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Genome editing and embryos: threat or resource for future generations?

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Genome editing and embryos: threat or resource for future generations?

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ABSTRACT: This paper aims to investigate the origins, development and the issues inherent in the practice and legal framework of genome editing and its application on human embryos. In the latter section, it seeks to define the existing tangled legal system on an international level, with an emphasis on three Countries, which regulate the matter in different fashion even resulting in conflicting outcomes.

KEYWORDS: Genome editing; embryos; moral issues; comparative perspective; suggestions.

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1. Introduction

Why is every person different? Where do talents come from? Can we prevent diseases? The study of the human genome seeks to provide increasingly precise answers to these basic questions in order to understand the importance of DNA, how much of an influence environment and lifestyles have, and whether, how and to what extent we can modify our genetic heritage. We are faced with new challenges and great opportunities, as well as some risks, which are part of the most fascinating of all explorations: looking for the reason why we are unique. In this work, we seek to answer some of the questions, which come to mind when we think about genome editing.

2. What is a human embryo?

Introducing the theme, we are about to examine, it is necessary to outline what do we talk about when discussing human embryos. After 24 hours from the union of one egg with one spermatozoa, it begins the second phase of pregnancy, called embryo period. It is here that the embryo is created and it grows, following the organism called zygote. During its first five days, when the two initial cells start to divide themselves into many others, it is called morula. After five days, it is called blastocisti. At this point, the embryo has a circular

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form and starts to create a cavity, which will help to create the placenta and the rest of the child's body. The very first days of blastocisti are the most important: it secures itself to the uterus, so that the process of pregnancy can start. Normally, this process of implantation stops fourteen days after the fecundation. After that, it will start to grow fast in order to assume a similar form to the one of a baby. From the eighth week on, the future baby has already all organs and starts to develop limbs; now the foetal phase starts. Summarizing, the embryo does not present a human form, while the foetus does, having already some organs and limbs[1].

The Constitutional Court[2] has a clear idea about what an embryo is: an entity full of life whose dignity is constitutionally relevant. The protection of it is not lower for it is affected by a genetic malformation; however, its safeguard needs to be balanced with other different constitutional principles[3].

In this regard, the Court of justice of the EU affirmed that: «Any human ovum must, as soon as fertilised, be regarded as a 'human embryo' within the meaning and for the purposes of the application of Article 6, paragraph 2, letter c) of the Directive 98/44/CE, since that fertilisation is such as to commence the process of development of a human being. That classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. Although those organisms have not, strictly speaking, been the object of fertilisation, because of the effect of the technique used to obtain them, they are, as appears from the written observations presented to the Court, capable of developing into a human being just as an embryo created by fertilisation of an ovum can do so»[4].

Later on, in another decision, it affirmed: «Article 6, paragraph 2, letter c), in the directive 98/44/CE of the European Parliament and Council, concerning the jurisdictional protection of the biotechnological inventions, must be interpreted in the sense that a non-fertilised human egg, which, though parthenogenesis, will divide and develop, is not a human embryo. This is justified by the fact that, in the light of the actual state of science, it has no capacity of developing in a human being. However, national judge has the duty to verify that such

[1] www.medicinaonline.co (ultima consultazione 13/11/2018)
[2] Judgment: n. 84/2016, Constitutional Court: «Quale che ne sia il, più o meno ampio, riconoscibile grado di soggettività correlato alla genesi della vita, non è certamente riducibile a mero materiale biologico».
Judgment: n. 229/2015, Constitutional Court: «La dignità dell'embrione, quale entità che ha in sé il principio della vita costituisce, comunque, un valore di rilievo costituzionale riconducibile al precetto generale dell'art. 2 Cost.»; «La tutela dell'embrione non è suscettibile di affievolimento (ove e) per il solo fatto che si tratti di embrioni affetti da malformazione genetica, e nella stessa è stata individuata la ratio della norma penale (art. 14, commi 1 e 6, della legge n. 40 del 2004) incriminatrice della condotta di soppressione anche di embrioni ammalati non impiantabili».
Judgments: n. 96/2015, 151/2009, Constitutional Court: «Come ogni altro valore costituzionale, anche la tutela dell'embrione è stata ritenuta soggetta a bilanciamento, specie al fine della tutela delle esigenze della procreazione ed a quella della salute della donna».
[3] V. MARZOCCO, *In potenza o in atto? La Corte costituzionale e lo statuto normativo dell'embrione*, in *BioLaw Journal*, n. 2, 2016.
[4] Judgment: Oliver Brüstle v. Greenpeace and V., 18 October 2011, Court of Justice (Grand Chambre).

circumstances occur».[5] So, while in Brüstle case the Court adopted a more protectionist approach and prohibited the patentability of a wider notion of human embryo, in this judgment it limits the same concept, in order to not impede scientific research in the biotechnological field[6].

The National Bioethics Committee was asked its opinion about the definition of embryo.[7] The Committee thinks that it is equipped of individual identity since the conception. In addition, those who consider it as an individual after its formation (between the eighth and the fourteenth day) think that it is necessary to respect it. The embryo is never considered as a thing, but something which belongs to the human species.

The importance of defining embryos is also related to the particular character of the stem cells that compose them: their totipotentiality. They are able to transform in any cell of our body, and scientists use this characteristic in order to produce new cells that will be implanted in other patients to replace their ill organs. The studies on this kind of cells permit scientists to understand how tissues are created and recreated. Stem cells are used also to test new drugs. The origin of the embryo stem cells let us think about the lawfulness of practices, which encourage producing embryos in order to destroy them for researches. The point here is the meaning we want to give to the term 'embryo'.

3. What is CRISPR-CAS9?

It is a new-born technique of genome editing, which applies on human embryos. CRISPR states for Clustered Regularly Interspaced Short Palindromic Repeats, and it's able to show particular portions of DNA containing regular and repeated sequences, to which is associated a complex of genes, called Cas (Crispr-ASociated). Those genes can codify enzymes and the result is a sort of immune system, defending the genome from

[5] Judgment: International Stem Cell Corporation v. Comptroller General of Patens, 18 December 2014, Court of Justice (Grand Chambre). The dispute began when the International Stem Cell Corporation (ISCO) asked for the registration of two licenses. The Hearing Officer at the English License Office denied its consent and adduced that those inventions were conceived as «utilisations of human embryos for commercial or industrial purpose»; thus their patentability it's forbidden, in the light of the UK law on licences (1977). In particular, it is the actualization of article 6, paragraph 2, letter c) of the European directive. ISCO appealed to the High Court of Justice, highlighting that in a precedent decision (Brüstle case, 2011), the Court of Justice prohibited the patentability of only those organisms which potentially could develop as humans; the ban does not comprehend the products of the parthenogenesis process, object of the two requested licenses (which were rejected). For the complexity of the matter at stake, the English judges preferred to return the question to the European Court of Justice.

[6] I. RIVERA, *La tutela dell'embrione umano e la brevettabilità del vivente alla luce dei più recenti sviluppi giurisprudenziali*, in *BioLaw Journal*, n. 1, 2015.

[7] Comitato Nazionale per la Bioetica, *Identità e statuto dell'embrione umano*. 22 Giugno 1996. «Il Comitato è pervenuto unanimemente a riconoscere il dovere morale di trattare l'embrione umano, sin dalla fecondazione, secondo i criteri di rispetto e tutela che si devono adottare nei confronti degli individui umani a cui si attribuisce comunemente la caratteristica di persone, e ciò a prescindere dal fatto che all'embrione venga attribuita sin dall'inizio con certezza la caratteristica di persona nel suo senso tecnicamente filosofico, oppure che tale caratteristica sia ritenuta attribuibile soltanto con un elevato grado di plausibilità, oppure che si preferisca non utilizzare il concetto tecnico di persona e riferirsi soltanto a quell'appartenenza alla specie umana che non può essere contestata all'embrione sin dai primi istanti e non subisce alterazioni durante il suo successivo sviluppo».

external attacks: Crispr-Cas sequences can recognise, cut and delete extraneous sequences of DNA. Such technique is comparable to a sort of 'molecular scissors'[8].

This means that targeted, highly efficient editing of DNA in cells has become relatively simple. However, our understanding of CRISPR-Cas9 is still at an early stage, and any potential treatments based on this technique are many years away.

The first clinical applications of CRISPR-Cas9 are likely to involve editing the DNA in somatic (non-reproductive) cells, e.g. by removing them from a patient and editing them in a lab to correct a harmful mutation before putting them back into the body[9].

Thanks to its simplicity and rapidity, it has become a popular technique among researchers who are now studying and manipulating those sequences to make them a genetic microsurgery instrument, used for "cutting and pasting" DNA fragments.

The first profile that needs to be clarified is the one regarding the difference between genetic therapy applied to the somatic line and the one applied to the germinal line. In the former, the intervention refers exclusively to the person interested, aiming at modifying the DNA of his cells. In the latter, the eugenic finality emerges from the transmissibility of the genetic modification to future generations. The therapy on the germinal line leads to a modification of all the cells of the organism, including gametes, through which the DNA will be transmitted to the baby. Different worries arise: for what concerns the somatic therapy, the problem is connected to the level of uncertainty and of efficiency of the techniques; while the germinal therapy can lead to more eugenic kind of problems: it can bring to an insecure and irreversible planning against nature[10].

In this context, strong contrast emerges between genetic (which aspires to selection) and medicine (which aims the preservation)[11]. The former guides the period of the pre-birth, intervening on the decision if it is worthy to come into the world; while the latter takes care of the individual who is already born. Medicine could be asked the reason for so many interventions on individuals who carry "programmed errors", with the risks that they can emerge in the future generations. This way healthy medicine turns to a catastrophic one.

[8] A. Brooks, *Human genome-editing research should proceed, say leading UK science bodies*, in *Wellcome Trust Magazine*, 2015.
[9] A. Brooks, *op. cit*.
[10] C. Casonato, *Diritto, Diritti ed Eugenetica: prime considerazioni su un discorso giuridico altamente problematico,* in *Humanitas*, n. 4, 2004, pp. 841-856.
[11] P. Sommaggio, *La Consulenza (Gen)etica, Nuovi Miti, Nuovi Oracoli, Libertà della Persona*, Milano, 2010.

4. Moral and Ethical issues

The topic we are discussing about collides with ethical and moral considerations, which can guide or impede it. Ethics cannot be a unique combination of rules and principles, rather has to be the result of collaboration and comparison between different moral visions. Ethics gives the chance to adapt itself to concrete needs.

Important is the relation between ethics and law. The debate is between those who consider that the law in act can be reinterpreted and others who think that it is necessary to define again legal categories, which are ancient. The law becomes jurisprudence: judges are invited to interpret laws. However, this interpretation can cause distortions and different answers. So, the question is: which law is compatible with ethics? The jurisprudential one, which can follow all the scientific progresses or the legislative one, which guarantees certainty towards different treatments? They are not distinct, rather they integrate themselves.

Ethical committees must operate when, after new scientific discoveries, the internal rules of auto discipline do not work anymore. They were created with an advisory aim; then the law has given them the function of public guarantee for patients, together with the one of vigilant on new experiments. They also have to divulgate opinions, which are compulsory in order to begin a new experimentation. Because they are not tribunals, their decisions cannot be contested.[12] One of the concerns of these committees is the respect of human dignity. In their reports, they try to state their position towards this matter. For instance: what does it mean the respect of the body? Does dignity imply the respect of this body? Is the body a property? Do I have a body or am I a body?

Sometimes this genre of considerations can lead to philosophical reflections. If the body is at spirit disposition, it can be seen as measurable, repairable, modifiable; it is an object that can be changed, as material. On the contrary, if the body is not just something in which I live, but something without which I cannot live, it is no more violable from medicine. This dualism, or monism, justifies conflicts between opposite values. For now, even though various proposals are advanced, it seems hard to find a uniform answer[13].

5. What is "eugenic"

[12] P. BORSELLINO, *Bioetica tra "morali" e diritto*, Milano, 2013.
[13] P. BORSELLINO, *op. cit*. Nota di Beatrice Magni.

Moral and ethical principles should guide the action of not only scientists but also policy makers and citizens. One of the consequences of their violation may be the so-called "eugenic deviation"[14] : a degeneration in the society, which aims to create perfect individuals, thanks to genetic manipulations, towards which modern knowledges in the genetic field can lead. Generally, there is a difference between the negative kind of eugenics, aimed at eliminating the predispositions to bad diseases, and a positive one, meant to potentiate the features of the subject.

Turning to the development of the eugenic conception during centuries, we must mention W. Bateson[15], who first formulated the term "genetics" (in 1905) that indicates all researches on the hereditariness of biological characters. The genetics studies genes, where there are a lot of information about our constitutive characters and about their transmission. The expression "genetic assets" states the relationship that each of us experiences with its own genetic information and, at the same time, we share with all human beings. The knowledge of the human genome brings consequently different repercussions on society and on its cultural structures; it lets ethical and legal problems emerge. Even though the first studies were focused on hereditariness (with G.J. Mendel, at the beginning of the 20th century) later, they specialised in another field, which is the one of eugenics[16]. Its birth occurred in the middle of the 19th century. A strong contribution in this sense was given by the theory of selection by C. Darwin (in his book "On the Origin of Species"), based on the idea of promoting the birth of new species and of more complex forms of life, able to face the environment[17]. Francis Galton[18] was the author of one of the first publications on hereditariness of intelligence. In his article (1865), he exposed for the first time his certainties on hereditariness of the human talent and suggested the possibility to focus on an overall improvement of the cultural level of the population in two ways: encouraging weddings and procreation between people who were intellectually superior. He was sure that the natural selection was impeded in human societies. He proposed the basis of a new science, finalised to impede degeneration, and name it eugenics, from "eu", which means good; and "genos", which means race, gender, ancestry. He defined it as the science aiming to improve the race. According to him, the protection of weak people contrasted with the theory of evolution, with the natural human selection. He affirmed: «For this reason we must leave morality outside our discussion (…) although is not possible to reach an agreement on the absolute morality, the essential points of eugenics are easy to define. Every human being would agree on the fact that it is better to be healthy than ill, powerful instead of weak (…) the aim of eugenics is to represent for each class its best models. Let us suppose for a while that eugenics could bring

[14] C. CASONATO, *op. cit.*
[15] British genetist, who lived in 19th century.
[16] P. SOMMAGGIO, *op. cit*.
[17] C.A. DEFANTI, *Eugenetica: un tabù contemporaneo. Storia di un'idea controversa*, Torino, 2012.
[18] English anthropologist and father of eugenic, for he first introduced the term. He lived during the 19th and 20th century.

the average quality of our population at the level of its best half and think about the benefits. The general tone of the domestic, social and political life would be more elevated. The entire race would be less frivolous and politically more prudent. (…) That what nature does blindly, slowly and cruelly, man can do in a more astute, rapid and kindly way». It is important to stress how genetic was, from its very beginning, at the service of the society; its scope was not the one of preventing degeneration, by giving birth only to valid individuals, but the one of looking for race enhancement. The natural selection is substituted by the artificial and programmed selection operated by humans[19]. Another scholar, W. Schallmayer[20], works on the Darwinian idea that the enhancement of the species goes through selection. A greater selection leads to a biological improvement of society, by the limitation of the reproductive possibilities of subjects who are considered biologically mad[21]. Galton believed that the majority of the character, mental and physical, were strictly determined by hereditariness. This conviction was at the same time its weak point: in fact, at that time a scientific explanation of hereditary mechanisms lacked. For a long time, scientists continued thinking about heredity in a phenotypical way: these studies focused mainly on the observable constitution of an organism. Only when Weismann[22] discovered the difference between somatic and germinal plasma, this conception attenuated. Galton's idea was the one of a social engineering, of a technocratic society, governed by the best. However, the most important question is: do races really exist? Genes are equal for the 99,9%, but then they mix due to intersections between populations. The clearest eugenic deviation can be found in racism: the term eugenics contains also the word race. A first definition of race was formulated in 1800: a group of human beings united by a combination of physical characters that are thought to be transmitted hereditarily. This definition brings together individuals on the basis of perceived somatic characters, concerning most of all the skin, the form of the skull, the dimensions of the body[23].

Turning back to the birth of eugenics, during the Wilhelmine epoch, the first eugenic society in the world, called "Gesellschaft für Rassenhygiene", was created. They thought that, without an intervention, the negative factors in the society could gain an advantage. The only way to improve or impede the deterioration of the level of health was eugenics: Schallmayer thought that it was easier to create healthy descendants than to make healthy someone who was already ill. From its very beginning, the Nazi regime was characterised by a series of eugenic measures (sterilization of those who suffered due to genetic illnesses; Nuremberg laws; experimentations on prisoners). What we always forget is that the Nazi regime was not the inventor, through its experts, of the idea of a direct interference on population in order to accelerate the human selection. The Reich used eugenics as a mean to obtain a particular idea of an enhanced humanity.

[19] C.A. DEFANTI, *op. cit*.
[20] German's first advocate of eugenics. He lived during the 19th and 20th centuries.
[21] P. SOMMAGGIO, *op. cit*.
[22] German Biologist who lived during the 19th and 20th century.
[23] C.A. DEFANTI, *op. cit*.

We should not forget that the aim of improving has always been part of this scientific instrument; it was not just a crazy idea of the third Reich. This is a simplistic way of thinking: it leads to assume that researches aiming at genetic improvement are a bad heritage of bad people[24]. It has to be said that not eugenics itself, but its manipulation in a political totalitarian project founded on racism and anti-Semitism was responsible of the abominations that were done by the Nazi regime.

Exploring the history of the XVIII and XIX century in England, eugenics started developing because of the industrial revolution, when the population faced a social degeneration. This decadence was due to the mix of races; some scholars thought that there was a hierarchy between races and that, even though they all had the same origins, the most elevated ones had to prevail. The English eugenics spread also during the Victorian age, characterised by imperialism. Eugenics found support also in the field of "hygienic": it pursued the care of illnesses through sterilization and interruption of pregnancy.

Turning to the eugenics in the USA, at the beginning of the 20th century was inaugurated the "Eugenics Record Office"[25]. On its Bulletin were described different kinds of "unfits" due to hereditary reasons. The aim of eugenics was to reduce the number of unfits thanks to segregation, sterilization, restrictive rules on wedding. The jurisprudential decision "Carrie Buck" is emblematic in this sense: a woman was affected by different illnesses but most of all she had a lower QI, as her mother did. The Supreme Court imposed her the surgical sterilization. The point of the Court was: «we have seen more than once that the public good can ask to the best ones their own life. It would be strange if it could not be possible to ask lower sacrifices to those who are harmful to the strength of the state (…) it is better for the entire world that the society prohibits to the unsuitable to procreate, than execute them for their crimes or let them die for their idiocy. The principle that stands behind the compulsory vaccination is enough wide to include the cut of the fallopian tubes»[26].

Even though not expressly overruled by any successive judgment, juridical solutions like this nowadays would be incompatible with all the constitutional principles accepted by the systems of the Western Legal Tradition (In Italy art. 32 of the Constitution prohibits sanitary compulsory treatments, which are not covered by law).[27]

Talking about Italian scholars and doctors, G. Sergi[28], for example, stated that it was necessary to introduce measures (as correct alimentation, environmental hygiene, and education) in order to avoid the process of

[24] P. SOMMAGGIO, *op. cit*.
[25] Research institute that gathered biological and social information about the American population, serving as a center for eugenics and human heredity research from 1910 to 1939.
[26] C.A. DEFANTI, *op. cit*.
[27] C. CASONATO, *op. cit*.
[28] Anthropologist who lived during the 19th and 20th century.

degeneration in the society. C. Gini[29] focused on the low level of prolificacy among high classes: he considered useful to encourage the procreation with some sagacity (wedding between youths, natural breastfeeding). A. Zuccarelli[30] proposed, instead, the practice of sterilization. While, E. Morselli[31] wrote a book on euthanasia, expressing firmly his opinion against the suppression of life for eugenic aims. Another important figure for eugenics and for his theory on races was the one of N. Pende[32], who classified individuals according to their biotype. He was contrary to biological racism. On the practical field the most significant innovation was the introduction of a preventive activity, in 1946, directed by some counsellors in Milan (referring to Luisa Gianferrari[33]), which consisted in pre-wedding visits. By suggesting not to have children to those who carried genetic diseases, they succeeded in fighting "thalassemia major". Concerning the relationship between eugenics and the Catholic Church, it is possible to affirm that the Church was not contrary to the idea of ensuring descendants a better destiny. It was firmly contrary to almost all the methods that eugenics suggested: sterilization and the use of contraceptives.

It is interesting to see how those ideologies spread before some important scientific discoveries were made. Around the half of the last century, three scientists, Avery, MacLeod and MacCarthy demonstrated that DNA composed the substance of genes. The two scientists F. Crick and J. Watson invented a descriptive model of the DNA structure. The rapidity through which the study of human genome has improved was possible thanks to huge financings. The project "human genome" is an example of this. It is about the localisation of the group of gene in order to stress their functions and their way to act. One of the most direct condemnations of the possible degradation of the human genome project, was the one of the Nobel prize S. Luria. He asked himself whether the Nazi project to eliminate all Jewish through homicide has been translated in a kinder program to refine human beings, correcting their genes, according to an ideal phenotype: the one of the white-Christian-successful man[34].

In order to avoid a eugenic deviation, the International and European community has stated fundamental rights and values[35].

[29] Statistician who lived during the 19th and 20th century.
[30] Doctor and Director of the museum of criminal anthropology, Naples.
[31] Doctor and psychiatrist who lived during the 19th and 20th century.
[32] Doctor who lived during the 19th and 20th century.
[33] Doctor, professor and geneticist, who lived during the 19th and 20th century.
[34] S. E. LURIA, Italian doctor and biologist, who lived during the 20th century.
[35] UNESCO underlines that researches on human genome have to respect dignity, human rights and avoid discrimination. The European Council has established, with the recommendation n. 934, that national legislations provide the right to have a genetic heritage, not modified, and if so, only for therapeutic interventions. In another regulation of the 1989, the Council of Europe affirms that genetic analysis cannot be used to modify or improve the population. The Convention on Human Rights and Biomedicine (Oviedo 1997) was ratified by Italy with the law n. 145/2001. It declares, at article 13: «Every intervention that has as its aim the modification of the human genome, cannot be started, except for prevention scope, diagnosis or therapy only if it has not as its aim the introduction of a modification on the descendants' genome». It is, at the same time, forbidden every eugenic selection of the sex of the future child, except for avoiding a genetic disease related to sex.

6. Bio-conservatives v. Bio-innovators

Then a new battle starts between two opposite tendencies: the one of bio-conservatives, who consider the human genome as an unavailable good and propose limits on its use or manipulation; and the one of bio-innovators, who support the philosophy of post-human. In 2004, the Italian Association called "Transumanisti" was born. The first point of its chart states: «humanity will be completely transformed from future technology. We foresee the possibility to reprogram the human condition in order to avoid the process of aging, intellectual limits, our imprisonment on this planet and sufferance in general». The manifesto affirms: «the cardinal idea of transhumanism can be sum up in a formula: it is possible and desirable to pass from a blind evolutionary phase to an aware evolution. We are ready to do what science makes possible, like keeping under control our destiny as species. (…) This project has nothing to do with the negative eugenics of the XIX century, practiced by USA, Nazi Germany and Scandinavian democracies of the XX century. The actual transhumanist model aims to guarantee the health and the enhancement of individuals and of their proles, taking as a starting point the happiness and the right to choice of the future baby».

A consideration, at this point, is deserved. If this practice has implications on descendants, in which way can their rights to choice and to self-determination be preserved? F. Fukuyama[36] talked about the threat of an illiberal society. According to other opponents, transhumanists are praising the concept of a new kind of man, sovereign of his own body, a so-called "demiurgo". A very banal criticism could emerge: is it correct that the man, who is imperfect and imprecise, "plays" at imitating the Creator, organizing and modelling species at his own pleasure? He is "playing God".

A first discrimination could arise between those who have the economic possibilities to choose the enhancement they want, and those who cannot. We should also reflect on what kind of anthropological assets would be preferred by those who will accede to the genetic modification. A reference model could disappear, as the concept of humanity itself. Will continuous mutation be the only element that human beings have in common? How will a human being recognise his similar, once the stability of human characters will be destroyed?[37]

7. Is eugenics free from consequences?

[36] American political expert.
[37] P. SOMMAGGIO, *op. cit*.

All the deviations, which eugenics can cause, pass across the intolerance against the others, who are different. What concerns is the possible depreciation of ill people. However, it is possible to combine the desire of having a healthy child with the attention towards problems and needs of disable people. A successful example could be the experiment conducted in Israeli concerning a disease called Tay Sachcs (which is a disease of the nervous system that can bring to death). It was organized a genetic counselling program in the Hebraic community, which consisted on a blood sample of all youths who attended religious schools. Tests' results were not published. When two members of the community had the intention to marry, they called to the centre, which gave them an answer concerning their union. This test has been widely accepted by the public and by religious authorities. There were no critics neither from disable people. Moreover, that kind of diseases were reduced.

Eugenics, brought to its extreme consequences, can lead to the creation of a utopic world, composed by genetically modified individuals who are perfect, identical and have prestigious roles in the society. Of course, there would be also the not genetically modified ones, who would be considered inferior. All this is represented in the science fiction film "Gattaca" (1997), which is related to psychological aspects, set in a near future, where there will be new class fights between those who are born genetically modified and those who are born with a natural genetic asset. A genetic registry database uses biometrics to classify those created as "valids", while those conceived by traditional means and more susceptible to genetic disorders are known as "in-valids". Vincent Freeman, the main character, is conceived without the aid of genetic selection. Years later, Vincent works as an in-valid, cleaning office spaces including that of Gattaca Aerospace Corporation, a space-flight conglomerate. He gains employment at Gattaca by using hair, skin, blood and urine samples from a donor, Jerome Eugene Morrow, who is a former swimming star paralyzed due to a car accident.

8. What role do genetic tests play in this context?

One of the problems raised by the development of new techniques, throughout which we can determine and study our human genome (see CRISPRS CAS. 9)[38], is using the information achieved for deviant purposes, like genetic tests. The problem is caused by the knowledge of their results: those could lead to discriminatory decisions, especially if in the hands of employers and insurance companies. Moreover, the deterministic conception could spread. This is the idea that everything the man does is related to a cause, that he is not responsible for his choices and that there are some conditions, especially physical ones that make the history

[38] See paragraph: *What is CRISPR-CAS9?*

of a particular man necessitated. Nowadays we can firmly affirm that not only our genes but also the environment determines our character.[39] This border between genes and environment is difficult to define.

One of the risks that we run due to the presence of genetic tests is the one of foreseeing more easily the characteristics of future babies, with the possibility for parents to "change" them as they prefer, creating genetically modified individuals in line with esthetical or intellectual canons. A real example of this is represented by the start-up, called "Human Code". It recently introduced "Baby Glimpse", a test which, by examining the parents' SLC2A2 gene (the glucose transporter gene), can allegedly forecast a child's eye or hair colour and might even be able to indicate their taste in food. Some experts, including doctors and public health officials, are concerned that a test like this may end up doing more harm than good.

A further negative outcome related to eugenic is the "consumption eugenic". Nowadays, it is discussed whether techno-science imposes its choices: it may give anyone the impression of being able to choose, while the choice is already imposed from the so-called "social construction of needs"[40]. The individual choice takes place, as for products, according to the satisfaction of those wishes that are at the basis of our consumer society. There could be a particular kind of product: the perfect baby. D. H. Rose[41] affirms that: «Albeit the dream of a perfect baby is absurd and, of course, impossible, it remains one of consumers' expectation, as many others like a home, a garden, a job, a perfect dress and so on». On turn, G. Gambino[42] says: «In relazione alla diagnosi pre nascita, tutti i bisogni nascono conformemente all'evoluzione della capacità diagnostica: le donne ne sentono la necessità solo dopo che nuovi test per particolari tipi di anomalie genetiche vengono inseriti sul mercato»[43].

9. How is the phenomenon regulated worldwide?

The aim of this part is to fix, as much as possible, how the concept of embryo genome editing is perceived globally. We first observe the issue from an international point of view, as it results from statements, regulations and principles placed at different levels, each with a different force and impact.

[39] P. BORSELLINO, *op. cit.*
[40] P. SOMMAGGIO, *op. cit*.
[41] American neuroscientist and founder of Centre for applied special tecnology, Massachussets.
[42] Italian professor of philosophy of law and member of the Ethic Committee "Leonardo Vaccari", Rome.
[43] «Relating to the pre-birth diagnosis, all the needs are conceptualized according to the evolution of the diagnosis capacity: women feel this necessity only after new tests for specific kind of genetic anomalies are inserted in the market».

The first international contribution[44] is provided by the 'Declaration of Inuyama' (1990), which tries to found the protection of safety for the next generations: since some types of genetic treatment could affect them and their consent cannot be obtained nor predicted, limits should be placed on DNA alterations in human germ cells and safety should be well established before germ-line therapy is undertaken (Par. 3 and 6).

Following, 'Oviedo Convention' (1997) affirms that in any case human dignity needs to be protected and to prevail over the sole interest of society or science (art. 1 and 2). In particular, it prohibits to discriminate a person on grounds of his/her genetic heritage (art.11). Furthermore, it provides that an intervention which modifies the human genome may be undertaken for preventive, diagnostic or therapeutic purposes, only if it aims not to introduce any modification in the genome of any descendants (art. 13). Lastly, article 18 admits research concerning in vitro embryos, as long as embryos are adequately protected; in any case, it forbids the creation of humans for research scope.

Through the years, UNESCO laid down three essential contributions. The Universal Declaration on the Human Genome and Human Rights (1997), which considers human genome as "the heritage of humanity" (art. 1) and protects diversity, seen as the genetic characteristics of every person (art.2). In line with this, it prohibits any research or practice concerning the human genome to prevail over respect for the human rights, fundamental freedoms and human dignity of individuals (art.10); again, germ-line intervention must never be contrary to human dignity (art. 24). The second is the 'International Declaration on Human Genetic Data' (2003) which prohibits discrimination based on genetic characteristics (art.3). Lastly, the 'Universal Declaration on Bioethics and Human Rights' (2005) provides a holistic approach: in applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account (art.8); moreover, their impact on future generations, including on their genetic constitution, should be given due regard (art.16).

On the European level, directive 2001/20, stated by the European Commission, aims to protect the germline identity, stating that no gene therapy trials may be carried out which result in modifications to the subject's germ line identity (art.9); editing of somatic cells is allowed but only with written authorisation.

The European Group on Ethics in Science and New Technologies (EGE)[45], which provides advice on ethical aspects of science and new technologies in relation to EU legislation or policies, drafted a 'Statement on Gene Editing' (2016). It concerns the current debate on banning human germ line modification, in light of the rise

[44] www.weforum.org (ultima consultazione 13/11/2018).
[45] An independent advisory body established by decision of the Commission (1991), towards which EGE refers its studies www.ec.europa.eu (ultima consultazione 5/06/2018).

of CRISPRCas9. The EGE feels that there must be a public debate on the issue due to the ethical, scientific and regulatory issues, involved by the matter.

For what concerns human rights, the 'European Convention on Human Rights (1950) prohibits «discrimination on any ground», as well as the 'European Charter of Fundamental Rights' (2012/C 326/02) does. The latter secures that «Human dignity is inviolable» (art. 1) and that «In the fields of medicine and biology, the following must be respected in particular […] the prohibition of eugenic practices, especially those aiming at the selection of persons» (art. 2); moreover, it prohibits «discrimination on any ground including genetic features, disability etc.» (art. 21).

The International Bioethics Committee[46], in its report called 'Moratorium based on safety and ethical concerns' (2015), not only claims for international cooperation when discussing of human genome (par. 115), but also recalls some values mentioned above, such as the respect of 'human dignity'; individual responsibility; respect for vulnerable people and personal integrity; privacy and confidentiality; equality, justice and equity; non-discrimination; respect for cultural diversity; solidarity and cooperation; social responsibility for health; sharing of benefits; protection of future generations and of biodiversity' (par. 116). Furthermore, in paragraph 118, it «recommends a moratorium on genome editing of the human germline», due to safety issues as well as the ethical issues with human gene editing.

Finally, in 2017, the National Academy of Sciences (NAS)[47] and the National Academy of Medicine (NAM)[48] tried to give a bold answer in a collaborative report, called 'Human Genome Editing: Science, Ethics, and Governance'. A Committee of international experts was appointed to explore the current state of the science and clinical applications; to point out the potential risks and benefits to human health; to determinate the standards concerning unintended consequences associated with editing specific genes. They also discussed issues of equity and access, and the ethical considerations on how this technology could influence societal attitudes towards disability and disease. Their final report established a set of seven governance principles with respect to human genome editing to apply globally across different political or cultural contexts: 1) promoting well-being (also known as principle of beneficence and no maleficence); 2) principle of transparency (implies openness and sharing information); 3) principle of due care (meaning to proceed with research only when it is supported by robust evidence); 4) principle of responsible science (which has to adhere to the highest international standards); 5) principle of respect towards persons (including individual

[46] Named 'Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights'.
[47] It is a United States non-profit, non-governmental organization, which provides independent, objective advice to the nation on matters related to science and technology.
[48] Analogous to NAS, it provides national advice on issues relating to biomedical science, medicine, and health, and serves as an adviser to the nation to improve health.

decisions, meaning that all people have equal moral value, regardless their genetic qualities); 6) principle of fairness (requires like cases to be treated alike, and that risks and benefits are equitably distributed); 7) principle of transnational jurisdiction (which aims to collaborative approaches to researches, while respecting different cultural contexts).

The rationale is that genome editing research is an international endeavour, thus those principles should be followed by all nations, both in scientific and regulatory processes. Though everyone agrees on its importance in understanding the links between genes and inheritable diseases (e.g. cancer, Alzheimer's disease, etc.), once researchers apply editing on human cells, they should be aimed only to prevention. Any further use for enhancement purposes should not be approved today, since public discussion needs to happen before. Despite germline editing is not yet possible, it is time to start thinking carefully about the implications of its use, rather than waiting until the decisions as to whether to proceed are imminent. The seven principles constitute a positive first step, yet they do not constrain nor provide external pressure. In this sense, targeted regulations on safety and efficacy of gene editing could infringe on people's ethical limits, while traditional medical product regulation don't. Furthermore, public opinion about genome editing on human embryos vary both among and within countries: public policies rage from permissive, to regulated or prohibitionist. It is interesting to scrutinize in which sense international norms and principles are applied (or ignored) when set in different context. With this purpose, we decided to analyse three Countries where those studies have been carried out the most: China, Mexico, United Kingdom.

10. China: desire to emerge and regulatory laxity

Though it has entered in the genomic race quite recently, thanks to its preparation and founds, China has the potential prevail globally in the field. In parallel, all the efforts by the national government to strengthen regulation concerning clinical stem cell research, clash with the particular norms established locally[49]. China is frustrated by its own socioeconomic and infrastructural diversity, and its political organization: the large size and the power concentration in Beijing have created contradictory developments between regulatory policies[50]. Another obstacle towards a proper national legislation is that Chinese biomedical policies are characterised by a 'post hoc pragmatism', consisting in quick administrative fixes on expressed concerns, in order to avoid social debates[51]. Leading Chinese bioethicist, Wang Yanguang, justifies this by explaining that

[49] L.F. FRIEDMAN, *These are the countries where it's 'legal' to edit human embryos,* in *Business Insider*, 2015. www.businessinsider.com (ultima consultazione 12/11/2018).
[50] M. SLEEBOOM-FAULKNER*, Regulatory capacity building and the governance of clinical stem cell research in China,* in *Oxford Academic*, 2017.
[51] ZHANG, JOY YUEYUE, *Lost in Translation? Accountability and Governance of Clinical Stem Cell Research in China,* in *Regenerative Medicine*, 2017.

the messiness of public views is perceived to be 'inefficient' to govern. He adds that only when researchers are criticised on a global level, policy makers react by promulgating a regulatory system[52]. Such pressure to address global scrutiny whilst preserving domestic creativity may led to regulatory patchworks, which can be disruptive to research[53]. As a product of those external pushes, in 2003 began China's national regulation on stem cell research: the Ministry of Science and Technology (MOST) and the Ministry of Health promulgated the 'Ethical Guidelines for Research on Human Embryonic Stem Cells'. According to many bioethicists[54], this was merely a government response to the critics towards China for creating the first human-rabbit hybrid embryos without any ethical review (2001). For this reason, instead of positive norms regarding domestic research, the Guidelines mainly consist in a repetition of Western ethical principles with little procedural guidance. This 'minimalist' approach to stem cell policies may have allowed Chinese scientists to gain some head start in the past; yet lately[55] an absence of clear and justifiable regulatory support has often left Chinese stem cell research in a limbo. In addition, the 'pragmatic' fix approach to identifiable concerns wills to promote innovation and development rather than attending moral scruples[56]. China appears as a crippled giant: despite its ambition and the efforts to become a global leader in this scientific field, it has an 'image problem', which is its lack of international credibility. As a result, during the last 15 years the post-hoc policy and a soft centralisation regulatory approach caused a massive loss of China's huge scientific potential[57].

Nevertheless, at the moment China has a primate: in 2015, it was the first nation to edit the genes of human embryos using the CRISPR-cas9 tool for non-germline genetic modifications of human tissue cells. While Western democracies are less likely to fund controversial projects, in China the lack of direct democratic systems helps officials in shaping public opinion and aligning it with government priorities. In some scientific areas, China rejected international norms to promote its own interests. The reason is that genetic enhancement can bring national advantages, especially from an economical point of view. We now find ourselves at a crossroads. If human enhancement is unethical or dangerous, then its emergence in China would be worrying, in particular for what concerns Chinese people. Moreover, given China's human rights record in other field, it is questionable whether international pressure would still have effect in future, when the enhancement of its population may strengthen its competitiveness on the world stage. Conversely, if

[52] Since this occurred in stem cell research (2003) and in related clinical studies (2009), is likely to happen also in embryonal researches and modifications.
[53] Various theories believe that Western states hold a global hegemony over life science industry development and regulatory standards; e.g. Birch (2012), Salter (2015).
[54] ZHANG, JOY YUEYUE, *op. cit*.
[55] E.g. the hybrid embryo research mentioned above, which China banned in order to silence criticism, was picked up by the United Kingdom seven years later, albeit at that time Chinese research had lost the lead.
[56] As pointed out by M. Sleeboom-Faulkner, professor of Social and Medical Anthropology at the University of Sussex.
[57] ZHANG, JOY YUEYUE, op. cit.

human enhancement is actually desirable, this trend should be welcome. As Western counties delay development of potentially great advances for humanity, China leads the way forward. It could even pressure those nations to relax restrictions and allow humanity as a whole to progress, by becoming healthier and more productive. In any case, for now, the future of genetic enhancement lays in China's hands[58].

As previously mentioned[59], in April 2015, Chinese scientists had edited the genes of human embryos for the first time ever, trying to modify a gene in a non-viable embryo that would have been responsible for a deadly blood disorder[60]. Actually, the Guidelines on Human Assisted Reproductive Technologies[61] states that «using human egg plasma and nuclear transfer technology for the purpose of reproduction, and manipulation of the genes in human gametes, zygotes or embryos for the purpose of reproduction are prohibited.»[62] So, the experiment was possible firstly for it was conducted on non-viable embryos: eggs fertilized by two sperm so that the embryo would never develop into genetically modified humans or otherwise. Secondly, because there is a great difference between legal bans and guidelines. Consistently with this, in the past 5 years China has increased stem cell research and practice, while at the moment it is perceiving gene editing in human embryos. China has the most liberal and favourable environments for those kind of studies, given that the research on spontaneously aborted human foetuses is lawful under written consent from the donor. Latest Chinese project (spring 2017) is the world's first clinical trial in using human embryonic stem cells to treat Parkinson's disease and it will continue to forge ahead. However, to become a trusted powerhouse in the field, a more transparent and structured governing framework, capable to speak to a tangled web of interests, is needed[63].

As pointed out, China has guidelines banning some researches, which constitute 'soft laws', not enforceable laws[64]; moreover, the sanctions for breaching ministry guidelines are often unclear[65]. People who violated the Guidelines[66] should not continue their research, yet the choice whether to apply that ban is largely left to local governments. To establish a proper regulation, in 2001 the Beijing Ministry of Health Medical Ethics Committee and the Southern Chinese Human Genome Research Centre Ethical, Legal, and Social Issues Committee (ELSI)[67], proposed ethical guidelines on human embryonic stem cell (hESC) research, which ban activities as reproductive human cloning and the buying and selling of human embryos for commercial purposes. They also aimed to establish a new organization in order to manage stem cell research in China

[58] G. OWEN SCHAEFER, *China may be the future of genetic enhancement,* in *BBC Future Magazine*, 2016.
[59] L.F. FRIEDMAN, *op. cit*.
[60] Yet they encountered serious challenges, suggesting there are still significant hurdles before clinical use becomes a reality.
[61] Published by the Chinese Minister of Health in 2003.
[62] According to Motoko Araki and Tetsuya Ishii, Offices of Health and Safety at Hokkaido University in Japan.
[63] ZHANG, JOY YUEYUE, *op. cit.*
[64] L.F. FRIEDMAN, *op. cit*.
[65] As noted in a Report from the Medical Research Council in the UK.
[66] Guidelines on Human Assisted Reproductive Technologies, see above.
[67] The two national Committees on medical ethics and bioethics.

from an ethical point of view, a responsibility divided between the Ministry of Health, the Ministry of Science and Technology and the local ethics committees. Subsequently, on November 2002, the 'Four Nos' for the scientific community, were published[68]: «Under no situation, under no circumstances, will human reproductive cloning experiments be endorsed, permitted, supported, or accepted». On 24th December 2003, hESC were enacted[69] : they include guidelines on stem cells from donated human embryos, those originated from germ cells and those obtained from somatic cell nuclear transfer. It is stated that any research aiming at human reproductive cloning and hybridizing human germ cells with germ cells of any other species shall be prohibited.

Yet no laws nor enforcement can be realistically expected in the short term. Rather than adopting foreign or international regulations, it is desirable to develop regulatory capacity building at national level[70]. In some countries, as China, a permissive regulatory regime is viewed as enabling [71]: its particular conditions of and local regulatory developments constitute both the limitations and the tools of regulatory capacity building[72].

In China, the efforts in creating a proper regulation are complicated by the entrenched financial and research interests and regulatory orientations in the various bionetworks. It could be defined as 'the double-edged sword of regulatory capacity building'[73]: from one hand, the necessity to create national regulation acknowledged by potential collaborators at home and abroad, from another to cater for the various bionetworks with the potential to fulfil China's political strategy as world leader in the field of stem cell science. In this sense, China is an old newcomer: its size, the state's ability to fund state-of-the-art cell science, its varied institutional landscape and its 'permissive' regulation had made China an early starter in the field[74]. Yet it should realise the importance to reconcile what has been achieved on a scientific level with an appropriate legislation, in order to include equally human rights and protection of Chinese people, helpless and vulnerable towards govern interests.

11. Mexico: genome editing between nationalism and progress

[68] Contained in a single-sentence directive promulgated by the Ministry of Health.
[69] The Ministry of Science and Technology and the Ministry of Health of China achieved the project brought by the two Committees.
[70] A. WAHLBERG, C. REHMANN-SUTTER, M. SLEEBOOM-FAULKNER, *From Global Bioethics to Ethical Governance of Biomedical Research Collaborations,* in *Social Science & Medicine*, 2013.
[71] M. SLEEBOOM-FAULKNER, H. CHEN, A. ROSEMANN, *Science and Public Policy,* in *Oxford Academic*, 2017.
[72] New regulation for clinical stem cell research in China: expected impact and challenges for implementation, M. Sleeboom-Faulkner 2016.
[73] M. SLEEBOOM-FAULKNER, H. CHEN, A. ROSEMANN, *op. cit.*
[74] M. SLEEBOOM-FAULKNER, P.K. PATRA, *The Bioethical Vacuum: National Policies on Human Embryonic Stem Cell Research in India and China,* in *Journal of International Biotechnology Law*, 2009.

Mexico has demonstrated to be one of the most important powers involved in the matter[75], despite that it tends not to be placed at the centre of the discussion. Because of its unique cultural, geographical and regulatory context, it is interesting to analyse how the Mexican conception of genome editing developed quite early and changed deeply through the years. In past centuries, Mexican government has pushed toward the research in genetic field, with the purpose to enhance domestic characteristics and differentiate the nation from the rest of the world. Thus, the main feature is the link between genetics and national identity, because of the articulations between biological and social repertoires established by the mestizo as a long-standing scientific and social object[76].

From 1910 to 1930, the nationalist project emerged in Mexico: physical anthropologists and other intellectuals tried to analyse the physical and psychological peculiarities of the Mexican people, such as their forms of life, gestures, temperament and history. Especially during the '30s, the figure of the 'mestizo', the pure Mexican man, was brought up to create a sort of national identity[77]. At the beginning, mestizo was meant to build an ideology on scientific basis and to legitimate the exclusion of people who were not originally Mexican: researchers and scientists collected samples, such as blood, cells, and tissues for this aim. Yet, instead of leading the Country to a racist deviation, these practices brought to an innovative genetic project that related genetic features to diseases which characterise Mexican population. In particular, during the post-revolutionary period (1940–2000) a 'mestizo ideology'[78] emerged in order to resist cultural dominance by the United States, and genomic research has thus attempted to develop techniques and knowledge that produce distinctive national profiles.

In 1999, Gerardo Jiménez-Sánchez[79] proposed a national research programme on medical genomics. The first results of the Human Genome Project (2000) showed that Mexico could not remain outside the genomic revolution and needed to create a genomic research institute. Furthermore, the arrival of DNA sequencing technologies in 21st century allowed more refined estimates of the degree of mestizaje[80].

Those factors led to the creation of the National Institute for Genomic Medicine (INMEGEN) in July 2004. INMEGEN started the so-called 'Mexican Genome Diversity Project' (MGDP) which, similarly to the previous

[75] Even though it's not in the spotlight as China is, maybe for the prevalence of United States of America.
[76] M. KENT, V. GARCIA-DEISTER, C. LOPEZ-BELTRAN, R. VENTURA SANTOS, E. SCHWARTZ-MARIN, P. WADE, *Building the genomic nation: 'Homo Brasilis' and the 'Genoma Mexicano' in comparative cultural perspective,* in *Social Studies of Science*, 2015.
[77] The process of nationalisation interested many fields: in line with the work of philosopher and politician José Vasconcelos, author of 'La raza cósmica', a group of students in the National Autonomous University of Mexico, drafted a manifest about what it meant to be Mexican, and prescribed a "mode of being" appropriate for the creation of an authentic and, consequently, a responsible 'homo mexicanus'.
[78] G. IZIQUIERDO, S. DIAZ PUEBLA, *La Ideología Mestizante, el Guadalupanismo y sus Repercusiones Sociales. Una Revisión Crítica de la 'Identidad Nacional,* in *Universidad Iberoamericana de Puebla/Lupus Inquisitor*, 2011.
[79] Medical doctor with a PhD in human genetics in Mexico.
[80] M. KENT, V. GARCIA-DEISTER, C. LOPEZ-BELTRAN, R. VENTURA SANTOS, E. SCHWARTZ-MARIN, P. WADE, *Building the genomic nation: 'Homo Brasilis' and the 'Genoma Mexicano' in comparative cultural perspective*, in *Social Studies of Science*, 2015.

biomedical projects, was accompanied by anthropo-historical questions. The resulting 'Map of the Mexican Genome' aspired to become both a biomedical research tool to establish the genetic basis of diseases specific to the Mexican population, and a molecular portrait of the Mexican mestizo[81]. Soon after 2001, the Consortium for the Creation of the Institute for Genomic Medicine was created to promote the project, composed by eminent physicians such as Juan Ramón de la Fuente[82] and Julio Frenk,[83] aiming to bring Mexican medical genomic research to a global level of excellence.

Nowadays, Mexico is well situated, economically and scientifically, to profit from the biotechnological possibilities which have been set up: the national genomic project provided access to high-tech sequencing and bioinformatics, as well as trained scientists who were already participating in cutting-edge research. However, the research tends to privilege local issues about health.

This historical excursus aims to point out how researches over the Mexican genome, which began to highlight the peculiarities and supremacy of Mexican people,[84] ended up discovering that this population is characterised by a predisposition to obesity and diabetes, problems in need of genetic solutions[85]. Consequently, the government, the geneticists and the medical community agree that improvements to health policy are the main goal of genomic research, despite disagreements over strategies and the roles of INMEGEN.

Simultaneously, in 2000 the Inter-Ministerial Commission for Safety of Genetically Modified Organisms (CIBIOGEM) was formed to coordinate biosafety policy and all aspects of the production, import, export and use of Genetic Modified Organisms[86]. In 2005, its work was formalised in the 'Law on Biosafety of Genetically Modified Organisms', in order to manage potential risks associated with GMOs and to promote their ethical development[87]. It specifically disclaims responsibility for regulating human genetic modification, by stipulating that 'human beings' are not considered 'organisms' for the purposes of the law (Article 3, XX) and excluding from its jurisdiction the human genome, the stem cell culture and the modification of human germ cells, which affect the General Health Act (GHA) and international treaties (Article 6, V). However, the GHA,

[81] G. DEISTER, LOPEZ-BELTRAN PAIS, *País de gordos/país de muertos: Obesity, death and nation in biomedical and forensic genetics in Mexico,* in *Social Studies of Science*, 2015.
[82] Former Minister of Health and at the time Dean at UNAM.
[83] Minister of Health (at that time) and current Dean of Harvard's School of Public Health.
[84] Or, more brutally, initially it was a 'race-based genome project.
HARTIGIAN, Translating "Race" and "Raza" between the United States and Mexico, 2013.
[85] M. KENT, V. GARCIA-DEISTER, C. LOPEZ-BELTRAN, R. VENTURA SANTOS, E. SCHWARTZ-MARIN, P. WADE, *op. cit.*
[86] M. MEDINA, *Genome Editing Transnational Regulatory Challenges: Lessons from Mexico, published by the National Independent University of Mexico,* in *Ethics, Medicine & public health*, 2016.
[87] Although these technologies were firstly conceived for agriculture.

as well as the other Mexican laws[88], leaves considerable uncertainty: though it contains a section on 'The Human Genome' (Título Quinto Bis), this mainly concerns the uses of genetic information. Genetic modification is not mentioned.

Similarly, to the regulation of research on human embryos, gametes and stem cells, genome editing has been a contested area in Mexico[89]. Though GHA and associated regulations contain various provisions that might be extensively interpreted to apply to this matter, they are too broad to ensure certainty.

We consider as an example Mexico City's criminal code: it proscribes the use of donated gametes for a different end from that in the donor's consent (Article 149), thus it could permit the use of gametes for scientific research, if consent is granted; yet fertilisation of eggs for any purpose other than reproduction is forbidden (Article 154). This precludes the creation of embryos specifically for genetic research, but not the use of supernumerary embryos in those researches. Moreover, it prohibits manipulation of human genes for any purpose other than eliminating or improving disease (Article 154, 1), but it is not clear on what this actually implies[90]. It forbids any procedure of genetic engineering for ''illicit ends' (Article 154, III), but fails to describe which ends would be licit.

Such lax provisions are leading to dangerous outcomes: Mexico has already become a destination for stem cell unlicensed therapies, in order to escape more restrictive laws in other jurisdictions[91]. This causes concerns among scientists, who claim that regulation could promote responsibility and prevent the marketing of unproven and potentially harmful intervention. The field of gene editing, as noted, has similarities and if unaddressed may go down the same route.

This proves that, to be effective, regulation must be enforceable and actually enforced. The GHA and its associated regulations prohibit the commercialisation of human tissues and cells and their derivatives (Articles from 315 to 327) and provide that any therapeutic procedures involving these materials must be gratuitous. They also affirm that healthcare providers and establishments must be authorised by the Federal Regulatory Commission for Sanitary Risks (COFEPRIS), whenever they conduct experimental medical procedures. However, there's no express reference to practices involving stem cells. Again, legislative terms are vague: those experimental therapies are easily available and operators can escape regulation by switching terms for activities. Moreover, the regulatory agency has failed to sanction healthcare providers and purveyors of dubious treatments. Such legislative inefficiency is partially explained by the current regulatory authorities lacking compliance mechanisms and resources, both human and financial, to pursue

[88] Explained in the following paragraphs.
[89] M. MEDINA, *op. cit*.
[90] M. MEDINA, *op. cit.*
[91] This is actually happening with stem cells, but in future could concern also embryo modifications and genome editing.

them, making it difficult to apply existing legal provisions. In this scenario, the absence of targeted legislation is not helpful[92].

Though in such innovative fields overregulation needs to be avoided, the current laissez-faire in Mexico is worrying for it allows any experimental stem cell treatments, putting at risk patients' lives and raising many ethical and legal issues. Whilst it is likely that gene editing research, especially on human embryos, will remain controversial, regulatory stalemate cannot be permitted.

The problem requires international cooperation to achieve an effective transnational regulatory solution. Yet, the mere export of regulations from a certain area to the rest of the world is dangerous, because principles coming from developed countries would dominate even where they should not. Additionally, gene editing and genetic modification cannot be the unique focus of international efforts. If a major concern is to prevent premature clinical reproductive application, then a holistic oversight of reproductive technologies is necessary, since it would control reproductive uses of gene editing.

Stringent regulatory hurdles may be seen as a disincentive for biotechnological development, while countries characterised by flexible norms might be seen as attractive by investors. Nevertheless, a de-regulated health technology market is not the way forward, as long as the patient welfare prevails on profit as the ultimate goal of science. Furthermore, Mexican weak legislative framework clashes with the considerations on transnational principles and ethical concerns; the seven principles[93] don't seem to be seriously taken into consideration yet. Anyway, the international community cannot just disregard the problem: if in the past such sources of worry could be accepted or at least tolerated, nowadays a minimum standard of care must be guaranteed anywhere, considering how easily patients can move and obtain outlaw treatments abroad.

12. United Kingdom: achieving innovation in accordance with the patients' dignity

UK played a key role in the process and was a pioneer in developing and regulating genome editing. In 1904, Francis Galton founded the creation of a biology and genetic course at the University of London; he aimed to contrast the decreasing of upper class population and to share the importance of the eugenics all over the world. Galton wanted to remove social plagues, such as alcoholism and venereal disease, and to enhance negative eugenics, by segregating retarded people. In this phase, eugenics was used to limit the reproduction

[92] M. MEDINA, *op. cit*.
[93] Provided by NAS and NAM in their collaborative report 'Human Genome Editing: Science, Ethics, and Governance', as exposed previously.

of the so called 'unfits', in favour of superior and apt people. Those practices developed genetics, the tool of eugenics. After WWII, the term 'eugenics' was substituted with 'human genetics', to distance from the Nazi inhuman experiments. Finally, in 1969 was created the 'Galton Institute', still active, which encourages progress in the genetic field and its ethical implications. Similarly to what occurred in Mexico, the project did not fulfil its original scope to enhance 'English race', rather it supported the research and helped the rise of public opinion about those matters[94].

Such progress is still happening: in 2016, UK researchers used for the first time a new genome editing technology called Crispr[95]. This proves that DNA editing can pin down previously elusive genetic processes taking place in embryonic development. Paul Nurse, chief executive of the Crick Institute, which conducted the research, states that applying the precautionary principle now will just stop something that could bring real benefits; to enhance progress, he claims for engagement of the society in this research[96]. The researchers involved in the project affirmed that UK is particularly suitable for human embryology, thanks to its supportive regulatory framework, as well as public and charitable agencies funding research in the field. The project was properly approved by the Human Fertilisation and Embryology Authority[97], not only in accordance with national regulations, but also with the provisions of the 'International summit on human gene editing'[98]. Indeed, research is permitted only if it aims to improve the state of technique, after a valuation of its potential benefits and risks, and to deepen the knowledge of human embryo and germinal cells; moreover, embryos and germinal cell subject to genome editing cannot be applied on a pregnancy. In second instance, clinic application of the genome editing on stem cells is permitted, on the basis of the existent norms on the somatic genetic therapy. Finally, the Authority does not permit to apply genome editing on germinal cells and on premature embryos, in order to born genetically modified babies. This may change when all the technical issues on efficacy and security will be solved, after comparing different moral conceptions provided by various Countries.

The editing of human germ cells or embryos is covered by the Human Fertilisation and Embryology Act[99] and regulated by the Human Fertilisation and Embryology Authority (HFEA), UK's independent regulator of treatment using eggs and sperm and of treatment and research involving human embryos[100]. Under the Act,

[94] C.A. DEFANTI, *Eugenetica: un tabù contemporaneo. Storia di un'idea controversa*, Torino, 2012.
[95] www.ft.com (ultima consultazione 5/6/2018).
[96] Report published by the British Science and Technology Committee on Parliament UK website, 20th April 2018. www.parliament.uk (ultima consultazione 5/6/2018).
[97] D. NERI, *Embryo editing: a proposito di una recente autorizzazione dell'HFEA,* in *BioLaw Journal*, n.1, 2016.
[98] Established in Washington by the U.S. National Academy of Sciences, the English Royal Society and by the Chinese Academy of Sciences on December 2015.
[99] Promulgated in 1990, and then amended in 2008.
[100] D. POCKLINGTON, *Genome editing of human cells,* in *Law and Religion*, 2015.

research can only be undertaken on embryos of up to 14 days of age and requires a specific HFEA licence[101]. Genome editing could be undertaken only if appropriately justified and supported by rigorous scientific and ethical review. The use of such material on humans or for treating patients is expressly prohibited under UK law and is unlikely to be allowed in any European jurisdiction at present[102].

Yet, the Secretary of State, in light of the latest developments, may change the definition of embryo, eggs, sperm, gametes (and other concepts), in order to allow new practices.

In 2015, HFEA published the 'Human Fertilisation and Embryology Regulations', which permit to edit the germ line under specific circumstances[103]. The committee noted that CRISPR Cas9 was a highly efficient and targeted method of gene disruption, potentially superior to other techniques available. Moreover, it underlined that working on human embryos is essential. Thus, such researches are not pointless, for they could develop treatments towards serious diseases and increase knowledge about the development of embryos. Besides, it guarantees that non-permitted embryos (e.g. those subjected to gene editing techniques) would not be implanted into the woman nor would an embryo be kept past the 14-day period.

Because of its economic and regulatory strength, UK has many projects going on[104]. One of the most ambitious is the '100,000 Genomes Project' (2017) which provided UK as world-leader in the genomic field.

The rise of new technologies brought instances on a legislative level and the Chief Medical Officer (CMO)[105] affirmed the necessity of public debate and discussion. Indeed, one of the recommendations from her report was for Genomics England and NHS England to engage in an extensive public dialogue on the shared social contract between patient, public, clinicians and academics in relation to genomic medicine. In response to the CMO's recommendation, Genomics England has proposed a "Public Dialogue programme".

Sir John Bell[106] believes that the UK is multiple years ahead of the rest of the world in handling the whole genome data, because of the access to a large storage of information owned by the National Healthcare System concerning the whole patient care. The partnerships between the NHS and industry is essential to develop new medicines and diagnostics using genomic data. By profiting of the commercial value of its

[101] Authorisation released under the terms seen before: the research must be in compliance with UK laws and with the Declaration of the International summit on human gene.
[102] Report published by the British Science and Technology Committee on Parliament UK website, 20th April 2018. www.parliament.uk (ultima consultazione 5/6/2018).
[103] Based on a dissertation by Dr. I. Turkmendag, Newcastle Law School (2016).
[104] www.parliament.uk (ultima consultazione 5/6/2018).
[105] The most senior advisor on health matters.
[106] Author of the Life Sciences Industrial Strategy.

datasets, it will be ensured the growth of the UK genomics and of new treatments, always considering consent and data safety safeguards.

In any case, Dr. Magdalini Papadaki[107] explains that the therapeutic use of genome editing is still at an early stage. It is constrained not only by ethic and legislative bonds, but also by the lack of infrastructures and competent professionals[108]. The point is that genome editing is new technology, which challenges the traditional approach to research and development[109].

Technological progress will depend, however, on the further evolution of the regulatory regime for genome editing, and the ethical debate that will underpin that. Given that not all uses of genome editing are ethically contentious or require any additional regulation[110], a significant debate exists around the ethics of editing germ cells or human embryo cells: whether it constitutes a sort of medical treatment, considering that the 'patient' does not yet exist; the unknown consequences on future generations and the inability to obtain their consent; the potential for genome editing to facilitate eugenics or 'designer babies', and what a market for genetic enhancement would mean for equality. In relation to those issues, UK research organisations published a joint statement on genome editing (2015), acknowledging that genome editing of human germ cells or embryos raises important ethical and regulatory questions, which need to be discussed before any decision about clinical application. The statement concluded that such research potentially leads to understand many key processes in biology, health and disease; thus, if conducted responsibly, which is in accordance with the current legal frameworks from an ethical end scientific point of view, those studies should proceed[111].

Moreover, genome editing cannot stray beyond what the people, represented by the Parliament, are comfortable with[112]. In this regard, stakeholders willing to carry out research into genome editing affirm that the existing regulations are adequate. Analogously, the Wellcome Trust[113], the Association of the British Pharmaceutical Industry and the Academy of Medical Sciences all agree that the 'Human Fertilisation and Embryology Act' provides a robust and flexible architecture to govern the use of embryos; therefore, they support using genome-editing in pre-clinical biomedical research, as long as it respects those legal and ethical prescriptions. In addition, the Department of Health and Social Care affirmed that the Government currently does not want to amend the 'Human Fertilisation and Embryology Act' to permit germline modifications[114].

[107] Member of the Association of the British Pharmaceutical Industry (ABPI).
[108] As affirmed by Professor Waseem Qasim, member of the Institute of Child Health.
[109] According to Dr. Papadaki.
[110] As stated by the Wellcome Sanger Institute, a non-profit British genomics and genetics research institute.
[111] According to the US National Academies (2017).
[112] Reporting what affirmed by Professor Chris Whitty, the then Interim Government Chief Scientific Adviser.
[113] Association of Medical Research Charities and Cancer Research, UK.
[114] Report published by the British Science and Technology Committee on Parliament UK website, April 2018.

In particular, the CMO did not want a review of the 14-day rule, explaining that there is an ethical debate, which will last another five to ten years[115].

In 2015, the UK Parliament became the first in the world to make mitochondrial donation lawful. Such a technique is quite different from Crispr-CAS9 for it allows women whose mitochondria carry serious inherited disease to give birth to children free from the same disease, by transferring 'packets' of the mother's nuclear DNA to a donor cell containing healthy mitochondria. This way, the children inherit DNA from the donor as from their mother and father (while Crispr consists in substituting parts of the DNA with genes able to codify enzymes, which delete extraneous sequences of DNA). Notwithstanding those differences, they are similar for the vulnerability of the subjects they involve, embryos. That is the reason why the British Medical Association proposed UK could apply to genome editing the same procedure of parliamentary and public engagement, which preceded regulations on mitochondrial donation regulations, as a model to regulate its specific application.

13. Italian laws and constitutional principles

Turning to Italian legislation, art. 4 of the Italian law n. 194/1978 on the voluntary interruption of pregnancy, provides that previsions of anomalies are a valid reason of abortion in the first 90 days of pregnancy. The Italian law lets the woman taking abortive choices with a eugenic background. On an opposite side, Italy states a law concerning Medically Assisted Procedure (MAP). It prohibits every form of eugenic selection (art. 13); states that once the egg is fecundated, the parents cannot retreat their will over the procedure, for they have signed a written consent (art. 6); and fixes that a maximum of three embryos can be produced, prohibiting their crioconservation and suppression, and imposing a unique implant (art. 14). This situation can be described as a paradox[116].

[115] The point is strongly debated in UK.
Report published by the British Science and Technology Committee on Parliament UK website, April 2018.
[116] Cape I, General Principles, Art. 1 *(Finalities).*
1. «In order to solve reproductive problems deriving from sterility and infertility, it is allowed the use of the medically assisted procedure, at the conditions and according to the methods provided by this law, which ensure all rights to the involved subjects, included the product of conception».
2. «The use of the medically assisted procedure is allowed whenever there are no other therapeutically and effective methods that can remove the causes of sterility and infertility».
Cape II, Access to the techniques, Art. 6, Par. 3 (Informed Consent).
3. «The will of both subjects to accede to the techniques involving medically assisted procreation is expressed through a written consent, together with the doctor responsible of the structure (…). The will can be revoked by each of the subjects until the fecundation of the egg».
Cape VI, Measures to safeguard the embryo, Art. 13, Par. 3, let. b) *(Experimentation on human embryos).*

In his article "Quello che rimane della legge 40"[117], Antonio D'Aloia affirms that: «Se si parte dalla premessa che la fase embrionale è la prima fase di vita di un individuo», that «la fecondazione è tale da dare avvio al processo di sviluppo di un essere umano»[118], and that «la clausola della dignità umana può applicarsi al concepito, sebbene con le caratteristiche sue proprie[119], può non apparire irragionevole o incostituzionale che la legge vieti la sperimentazione e la ricerca clinica sull'embrione umano»[120] [121]. However, the prohibition to any kind of eugenic selection or the production of embryos only finalized to research, differ from impeding in any case the crioconservation of the biological material, from excluding the possibility for the woman to refuse the implant, and from prohibiting the couple to donate supernumerary embryos. The scientific level of developing reached nowadays, 12 years after l. 40/2004, makes it possible to conduce researches on blastocisti with interventions that can preserve the embryo's integrity.[122] A very simple question emerges: is it opportune to modify art. 13 of the Italian law, in order to allow scientific research only on those embryos which cannot be used, because are abandoned or ill?[123] After those considerations, we could ask ourselves if, with law n. 40 remaining unvaried, it would be possible to apply the techniques of genome editing for therapeutic aims, once the experimentation phase has passed. I personally think that this possibility can really be present if we consider the second paragraph of art. 13, which says that clinical and experimental research on human embryos is allowed at the condition that therapeutic and diagnostic aims are pursued.

3. «Nevertheless, the following practices are forbidden. *b)* every form of eugenic selection of embryos or gametes and every kind of intervention that, throughout selection, manipulation and artificial techniques, is finalized to alter the embryo's or the gamete's genetic asset or to predetermine their genetic characteristics, except for interventions with diagnostic and therapeutic aims, referring to point 2 of this article». Art. 14. *(Limits to the application of technics on embryos).*

1. «It is forbidden the crioconservation (technique) and the suppression of embryos, referring to what has been provided from law 22nd may 1978, n. 194».

2. «The techniques to produce embryos, considering the technical and scientific evolution and referring to what it is provided from art. 7, point 3, must not create a number of embryos superior than the one necessary to a unique and contemporary implant; anyway, they must be no more than three».

[117] A. D'ALOIA, *Quel che resta della Legge 40*, in *BioLaw Journal*, n. 2, 2014.

[118] Judgment: Brüstle v. Greenpeace eV, 18 October 2011, Court of Justice, par. 35.

[119] Judgment: n. 35/1997, Constitutional Court.

[120] «If we start from the basic assumption that the embryo phase is the first phase of life, that fecundation is able to start the process of creating a human being, and finally, that the dignity clause applies also to the product of consumption, it could not be unconstitutional a law that prohibits the research and the experimentation on human embryos».

[121] S. PRISCO, *Il diritto e l'embrione come soggetto di narrazioni*, in *BioLaw Journal*, n. 2, 2016.

[122] G. BALDINI, *Embrioni soprannumerari, ricerca scientifica e divieti normativi Riflessione a margine delle prime pronunce della giurisprudenza italiana e della Corte EDU*, in *BioLaw Journal*, n. 2, 2016.

[123] Judgment: n. 229/2015, Constitutional Court, «L'art. 13, commi 3, lettera b), e 4, della legge n. 40 del 2004 va incontro a declaratoria di illegittimità costituzionale, nella parte, appunto, in cui vieta, sanzionandola penalmente, la condotta selettiva del sanitario volta esclusivamente ad evitare il trasferimento nell'utero della donna di embrioni che, dalla diagnosi preimpianto, siano risultati affetti da malattie genetiche trasmissibili rispondenti ai criteri di gravità di cui all'art. 6, comma 1, lettera b), della legge n. 194 del 1978, accertate da apposite strutture pubbliche». According to the Constitutional Court, art. 13 (L. 40/2004) should be modified in order to permit the selection of healthy embryos before implantation.

Turning to the Constitution of the Italian Republic, we can mention some articles[124], which safeguard in general the human being. There are also some articles protecting scientific research[125]. Perhaps, a balance between different constitutional principles is necessary, in order to establish which one has to prevail in any concrete case[126]. It is also difficult to identify the object of the protection provided by the constitutional articles, for the genome is something in constant evolution. In particular, the Constitutional Court interprets art. 2 Cost.[127] in accordance with the circumstances it faces: in some cases, it extends it to the safeguard of the embryo, so that it does not permit its manipulation[128]; in others it oppositely states that art. 2, protecting «the right to have a child not affected by genetic diseases»[129], covers the possibility to access to the MAP and select healthy embryos. Such inconsistency reflects the fact that constitutional concepts, such as inviolable human rights, can be stretched and adapted to opposite needs.

14. Can we advance any proposals to regulate such a tangled subject?

In conclusion, it is difficult to advance a final solution to regulate the matter. Some authors argue that it's better to provide restrictions on the fundamentally useful basic research regarding CRISPR-Cas9[130], while others believe that until there is a social and scientific consensus, the clinical application should be prevented[131]. Many believe that the guidelines should be constantly updated. For others, there should be a moratorium[132], so that the techniques on the clinical use of human germline editing can develop[133], before

[124] Art. 2: «The Republic recognises and guarantees the inviolable rights of the person, as an individual and in the social groups where human personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled». Art. 32: «The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any given health treatment except under the provisions of the law. The law cannot under any circumstances violate the limits imposed by respect for the human person».

[125] Art. 9: «The Republic promotes the development of culture and of scientific and technical research. It safeguards natural landscape and the historical and artistic heritage of the Nation». Art. 33: «The Republic guarantees the freedom of the arts and sciences, which may be freely taught. The Republic lays down general rules for education and establishes state schools for all branches and grades. Entities and private persons have the right to establish schools and institutions of education, at no cost to the State. The law, when setting out the rights and obligations for the non-state schools, which request parity, shall ensure that these schools enjoy full liberty and offer their pupils an education and qualifications of the same standards as those afforded to pupils in state schools. State examinations are prescribed for admission to and graduation from the various branches and grades of schools and for qualification to exercise a profession. Institutions of higher learning, universities and academies, have the right to establish their own regulations within the limits laid down by the laws of the State».

[126] Judgment: n. 84/2016, Constitutional Court: «Come ogni altro valore costituzionale, anche la tutela dell'embrione è stata ritenuta soggetta a bilanciamento, specie al fine della «tutela delle esigenze della procreazione» ed a quella della salute della donna (sentenze n. 151 del 2009 e n. 96 del 2015)».

[127] «The Republic recognises and guarantees the inviolable rights of the person, as an individual and in the social groups where human personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled».

[128] Judgment: n. 229/2015, Constitutional Court.

[129] Judgment: n. 96/2015, Constitutional Court.

[130] N. BAUMANN, *How to use the medical subject headings (MeSH)*, in *International Journal of Clinical Practice*, 2016.

[131] D. BALTIMORE, *A prudent path forward for genomic engineering and germline gene modification',* in *PMC magazine*, 2015.

[132] Temporary suspension of a law.

[133] I. TURKMENDAG, *The legal framework for genome editing and the UK's case study, published by the Newcasle University*, 2016.

settling the matter. Finally, some claim for a calm approach to regulation, in order to prevent 'heavy-handed intervention'[134]. However, there is uncertainty as to how such a calm approach could be developed due to the various options on offer which, when combined with the ethical issues of human gene editing, each have their own difficulties and benefits. In general, most commentators emphasise that there is a need for open public discussion.

We believe that the best option would be the creation of a completely innovative set of rules and new legal concepts: in fact, it could solve all the interpretative doubts implicated in the analogic application of old statements. Besides it would give the subject the autonomy it deserves[135]. From the analysis of the legislations proposed, one thing they have in common is the necessity of promoting public debate before setting any regulation. Anyway, our opinion is that the best model, in terms of guarantees and standards, is the one provided by the UK. While China adopted a brave approach, which is undoubtedly positive for the scientific progress, it's necessary to remember the delicacy of the matter and the subjects involved. On the other hand, the Italian approach is more conservative and guarantees the protection of human rights. However, this could prevent the possibilities of progress and development of the subject. Besides, our opinion is that excluding citizens from the decision-making process, e.g. as China does, may seem positive for rapid progress today, since it is not stopped by the need of achieving public consensus; yet, it might be harmful in the future, because people could start reacting against unaccepted practices that government has conducted for years. In short providing specific programmes to involve public discussion (as happens in the UK), is the optimal solution in a long-term perspective.

The ideal model of regulation should cover the progress in scientific field with an effective protection of fundamental rights. A system providing a certain burden of freedom within genetic modifications, yet always limited to therapeutic aims. It should establish supervising authorities, consisting in public bodies, subject to the Ministries of Health and Research and funded by the State; this way, they would be independent from private interests, finalized to the patentability of the researches. The outcome would be a framework characterised by 'ad hoc' laws which are truly enforced.

Finally, we wondered whether and how far legislators should base an innovative set of rules on ethics.

Though it's hard to advance proposals, in our point of view an international model of regulation should be settled. Both national and international policy makers should understand that the technique improves day by day and urges regulation. Albeit they still seem to consider genome editing as a possibility concerning the future, the truth is that it is a nowadays struggle and postponing the creation of its legal bonds will not make

[134] I.G. COHEN, E.Y. ADASHI, *Embryo Disposition Disputes: Controversies and Case Law,* in *Hastings Center Report*, 2016.
[135] Overcoming what happened with the MAP law in Italy (extensively applied to genetic modification) or in the same way, what happened in China with stem cells.

it easier. The difficulty lies on the fact that universally accepted and shared values don't exist. Furthermore, such discipline should be built on many elements, in particular jurisdiction, ethics, deontology and on the personal responsibility of the individual. To succeed, a process of cultural evolution, connected with the scientific progress, is needed, now[136].

[136] C. CASONATO, *Diritto, Diritti ed Eugenetica: prime considerazioni su un discorso giuridico altamente problematico, Humanitas*, pp. 841-856, n. 4, 2004.