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Office address and contact details:

Department of Law - University of Perugia  
Via Pascoli, 33 - 06123 Perugia (PG) - Telephone 075.5852437  
Email: [complawreview@gmail.com](mailto:complawreview@gmail.com)

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# HUMAN GENOMICS AND SURROGATE MOTHERHOOD: LEGAL PLURALISM AND THE CIRCULATION OF MODELS

*Andrea Stazi\**

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*The evolution of knowledge on biogenetic processes, the decoding of the human genome and many other living species, the new discoveries about the interactions between genes and the functioning of DNA allow today unprecedented application developments.*

*The circulation of reproductive materials and surrogate motherhood, with the related problems regarding the exploitation of the human body, and genome modification interventions, with the consequent doubts regarding the impact on health and evolution, touch the very essence of the human being and therefore find different answers in the various legal systems.*

*From a comparative point of view, the phenomena that emerge are those of legal pluralism and the circulation of models, as expressions of the necessary relationship between multidimensional but complementary tools that can operate according to the cases in a contrasting or subsidiary way.*

*In this scenario, the most complex challenges to face are those of balancing fundamental rights and the effectiveness of the forecasts and tools adopted, to protect the "good of human life" today more at stake than ever.*

\* Associate Professor of Comparative Law and New Technologies Law and Director of InnoLawLab - Laboratory of Innovation Law at the European University of Rome; Visiting Associate Professor in Biotechnology Law at the National University of Singapore (andrea.stazi@unier.it).

## I. INTRODUCTION. EVOLUTIONARY PROFILES AND CRITICAL ISSUES OF HUMAN GENETIC ENGINEERING IN COMPARATIVE LAW

The evolution of knowledge on biogenetic processes, the decoding of the human genome and many other living species, the new discoveries about the interactions between genes and the functioning of DNA<sup>1</sup> allow today unprecedented application developments.

Through the multidisciplinary synergy of molecular biology, chemistry, information technology and genetic engineering original models or genetic systems have been constructed from scratch, assembling portions of genome together, both copied from natural sequences, and the result of completely artificial sequences created in the laboratory<sup>2</sup>.

On the other hand, these scenarios also pose relevant legal and ethical issues, in particular with respect to the impact on weak subjects and on the future evolution of the species. In a technically complex field open to global developments that go beyond individual national areas, legal analysis comes up against many difficulties. The relationship between the freedom of scientific research and the protection of human health has always been in problematic terms, especially in the field of experimentation, access to cutting-edge therapies and respective limits<sup>3</sup>.

Given the transnational dimension in which applied science moves and the difficult identification of shared and universally valid principles, the main challenge is to establish forms

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<sup>1</sup> Abbreviation of deoxyribonucleic acid, responsible for the conservation and transmission of genetic information; see: B Alberts, A Johnson, J Lewis, M Raff, K Roberts, P Walter, *Molecular Biology of the Cell*, Garland, New York, 2014 (6th ed.), p. 173 ff.

<sup>2</sup> Starting from single functional genetic units, so called BioBricks, capable of expressing different characters and functions, it is possible not only to replicate existing portions of genomes, but to create complex and original biomolecular systems resulting from an artificial biological process, or to graft synthetic genes into existing organisms and natural genomes to express there their functional characters. On the subject, see: JW Szostak, DP Bartel, PL Luisi, *Synthesizing life*, in *Nature*, 2001, n. 409, p. 387 ff.; D. Baker *et al.*, *Engineering life: building a fab for biology*, in *Scientific American*, 2006, vol. 294, no. 6, p. 44 ff.

<sup>3</sup> See, among others: T. Minssen, *Patenting human genes in Europe - and how it compares to the US and Australia*, in D. Matthews, H. Zech (eds.), *Research Handbook on Intellectual Property and the Life Sciences*, Edward Elgar, Cheltenham, 2017, p. 26 ff.; S. Ghosh, *Patenting human genes in the United States*, *ivi*, p. 41 ff.; A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, Edward Elgar, Cheltenham, 2015; C. Casonato (edited by), *Life, Technology and Law*, Cedam, Padua, 2007; G. Comandè, G. Ponzanelli (edited by), *Scienza e diritto nel prisma del diritto comparato*, Giappichelli, Turin, 2004; CM Romeo Casabona, *Los genes y sus leyes. El derecho ante el genoma humano*, Comares, Bilbao-Granada, 2002.

and limits of the freedom of research and care in a scenario in constant evolution in the various countries, with the relative differences in socio-cultural sensitivity and ethical-legal approaches<sup>4</sup>.

## II. GENOMIC DEVELOPMENTS, GENETIC TREATMENTS AND SPECIES EVOLUTION

Human genetic engineering, that is the alteration of the genetic or hereditary material of a human organism to eliminate undesirable characteristics or to produce new desirable ones, has been developed essentially to help limit or even put an end to the spread of disease. With the advent of genetic engineering and its evolution with the development of genomic medicine<sup>5</sup>, scientists can now change the way genomes are composed to limit or end certain diseases that occur as a result of a genetic mutation<sup>6</sup>.

Today genetic engineering is used to combat problems such as cystic fibrosis, diabetes and many other diseases. It therefore has the potential to improve the quality of life and allow for a longer life span<sup>7</sup>.

Clearly, one of the biggest advantages of this field is the prospect of helping to cure diseases in unborn babies. Having a genetic screening of a fetus can allow the treatment of the unborn child. Such an intervention may affect the growing spread of diseases in future generations<sup>8</sup>.

These developments present important opportunities for both treatment and research, based on the combination of coding genes and their use in organisms, drugs, *etc.* Genomics, gene therapy and synthetic biology could represent revolutionary solutions for the diagnosis, prevention and treatment of numerous pathologies, not only of genetic origin. In addition to the possibility of

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<sup>4</sup> See: S. Shrestha, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, TLI Think! Paper 83/2017, available online on: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3049616](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3049616), p. 2 ss.; R. Prasad, *The Fertility Tourists*, in *The Guardian*, 30 July 2008, available online at: <https://www.theguardian.com/lifeandstyle/2008/jul/30/familyandrelationships.healthandwellbeing>.

<sup>5</sup> Genomic medicine is an emerging discipline that studies the functions and interactions between the genes in the genome, using genomic information about an individual as part of their clinical care (e.g. for diagnostic or therapeutic decision-making), along with the health outcomes and policy implications of that clinical use; see: US National Human Genome Research Institute, *Genomics and Medicine*, available online at: <https://www.genome.gov/health/Genomics-and-Medicine>; S.C. Roth, *What is genomic medicine?*, in *Journal of the Medical Library Association*, 2019, vol. 107, no. 3, p. 442 ff.

<sup>6</sup> In this regard, see, among others: SAA Patra *Effects of Genetic Engineering - The Ethical and Social Implications*, in *Annals of Clinical and Laboratory Research*, 2015, vol. 3, no. 1, p. 5 f.

<sup>7</sup> In this regard, see: A. Fischer, S. Haccin-Bey, M. Cavazzana-Calvo, *Gene therapy of severe combined immunodeficiencies*, in *Nature Review Immunology*, 2002, vol. 2, no. 8, p. 615 ff.

<sup>8</sup> See: SAA Patra, *Human, Social, and Environmental Impacts of Human Genetic Engineering*, in *Journal of Biomedical Sciences*, 2015, no. 4, p. 2 ff.

intervening on the genome through the insertion of genes that protect a hereditary or supervening functional problem, the creation of artificial vaccines or genetic drugs, or synthetic organisms for the production of biological substances, becomes possible for therapeutic purposes<sup>9</sup>.

These potentials of genomics and synthesis biotechnologies, together with the free usability of the so-called "coding units" in experiments, products and therapeutic protocols, make the maximum possible diffusion of such techniques desirable.

In such a perspective, many scholars have highlighted the importance of promoting the development of human genetic engineering through models of regulations of the most open use of access to basic genetic resources and sharing of scientific discoveries and results<sup>10</sup>.

However, the benefits mentioned so far are not without risk. In this sense, some note that, since genetic engineering uses the viral vector that carries the functional gene within the human body, the repercussions are still largely unknown. The exact location of functional genes is not often clear, sometimes they may even replace important genes instead of mutated genes. This could lead to a different health or disease condition for humans. Furthermore, as the defective genes are replaced with a functional gene, there will be a reduction in genetic diversity. As a result, it is claimed that if humans have identical genomes, the population as a whole will be more sensitive to viruses or any other form of disease<sup>11</sup>.

An accident in the design of the genetics of a virus or bacterium, again, could lead to the development of a stronger type, which could cause a serious epidemic when released. This could be fatal in human genetic engineering, creating problems ranging from minor medical problems to death<sup>12</sup>.

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<sup>9</sup> See: A. Nordberg et al., Cutting edges and weaving threads in the gene editing (A)evolution: reconciling scientific progress with legal, ethical, and social concerns, in *Journal of Law and the Biosciences*, 2018, vol. 5, no. 1, p. 35 ff.

<sup>10</sup> The relationship between freedom of scientific research, protection of human health and limits to research, as is known, has always posed multiple problematic issues, especially with regard to the profiles of experimentation, access to therapies, their respective limits and the balance of fundamental rights. In this regard, see among others: G. Ghidini, *Rethinking Intellectual Property, Balancing Conflicts of Interests in the Constitutional Paradigm*, Edward Elgar, Cheltenham, 2018, p. 69 ff.; A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., p. 49 ff.

<sup>11</sup> See: D.D. Trump, *Synthetic biology regulation and governance: Lessons from TAPIC for the United States, European Union, and Singapore*, in *Health Policy*, 2017, vol. 121, p. 1139 ff.; WR Fleischmann Jr, *Viral Genetics*, in *Id.*, *Medical Microbiology* (4th edition), University of Texas Medical Branch at Galveston, 1996, available online at: <https://www.ncbi.nlm.nih.gov/books/NBK8439>.

<sup>12</sup> See: DK Mercer *et al.*, Fate of free DNA and transformation of the oral bacterium *Streptococcus gordonii* DL1 by plasmid DNA in human saliva, in *Applied and Environmental Microbiology*, 1999, vol. 65, no. 1, p. 6 ff.

Other arguments against genetic engineering are those that a) denounce the risk of "playing God"<sup>13</sup>, b) affirm that genes represent a "common heritage of humanity"<sup>14</sup>, and according to the most radical approach they should be handed down generation after generation without human intervention, or c) remark that genes exist naturally in organisms and should not be interfered with<sup>15</sup>.

Further questions are then raised regarding the effects of using such a technology, including in particular, that according to which once an altered gene is inserted into an organism, the process cannot be reversed, with the risk of developing forms of infectious diseases that give rise to global epidemics<sup>16</sup>.

On the other hand, with regard to the aforementioned objections to human genetic engineering, it has been noted first of all how it can be considered analogous to other human intrusions in nature, among which those for the benefit of life are of particular importance, such as the use of medicines possibly obtained thanks to the genetic engineering itself<sup>17</sup>.

Regarding the interest of humanity, then, actually it seems to be able to be served precisely through the development of scientific and technological researches that allow to offer solutions to problems of central importance such as those of health, reproduction, *etc.* Finally, with respect to the issues relating to the effects, it is highlighted that they are not exclusive to the genetic engineering sector, and must be evaluated and addressed with reference to the specific context<sup>18</sup>.

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<sup>13</sup> See: M. Bratton (edited by), *God, Ethics & the Human Genome*, Church House Publishing, London, 2009; J. Boyle, *Enclosing the Genome: What Squabbles Over Genetic Patents Could Teach Us*, in F. Scott Kieff (edited by), *Perspective on Properties of the Human Genome Project*, Elsevier Academic Press, San Diego, 2003, p. 97 ff.; J. Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World*, JP Tarcher/Putnam, New York, 1998, p. 60 ss.; MJ Hanson, *Religious Voices in Biotechnology. The Case of Gene Patenting*, in *Hastings Center Law Report*, 1997, vol. 27, p. 1 ff.

<sup>14</sup> Or "common interest of humanity" or "public good". See, *ex multis*: ER Gold, BM Knoppers (edited by), *Biotechnology IP & Ethics*, LexisNexis, Markham, 2009, p. 47 ff.; BM Knoppers, Y. Joly, *Our Social Genome?*, in *Trends in Biotechnology*, 2007, vol. 25, p. 284 ff.

<sup>15</sup> See: S. Sterckx, *European Patent Law and Biotechnological Inventions*, in S. Sterckx (edited by), *Biotechnology, Patents and Morality*, Ashgate Publishing, Farnham, 1997, p. 1 ff.

<sup>16</sup> The public reaction to the use of rDNA in genetic engineering has been mixed. The production of medicines through the use of genetically modified organisms has been generally welcomed. However, critics fear that the disease-producing organisms used in some experiments may develop extremely infectious forms that could cause epidemics worldwide. On this point, see: K. Deuschle *et al.*, *Genetically encoded sensors for metabolites*, in *Cytometry Part A*, 2005, vol. 64, no. 1, p. 3 ff.

<sup>17</sup> On this point, see: F. Vandenabeele, *Patentability of Living Organisms: Legal and Ethical Aspects of the Question*, McGill University, Montreal, 2005, p. 68; B. Hoffmaster, *The Ethics of Patenting Higher Life Forms*, in *Intellectual Property Journal*, 1988, vol. 4, p. 1 ff.

<sup>18</sup> See: B. Hoffmaster, *The Ethics of Patenting Higher Life Forms*, *cit.*, p. 1 ff. With regard to the debate between positions contrary and in favor of human genetic engineering, and the relative patentability, see also: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, *cit.*, p. 37 ff.

### III. CIRCULATION OF REPRODUCTIVE MATERIALS, SURROGATE MOTHERHOOD AND LIMITS TO EXPLOITATION

Human genetic engineering includes a series of profiles relating to the modifications artificially introduced into the genetic information of human cells through the insertion of other genetic information. Among them, the profile relating to stem cells and reproductive tissues from the female body is particularly interesting here: oocytes, embryos, fetal tissue and umbilical cord blood, with the related increasingly widespread circulation and industrial use phenomena of themselves<sup>19</sup>.

The demand for embryonic stem cells has already led to a growing demand for oocytes for in vitro fertilization treatments and for further technological developments related to the application of genetic engineering to reproduction. Thus, the sale of reproductive materials has become an attractive option for women living in the poorest economies<sup>20</sup>.

Some scholars state that, in order to give life to them, the woman puts in place a "working" activity through various forms of commitment: respect for the procedure, self-care, taking drugs, risk *in vivo* and the transformation of one's body. With this in mind, women's production of the aforementioned reproductive materials, particularly in the poorest countries, is considered likely to give rise to forms of exploitation of female labor<sup>21</sup>.

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<sup>19</sup> In this regard, see: S. Shrestha, Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?, cit., p. 5; PR Brezina, N. Ning *et al.*, Recent Advances in Assisted Reproductive Technologies, in Current Obstetrics and Gynecology Reports, 2012, vol. 1, no. 4, p. 166 ff.

<sup>20</sup> In this regard, see: D. Dickenson, Commodification of Human Tissue: Implications for Feminist and Development Ethics Commentary, in Developing World Bioethics, 2002, vol. 2, no.1, p. 55 ss. ; C. Waldby, Melinda Cooper, From Reproductive Work to Regenerative Labor: The Female Body and the Stem Cell Industries, in Feminist Theory, 2010, vol. 11, no. 1, p. 13. With regard to fetal material collected from abortions, even in countries where there is strict regulation, and even more evidently in developing countries, women often remain lacking in knowledge on the use of their fetal material for research purposes; on this point, see: N. Pfeffer What British Women Say Matters to Them about Donating an Aborted Fetus to Stem Cell Research: A Focus Group Study, in Social Science & Medicine, 2008, vol. 66, no. 12, p. 2544 ff. ; C. Waldby, Melinda Cooper, From Reproductive Work to Regenerative Labor: The Female Body and the Stem Cell Industries, cit., p. 7 ff. A recent study conducted in India found that hospitals advertise female abortion through risky procedures, taking advantage of cultural preference for male offspring. Subsequently, they retain aborted female fetuses which, to the patient's knowledge, are intended for further research, but in reality for hospitals they represent a *business* of selling reproductive material (see: M. Mies, Patriarchy and Accumulation on a World Scale, Zed Books, London, 2014, 3rd edition, especially p. 151).

<sup>21</sup> Thus, among others: L. Del Savio, G. Cavaliere, The problem with commercial surrogacy. A reflection on reproduction, markets and labor, in BioLaw Journal, 2016, no. 2, p. 73 ff.; C. Waldby, Melinda Cooper, From Reproductive Work to Regenerative Labor: The Female Body and the Stem Cell Industries, cit., p. 3 ff.

In this sense, it is noted that a large number of countries do not regulate these areas of transaction, giving way to a global market whereby multinationals can buy reproductive material at low prices and sell them for profit, giving rise to a sort of "reproductive tourism"<sup>22</sup>.

In recent years, in particular, there has been a notable growth in the use of gestation carried out, on behalf of a parent or a pair of client parents, by a woman who is or is not also a donor of the oocyte<sup>23</sup>. Despite the concrete difficulties in data collection, the Permanent Bureau of The Hague Conference has noted the exponential growth in the use of this practice, highlighting how the estimates can only be undersized compared to reality.

What emerges is that with the tightening of the rules on transnational adoption and the progress of medicine there has been an increase in the demand for surrogate motherhood in general<sup>24</sup>. Consequently, a series of fundamental legal issues related to this practice have emerged, including in particular the determination of kinship, the civil status of the child, the nationality of the child, the right to family life, the commercial exploitation of the human body and the commodification of the child<sup>25</sup>.

While in the traditional surrogacy, or by conception and gestation, the woman who completes the pregnancy is also a donor of the female gamete, in the surrogacy by gestation alone, or in the

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<sup>22</sup> See: GKD Crozier, D. Martin, How to address the ethics of reproductive travel to developing countries: a comparison of national self-sufficiency and regulated market approaches, in *Developing World Bioethics*, 2012, vol. 12, no. 1, p. 45 ff.; R. Prasad, *The Fertility Tourists*, cit.; RF Storrow, *Quests for Conception: Fertility Tourists, Globalization and Feminist Legal Theory*, in *Hastings Law Journal*, 2005-2006, vol. 57, p. 295 ff.; G. Pennings, *Reproductive tourism as moral pluralism in motion*, in *Journal of Medical Ethics*, 2002, vol. 28, no. 6, p. 337 ff.

<sup>23</sup> In this regard, see: S. Allan, *Commercial Surrogate and Child: Ethical Issues, Regulatory Approaches, and Suggestions for Change*, Working Paper, May 2014, available online at: <http://ssrn.com/abstract=2431142>; Y. Ergas, *Babies without borders: human rights, human dignity, and the regulation of international commercial surrogacy*, in *Emory International Law Review*, 2013, vol. 27, p. 124 ff.

<sup>24</sup> Permanent Bureau of The Hague Conference, *A study of legal parentage and the issues arising from international surrogacy arrangements*, Prel. Doc. N. 3C, March 2014, par. 125 ff., and *Id.*, *A preliminary report on the issues arising from international surrogacy arrangements*, Prel. Doc. N. 10, March 2012, 16, n. 94; CA Choudhury, *Transnational Commercial Surrogacy: Contracts, Conflicts, and the Prospects of International Legal Regulation*, Oxford Handbook online in *Law 2016 & Florida International University Legal Studies Research Paper No. 16-18.*, available online at: <https://ssrn.com/abstract=2753783>, p. 3 ss .; S. Mortazavi, *It Takes a Village to Make a Child: Creating Guidelines for International Surrogacy*, in *Georgetown Law Journal*, 2011-2012, vol. 100, p. 2249 ff.; SR Nilanjana, *Protecting the Rights of Surrogate Mothers*, in the *New York Times*, 4 October 2011, available online at: <https://www.nytimes.com/2011/10/05/world/asia/05iht-letter05.html>.

<sup>25</sup> See: European Parliament - Policy Department on Citizens' Rights and Constitutional Affairs, *Regulating international surrogacy arrangements - state of play*, 2016, available online at: [http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/571368/IPOL\\_BRI\(2016\)571368\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/571368/IPOL_BRI(2016)571368_EN.pdf), p. 1 ff.

strict sense, the egg is donated by a third woman. In practice, the latter is the most used technique, so the pregnant woman is usually not genetically linked to the child<sup>26</sup>.

The surrogacy can be altruistic, that is unpaid, with the only exception of the reimbursement of medical expenses incurred by the surrogate mother for the purposes of pregnancy, or commercial, where the payment of an economic consideration to the surrogate mother is agreed between the parties, in addition than to the intermediaries involved<sup>27</sup>.

In this context, in recent decades we have witnessed the rapid expansion of the markets for transnational surrogate motherhood, in which couples from the most developed countries, to avoid the high costs of their domestic industries and/or legal impediments<sup>28</sup>, turn to women of the least developed countries to carry children on their own at significantly lower costs<sup>29</sup>.

Beyond the ethical-legal issues inherent in the surrogacy of motherhood<sup>30</sup>, it is noted that the transactional dimension accentuates the critical issues of the practice itself, including first of all

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<sup>26</sup> Since the sperm may also come from a donor, it is possible that the child has no biological link with the aspiring parents. See: NF Bromfield, K. Smith Rotabi, *Global Surrogacy, Exploitation, Human Rights and International Private Law: A Pragmatic Stance and Policy Recommendations*, in *Global Social Welfare*, 2014, vol. 1, no. 3, p. 123 ff.

<sup>27</sup> See again: The Permanent Bureau of The Hague Conference, *A study of legal parentage and the issues arising from international surrogacy arrangements*, cit., par. 139 ff.; CA Choudhury, *Transnational Commercial Surrogacy: Contracts, Conflicts, and the Prospects of International Legal Regulation*, cit. p. 4 f., and *Id.*, *The Political Economy and Legal Regulation of Transnational Commercial Surrogate Labor*, in 48 *Vanderbilt Journal of Transnational Law*, 2015, vol. 48, no. 1, p. 42 ff. States that allow only altruistic surrogate motherhood reject the commodification of female reproductive capacity implicated in commercial surrogate motherhood, but the distinction between the two cases is not so evident in practice; see: SR Anleu, *Surrogacy: For Love But Not for Money ?*, in *Gender & Society*, 1992, vol. 6, no. 1, p. 30 ff.

<sup>28</sup> Such impediments may consist in the generalized prohibition of resorting to the practice or in various forms of restriction related to the sexual orientation or age of the aspiring parents. See: UR Smerdon, *Crossing bodies, crossing borders: international surrogacy between the United States and India*, in *Cumberland Law Review*, 2008, vol. 39, 15 ss. ; M. Mies, *Why do we need all this? A call against genetic engineering and reproductive technology*, in *Women's Studies International Forum*, 1985, vol. 8, no. 6, p. 553 ff., who found that the phenomenon simultaneously produces the risk that women in developing countries are used for commercial purposes by developed countries and companies, and that there is a real market competition which leads developing countries to adopt and try to exploit more permissive laws on the matter, leaving poorer women to bear the weight of marketing their bodies.

<sup>29</sup> Traditionally, a privileged destination for these practices had been India. When the country tightened its surrogacy laws, the Indian clinics opened branches or transferred their services to the neighboring country, Nepal, which was free of domestic surrogacy laws. The phenomenon emerged forcefully following the earthquake in Nepal in April 2015, when it was reported that Israel evacuated children leaving surrogate mothers vulnerable and unaided. See: D. Kamin, *Israel Evacuates Surrogate Babies from Nepal but Leaves the Mothers Behind*, in *Time*, April 28, 2015, available online at: [www.time.com/3838319/israel-nepal-surrogates](http://www.time.com/3838319/israel-nepal-surrogates); B. Dahal, *Wombs for rent*, in *Nepali Times*, 30 January 2015, available online at: [www.nepalitimes.com/article/nation/wombs-toletsurrogacy-nepal.1991](http://www.nepalitimes.com/article/nation/wombs-toletsurrogacy-nepal.1991).

<sup>30</sup> See: Y. Margalit, *In Defense of Surrogacy Agreements: A Modern Contract Law Perceptive*, in *William & Mary Journal of Women and the Law*, 2014, vol. 20, p. 423 ff.

the potential exploitation of the conditions of economic hardship of surrogate mothers<sup>31</sup>. In this perspective, both the importance of global and local inequalities as bases of reproductive tourism are highlighted<sup>32</sup>, and the impact that practice would have on inequalities contributing to aggravate them<sup>33</sup>.

In the same sense, it is therefore stated that even the possible provision in developed countries of strict research laws for the purpose of human genetic engineering, while reproductive material and/or surrogate motherhood can be purchased from less developed countries and with more permissive regulations, it risks leaving unchanged the possibilities of exploitation of the human body on which they are based, more stringent rules should be dictated regarding the cross-border surrogacy, also regarding the transparency of the supply chain<sup>34</sup>.

Currently, very few countries allow commercial surrogate motherhood, while others allow altruistic surrogate motherhood. Today only India, Nepal, Thailand, Cambodia, Israel, Russia, Ukraine, Mexico, Venezuela, and some States in the United States allow commercial motherhood<sup>35</sup>.

In some of these systems, moreover, following numerous criticisms and controversies, while commercial surrogate motherhood with respect to local client parents is allowed, bans on

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<sup>31</sup> Thus, among others: G. Labadie - Jackson, *The Reproductive Rights of Latinas and Commercial Surrogacy Contracts*, in *Texas Hispanic Journal of Law & Policy*, 2008, vol. 14, p. 49 ff.

<sup>32</sup> In this regard, see: LC Ikemoto, *Reproductive Tourism: Equality Concerns in the Global Market for Fertility Services*, in *Law & Inequality*, 2009, vol. 27, p. 277 ss.; A. Donchin, *Reproductive tourism and the quest for global gender justice*, in *Bioethics*, 2010, vol. 24, p. 323 ff.

<sup>33</sup> See S. Allan, *Commercial Surrogate and Child: Ethical Issues, Regulatory Approaches, and Suggestions for Change*, cit., P. 3; J. Rimm, *Booming baby business: regulating commercial surrogacy in India*, in *University of Pennsylvania Journal of International Law*, 2009, vol. 30, p. 1445 ff.

<sup>34</sup> In this sense, see: S. Shrestha, *Genetically Modified Organisms and Human Genetic Engineering: How Should National Policy-Makers Respond to Perceived Risks Beyond National Borders?*, cit., p. 7; C. Wei Teng *et al.*, *An Analysis of Supply Chain Strategies in the Regenerative Medicine Industry*, in *International Journal of Production Economics*, 2014, vol. 149, p. 211 ss.; P. Glasner, *Banking on Immortality? Exploring the Stem Cell Supply Chain from Embryo to Therapeutic Application*, in *Current Sociology*, 2005, vol. 53, no. 2, p. 355 ss.; D. Dickenson, *Commodification of Human Tissue: Implications for Feminist and Development Ethics Commentary*, cit., P. 60.

<sup>35</sup> See: Wikipedia, *Surrogacy laws by country*, available online at: [https://en.wikipedia.org/wiki/Surrogacy\\_laws\\_by\\_country](https://en.wikipedia.org/wiki/Surrogacy_laws_by_country); Cornell Law School International Human Rights Policy Advocacy Clinic and National Law University Delhi, *Should Compensated Surrogacy Be Permitted or Prohibited? Policy Report Evaluating the New York Child-Parent Security Act of 2017 that Would Permit Enforceable and Compensated Surrogacy*, Cornell Law Faculty Publications, September 2017, available online at: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3039011](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3039011); K. Trimmings, P. Beaumont, *General Report on Surrogacy*, in *Iidd.* (edited by), *International Surrogacy Arrangements: Legal Regulation at the International Level*, Hart Publishing, Oxford, 2013, p. 439 ff.

transnational surrogate motherhood have recently been introduced in India, Nepal, Thailand and Cambodia<sup>36</sup>.

In almost all States that allow commercial surrogate motherhood, the clinic is the first point of contact for the commissioning of parents. The clinic proposes a surrogate mother to provide gestational service, often through brokers who search villages through word of mouth or advertising. In India, clinics also draw up contracts, receive payment from parent clients, perform medical procedures, and regulate and control gestation. The central and perhaps most important aspect of the contract is that the surrogate has no parental rights over the child<sup>37</sup>.

In India, the problem of widespread illiteracy poses questions about the fairness of the contract. In this sense, it has been argued that some surrogate mothers may not be adequately informed before contracting, thus resulting in vulnerability to exploitation by the more aware contractors. In terms of compensation, according to available data, Indian surrogate mothers can get between \$ 2000 and \$ 35,000<sup>38</sup>.

In the United States, compensated surrogate motherhood is allowed in a limited number of States, and these are attracting more foreign aspiring parents. Unlike most countries that allow commercial surrogacy, where clinics are the primary referents for the procedure as mentioned, in the United States there are intermediary companies specialized in identifying the surrogate mother, drawing up the contract between the same and would-be parents, and coordinate them

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<sup>36</sup> In this regard, see among others: K. Naren, Prime Minister Warns Mothers Against Surrogacy in Midst of Ban, *Cambodia Daily*, 22 February 2017, available online at: <https://www.cambodiadaily.com/morenews/prime-minister-warns-mothers-against-surrogacy-inmidst-of-ban-125583>; R. Abrams, Nepal Bans Surrogacy, Leaving Couples With Few LowCost Options, *New York Times*, 2 May 2016, available online at: <https://www.nytimes.com/2016/05/03/world/asia/nepal-bans-surrogacy-leaving-couples-with-few-low-cost-options.html>; R. Kumar, India's Surrogacy Tourism Takes a Hit, in *Foreign Affairs*, 11 December 2015, available online at: <https://www.foreignaffairs.com/articles/india/2015-12-11/indiassurrogacy-tourism-takes-hit>; New Thai Surrogacy Law Bans Foreigners, *SBS*, 1 August 2015, available online at: <http://www.sbs.com.au/news/article/2015/07/31/new-thai-surrogacy-law-bans-foreigners>. In particular, until 2015 the Indian surrogate mother market was valued at over 2 billion dollars, with a large number of client parents coming from abroad but also a strong internal demand. Since 2002, around 25,000 children would be born to surrogate mothers, and over 350 facilities providing these services; v. : R. Kumar, India's Surrogacy Tourism Takes a Hit, *cit.*; P. Shetty, India's Unregulated Surrogacy Industry, in *The Lancet*, 2012, vol. 380, no. 9854, p. 1633 ff.

<sup>37</sup> See: A. Pande, *Wombs in Labor: Transnational Commercial Surrogacy in India*, Columbia University Press, New York, 2014, p. 66 ff.

<sup>38</sup> Figures that represent several years of average wages, often providing enough capital to purchase land and a house, and to pay for the surrogate's children. In this regard, see: D. Bhattacharjee, Commercial Surrogacy in India: Bans, "Altruism" and the Women Involved, in *Economic & Political Weekly*, 2016, vol. 51, no. 14, p. 27 ff.; Raksha Kumar, India's Surrogacy Tourism Takes a Hit; UR Smerdon, Crossing bodies, crossing borders: international surrogacy between the United States and India, *cit.*, p. 32.

with the clinic that will provide medical services. As for costs, they can typically range between \$ 60,000 and \$ 150,000<sup>39</sup>.

Despite these costs, recent reports suggest that the United States has increasingly become a destination that attracts aspiring parents from Europe and China<sup>40</sup>, as they guarantee medical services to provide adequate assistance and the regulation of practice is more reliable than that of other countries<sup>41</sup>.

In those eighteen US States where - as in at least forty other countries including India - state regulations have not imposed any protection for surrogates<sup>42</sup>, the surrogate motherhood industry has developed strong basic protections for women who sell gestational services. For example, would-be parents are expected to pay for legal representation, life insurance and surrogate health insurance.

Conversely, the surrogate motherhood industry in India has not been providing similar basic protections for surrogate mothers. Scholars believe that this is because American courts are more accessible, also thanks to the possibility of establishing contingent fees<sup>43</sup> - prohibited in India - and sentences are made faster than in Indian courts<sup>44</sup>.

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<sup>39</sup> See: CA Choudhury, *The Political Economy and Legal Regulation of Transnational Commercial Surrogate Labor*, cit., P. 42 ff.; UR Smerdon, *Crossing bodies, crossing borders: international surrogacy between the United States and India*, cit., p. 32.

<sup>40</sup> See: C. Fenton-Glynn, *Outsourcing Ethical Dilemmas: Regulating International Surrogacy Arrangements*, in *Medical Law Review*, 2016, vol. 24, no. 1, p. 59 ss.; A. Harney, *Rich Chinese hire American surrogate mothers for up to \$ 120,000 a child*, *The Telegraph*, Sept. 23, 2013, available online at: <http://www.telegraph.co.uk/news/worldnews/asia/china/10328132/Rich-Chinese-hire-American-surrogate-mothers-for-up-to-120000-a-child.html>; S. Yan, *Chinese are hiring surrogate moms in America*, in *CNN Money*, 23 August 2015, available online at: <http://money.cnn.com/2015/08/23/news/china-us-surrogacy>.

<sup>41</sup> In particular, a number of jurisdictions in the United States have confirmed surrogate maternity contracts, and with sentences such as *Baby M*, *Johnson v. Calvert* and *KM v. EG*, the courts confirmed the rights of aspiring parents over the surrogate mother. In re *Baby M*, 537 A.2d 1227, 1234 (NJ 1988); *Johnson v. Calvert*, 851 P.2d 776, 778 (Cal. 1993); *KM v. EG*, 117 P.3d 673, 673 (Cal. 2005).

<sup>42</sup> On this point, see: Cornell Law School International Human Rights Policy Advocacy Clinic and National Law University Delhi, *Should Compensated Surrogacy Be Permitted or Prohibited?*, cit., p. 21 ss.; BA Patton, *Buying a newborn: globalization and the lack of federal regulation of commercial surrogacy contracts*, in *UMKC Law Review*, 2010-2011, vol. 79, p. 513 ff.

<sup>43</sup> The contingent fee (in the United States), or conditional fee (in England and Wales), is the compensation for the provision of legal services established so that the payment is due only where a favorable result for the customer is achieved.

<sup>44</sup> Despite being a common law country like the United States, and as in the eighteen American States, the regulation in this matter does not provide protections for surrogate mothers. S. Kalantry, *Regulating Markets for Gestational Care: Comparative Perspectives on Surrogacy in the United States and India*, in *Cornell Journal of Law and Public Policy*, 2018, vol. 27, no. 3, p. 685 ff., who also notes that another explanation of the reason why the Indian surrogate motherhood industry does not offer the same level of surrogate protection compared to the US industry may be found in the greater relative economic inequality between the surrogate and the aspiring parents. in the two countries. In the United States, many businesses in the sector refuse to consider women below the federal poverty line, as contracts with them would be more likely to be invalidated by the courts for reasons of coercion or unawareness. Regarding the negotiation of contracts "in the shadow of the

In the European Union, surrogate motherhood is regulated in various ways in different Member States. Some jurisdictions, such as France, Germany, Italy and Sweden, prohibit both selfless and commercial surrogate motherhood, while others, such as Greece and the UK, allow practice until it is commercial, and still others have adopted very limited rules, or even none, on the subject<sup>45</sup>.

The main legal issues that emerge in the relevant jurisprudence concern mainly the determination of parenthood, marital status, nationality and right to family life of the child, and commercial exploitation of the human body of the surrogate mother and the child himself<sup>46</sup>. Although family law in general and surrogate motherhood in particular are essentially issues of national competence, the European Union has the power to act on aspects with transnational implications<sup>47</sup>.

Numerous refusals to recognize cross-border surrogate motherhood agreements and their consequences have been contested before the European Court of Human Rights for violating the rights of the child to respect for private and family life<sup>48</sup>.

In the *Mennesson and Labassée* cases<sup>49</sup>, it was found that the refusal to recognize foreign birth certificates resulting from international surrogate motherhood agreements resulted in a lower status for the child in French hereditary legislation<sup>50</sup> and practical difficulties in social security and school education.

The European Court of Human Rights, following its previous jurisprudence dictated by the fundamental principle of the best interest of the child<sup>51</sup>, stated that these consequences deriving

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law", see: RH Mnookin, L. Kornhausert, *Bargaining in the Shadow of the Law: The Case of Divorce*, in *Yale Law Journal*, 1979, vol. 88, no. 5, p. 950 ff. (968).

<sup>45</sup> See: European Parliament - Policy Department on Citizens' Rights and Constitutional Affairs, *A comparative study on the regime of surrogacy in EU Member States*, May 2013, available online at: [http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL-JURI\\_ET\(2013\)474403](http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL-JURI_ET(2013)474403), which highlighted which three key issues to be addressed were the certainty regarding the legal parenthood of the minor, the child's right to leave the country of origin, and the the right of the same to reside permanently in the receiving country. See also: *Id.*, *Recognition of Parental Responsibility: Biological Parenthood v. Legal Parenthood, i.e. Mutual Recognition of Surrogacy Agreements: What is the Current Situation in the MS? Need for EU Action ?*, October 2010, available online at: [http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL-JURI\\_NT\(2010\)432738](http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL-JURI_NT(2010)432738).

<sup>46</sup> See: European Parliament - Policy Department on Citizens' Rights and Constitutional Affairs, *A comparative study on the regime of surrogacy in EU Member States*, cit., p. 22 ff.

<sup>47</sup> Art. 81, par. 3 of the Treaty on the Functioning of the European Union.

<sup>48</sup> See art. 8 of the European Convention on Human Rights.

<sup>49</sup> *Mennesson v. France*, case no. 65192/11, June 26, 2014; *Labassée v. France*, case no. 65941/11, June 26, 2014.

<sup>50</sup> In contrast to what the Court decided in *Marckx v. Belgium*, case no. 6833/74, June 13, 1979.

<sup>51</sup> Regarding which see, among others: K. Smith Rotabi *et al.*, *Regulating Commercial Global Surrogacy: The Best Interests of the Child*, in *Journal of Human Rights and Social Work*, 2017, vol. 2, no. 3, p. 64 ff.

from the refusal to grant citizenship amounted to a violation of the child's right to privacy. This ruling was recently confirmed in the Foulon and Bouvet cases, where the applicants complained that their children had no right to open a bank account in France because they had been denied French nationality<sup>52</sup>.

With regard to the issue of legal parenting, prohibition States apply their own kinship laws. In the French cases mentioned above and in the Paradiso and Campanelli case<sup>53</sup>, France and Italy refused to establish a legal relationship between the child and the aspiring parents in application of their national law. Consequently, the European Court ruled that the child's right to respect for private life had been violated, since the lack of filiation would have a negative impact on the formation of the identity of the child and on the child's right to preserve that identity, being therefore incompatible with the principle of the best interest of the child.

Another related question that emerges in similar cases - as noted by the Court in the Paradiso and Campanelli decision - is that concerning the child's right to access information relating to his identity,<sup>54</sup> therefore including the parent-child relationship and nationality<sup>55</sup>.

A central problem highlighted in the Paradiso and Campanelli case was the removal of the child from his family environment, following the Italian State's refusal to recognize his birth certificate. According to the jurisprudence of the ECHR, the existence of a family life within the meaning of Article 8 depends mainly on the presence of *de facto* ties. Even if the aspiring parents were not considered *de jure* by the Italian authorities as the child's legal parents, they were seen as social parents *de facto*, so a violation of the child's right to family life was found<sup>56</sup>.

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<sup>52</sup> Foulon v. France, case no. 9063/14, 21 July 2016; Bouvet v. France, case no. 10410/14, 21 July 2016.

<sup>53</sup> Paradiso and Campanelli v. Italy, case no. 25358/12, 27 January 2015. In Italy, see recently the decision no. 12193/19 of 8 May 2019 of the United Sections of the Supreme Court of Cassation, which denied the recognition of the effectiveness of the foreign court order with which the relationship of filiation between a child born abroad through surrogate motherhood and an aspiring parent was ascertained Italian. The Court, in fact, found obstacles to that recognition in the ban on the substitution of maternity provided for by art. 12, sixth paragraph, of law no. 40 of 2004, qualifiable as a principle of public order, as it is placed to protect fundamental values, such as the human dignity of the pregnant woman and the institution of adoption. The Cassation thus confirmed once again the strong disadvantage for the practice already reiterated even a few months earlier in the Cassation decision Crim. Sec. VI no. 2173/19 of 17 January 2019, which had condemned the natural mother for the crime of entrusting a child to third parties even in the absence of the provision of compensation.

<sup>54</sup> See: Gaskin v. United Kingdom, case no. 10454/83, 7 July 1989.

<sup>55</sup> Thus: R. Blauwhoff, L. Frohn, International Commercial Surrogacy Arrangements: The Interests of the Child as a Concern of Both Human Rights and Private International Law, in C. Paulussen *et al.* (edited by), Fundamental Rights in International and European Law - Public and Private Law Perspectives, Springer, Berlin, 2016, p. 211 ff.

<sup>56</sup> Being the decision to remove the child from his family environment is an extreme measure that State authorities should have used only as an *extrema ratio*.

According to the jurisprudence of the ECHR, therefore, the refusal to recognize foreign birth certificates of surrogate children amounts to a violation of the child's fundamental right to private and family life due to the consequences that this entails<sup>57</sup>.

In this context, given the differentiated national approaches and the consequent cases of legal uncertainty that arise in this matter, the European Union institutions are wondering about the possibility of intervention at EU level. Currently, the feasible options appear: a) coordination of the effects of the family status conflicts<sup>58</sup>, up to possible interventions aimed at making mutual recognition of family states mandatory; b) the adoption of *soft law* tools and actions support at national level; c) cooperation in ongoing activities on the subject within international organizations<sup>59</sup>.

In the current scenario of absence of an international regulatory framework described so far, in the last few years various hypotheses have been proposed regarding interventions that can provide univocal indications regarding the lawfulness of the practice of surrogate motherhood and/or the legal issues to which it gives rise.

In this debate, according to some, the only necessary action would be to adapt the existing framework for international adoption to cases of transnational surrogacy agreements<sup>60</sup>. According to others, there is a need to develop a separate international tool dedicated to surrogate motherhood<sup>61</sup>. In the meantime, work has started in international fora, such as the

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<sup>57</sup> European Parliament - Policy Department on Citizens' Rights and Constitutional Affairs, *Regulating international surrogacy arrangements - state of play*, cit., P. 2.

<sup>58</sup> As for example in the area of succession or in the area of parental responsibility.

<sup>59</sup> Thus: European Parliament - Policy Department on Citizens' Rights and Constitutional Affairs, *Regulating international surrogacy arrangements - state of play*, cit., p. 4 f.

<sup>60</sup> See for example: C. Thomale, *State of play of cross-border surrogacy arrangements - is there a case for regulatory intervention by the EU ?*, in *Journal of International Private Law*, 2017, vol. 13, no. 2, p. 463 ff., according to whom accelerated procedures could be put in place when the genetic descent of the children substituted by the aspiring parents can be ascertained or when the legal relationship of an aspiring parent is already established independently, and the aspiring parents could also be put in place at the top of the list of candidates taken into consideration in the adoption process; M. Wells-Greco, *The Status of Children Arising from Inter-Country Surrogacy Arrangements*, Eleven international publishing, The Hague, 2015.

<sup>61</sup> In this sense, among others: R. Blauwhoff, L. Frohn, *International Commercial Surrogacy Arrangements: The Interests of the Child as a Concern of Both Human Rights and Private International Law*, cit., p. 211 ss.; K. Trimmings, P. Beaumont, *International Surrogacy Arrangements: Legal Regulation at the International Level*, Hart Publishing, Oxford, 2013, and *Iidd.*, *International Surrogacy Arrangements: An urgent need for Legal Regulation at the International Level*, *Journal of Private International Law*, 2011, vol. 7, no. 3, p. 627 ff., according to which the primary objectives of a convention should be the development of a system of legally binding rules that should be observed with regard to international surrogacy agreements, a supervision system to ensure that these standards are observed, and a cooperation framework and communication channels between the jurisdictions involved.

intergovernmental organization of The Hague Conference on private international law<sup>62</sup>, or the non-governmental organization International Social Service<sup>63</sup>.

#### IV. GENOMIC MEDICINE AND IMPACT ON EVOLUTION: THE CASE OF EMBRYOS WITH MODIFIED DNA

Nowadays, genome modification interventions are possible which allow to structurally modify the genetic material of human beings and other living beings in order to treat diseases or even decide the characteristics of the descendants. Sometimes babies are born with serious pathologies and disorders due to the presence of genetic anomalies at the level of mitochondrial DNA, which can be the result of genetic recombination that occurs at the time of fertilization of the oocyte by the spermatozoon, or be transmitted to who comes into the world from the mother's egg cell<sup>64</sup>.

Currently, in the field of reproductive medicine and genomics in general, interventions are being developed respectively to prevent transmission to the unborn child or to treat an increasing number of diseases of mitochondrial or subsequent origin in the adult patient<sup>65</sup>. Genetic modification in humans, today in particular through CRISPR technologies, is now part of the tools available to researchers and is increasingly used<sup>66</sup>.

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<sup>62</sup> In 2015, The Hague Conference on Private International Law, an intergovernmental organization with 80 members, including all EU Member States and the EU itself, set up a group of experts - so-called The Parentage / Surrogacy Project - to examine private international law issues affecting the status of children, including issues arising from international surrogate motherhood agreements. Among the options under consideration by the experts, there is precisely that of developing a multilateral tool on the subject.

<sup>63</sup> Also in 2015, the International Social Institute, a global foundation based in Switzerland created to help families facing cross-border challenges, brought together a group of experts to collaborate in drafting some key principles. The principles indicated so far refer to the main international instruments on the rights of the child, remembering that children are holders of individual rights and need special safeguards that include human dignity, the primacy of the best interests of the child, non-discrimination, prevention the sale and trafficking of the child, the right to registration of birth and nationality and access to one's identity, as well as clear rules on what would happen in the event of violation of the international surrogacy agreement, abandonment of the child, *etc.*

<sup>64</sup> Since mitochondrial DNA is transmitted to the unborn child only by the woman.

<sup>65</sup> On the topic, among others, see: T. Ishii, Reproductive Medicine Involving Mitochondrial DNA Modification: Evolution, Legality, and Ethics, in *European Medical Journal Reproductive Health*, 2018, vol. 4, no. 1, p. 88 ff., available online at: <https://www.emjreviews.com/reproductive-health/article/reproductive-medicine-involving-mitochondrial-dna-modification-evolution-legality-and-ethics>; L. Craven *et al.*, Novel reproductive technologies to prevent mitochondrial disease, in *Human Reproduction Update*, 2017, vol. 23, no. 5, p. 501 ss, available online at: <https://academic.oup.com/humupd/article/23/5/501/3885847>.

<sup>66</sup> Clustered Regularly Interspaced Short Palindromic Repeats, that is short palindrome repeats grouped and separated at regular intervals. CRISPR technologies allow to add, modify or remove genetic or altered material in particular positions in the genome, and are very useful for the development of precise genetic modifications

In different countries there are different cultural conceptions and regulatory approaches regarding the applications and restrictions to be placed on the use of genetic engineering and genomic medicine, but somatic cell gene therapy in humans is already in use in some countries<sup>67</sup>. While a wide bioethical debate has developed in Europe and a complex legal path regarding research and therapy activities on human embryos<sup>68</sup>, in China since April 2015 some researchers have announced that they have applied CRISPR technology to non-viable human embryos<sup>69</sup>. Later, another Chinese research team demonstrated that CRISPR was also effective as a genetic modification tool compared to available human embryos<sup>70</sup>.

In September 2015, a team of British researchers asked for authorization to apply the CRISPR technique in embryos left over from in vitro fertilization donated by their parents, with the aim of studying pre-human embryonic development. In February 2016, the British Human Fertilization and Embryology Authority granted the world's first authorization for research on healthy embryos, both newly formed and up to seven days of development. Furthermore, it clarified that embryos must be destroyed after the experimental process, since it is strictly forbidden to transfer genetically modified embryos to a woman or to use them for other purposes<sup>71</sup>.

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in different cells, tissues and organisms, including mammals and human embryos. In recent years, they have quickly become accessible for science labs around the world, and data indicate exponential growth in their use. In this regard, see among others: US National Library of Medicine, What are genome editing and CRISPR-Cas9 ?, May 2019, available online at: <https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting>; R. Stein, First US Patients Treated With CRISPR As Human Gene-Editing Trials Get Underway, in NPR, April 16, 2019, available online at: <https://www.npr.org/sections/health-shots/2019/04/16/712402435/first-us-patients-treated-with-CRISPR-as-gene-editing-human-trials-get-underway?t=1558452210082>; I. de Lecuona *et al.*, Gene Editing in Humans: Towards a Global and Inclusive Debate for Responsible Research, in *Yale Journal of Biological Medicine*, 2017, vol. 90, no. 4, p. 673 ss.; H. Ledford, CRISPR, the disruptor, in *Nature*, 3 June 2015, available online at: <https://www.nature.com/news/crispr-the-disruptor-1.17673>.

<sup>67</sup> See, among others: J. Santaló, M. Casado (edited by), Document sobre bioètica i edició genòmica en humans, Edicions de la Universitat de Barcelona, Barcelona, 2016, available online at: <http://www.publicacions.ub.edu/refs/observatoriBioEticaDret/documents/08543.pdf>

<sup>68</sup> For which see below the references included in this paragraph.

<sup>69</sup> In particular, they reported that the CRISPR system had been able to effectively break down endogenous genes in human triploid zygotes; v. : P. Liang *et al.*, CRISPR / Cas9-mediated gene editing in human triploid zygotes, in *Protein & Cell*, 2015, vol. 6, no. 5, p. 363 ff.

<sup>70</sup> See L. Tang *et al.*, CRISPR / Cas9-mediated gene editing in human zygotes using Cas9 protein, in *Molecular Genetics and Genomics*, 2017, vol. 292, n. 3, p. 525 ff.

<sup>71</sup> In this regard, see: F. Hirsch, L. Montoliu, ARRIGE: Toward a Responsible Use of Genome Editing, in Z. Koporc (ed.), *Ethics and Integrity in Health and Life Sciences Research*, Emerald Publishing, Bingley, 2019, p. 115 ff. (117 ff.); I. de Lecuona *et al.*, Gene Editing in Humans: Towards a Global and Inclusive Debate for Responsible Research, in *Yale Journal of Biological Medicine*, 2017, vol. 90, no. 4, p. 673 ff.; see also: R.J. Castro, Mitochondrial replacement therapy: the UK and US regulatory landscapes, in *Journal of Law and the Biosciences*, 2016, p. 1 ff.; A. Nordberg, T. Minssen, A 'Ray of Hope' for European Stem Cell Patents or 'Out of the Smog into the Fog'? An Analysis of Recent European Case Law and How It Compares to the US, in *IIC*, 2016, vol. 47, no. 2, p. 138 ff.

Also in 2016, the first gene therapy protocol was approved in the United States through the application of CRISPR technology<sup>72</sup>. At the same time, in China, less than a year after the publication of the genetic modification of triploid human embryos, such a technology was introduced to treat serious tumors in patients who did not respond to chemotherapy and without the possibility of donors<sup>73</sup>.

In November 2018, He Jiankui, then of the Southern University of Science and Technology in Shenzhen, claimed to have altered DNA embryos in such a way as to give unborn children and their descendants resistance to HIV. This germline modification approach involves changing DNA in embryos or sperm or eggs and is prohibited in many countries, including China<sup>74</sup>.

The experiment, applying CRISPR technology, gave birth to twins born last fall, while the arrival of another child on which the same technique was applied has also been announced. The experiment resulted for the researcher in a criminal sentence<sup>75</sup> and a worldwide condemnation for the premature use of a still defective technique that could adversely affect the development and health of children in unnecessary and unjustified medical intervention<sup>76</sup>.

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<sup>72</sup> See: J. Kaiser, First proposed human test of CRISPR passes initial safety review, in *Science*, June 21, 2016, available online at: <https://www.sciencemag.org/news/2016/06/first-proposed-human-test-CRISPR-passes-initial-safety-review>.

<sup>73</sup> See again: J. Santaló, M. Casado (edited by), *Document sobre bioètica i edició genòmica en humans*, cit.

<sup>74</sup> See in particular: Ethical Guiding Principles for the Research of Human Embryonic Stem Cell (人胚胎干细胞研究伦理指导原则 [现行有效]), December 2003; A. Rosemann *et al.*, The regulatory and legal situation of human embryo, gamete and germ line gene editing research and clinical applications in the People's Republic of China, Nuffield Council on Bioethics, May 2017, available online at: <http://nuffieldbioethics.org/wp-content/uploads/Background-paper-GEHR.pdf>. Regarding the prohibitions in other countries, in addition to referring below in this paragraph, see: R. Yotova, The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law, Nuffield Council on Bioethics, June 2017, available for consultation online at: <http://nuffieldbioethics.org/wp-content/uploads/Report-regulation-GEHR-for-web.pdf>; UNESCO panel of experts calls for ban on "editing" of human DNA to avoid unethical tampering with hereditary traits, available online at: <https://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits?language=fr>; in doctrine: L. Liao, L. Li, RC Zhao, Stem cell research in China, in *Philosophical Transactions of the Royal Society of London B: Biological Sciences*, 2007, vol. 362, no. 1482, p. 1107 ff., available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2435574>; in a critical key: L. Jiang, Will the First Administrative Measure on Clinical Stem Cell Research End the Wild East Scientific Feast?, in *Biotechnology Law Report*, 2016, vol. 35, no. 1, p. 27 ff., available online at: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2745233](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2745233).

<sup>75</sup> On 30 December 2019, the Shenzhen Nanshan District People's Court sentenced the researcher to three years imprisonment and RMB 3 million fine.

<sup>76</sup> See in particular: Chinese Academy of Medical Sciences (C. Wang *et al.*), Gene-edited babies: Chinese Academy of Medical Sciences' response and action, in *The Lancet*, December 3, 2018, vol. 393, no. 10166, p. 25 f., available online at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)33080-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)33080-0/fulltext); Statement by the Council of Europe Committee on Bioethics, Ethics and Human Rights must guide any use of genome editing technologies in human beings, 30 November 2018, available online at: <https://www.coe.int/en/web/portal/-/ethics-and-human-rights-must-guide-any-use-of-genome-editing-technologies-in-human-beings->; in doctrine: M. Kwan, Human Gene Editing and Human Rights: An Uncertain

The possibility of using technologies such as CRISPR to correct anomalies and treat genetic diseases raises many ethical-legal questions, which emerged especially in the debate regarding research on embryos and interventions on mitochondrial anomalies of the unborn child<sup>77</sup>.

The first group of questions is that relating to the consequences for the people concerned: the procedures could prevent or cure the onset of very serious diseases caused by mitochondrial anomalies, but some fear the risk of further and unforeseeable damage<sup>78</sup>. A second group of questions concerns the legitimacy of interventions aimed at modifying the genome of the person who will be born or of the one already living, regardless of the effects for it and for future generations. Finally, there is the fear that the procedures for correcting mitochondrial anomalies may have negative consequences not for those who will come into the world, but for other people who with the development of these techniques could be discriminated against or penalized.

On the other hand, it is objected that the procedures that allow to modify the mitochondrial DNA of the oocyte will bring benefits not only to people who want to have a child, but also to the person who will be born without being sentenced to a life of suffering or death due to mitochondrial abnormalities. According to this view, the risk that these interventions aggravate the anomalies or produce different ones does not appear particularly significant, considering the most recent experiments conducted on animals and embryos that seem to confirm the safety of these interventions<sup>79</sup>.

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Future, in Human Rights Series, 2019, available online at: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3364082&download=yes](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3364082&download=yes); R. Alta Charo, Germline Engineering and Human Rights, in *American Journal of International Law*, 2018, vol. 112, p. 344 ff.

<sup>77</sup> See, among others: Nuffield Council on Bioethics, *Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review*, 2012, available online at: [http://nuffieldbioethics.org/wp-content/uploads/2014/06/Novel\\_techniques\\_for\\_the\\_prevention\\_of\\_mitochondrial\\_DNA\\_disorders\\_compressed.pdf](http://nuffieldbioethics.org/wp-content/uploads/2014/06/Novel_techniques_for_the_prevention_of_mitochondrial_DNA_disorders_compressed.pdf); AL Bredenoord, P. Braude, *Ethics of mitochondrial gene replacement: from bench to bedside*, in *British Medical Journal*, 2010, p. 341 ff.; A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., p. 66 ff.

<sup>78</sup> In particular, regarding issues related to the consequences of transferring genetic material from one oocyte to another to prevent genetic abnormalities in mitochondrial DNA, the major concern is that different portions of DNA - one inherited from the mother, the other taken from the donor and introduced into the oocyte - may cause further diseases in the child himself and in future generations (being germ changes), or modify the expression of nuclear DNA genes, with unrecognizable effects that would emerge only in the future. In this regard, see: Nuffield Council on Bioethics, *Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review*, cit., p. 59; S. Graumann, H. Haker, *Some Conceptual and Ethical Comments on Egg Cell Nuclear Transfer*, in *Politics and the Life Sciences*, 1998, vol. 17, no. 1, pp. 16-18; H. Jonas, *The Imperative of Responsibility: In Search of an Ethics for the Technological Age*, University of Chicago Press, Chicago, 1985.

<sup>79</sup> See: Human Fertilization and Embryology Authority, *Third scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception*, June 2014, available online at:

Further criticisms, again in terms of consequences for the unborn child, draw attention to the fact that those who come into the world will inherit their genome not from two but from three people<sup>80</sup>. To this some scholars reply, recalling the analogy with organ donation, that the donor of an oocyte could not by virtue of this fact be considered a sort of second mother as it will have no affective-educational responsibilities or ties with the child<sup>81</sup>.

With regard to the question of the intrinsic illegitimacy of the interventions aimed at correcting the mitochondrial DNA, as the manipulation of the genome they would produce is considered unacceptable<sup>82</sup>, or there is fear of the "slippery slope"<sup>83</sup> to which they could give rise compared to further developments even more problematic<sup>84</sup>, the supporters' response is based on the observation that the moral acceptability of such techniques should be assessed not so much with regard to their consequences on the genetic code of the unborn child<sup>85</sup>, as with respect to the foreseeable effects that they will have on its existence.

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[https://www.hfea.gov.uk/media/2614\\_third\\_mitochondrial\\_replacement\\_scientific\\_review.pdf](https://www.hfea.gov.uk/media/2614_third_mitochondrial_replacement_scientific_review.pdf), and *Id.*, Scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception, April 2011, available online at: [http://www.hfea.gov.uk/docs/2011-04-18\\_Mitochondria\\_review\\_-\\_final\\_report.pdf](http://www.hfea.gov.uk/docs/2011-04-18_Mitochondria_review_-_final_report.pdf); K. Einhardt, DK Dowling, EH Morrow, Mitochondrial Replacement Evolution, and the Clinic, in *Science*, 2013, vol. 341, n. 6152, pp. 1345 s.; M. Tachibana *et al.*, Towards germline gene therapy of inherited mitochondrial diseases, in *Nature*, January 31, 2013, vol. 493, n. 7434, p. 627 sqq., And *Id. Et al.*, Mitochondrial gene replacement in primate offspring and embryonic stem cells, in *Nature*, 17 September 2009, vol. 461, n. 7262, p. 367 ss.; D. Cyranoski, DNA-swap technology almost ready for fertility clinic, in *Nature*, 24 October 2012, available online at: <https://www.nature.com/news/dna-swap-technology-almost-ready-for-fertility-clinic-1.11651>. *Contra*: PF Chinnery *et al.*, Correction: The Challenges of Mitochondrial Replacement, in *PLoS Genetics*, 2014, vol. 10, no. 6, available online at: <https://journals.plos.org/plosgenetics/article?id=10.1371/journal.pgen.1004315>.

<sup>80</sup> In this regard, v.: F. Baylis, The ethics of creating children with three genetic parents, in *Reproductive BioMedicine Online*, 2013, vol. 26, no. 6, p. 531 ff., available online at: [https://www.rbmojournal.com/article/S1472-6483\(13\)00132-6/pdf](https://www.rbmojournal.com/article/S1472-6483(13)00132-6/pdf); F. Taylor, Three-parent embryos for mitochondrial disorders, in *Christian Medical Fellowship Files*, 2013, n. 51, available online at: <http://www.cmf.org.uk/publications/content.asp?context=article&id=26082>; J. Anton, Ethical issues of new techniques to avoid mitochondrial disease, Ethics and Law Advisory Committee (HFEA), June 8, 2011, ELAC (06/11) 1, p. 1 ff.

<sup>81</sup> In this sense: A. Murdoch, IVF and the prevention of mitochondrial DNA disease: the moral issues, in *Bionews*, 3 May 2011, available online at: [http://www.bionews.org.uk/page\\_94023.asp](http://www.bionews.org.uk/page_94023.asp); J. Anton, Ethical issues of new techniques to avoid mitochondrial disease, cit., pp. 7-9.

<sup>82</sup> See: UK Parliamentary Office of Science and Technology, Preventing Mitochondrial Disease, PostNote n. 431, March 2013, p. 4, available online at: [https://www.parliament.uk/documents/post/postpn431\\_Preventing\\_Mitochondrial\\_Disease.pdf](https://www.parliament.uk/documents/post/postpn431_Preventing_Mitochondrial_Disease.pdf); PF Chinnery *et al.*, Correction: The Challenges of Mitochondrial Replacement, cit.

<sup>83</sup> In this regard, see: UK Parliamentary Office of Science and Technology, Preventing Mitochondrial Disease, cit., p. 4; A. Stazi, Biotechnological Inventions and Patentability of Life. The US and European Experience, cit., p. 42 f.; LR Kass, The challenge of bioethics. Life, freedom and defense of human dignity, Lindau, Turin, 2002; J. Habermas, The future of human nature. The risks of a liberal genetics, Einaudi, Turin, 2002.

<sup>84</sup> Think, for example, of the recent case of Chinese twins with DNA modified through the CRISPR technique which has been referred to above.

<sup>85</sup> As noted for example: AL Bredenoord *et al.*, Ethics of modifying the mitochondrial genome, in *Journal of Medical Ethics*, 2011, vol. 37, no. 2, p. 97 ff.

Vice versa, it is argued that there is a moral obligation to rectify those genetic anomalies that determine conditions of life harmful to those who will come into the world and that it would be irresponsible, in the name of the right to genetic integrity and an unmanipulated genome, to condemn individuals who will exist to suffer serious diseases<sup>86</sup>.

Finally, with regard to the possible discriminatory effects deriving from the use of these technologies, there has been the concern that they could reduce the social acceptance or moral value of people with genetic problems or anomalies. It is objected that rather than giving up opportunities for the prevention or treatment of genetic diseases, policies should be promoted that favor the acceptance of people affected by them<sup>87</sup>.

Regarding the regulation of the applications of genetic engineering and genomic medicine to the human being, in the United States, although in 2009 President Obama adopted an Executive Order with which he removed the limits to federal funding for cell research embryonic stem cells, since 1996 the Dickey-Wicker Amendment prohibits federal funding for the creation of human embryos for research purposes or for research in which embryos are destroyed<sup>88</sup>, as also reiterated in the National Institute Human Stem Cell Research Guidelines of Health<sup>89</sup>.

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<sup>86</sup> In this sense, see: PN Ossorio, *Inheritable Genetic Modifications: Do We Owe Them to Our Children?*, in AR Chapman, MS Frankel (ed.), *Designing our Descendants. The Promise and Perils of Genetic Modification*, Johns Hopkins University Press, Baltimore, 2003, p. 252 ss.; A. Buchanan, DW Brock, N. Daniels, D. Wikler, *From Chance to Choice. Genetics & Justice*, Cambridge University Press, Cambridge, 2001. See also, regarding the debate on the so called human improvement: DB Resnik, *The Moral Significance of the Therapy – Enhancement Distinction in Human Genetics*, in H. Kuhse, U. Schüklenk, P. Singer (edited by), *Bioethics. An Anthology*, Wiley-Blackwell, Hoboken, 2015 (3rd edition), p. 189 ss.; J. Harris, *Enhancing Evolution: The Ethical Case for Making Better People*, Princeton University Press, Princeton, 2010; J. Savulescu, N. Bostrom (edited by), *Human Enhancement*, Oxford University Press, Oxford, 2009.

<sup>87</sup> In this regard, see: J. Harris, *Scientific Research Is a Moral Duty*, in H. Kuhse, P. Singer (edited by), *Bioethics. An Anthology*, Wiley-Blackwell, Hoboken, 1999, p. 165 ff. Finally, scholars warn about the risk for donor women that the development of the industry linked to the increase in the demand for oocytes that the aforesaid interventions would produce can bring some women in conditions of need to be pushed to sell their oocytes, undergoing several times to hormonal cycles that could compromise their health. With regard to issues related to regulatory approaches and on the topic, see *supra* at previous paragraph.

<sup>88</sup> *Balanced Budget Downpayment Act*, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996). In doctrine, see: J. Franz, K. Hiler, *New Developments in Human Gene Editing Face an Ethical and Regulatory Quagmire in the US*, in *Science Friday*, 27 August 2017, available online at: <https://www.pri.org/stories/27.08.2017/new-developments-human-gene-editing-face-ethicaland-regulatory-quagmire-us>; A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., p. 78 ff.

<sup>89</sup> *National Institutes of Health Guidelines for Human Stem Cell Research*, 74 Fed. Reg. 32,170, 7 July 2009; on the applicability of the Guidelines to CRISPR-based research due to similar ethical issues, see: FS Collins, *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, National Institute of Health, April 2015, available online at: <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-fundingresearch-using-gene-editing-technologies-human-embryos>.

Furthermore, in 2016 the Chamber of Representatives added a further provision in the Consolidated Appropriations Act which prohibits the FDA from recognizing applications for a waiver for the experimental use of a drug or biological product in research where a human embryo is intentionally created or modified to

U.S. researchers can, however, conduct such research if they obtain private funding<sup>90</sup>. Critics of this system argue that allowing private funding of human embryo research diminishes the government's ability to regulate research that could have far-reaching impacts, proposing the lifting of the federal funding ban to give US regulators a greater control power<sup>91</sup>.

In Europe, the Council of Europe Convention on Human Rights and Biomedicine - which is open for signature by all States - established in Article 13 that interventions that seek to modify the human genome can only be undertaken for preventive, diagnostic or therapeutic purposes, and only where their purpose is not to introduce any modification in the genome of the descendants<sup>92</sup>.

With regard to research on human embryos, the European Union Framework Program for Research and Innovation Horizon 2020 reiterated the exclusion of funding for research activities aimed at producing heritable modifications of the human genome, to create human embryos for the stem cell extraction, or to human cloning. On the other hand, the possibility of financing research on human stem cells, both in the adult and embryonic state, is envisaged, depending on

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include a heritable genetic modification (Consolidated Appropriations Act, Pub. L. No. 114-113, § 749, 129 Stat. 2242, 2283, 2016).

<sup>90</sup> National Research Council and Institute of Medicine of the National Academies, *Guidelines for Human Embryonic Stem Cell Research*, The National Academies Press, Washington, 2005, available online at: <https://www.nap.edu/catalog/11278/guidelines-for-human-embryonic-stem-cell-research>; Final Report of the National Academies Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies Guidelines for Human Embryonic Stem Cell Research, available online at: <https://www.nap.edu/catalog/12923/final-report-of-the-national-academies-human-embryonic-stem-cell-research-advisory-committee-and-2010-Amendments-to-the-national-academies-guidelines-for-human-embryonic-stem-cell-research>.

<sup>91</sup> Commission on Pediatric Research & Commission on Bioethics, *Human Embryo Research*, in *Pediatrics*, 2001, vol. 108, p. 813 ff.; KRW Matthews, S. Tsao, *Contrasting Views on Embryo Research and Funding: A Survey of US Physicists and Biologists*, Rice University's Baker Institute for Public Policy, 2016, available online at: <https://www.bakerinstitute.org/media/files/Research/eb06d8b5/STPPoster-ISSCR2016-Embryo.pdf>. For a broad analysis of the regulatory and institutional framework in the United States, as well as the different reform options, see: T. Tomlinson, *A CRISPR Future for Gene-Editing Regulation: A Proposal for an Updated Biotechnology Regulatory System in an Era of Human Genomic Editing*, in *Fordham Law Review*, 2018, vol. 87, no. 1, p. 437 ff.

<sup>92</sup> Human Rights and Biomedicine Convention, or Oviedo Convention, signed in Oviedo on April 4, 1997. Regarding research on human embryos, a first option is to not allow it, as requested by numerous scientists and public interest groups, including UNESCO. Opponents of embryo research argue that, on the one hand, such research is morally inadmissible because of the damage it can cause to human life, at least potential; on the other, it would not be necessary for medical purposes because of the ability to carry out preventive screening on embryos for genetic defects, or for the growing usefulness and relative increasing use in the search for somatic cells instead of embryonic stem cells. On the other hand, advocates of research on human embryos claim that current in vitro fertilization procedures do not guarantee that embryos will be free from genetic defects, and that genomic medicine has the potential to prevent disease not only in the unborn child, but also in future generations. On these profiles, see among others: C. Gyngell *et al.*, *The Ethics of Germline Gene Editing*, in *Journal of Applied Philosophy*, 2017, vol. 34, p. 498 ff.; A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, *cit.*, p. 71 ff.

both the contents of the scientific proposal and the legal context existing in the Member State or in the Member States concerned, subject to indication of the details concerning the licensing and control measures to be taken by the competent authorities of the Member States, as well as the ethical authorizations that will be granted<sup>93</sup>.

The European Convention on Human Rights and Biomedicine prohibits the creation of human embryos for research purposes<sup>94</sup>. Several Member States, notably Belgium and the United Kingdom, have refused to sign the Convention because they consider it too restrictive.

Belgium, in particular, in 2003 adopted its own regulatory regime on in vitro embryo research<sup>95</sup>, which allows research on them up to the fourteenth day as long as they are useful for therapeutic purposes<sup>96</sup>, and the existing supernumerary embryos are used before producing new ones<sup>97</sup>. From a procedural point of view, a commission was therefore set up to evaluate the proposed research projects involving the use of human embryos and to determine which projects meet the requirements established by law<sup>98</sup>.

In the United Kingdom, based on the Human Fertilization and Embryology Act<sup>99</sup>, the Human Fertilization and Embryology Authority similarly regulates the use of human embryos in research, requiring that researchers - after approval of the application by an ethics committee - obtain a license for each project<sup>100</sup>, the research meets one of the purposes of the Embryology Act<sup>101</sup>, the donors have consented to the donation for research purposes, the embryos involved in the research cannot be implanted in a woman, and the embryos are not allowed to develop beyond the fourteen days. Once a research team submits an application, the HFEA commissions

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<sup>93</sup> Regulation (EU) no. 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing the research and innovation framework program (2014-2020) - Horizon 2020 and repealing decision no. 1982/2006/EC, art. 19, no. 4; see also: decision no. 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the seventh framework program of the European Community for research, technological development and demonstration activities (2007-2013), art. 6, no. 3.

<sup>94</sup> G. Pennings *et al.*, Human Embryo Research in Belgium: An Overview, in *Fertility & Sterility*, 2017, vol. 108, p. 96 ff.

<sup>95</sup> Loi relative à la recherche sur les embryons in vitro, 11 May 2003.

<sup>96</sup> Therefore excluding actions aimed at other purposes, such as sex selection for non-medical reasons, eugenic practices and reproductive cloning.

<sup>97</sup> On this point, see: CB Cohen: Use of "excess" human embryos for stem cell research: Protecting women's rights and health, in *Women's Health Issues*, 2000, vol. 10, p. 121 ff.

<sup>98</sup> See: G. Pennings, New Belgian Law on Research on Human Embryos: Trust in Progress Through Medical Science, *Journal of Assisted Reproduction and Genetics*, 2003, vol. 20, no. 8, p. 343 ff.

<sup>99</sup> Issued in 1990 and subsequently amended in 2008 and 2015.

<sup>100</sup> See: E. Callaway, UK Scientists Gain License to Edit Genes in Human Embryos, in *Nature*, February 1, 2016, available online at: <https://www.nature.com/news/uk-scientists-gain-license-to-editgenes-in-human-embryos-1.19270>.

<sup>101</sup> That is, increasing knowledge or developing treatments for serious diseases, increasing knowledge of the causes of congenital diseases, promoting progress in the treatment of infertility, *etc.*

peer reviews and performs clinical inspections to ensure compliance with the standards of the Embryology Act, and in case the criteria are met it recognizes a research license valid for up to three years<sup>102</sup>.

In Spain, research and experimentation on pre-embryos, as well as on gametes, are authorized provided that a series of specific conditions are respected<sup>103</sup>. In Germany, the production of stem cells from human embryos is banned, but the use for research purposes of embryonic stem cells imported before 1 May 2007 is permitted<sup>104</sup>. In Italy, the extraction of stem cells for research purposes from a human embryo is expressly prohibited by law no. 40/2004<sup>105</sup>.

Finally, the option of using adult stem cells for research with therapeutic purposes has recently developed<sup>106</sup>, which - despite the complexities of their use - appear to offer interesting application potential<sup>107</sup>. Still, today it is possible to take stem cells from the umbilical cord and create banks of autologous cells for each newborn, which can be used even after decades<sup>108</sup>. In such cases, the sampling must meet the requirements of having therapeutic purposes, not endangering the health of the patient to be treated, and following prior informed consent<sup>109</sup>.

In this scenario, in recent years the development of new and more effective genetic engineering techniques and genomic medicine, including in particular the so-called CRISPR, has given impetus to a growing debate about the options for a regulation of similar practices and the increasingly complex issues they give rise to.

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<sup>102</sup> Human Fertilization & Embryology Authority, Code of Practice, 2017 (8th edition), par. 200 ff.

<sup>103</sup> Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida, art. 14 ff.

<sup>104</sup> Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen of 2002, amended in 2008, art. 4.

<sup>105</sup> Law n. 40 of 19 February 2004, Norme in materia di procreazione medicalmente assistita, art. 13, par. 1-3.

<sup>106</sup> See, for example: Pontifical Academy for Life, Declaration on the production and scientific and therapeutic use of human embryonic stem cells, available online at: [http://www.vatican.va/roman\\_curia/pontifical\\_academies/acdlife/documents/rc\\_pa\\_acdlife\\_doc\\_20000824\\_cellule-staminali\\_it.html](http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_it.html).

<sup>107</sup> On the other hand, more and more advanced and effective solutions have developed; in this regard, see: DA Prentice, Successful Standard for Regenerative Medicine, in *Circulation Research*, 2019, vol. 124, no. 6, p. 837 ss.; N. Rajabzadeh et al, Stem cell-based regenerative medicine, in *Stem Cell Investigation*, 2019, vol. 6, no. 19; T.K. Ng et al, Pluripotent Adult Stem Cells: A Potential Revolution in Regenerative Medicine and Tissue Engineering, in D. Bhartiya (ed.), *Pluripotent Stem Cells*, 2013, available at: <https://www.intechopen.com/books/pluripotent-stem-cells>.

<sup>108</sup> In this regard, see at European level: European Group on Ethics in Science and New Technologies, Opinion n° 19 - 16/03/2004 - Ethical aspects of umbilical cord blood banking, available online at: [http://ec.europa.eu/european\\_group\\_ethics/docs/avis19\\_en.pdf](http://ec.europa.eu/european_group_ethics/docs/avis19_en.pdf).

<sup>109</sup> See: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., P. 92.

In the absence of internationally shared solutions<sup>110</sup>, important initiatives have come from international forums where scientists, bioethics experts and law scholars discuss the options that allow to promote technological innovation while respecting principles and rules as shared as possible.

In March 2017, the Scientific Advisory Council of European Academies launched a report entitled "Genome editing: scientific opportunities, public interests and policy options in the European Union". The document is a broad summary of the state of the art and the perspectives of genome modification and provides a contribution to the debate on regulatory options.

The proposed approach is based on a rigorous analysis of the benefits and risks of each type of intervention, with particular caution with respect to the interventions on the germ line. In this regard, also considering the effects not only on individuals but also on future generations that will bring genetic alterations and the possibility that biological improvements beyond disease prevention and treatment may exacerbate social injustices or be used coercively, the report states that it would be irresponsible to proceed until the relevant scientific, ethical, safety and effectiveness issues to which they give rise will have been resolved<sup>111</sup>.

Also in 2017, the American College of Medical Genetics and Genomics report entitled "Genome editing in clinical genetics: points to consider" focused on the analysis of the CRISPR system and suggested a number of points to consider regarding the potential clinical application of the genome modification aimed in particular at geneticists, noting among other things that these interventions in the human embryo are premature and should be the subject of a vigorous ethical debate and further refinement of the technological aspects<sup>112</sup>.

In the same year, a report by the US National Academies of Sciences and Medicine examined the different types of genome modification and indicated a series of principles and recommendations for the conduct and supervision of the ethical-regulatory issues posed by

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<sup>110</sup> Notwithstanding the recent jurisprudential developments which seem to prefigure at least a possible common western approach on some relevant aspects such as the limits of patentability; see: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., p. 293 ff.

<sup>111</sup> European Academies' Science Advisory Council, *Genome editing: scientific opportunities, public interests and policy options in the European Union*, 2017, available online at: [http://www.easac.eu/fileadmin/PDF\\_s/reports\\_statements/Genome\\_Editing/EASAC\\_Report\\_31\\_on\\_Genome\\_Editing.pdf](http://www.easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Report_31_on_Genome_Editing.pdf).

<sup>112</sup> ACMG Board of Directors, *Genome editing in clinical genetics: points to consider - A statement of the American College of Medical Genetics and Genomics*, in *Genetics in Medicine*, 2017, vol. 19, no. 7, p. 723 f., available online at: <https://www.nature.com/articles/gim2016195>.

them, leaving open the possibility of expansion following future technological advances and developments in the debate on the subject<sup>113</sup>.

In February 2019, following the announcement in November 2018 of the germinal modification experiment that led to the birth of twins with modified DNA, the Chinese government issued a draft regulation that would require national approval for clinical research which involves genetic modification and other "high-risk biomedical technologies"<sup>114</sup>.

Finally, in March 2019, the World Health Organization Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing - established in December 2018 after the Chinese experiment that produced babies from genetically modified embryos<sup>115</sup> - in addition to say that it is irresponsible for anyone to proceed with the clinical applications of germline modification of the human genome at this time, asked WHO to start working on establishing a central register for genome research, in order to create an open and transparent database on the work in progress on the subject<sup>116</sup>.

#### V. FINAL CONSIDERATIONS. LEGAL PLURALISM AND THE CIRCULATION OF MODELS

The cases examined represent clear examples of the complex issues that human genetic engineering gives rise to in today's global scenario characterized by technical-scientific evolution and cross-border mobility, as well as the fundamental relevance of the comparative method for the purposes of their approach.

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<sup>113</sup> National Academy of Sciences, National Academy of Medicine, Human Genome Editing. Science, Ethics, and Governance, The National Academies Press, Washington DC, 2017, available online at: <https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance>, especially p. 181 ff.

<sup>114</sup> See: D. Normile, China tightens its regulation of some human gene editing, labeling it 'high-risk', in *Science*, February 28, 2019, available online at: <https://www.sciencemag.org/news/2019/02/china-tightens-its-regulation-some-human-gene-editing-lbeling-it-high-risk>; D. Cyranoski, The CRISPR-baby scandal: what's next for human gene-editing, in *Nature*, February 26, 2019, available online at: <https://www.nature.com/articles/d41586-019-00673-1>.

<sup>115</sup> WHO establishing expert panel to develop global standards for governance and oversight of human genome editing, 14 December 2018, available online at: <https://www.who.int/ethics/topics/human-genome-editing/en>.

<sup>116</sup> The Committee invited all those conducting research on the human genome to open discussions with it to better understand technological profiles and current protocols, and help ensure that they meet current best scientific and ethical practices. Over the next two years, the Committee will consult a wide range of stakeholders and provide recommendations for a framework of rules that is sustainable and appropriate for use at international, regional, national and local levels. See: WHO expert panel paves way for strong international governance on human genome editing, 19 March 2019, available online at: <https://www.who.int/news-room/detail/19-03-2019-who-expert-Panel-paves-way-for-strong-international-governance-on-human-genome-editing>.

The circulation of reproductive materials and surrogate motherhood, with the related problems regarding the exploitation of the human body, and genome modification interventions, with the consequent doubts regarding the impact on health and evolution, touch the very essence of the human being and therefore find very different answers in the various systems, according to the cultural, religious, bioethical, constitutional peculiarities, *etc.*

On these issues, therefore, the decisive impact of extra-legal elements on the configuration of the responses of the various regulatory approaches is particularly evident. On the other hand, within the legal framework, there is a constant multilevel dialectic and dynamics, in particular among legislative and jurisprudential formants<sup>117</sup>, but not only, given the importance of further contributions by instruments such as principles or recommendations dictated by international, transnational or national bodies, opinions of bioethics committees, *etc.*<sup>118</sup>.

Even in the systems in which absolute prohibitions are foreseen for the practice of surrogate motherhood or genomic modification interventions on embryos, they suffer the effects produced or by internal or external influences at a legal level, for example on the jurisprudential level - think of the aforementioned judgments of the ECHR on surrogate motherhood - or by practices that circumvent regulatory provisions, such as in cases of transnational surrogate motherhood or embryo DNA modification interventions *etc.*, carried out in systems where control and enforcement with respect to these practices are not effective<sup>119</sup>.

Paradigmatic in this sense was the announcement in November 2018 of the birth of two Chinese twins with modified DNA, which highlighted the problem for the attention of legislators, institutions and experts at a global level, posing a series of complex questions regarding relevant human rights in cases of children born with the use of similar techniques<sup>120</sup>.

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<sup>117</sup> According to a trend represented through the image of the "pressure" of cases on law; see: C. Harlow, R. Rawlings, *Pressure Through Law*, Routledge, London, 1992.

<sup>118</sup> In this regard, see: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., p. 66 ff.

<sup>119</sup> See: M. Kwan, *Human Gene Editing and Human Rights: An Uncertain Future*, cit., p. 1 f.

<sup>120</sup> For a classification in this sense, see: E. Kleiderman, A. Boily. *BM Knoppers, Genetically Enhanced Minors: Whose Responsibility ?*, in *American Journal of Bioethics*, 2018, vol. 18, no. 6, p. 1 ss. ; M. Kwan, *Human Gene Editing and Human Rights: An Uncertain Future*, cit., p. 2 f., who underlines how children born with these techniques, in particular if they were subsequently monitored by scientists or by the government, or in any case with respect to developments in their relationship life such as for example the practice of sport, can risk to see their rights to human dignity, private and family life, personal and movement freedom, and non-discrimination affected. This, moreover, also recalling considerations on human rights in support of the application of genomic modifications, such as the right to life and the best interest of the child, such as to treat a disease before birth (art. 3 and 6 of the Convention on the rights of the UN child of 1989), or the right to share the benefits of scientific progress (art. 27 UN Universal Declaration of Human Rights of 1948, and art. 15 (b) International Convention on Economic, Social and Cultural Rights of 1966).

On the other hand, even where the legal system takes a partially open approach, for example by regulating altruistic forms of gestation for others, this does not prevent an outward mobility, aimed at overcoming the existing national limits<sup>121</sup>. In the States that allow surrogacy, including commercial maternity, then, in addition to the issues related to the fundamental rights at stake, there are regulatory gaps and exploitation risks deriving from the abandonment of the regulation to private contracts between the client parents, the clinic or the intermediary and the surrogate<sup>122</sup>. From a comparative point of view, the phenomena that emerge are those of legal pluralism and the circulation of models<sup>123</sup>, as expressions of the wide relations between: i) cultural, moral and socio-economic issues; ii) legislative and other regulatory or self-regulatory sources; iii) jurisprudential decisions - which may possibly convey constitutional principles; iv) other soft law rules, also of non-State or non-legal origin (e.g. bioethical or religious) - all of which represent multidimensional but complementary tools that can operate according to the cases in a contrasting or subsidiary way<sup>124</sup>.

Thus, it is necessary to identify, within the models which are considered of greater importance with regard to the aforementioned practices, the legislative and regulatory, but also self-

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<sup>121</sup> As in the cases of the United Kingdom and China; see.: C. Fenton-Glynn, *Outsourcing Ethical Dilemmas: Regulating International Surrogacy Arrangements*, cit., p. 59 ff.; S. Yan, *Chinese are hiring surrogate moms in America*, cit.

<sup>122</sup> In this sense: CA Choudhury, *Transnational Commercial Surrogacy: Contracts, Conflicts, and the Prospects of International Legal Regulation*, cit., p. 18 f.

<sup>123</sup> Regarding which, see *ex multis*: G. Swenson, *Legal Pluralism in Theory and Practice*, in *International Studies Review*, 2018, vol. 20, no. 3, p. 438 ff.; L. Niglia (edited by), *Pluralism and European Private Law*, Hart Publishing, Oxford, 2013; M. Graziadei, *Legal Transplants and the Frontiers of Legal Knowledge*, in *Theoretical Inquiries in Law*, 2009, vol. 10, no. 2, p. 72 ff., available online at: <http://www7.tau.ac.il/ojs/index.php/til/issue/view/56>; VV Palmer, *Mixed Legal Systems... and the Myth of Pure Law*, in *Louisiana Law Review*, 2007, vol. 67, no. 4, p. 1205 ff., available online at: <https://digitalcommons.law.lsu.edu/cgi/viewcontent.cgi?article=6210&context=lalrev>; WW Burke-White, *International Legal Pluralism*, in *Michigan Journal of International Law*, 2004, vol. 25, p. 963 ff., available online at: [https://scholarship.law.upenn.edu/faculty\\_scholarship/961](https://scholarship.law.upenn.edu/faculty_scholarship/961); GR Woodman, *Ideological Combat and Social Observation: Recent Debate About Legal Pluralism*, in *Journal of Legal Pluralism and Unofficial Law*, 1998, vol. 30, no. 42, p. 21 ff. On the relation between legal pluralism and multiculturalism, see: *Theoretical Inquiries in Law*, 2008, vol. 9, no. 2, dedicated to *Legal Pluralism, Privatization of Law and Multiculturalism*, available online at: <http://www7.tau.ac.il/ojs/index.php/til/issue/view/54>.

<sup>124</sup> On the complexity of the interpretation of transnational and non-state or non-legal sources in such a scenario, see for all: S. Ferreri, *General Report: Complexity of Transnational Sources*, in *European Review of Private Law*, 2012, vol. 20, no. 1, p. 3 ff. See also: A. Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience*, cit., p. 243 ff. With regard to the circulation of the models on body parts disposal or intervention and on surrogacy, see eg: M. Tallacchini, *Medical Technologies and EU Law: The Evolution of Regulatory Approaches and Governance*, in M. Cremona (edited by), *New Technologies and EU Law*, Oxford University Press, Oxford, 2017, p. 9 ff.; K. Trimmings, P. Beaumont, *Parentage and surrogacy in a European perspective*, in JM Scherpe (edited by), *European Family Law, Volume III. Family Law in a European Perspective*, Edward Elgar, Cheltenham, 2016, p. 232 ff.

regulatory and extra-legal - such as cultural, moral, economic - elements that are key factors with respect to the circulation of the models.

This analysis can also be of great help for balancing the different fundamental rights and interests, individual and public, which coexist in these areas: think of aspects such as personal identity, recognition of parenting and citizenship, authorization or registration of practices, *etc.*<sup>125</sup>. On the other hand, given the considerable differences in sensitivity and approaches with respect to these issues in the various legal systems, it seems unlikely that an instrument of international law or private international law could be adopted to dictate solutions with regard to the most controversial profiles mentioned last.

Rather, as far as surrogate motherhood is concerned, a viable way could be that of an instrument that addresses issues of parenting and citizenship in general and also includes indications on surrogate motherhood: this appears, moreover, the path taken by The Hague Conference<sup>126</sup>.

With regard to genome modification interventions, especially at embryonic level, similarly, the key issues of respect for human rights and the transparency of the activities carried out in this area require international coordination that can at the same time provide guiding principles and develop a mechanism for recording the activities carried out, as prefigured in the initiative underway by the WHO<sup>127</sup>.

In both cases, evidently, the most complex challenges to face are those of balancing fundamental rights and the effectiveness of the tools and provisions adopted, to protect the "good of human life" more at stake today than ever.

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<sup>125</sup> See: C. Fenton-Glynn, *Outsourcing Ethical Dilemmas: Regulating International Surrogacy Arrangements*, cit., p. 69 ff.

<sup>126</sup> Recalled above at the end of par. III. In this sense, see: CA Choudhury, *Transnational Commercial Surrogacy: Contracts, Conflicts, and the Prospects of International Legal Regulation*, cit., p. 20.

<sup>127</sup> See: WHO expert panel paves way for strong international governance on human genome editing, cit. ; for a wish based on a solid analysis of human rights, see: M. Kwan, *Human Gene Editing and Human Rights: An Uncertain Future*, cit., p. 3.