human body might be modified, with regard to both the individual and to the human species. This may be argued because transhumanism entails to rethink the human body to some extent. However, also in line with the view advanced by Julian Huxley, admissible interventions are those that help human nature to express its potentiality, as Dante Alighieri said in the Divina Commedia, a form of “trasumanar”,68 that, consistently with the views of Julian Huxley, transcends human nature without getting at odds with it. A “trasumanar” that is not confined to some individuals, but which is intended to achieve the whole species and future generations. Which would be necessary, it can be observed, if we consider to conceive transhumanistic solutions, in this sense, as a strategic means to be scheduled by States as a response to the Anthropocene and the threats it poses to human health.

In this regard, the views expressed in scholarship can be very conflicting: they are often described through the dichotomy between bioconservatives and transhumists. However, beyond any classification, in practice at the extremes, we find those who

68 As stressed by RODOTÀ, S., Il diritto di avere diritti, cited above n. 13, p. 365. ALIGHIERI, D., Divina Commedia, Canto I, 70-71. “Trasumanar significar per verba | non si poria”: Dante Alighieri describes as “trasumanar” the transition to Paradise, through the overcoming of his human condition.
reject the idea that human nature, intended in relation to Darwinian evolution, can be altered. In this sense, Hans Jonas supported the integrity of the human species, that is inalterable. In a similar vein, it was argued that any modification of the genetic identity of the human being would even amount to a crime against humanity, as was paradigmatically claimed by George Annas. And in this regard any modification should be rejected, even those aimed at improving human health through human germline alterations of therapeutic nature, not just those aimed at enhancement. On the contrary some other scholars have supported a restricted conception of genetic identity, stressing that it would encompass only core traits of the person. Therefore, any alteration concerning the pathological traits and their elimination would not actually affect the genetic identity of the individual and would be admissible. Moreover, it has also been stressed that genetic identity should not be overlapped with genetic integrity that is the right to a non-modified genetic heritage. However, with reference to this aspect it was stressed that “[t]he association of the right to genetic integrity […] with the right to genetic identity […] focuses solely upon the perils of the [genetic manipulation] without considering the potential benefits that can be derived from human genetic interventions” and that “[t]he right to genetic identity, therefore, should both foresee the integrity but also the changeability of one’s genetic architecture.”


71 The whole quotation reads: “[I]t is important to understand that not every intervention on the human genome aimed at modifying the germline necessarily equates to a eugenic practice. Therefore, it is more appropriate to follow the drafting example of the Charter of Fundamental Rights of the European Union’s art 3, “Right to the integrity of the person”, which unlike the Oviedo Convention, does not enshrine any general prohibition of germline genetic modifications. Article 3, refers instead to the prohibition of eugenic practices (in particular those aiming at the selection of persons) specifically and to the reproductive cloning of human beings (art 3.2). Contrary to the initiatives in the 1980s and 1990s led by European institutions, the right to genetic integrity is no longer formulated in terms of a general right to a non-modified genetic heritage or as an equivalent of a right to genetic identity. The association of the right to genetic integrity (and, subsequently, the right to a non-modified genetic heritage) with the right to genetic identity constitutes an old fashioned, narrow and detrimental view of human genetic manipulation, which focuses solely upon the perils of the latter without considering the potential benefits that can be derived from human genetic interventions. The right to genetic identity, therefore, should both
This seems particularly true when a given intervention of genome editing or any modification of the human body prescinding from genetics is practiced for therapeutic purposes and, in some way, in order to restore previous better or optimal health conditions.

That being said, it may be argued that the basic point seems to be precisely the dichotomy between any intervention that is made on the human body, either genetically or not, for therapeutic purposes or for enhancement purposes.

As Professor Stefano Rodotà stressed, we should be careful and make the necessary distinctions if we do not want to limit ourselves to ideological considerations.72

A particular focus is made here primarily and especially on genetic interventions, as they are suggested as, possibly, the more appropriate and targeted approach since the adverse impact of the Anthropocene are likely to affect individuals and the whole human species epigenetically. In this regard several distinctions have to be made, as genetic interventions may be of two kinds: on the one hand, they can affect the human germline and, as such, they are transmissible to future generations; on the other hand, they can concern somatic cells, therefore the only affect the individual on which the modifications are made. Another important and highly discussed practice is human cloning, which can be of two different types, either reproductive, which entails the creation of a human embryo through the technique of nuclear transfer and the subsequent implantation in the uterus, or therapeutic, which consists in the creation of an embryo that, differently from what happens in human reproductive cloning is not implanted in the uterus but, otherwise, is used for obtaining of embryonic cells, that are pluripotent, that are destined to be used for somatic therapy or for, example, for foresee the integrity but also the changeability of one’s genetic architecture: the right to personal identity may perfectly encompass the right to individual genetic modification.” GOMES DE ANDRADE, N. N., “Human Genetic Manipulation and the Right to Identity: the Contradictions of Human Rights Law in Regulating the Human Genome”, SCRIPTed, n° 7 (3), December 2010, pp. 429-452, 437. Also see, in particular, pp. 432-433. Moreover, the individual genetic identity and integrity should not be overlapped with the genetic identity and integrity of the species.

72 RODOTÀ, S., Il diritto di avere diritti, cited above n. 13, p. 354.
regenerative medicine. The two practices considered are particularly relevant, as the international community has expressed its consensus about their prohibition, that was also enshrined in two outstanding international law sources, namely Article 11 of the UNESCO Universal Declaration on Human Genome and Human Rights and Article 13 of the European Convention on Biomedicine and Biorights and Article 1 of its Additional Protocol on Human Cloning, which were mentioned previously in Paragraph 4. However, the international landscape now appears to be in progress and it may be argued that some appropriate reconsideration should be made. In light of the statements issued between 2015 and 2017, the UNESCO and the COE themselves seemed to have shifted to a position of prohibition to a position of stand-by until the outcomes scientifically achievable are clarified, with particular regard to human germline alterations.

This was somehow unavoidable since China conducted a very interesting experimentation—although not as successful as wished—on Beta-Thalassemia by relying on human germline alterations in 2015 and, in the same year,
the United Kingdom has adopted its Regulation that allows mitochondrial replacement therapy (MRTs). Similarly the debate is quite intense also with regard to human cloning. Once again, the distinction among the purposes pursued turns out to be of basic importance: in fact, a divergence of views exists with respect to human therapeutic cloning; whilst some countries have already adopted targeted regulation that allows it domestically, other States wish for a blanket ban on human cloning that would make no distinction between therapeutic and reproductive purposes. The clash among the pluralistic States’ positions has practically paralyzed the possibility to adopt a treaty on the issue, in particular aimed at forbidding human reproductive cloning. The experience of the United Nations in 2005 is particularly emblematic: the goal originally pursued, that is adopting an international convention on the prohibition, had to be changed as the negotiation came to an impasse. The outcome achieved is the UN Declaration on Human Cloning; of course, as a soft law tool, it has a moral and political persuasiveness on States, but of it is not a binding instrument. What is more, it is significant to notice that the international community appeared to be split when it came to vote the approval of the Declaration: 84 States voted in favour, whilst 34 voted against and 37 abstained. The divergence of views also accounted for the impossibility to adopt a convention when the UNESCO tried this route again several years later on two occasions, the first time in 2008 and then in 2014. The fact that human therapeutic cloning was successfully experimented in the United States in 2013 gave an impulse to the UNESCO’s engagement but was not enough for helping to overcome the divergences.

77 In this regard is of little help to stress that MRTs would concern mitochondrial and not nuclear DNA, as in the end the modifications made would affect the human germline, as was argued in order to provide a justification on the admissibility of this practice. See: SCOTT, R., WILKINSON, S., “Germline Genetic Modification and Identity: the Mitochondrial and Nuclear Genomes”, Oxford Journal of Legal Studies, n° 37 (4), 2017, pp. 886–915. In this regard, with respect to the view of the Council of Europe, see Council of Europe, Recommendation 2115 (2017), cited above n. 50, para. 2.
79 Ibid.
These considerations are helpful to highlight that the distinction between therapeutic interventions and alterations made for other purposes is of key importance for clarifying which practices may be arguably allowed.

The debate in scholarship seems to have basically embraced this perspective. In this respect, it could be helpful to recall that view which was emblematically upheld by John Harris\(^{81}\) and would allow human germline alterations for therapeutic purposes assuming that a duty exists to improve the health of present and future generations if the necessary means and techniques are available. In this respect Harris stressed that, nonetheless, any therapeutic intervention also implies some enhancement, as it determines an improvement of human health. However, it is interesting to consider that the criterion of “normality”\(^{82}\) suggested in scholarship as a means for distinguishing feasible practices from the forbidden ones, might be helpful for our purposes. This would pave the way to the acceptability of any alteration of the human body that is capable of creating a situation of “normality” that the subject affected never enjoyed or, otherwise, to restore a condition of “lost” normality. In practice, it is not always easy to distinguish therapeutic from enhancement interventions. For example, it was suggested that the criterion of “normality” would help to identify “therapeutic” modifications of the

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\(^{82}\) RODOTÀ, S., *Il diritto di avere diritti*, cited above n. 13, pp. 348 ff. It is interesting to recall here how the standard of normality was taken into account in the context of sport competitions. In this regard the case of Oscar Pistorius is emblematic. In particular, the International Association of Athletics decided that he was not eligible for Olympic qualifying events: as a double amputee sprinter, his carbon fiber prosthetics “should have been” considered as technical aids which [gave] him an advantage over other athletes not using them”. However, the decision was overturned by the Court of Arbitration for Sport of Lausanne that it was not proven that Oscar Pistorius got an advantage from the equipment, therefore he had to be considered eligible for participating in Olympic qualifying events. In this regard, his condition was considered not to exceed what we could call the normal standards for eligibility. A different issue that, nevertheless, seems interesting to recall here, is genetic doping, which is defined by the Anti-Doping Agency as “the non-therapeutic uses of genes, genetic elements and/or cells that have the capacity to enhance athletic performance” and in 2003, for the first time, was included in the Prohibited List – International Standard, related to the World Anti-Doping Code, of the World Anti-Doping Agency of the UNESCO. The List is an Annex of the UNESCO International Convention against Doping in Sports. See: VERDUGO GUZMÁN, S. I., “El dopaje genético y la manipulación de genes en el deporte”, *IUS ET SCIENTIA*, n° 3 (1), 2017, pp. 227-234; UNAL, M., OZER UNAL, D., “Gene doping in sports”, *Sports Medicine*, n° 34 (6), 2004, pp. 357-362.
human genome insofar as they entail “corrective” interventions, in order to prevent the onset of genetic diseases. Enhancing alterations, instead, would be those intended to bring about an improvement of some traits of the subject treated, even when no pathological exigency required it as, for instance, modifications aimed at increasing the intellectual capacity of an individual. Despite the difficulties that may emerge, this standard seems helpful, and it would also help to theorize an ethical justification to such practices as personalized medicine, pharmacogenetics or pharmacogenomics and regenerative medicine.

Such practices have a different impact on the human being than genome editing and the legal issues they raise are different from those posed by human therapeutic cloning. In particular, these practices do not entail any alteration of the genetic identity, otherwise they rely on it in order to advance customized diagnostic and therapeutic responses. More than the genetic integrity of the subjects concerned, the protection of the genetic information and related issues of non-discrimination on a genetic basis are at stake. Nevertheless, as anticipated, the above-mentioned conception of genetic identity is relevant in this respect too for providing justification: personalized medicine, indeed, consists in providing customized medical care according to the genetic makeup of a specific patient. Its conceptual elaboration dates back to the early twentieth century, when the English doctor Archibald Garrod theorized a “chemical individuality”, \(^\text{83}\) arguing that an interconnection existed between metabolic alterations and congenital and inheritable alterations, by making reference, thus, to genetic susceptibility, that is a conception of basic importance. The conception of individualized medicine was taken up in the 1940s by Beadle and Tatum, that succeeded to highlight the role of enzymes in the metabolic processes connected to the genes that codify them. \(^\text{84}\) In this way, it was defined the genetic variability among individuals which is of basic importance from

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several viewpoints. On the one hand, it has constituted the basis for pharmacogenetics or pharmacogenomics, a therapeutic approach that relies on the interplay between the peculiar genetic makeup of each individual and the connected specific drug response. It is likely that soon, thanks to the relentless scientific progress, it will be possible to sequence the personal genome, entirely and in real time, a possibility that goes well beyond the diagnostic helpfulness of genetic testing. If, on the one hand, such achievements are of fundamental importance for the individual therapeutic success, on the other hand they pose a threat to social justice, equality and genetic discrimination and stigmatization.

For example, it might lead to the “selection” of the diseases to be treated, giving priority to the disorders that are prevalent in the population. What is more, pharmacogenomics and pharmacogenetics may raise issues of protection and confidentiality of the genetic information and may lead to discriminations and stigmatisation that might affect the subject specifically concerned, for example in the labour market or in relation to insurance issues. This is why an ethical and human rights-consistent approach is of basic importance, and clearly requires adequate and equitable allocation of the resources available as well, since access to these technologies...

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GINSBURG, G. S., WILLARD, H. F., Genomics and Personalized Medicine, Amsterdam, Boston, Heidelberg, London, New York, Oxford, Paris, San Diego, San Francisco, Sidney, Tokyo, Elsevier, Vol. 1 and 2, 2012. LÓPEZ-LÓPEZ, M., GUERRERO-CAMACHO, J. L., FAMILIAR-LÓPEZ, I. M., JUNG-COOK, H., CORONA-VÁZQUEZ, T., ALONSO-VILATELA, M. E., “Pharmacogenomics: the quest for individualized therapy”, Revista de Neurologia, no 39 (11), 2004, pp. 1063-1071. There are still different views in scholarship about the two expressions “pharmacogenetics” and “pharmacogenomics”; however, despite and beyond this disagreement, this study shares the view according to which “pharmacogenetics” refers to a specific gene or group of genes, whilst “pharmacogenomics” refers to the analysis of articulated processes that might come to affect the whole genome. The development of the study on pharmacogenetics and pharmacogenomics received a great impulse from the Human Genome Project and especially by the whole sequencing of the human genome.


87 RUÍZ-CANELA LÓPEZ, M., “Farmacogenética y farmacogenómica” and GINSBURG, G. S., WILLARD, H. F., Genomics and Personalized Medicine, both cited above n. 85. MALPAS, P. J., "Is genetic information relevantly different from other kinds of non-genetic information in the life insurance context?", Journal of Medical Ethics, n° 34, 2008, pp. 548-551. NEBERT D. W., "Pharmacogenetics and pharmacogenomics: why is this relevant to the clinical geneticist?", Clinical Genetics, n° 56 (4), 1999, pp. 247-258.
is expensive. However, from a perspective of personalized medicine and transhumanism, regenerative medicine appears even more relevant, due to its impact on the physical integrity of the subject treated for the goal of regenerating cells and tissues. In fact, cellular regenerative medicine\textsuperscript{88} entails specific practices that require a direct “manipulation” of the human body, for example implantation of cell preparations, systemic infusion or a combination of therapy with mesenchymal cells and genetic therapy. It appears clear that it would be a helpful means for coping with the deterioration of the human body that exposure to Anthropocene’s adverse effects might cause which is even more interesting since the relevance of the impact of the environmental factors in triggering genetic disorders has proven stronger than we thought. And this is of basic importance for finding a way for treating polygenic disorders as, for instance, some types of cancer, diabetes and psychiatric and cardiovascular diseases.\textsuperscript{89} What is more, cellular regenerative medicine may offer an alternative to human therapeutic cloning, without raising the same ethical concerns with regard to the use of human embryos – although create by the technique of nuclear transfer – and the related moral questions concerning human life. Another important branch of regenerative medicine is represented by bioprinting of tissues and organs for transplantation, a technique which has so far been successfully used all over the world. In this regard are eloquent evidence of the promising viable application of bioengineering the experiences of Dr. Takanori Takebe, in the context of a research project carried out by a team led by the Cincinnati Children’s Center for Stem Cell and Organoid Medicine (CuSTOM) and Yokohama City University, who succeeded to create some liver tissues suitable for therapeutic transplantation by using skin cells, and


of the American company Organovo, that similarly succeeded to print liver tissues with its 3D NovoGen BioPrinting.\textsuperscript{90}

Under this premise, the admissibility of this kind of practices, capable of having an important impact on the human body through its manipulation, either genetic or not, was affirmed in scholarship by supporters of transhumanism by claiming that identity is the result of each individual’s will. It is the human being to “structure”, to define his own identity. From a more moderate but, possibly, argumentatively stronger viewpoint, we could consider these issues as a matter of autonomy, which would also help to tackle the risks of being ideological highlighted by Professor Rodotà and would help to bridge possible gaps with human dignity.\textsuperscript{91}

Of course, some legislative efforts at all levels would be indispensable for preventing discriminatory practices and eugenic drifts: international guidance for concerted domestic implementation is of fundamental importance. Risks of discrimination and stigmatisation might be posed not only when diagnosis might lead to discovering the susceptibility to a given disease, for example through genetic testing, but misuse of the therapeutic means itself might lead to such distorted consequences as unequal allocation of the means available or even to serious social injustice. For example, by creating an élite of subjects who would enjoy of improvement of their potential due to their privileged social status. Another serious risk, possibly more dystopic but not unlikely, is the use of advanced therapeutic means for creating a subdued working class, that might recall the dystopia described in Aldous Huxley’s masterpiece \textit{Brave New World}.\textsuperscript{92}

\section*{7. ADVANCING SOME POSSIBLE EVOLUTION IN EUROPE}

The content of the right to health in the EU and in the COE has to be read consistently with the common core elaborated in the international landscape that, as


\textsuperscript{92} HUXLEY, A., \textit{Brave New World}, London, Chatto & Windus, 1932.
authoritatively observed in scholarship, has come to amount to an international *opinio iuris*.

However, the point is whether this “incorporation” may help to improve the protection of the right to health and the right to access to health care in the framework of the EU and of the COE for facing the challenges of the Anthropocene, especially through the use of the most advanced solutions made available by scientific progress. Thus, primarily, possible ways of integration are considered to subsequently suggest how the protection may be enhanced.

The EU would clearly benefit from some internationally shared guidance when elaborating its policies at the intersection between health and environment and similarly when interpreting and applying Article 35 of the CFR, given the programmatic nature of this provision. This would also concur to enhance justiciability before the ECJ and to positively affect Member States’ implementation of EU law concerning both health and environmental sector in their domestic legal orders, in line with the scope of application of the CFR as defined in Article 51(1) therein.

Similarly, reference to the internationally shared conception of the right to health would benefit the case law of the Strasbourg Court. For example, through a – long awaited - environmental reading of Article 3 of the ECHR for providing adequate responses to the threats posed by the Anthropocene to human health, consistently with the relevant lines of jurisprudence elaborated so far. Any achievement of the ECtHR would also benefit the protection ensured by the EU pursuant to Article 52(3) of the CFR, where it identifies the minimum scope and meaning of the entitlements enshrined in the CFR by reference to the ECHR. Again, in the post-Lisbon framework, the level of protection elaborated in the Strasbourg jurisprudence is a standard of evaluation of the legitimacy of EU’s policies and actions, in line with Article 6 of the TEU.

The point is now how the content of the right to health and to access to health care may be reconsidered in the EU and in the COE in light of these considerations with
regard to the challenges of the Anthropocene and whether it allows a bioethically-oriented reading, also capable of embracing accessibility to biomedical progress.

Some possible but not exhaustive paths are advanced. Primarily, reference to the 4As-Scheme would help and, especially, its reading in light of the principles of bioethics.

From a social perspective, “availability” and “accessibility” would benefit from some reference to the principles of solidarity, justice, universality and vulnerability, in order to promote an equal allocation of resources - that should be made available in sufficient quantity and without discrimination - also capable of minimizing the risks of commodification of vulnerable subjects. For example, vulnerability would prompt socially and economically disadvantaged people to join medical experimentation, because they wish for some financial gain or for accessing therapies that are not yet available in the pharmaceutical market. Sometimes, when the burden of the costs of health care is not adequately assumed by the public sphere, medical experimentation may result to be the only feasible way to access medications for the poorest. Again, economic accessibility entails that resources be affordable for everyone. The reading advanced seems to suit the criteria of allocation of health resources represented by “rights” according to Professor Daniels’ classification, that the EU has embraced, and also seems to be consistent with a human rights-based approach in the framework of the COE.

Similarly, it may be argued that the standards of accessibility and acceptability would benefit from some reference to the bioethical principles concerning the individual sphere, as non-maleficence and beneficence, autonomy and information which would respectively improve the access to specific information on health and Anthropocene and education on individual approach to the risks connected. Furthermore, these principles would enhance the respect for medical ethics and cultural appropriateness of medical services and assistance. A similar consideration may be put forward with regard to the standard of quality, where it implies that “goods and services be scientifically and medically appropriate and of good quality”. In this sense, health care should be
adequate to meet the challenges of the Anthropocene, which also means appropriate education and skills of the medical personnel. Again, it may also provide some justification for the incorporation of instruments made available by biomedical progress, in order to ensure adequate quality of health care in response to the specific health risks posed by the Anthropocene, which may not always be coped with according to usual medical protocols and means. It is in this regard that the advanced techniques taken into consideration in this study may be a helpful reference, human therapeutic cloning, pharmacogenetics, pharmacogenomics and regenerative medicine. Of course, human germline editing too may be a helpful solution to take into account: however, still the normative and ethical approach to the admissibility of this kind of intervention need scientific evidence of its benefits and of its safety to make the time ripe for acceptance. Nevertheless, surely time is ripe for the discussion, as the experience of the United Kingdom with MRT demonstrates.

Last but not least, human dignity would underpin accessibility to advanced biomedical preventive and therapeutic solutions as a means for enabling human beings to enjoy a dignified existence and the full personal development when facing up to the adverse impact of the Anthropocene on their health. Which is exactly what was desirable in the views of Julian Huxley.

The view advanced may find some further enhancement by reference to Article 15 of the ICESCR - it is noteworthy that all European States have signed and ratified it - and to the system of the Oviedo Convention, consistently with Article 31(3)(c) of the Vienna Convention on the Law of the Treaties.

In fact, under Article 15 of the ICESCR, that enshrines the right to enjoy the benefits of scientific progress, States are bound to take steps “to achieve the full realization of this right” [that] shall include [the actions] necessary for the conservation, the development and the diffusion of science and culture”. States are under positive and negative obligations in light with their threefold duty to respect, to protect and to
fulfil,\textsuperscript{93} which addresses for example, the freedom of research but also ensuring availability and accessibility of scientific progress not only in the public sphere but also in those areas of privatization and commercialization of science and health. In this regard, some precious guidance will be provided by the forthcoming General Comment on the right to science on Article 15(1)(b), which will be soon adopted by the Committee on Economic, Social and Cultural Rights. However, in the meantime, some helpful interpretive guidance can be offered by Article 27 of the Universal Declaration on Human Rights (UDHR),\textsuperscript{94} which is the archetype of UN human rights treaties.

In fact, interpretive reference to Article 27 of the UDHR would provide some justification to the adoption of an inclusive and democratic approach to States duties under the right to enjoy the benefits of scientific progress. This is so because this provision foresees that everyone has the rights to “share in scientific advancement and its benefits” which, through reference to the verbs “participer” and “participar” respectively used in the French and Spanish version of the UDHR, should be intended as the right to actively participate in scientific progress and its benefits.\textsuperscript{95} This seems all the more true when one considers that, according to Article 15(2) of the ICESCR, States are under an obligation to take all the steps to achieve the “full realization” of this rights, “includ[ing] those necessary for the conservation, the development and the diffusion of science”.

Moreover, it may be argued that this view appears consistent with the rationale underlying the conception of “benefit sharing”, that is contemplated in Article 12 of the UNESCO Universal Declaration on Human Genome and Human Rights, which provides that “benefits from advances in biology, genetics and medicine, concerning the

\textsuperscript{93} See DONDERS, Y., “The right to enjoy the benefits of scientific progress: in search of state obligations in relation to health”, Medicine, Health Care, and Philosophy, n° 14 (4), November 2011, pp. 371–381.


\textsuperscript{95} MANCISIDOR, M., “Is There Such a Thing as a Human Right to Science in International Law? “, ESIL Reflections, n° 4(1), (7 April 2015), available at http://www.esil-sedi.eu/node/896 last visited 13 September 2018; MANCISIDOR, M., “Historia del Derecho Humano a la Ciencia”, in Die Subversive Kraft der Menschenrechte, HUHLE, N., HUHLE, T., (eds.), Oldenburg, Paulo Freire Verlag, 2015. For further views and assessments on human rights in general and, in particular, on the right to science, it may also be interesting to visit the blog of Professor Mikel Mancisidor at http://mikelmancisidor.blogspot.it/.
human genome, shall be made available to all”. Some further clarification and guidance on the understanding of the conception of benefit sharing and on the possibility to consider it from a socially inclusive perspective are offered by Article 19 of the UNESCO International Declaration on Human Genetic Data, where it provides that “benefits […] should be shared with the society as a whole and the international community”. In practice, States shall provide effectiveness to this principle by ensuring “provision of new diagnostics, facilities for new treatments or drugs stemming from the research” besides “support to health services”.

The view advanced above may arguably provide some justification under international law to the theorization of accessibility to healthcare as also including genome editing, human therapeutic cloning, pharmacogenetics and pharmacogenomics and regenerative medicine, in light of a human rights-based approach and as a way of understanding benefit sharing, as a response to the threats posed by the Anthropocene to human health and integrity. Of course, adequate assessment of the risks connected to such advanced applications as genome editing, human therapeutic cloning, pharmacogenetics or pharmacogenomics ad regenerative medicine is fundamental. In this respect, the precautionary principle should be taken into consideration as a reference of primary importance.

Also the Oviedo Convention and its Additional Protocols may be helpful for developing a regional human rights-based approach. This may be argued because they have proven capable of enhancing the protection of fundamental rights, especially in relation to access to healthcare and the enjoyment of some advanced biorights, when used as a support to the interpretation of the ECHR, as the case law of the ECHR has demonstrated on many occasions - the cases mentioned in the section on the COE are emblematic examples, as for instance the Costa and Pavan judgment. Surely, the COE’s system would be a helpful reference also for the interpretation of the CFR – especially pursuant to Article 52(3) CFR - and EU law in general. Due to the epigenetic impact of the Anthropocene and the progress and promises of personalized medicine, particular attention is devoted here to the Additional Protocol on Genetic Testing for Health
Purposes. It seems relevant to stress especially the importance of the principle of non-discrimination ad non-stigmatisation on the grounds of the genetic heritage embodied in Article 4, which sets a specific prohibition in this respect. This principle is also contemplated by the UNESCO Universal Declaration on Human Genome and Human Rights at Article 6, according to which “no one shall be subject to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity” and by the UNESCO International Declaration on Human Genetic Data at Article 7, which also includes reference to proteomic data and which extends the protection it ensures to the stigmatization of an individual, a family, a group or communities.

The importance of genetic testing is closely related to access to personalized medicine, and to customized therapeutic approaches as pharmacogenetics or pharmacogenomics. This is why ensuring adequate and effective protection to the genetic information resulting from genetic testing should be a basic goal for States when defining their policies in this regard, which may be intended as a way for adopting the “appropriate measures [for] prevent[ing] stigmatisation of persons or groups in relation to genetic characteristics” pursuant to above-mentioned Article 4(2) of the Additional Protocol on Genetic Testing for Health Purposes. This kind of discriminations, indeed, might assume particular importance in those countries that adopt an insurance-based health system, as it is more likely to affect persons with a genetic predisposition to a disease that might be triggered by the Anthropocene.

8. CONCLUSIONS

Which evolution can we reasonably expect? Possibly, we can be reasonably but wisely expect some improvement of accessibility of healthcare from a general viewpoint. The EU and the COE so far have proven quite capable of handling the weaknesses in their systems, normatively and judicially. In this regard, we can expect a growing engagement, in line with the international increasing efforts in tackling the Anthropocene. In practice, combined strategies seem the most suitable option: managing the impact of the Anthropocene, requires combined action that addresses both
the environmental and the health sphere. Improvement of living conditions (for example: food and water security; reduction of pollution; enhanced preventive health care; investing in research) is basic; although costly, in the long term is rewarding, just like ensuring equal access to health care. Again, the relentless progress of biomedicine and biotechnology is likely to provide new resources and make them available, accessible and more affordable for a growing part of the population. Of course, pharmacogenetics or pharmacogenomics, regenerative medicine, human cloning for therapeutic purposes and all therapeutic interventions concerning the human genome, especially human germline alterations, still require time and further scientific evidence of the benefit they can offer in the short and long term. However, the fact that some techniques, as the mitochondrial replacement therapy, are already available and can help to improve the health and the living conditions of the descendants and, in a prospective way, of the future generations, makes it compelling to define a human rights-based approach. As Professor Rodotà said, human rights can be more effective than prohibitions; and, arguably, we can suggest that human germline modifications and human therapeutic cloning should be wisely reconsidered, but responsibly. A bioethical approach may arguably be the reasonable solution for elaborating rules that can ensure adequate protection to the human being, especially to the most vulnerable persons. This may be the viable path to ensure that human nature can express its potentiality without being distorted or used for serving unethical purposes, even through the exploitation of the most vulnerable subjects, for example in the experimentation.

Human rights law and bioethics will play a fundamental role to ensure social justice and hopefully mark the Anthropocene as the era when law stopped “lag[ging] behind science” or, at least, succeeded to keep pace with it better than it has done so far.

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