

COMMENTS

THE FIRST CASE OF HUMAN GENOME EDITING: CRIMINAL LAW PERSPECTIVE

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This article analyzes the legal assessment of the human genome modification experiment at the pre-implantation stage conducted by a group of scientists headed by He Jiankui, professor at the Southern University of Science and Technology (SUSTech) in Shenzhen, Guangdong Province, China, by means of the CRISPR/Cas9 technology. Chinese scholars have different opinions concerning He Jiankui's experiment, but on the whole condemn it as illegal. Though CRISPR/Cas9 has been applied for quite a long time, the legislation of most developed countries is not ready to respond. The author of the article underlines the fact that despite the consolidated opinion of scholars, there is no binding international act which would restrict human genome editing. The author relies on Chinese sources in considering the main approaches to the assessment of He Jiankui's actions in terms of criminal law (illegal medical activity, forgery of documents or fraud). Based on the analysis of Chinese criminal law doctrine, the author offers possible models of classifying separate actions related to human genome manipulation. The following cases of human genome manipulation are considered by the author as publicly dangerous and criminally liable: (a) when the embryo genome is changed by genetic engineering technologies for the purpose of its further implantation in the situation where the child's parents are not aware of such intervention and its possible implications; (b) when genetic therapy or any other gene transfer (transgenesis) is applied to a person who is not aware of the nature of such manipulation and the possible implications of the application of the technology.

Keywords: He Jiankui; genome editing; genetics; criminal law of China; criminal liability; public danger.

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Introduction

The discovery of CRISPR functions – a special locus of bacteria able to cooperate with Cas proteins which complementarily connect RNA with nucleic acids of foreign elements and later destroy these elements – opened a new era in genetic engineering.¹

CRISPR/Cas9 technology provides the opportunity to edit genetic material rather than simply removing a gene or introducing a new gene in the existing sequence.

The possible application of human genome editing technology has caused a great deal of discussion on the ethical and legal consequences. In 2015, a group of leading scholars published their opinion in *Nature*, calling for agreement among scientists not to edit reproductive cells:

In our view, genome editing in human embryos using current technologies could have unpredictable effects on future generations. This makes it dangerous and ethically unacceptable. Such research could be exploited for non-therapeutic modifications. We are concerned that a public outcry about such an ethical breach could hinder a promising area of therapeutic development, namely making genetic changes that cannot be inherited. At this early stage, scientists should agree not to modify the DNA of human

¹ Alexandre Loureiro & Gabriela J. da Silva, *CRISPR-Cas Converting a Bacterial Defence Mechanism into a State-of-the-Art Genetic Manipulation Tool*, 8(1) *Antibiotics* 18 (2019) (Sep. 25, 2019), also available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6466564/>.

reproductive cells. Should a truly compelling case ever arise for the therapeutic benefit of germ line modification, we encourage an open discussion around the appropriate course of action.²

Ethical and legal questions were discussed at the First International Summit on Human Genome Editing (2015). A special emphasis was put on the difference between the clinical application of somatic cells when mutation is restricted by one individual and germ line cells whose genome defects may be inherited by future generations.³

The Summit declaration specifically stated:

Germ line editing poses many important issues, including: (i) the risks of inaccurate editing (such as off-target mutations) and incomplete editing of the cells of early-stage embryos (mosaicism); (ii) the difficulty of predicting harmful effects that genetic changes may have under the wide range of circumstances experienced by the human population, including interactions with other genetic variants and with the environment; (iii) the obligation to consider implications for both the individual and the future generations who will carry the genetic alterations; (iv) the fact that, once introduced into the human population, genetic alterations would be difficult to remove and would not remain within any single community or country; (v) the possibility that permanent genetic “enhancements” to subsets of the population could exacerbate social inequities or be used coercively; and (vi) the moral and ethical considerations in purposefully altering human evolution using this technology. It would be irresponsible to proceed with any clinical use of germ line editing unless and until (i) the relevant safety and efficacy issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (ii) there is broad societal consensus about the appropriateness of the proposed application. Moreover, any clinical use should proceed only under appropriate regulatory oversight. At present, these criteria have not been met for any proposed clinical use: the safety issues have not yet been adequately explored; the cases of most compelling benefit are limited; and many nations have legislative or regulatory bans on germ line modification. However, as scientific knowledge advances and societal views evolve, the clinical use of germ line editing should be revisited on a regular basis.⁴

² Edward Lanphier et al., *Don't Edit the Human Germ Line*, 519(7544) *Nature* 410, 410–411 (2015).

³ On Human Gene Editing: International Summit Statement, The National Academies of Sciences, Engineering, and Medicine, 3 December 2015 (Sep. 25, 2019), available at <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a>.

⁴ *Id.*

The ethical consensus reached at the Summit in 2015 soon came under attack in terms of human genome editing technologies applied to human reproductive cells to treat incurable inheritable diseases. Thus, on 6 November 2018 *The CRISPR Journal* published an article under the title “Draft Principles for Therapeutic Assisted Reproductive Technologies.”⁵ The authors of the article point out that though the pre-implantation genetic diagnosis is rather effective and available, public opinion is not unanimous concerning the possibility of genetic surgery application at the pre-implantation stage, i.e. concerning the possibility to edit the embryo genome before its implantation. The authors express their own opinion on “matters of ethics and red lines,” formulating five main principles:

1. Mercy for families in need. The broken gene, infertility or incurable disease should not spoil the life or affect the relations of a loving couple. For some families, early genetic surgery might be the only reliable means to cure a hereditary disease and relieve a child’s sufferings.

2. Only for serious diseases, never for vanity. Genetic surgery is a serious medical procedure which must not be resorted to for some esthetic purpose, to improve or choose the gender of a child, or by any other means which can jeopardize the welfare, joy and free will of a child. Nobody has the right to determine the genetics of a child except in the situation where it is necessary to prevent a disease. Potentially, genetic surgery puts a child in a state of risk which may be permanent. The application of genetic surgery is admissible only when the risks of the operation are justified by a serious medical need.

3. Respect a child’s autonomy. Life is not restricted to our physical body and DNA. After genetic surgery, a child has equal rights to live freely, to choose his or her future occupation or citizenship, and the right to have a private life. There are no obligations on the parent of such a child, or any organization, including the question of payment for the operation.

4. Genes do not define us. Our DNA does not predetermine our aim in life or what we can achieve. We can prosper by hard work, nutrition and support from society and the people we love. Whatever genes we have, we are all equal in our potential and dignity.

5. Everyone deserves freedom from genetic diseases. The health of a person must not depend on wealth. Organizations developing genetic treatments must be morally obliged to treat a person regardless of origin.

It is likely that the article published in *The CRISPR Journal* pursued the aim of serving as the background for the further events at the Second International Summit on Human Genome Editing held in Hong Kong. On 25 November 2018, one of the authors of the article, He Jiankui, professor at the Southern University of Science

⁵ He Jiankui et al., *Draft Principles for Therapeutic Assisted Reproductive Technologies*, 1 (6) *CRISPR Journal* 1 (2018).

and Technology (SUSTech) in Shenzhen, Guangdong Province, China, declared the success of his research experiments on mice and monkey embryos. He also succeeded in working with human embryo stem cells and human embryos with the purpose of specifically removing the CCR5 gene. This gene plays a key role in how the human immunodeficiency virus (HIV) infects cells. The targeted removal of the gene was conducted by the CRISPR/Cas9 “genetic scissors” technology in the process of recombination by means of the DNA-vector by the building-in of the CCR5-Δ32 gene in the chromosome of mutation. The said mutation makes the accession of the virus to the T cell impossible.⁶ Certain that the technology used to remove the gene was reliable and safe, the group headed by He genetically edited the human fertilized ovum. The edited embryos were successfully implanted and, as a result, the pregnancy led to the birth of twin sisters, who were named Nana and Lulu.⁷ Additionally, He stated that at the time the Summit was held there was one more pregnancy with a similarly genetically edited embryo.⁸

The experiments announced by He Jiankui caused a harsh and negative response among genetic scientists.⁹ *The CRISPR Journal* later edited the article “Draft Principles for Therapeutic Assisted Reproductive Technologies”¹⁰ due to a conflict of interest: He was interested in promoting a positive attitude towards human genome editing for therapeutic purposes. It is interesting to note that those who have committed crimes or other offenses often resort to a similar logic to change or justify their purposes so as to classify the actions committed as legitimate.¹¹ At the same time, the publication of the article by the He group in *The CRISPR Journal* came about just at the right time, since matters of law and ethics when editing the human genome are more than topical. It is quite tempting to conduct the pre-implantation editing of the human genome by means of the rather simple technology of “genetic scissors” and either give desirable

⁶ Kristina Allers & Thomas Schneider, *CCR5Δ32 Mutation and HIV Infection: Basis for Curative HIV Therapy*, 14 *Current Opinion in Virology* 24 (2015).

⁷ Alice Park, “They Will Be Studied for the Rest of Their Lives.” *How China’s Gene-Edited Twins Could Be Forever Changed by Controversial CRISPR Work*, *Time*, 29 November 2018 (Sep. 25, 2019), available at <https://time.com/5466967/crispr-twins-lives/>.

⁸ Second International Summit on Human Genome Editing: Continuing the Global Discussion (Workshop Proceedings) (January 2019), at 3 (Sep. 25, 2019), available at <https://www.nap.edu/read/25343/chapter/1>.

⁹ *Id.*

¹⁰ Retraction of: Draft Ethical Principles for Therapeutic Assisted Reproductive Technologies by He, J et al., *CRISPR J* 2018; fast track. DOI: 10.1089/crispr.2018.0051, 2(1) *CRISPR Journal* 65 (2019).

¹¹ Ратинов А.Р., Ефремова Г.Х. Психологическая защита и самооправдание в генезисе преступного поведения // Личность преступника как объект психологического исследования: Сборник научных трудов [A.R. Ratinov & G.Kh. Efremova, *Psychological Defense and Self-Justification When Committing a Crime in Personality of a Criminal as an Object of Psychological Research: Collection of Scientific Papers*] 44 (Moscow: Publishing House of the All-Union Institute for the Study of Causes and the Development of Crime Prevention Measures, 1979).

features to a child or remove undesirable features. On 10 June 2019, *Nature* published material which said that Russian scholar Denis Rebrikov intended to apply a similar technology in Russia. The article put special emphasis on the fact that to reduce the chances that he would be punished Rebrikov planned first to seek approval from three Russian government agencies, including the Health Ministry.¹²

The commercially attractive technology, which is available and, what is more important, in demand, will lead to new cases of human genome editing, many of which are likely to be unknown to the public. Therefore, we must resolve the ethical and legal questions, especially in terms of criminal law, concerning the assessment of genetic editing of the human genome, because it is a fact we cannot deny.

1. He's Case as a Challenge to International Law?

1.1. Preliminary Remarks

We should mention that at the time of this writing He Jiankui is under house-arrest in Shenzhen and faces criminal prosecution.¹³ The present article does not pursue the aim of determining whether He is guilty of what he is or can be charged with. Our aim is to legally analyze the events of the first genetic editing of a human being.

At our disposal we have only data published from the He Jiankui case, which is based on the announcement made by He at the Second International Summit on Human Genome Editing.

Due to the closed nature of the activities of the Chinese law enforcement bodies, detailed information on the accusations made against He are not available. Our conclusions are based on Chinese sources (normative acts, doctrine), publications in Chinese journals and the private opinions of Chinese scholars. In all cases, except where otherwise specifically stated, we have relied on original sources of information.

1.2. Is There an International Ban on Human Genetic Editing?

He's experiment was the first serious violation of the principles on conducting genetic research and practical application of the knowledge received at the Conference on Recombinant Technologies (the Asilomar exhibition complex, Monterey, California) in 1975.¹⁴ These principles are not legal norms but rather rules of professional ethics. At the same time, we cannot say that exactly these principles served as the foundation for legal regulation of issues connected with genetic research and experiments conducted in different countries all over the world. Before the Asilomar Conference,

¹² David Cyranoski, *Russian Biologist Plans More CRISPR-Edited Babies*, 570(7760) *Nature* 145, 145–146 (2019).

¹³ Elsie Chen & Paul Mozur, *Chinese Scientist Who Claimed to Make Genetically Edited Babies Is Kept Under Guard*, *New York Times*, 28 December 2018 (Sep. 25, 2019), available at <https://www.nytimes.com/2018/12/28/world/asia/he-jiankui-china-scientist-gene-editing.html>.

¹⁴ Кулделл Н., Берштейн Р., Ингрэм К., Харт К.М. На пути к синтетической биологии [Natalie Kuldell et al., *On the Way to Synthetic Biology*] 91 (Moscow: DMK Press, 2019).

scholars voluntarily refused to conduct experiments with recombinant DNA and their decision was confirmed by the Committee of the National Academy of Sciences of the United States of America. The Committee said that to introduce a moratorium it was enough to demonstrate just the potential risk and not to prove the risk.¹⁵ During the moratorium scholars assessed the risks and formulated rules of safety when conducting experiments with recombinant DNA. In particular, they developed safety measures to prevent the spread of genetically modified organisms outside the laboratories. They also passed a decision to refuse to apply the received results in practice if there were no data on the potential risks or such data were not sufficient enough.¹⁶

Cloning and the activities of genetic engineers have become possible due to further development of recombinant technologies. Since modern technologies have moved closer to the possibility to change the human genome, there is an increased concern over the necessity to formally regulate the use of new technologies in relation to a human being. In 1993, the International Bioethics Committee (IBC) at UNESCO was established for the purpose of being the first global body on bioethics.¹⁷ In 2005, the UNESCO member states adopted the Universal Declaration on Bioethics and Human Rights offered by the IBC to resolve the ethical questions caused by the rapid changes in medicine and technologies. The Declaration states that the human genome is part of humanity's heritage. The Declaration contains rules to be complied with to respect human dignity, rights and basic freedoms.

In 2015, the IBC published its Report on Updating Its Reflection on the Human Genome and Human Rights.¹⁸ The Report states that

genetic therapy can become a crucial point in the history of medicine, and editing of the human genome is undoubtedly one of the most promising scientific achievements for the sake of the whole humanity.

However, in the Report experts warn that:

This development requires specific precautionary measures and causes great concerns, especially if editing of the human genome shall be applied

¹⁵ Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72(6) Proceedings of the National Academy of Sciences 1981 (1975) (Sep. 25, 2019), also available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC432675/>.

¹⁶ *Id.*

¹⁷ *Хаве Х.Т. Деятельность ЮНЕСКО в области биоэтики // Казанский медицинский журнал. 2008. Т. 89. № 4. С. 377 [Henk ten Have, UNESCO Activity in the Sphere of Bioethics, 89(4) Kazan Medical Journal 377 (2008)].*

¹⁸ IBC Report on Updating Its Reflection on the Human Genome and Human Rights (2015) (Sep. 25, 2019), available at <https://unesdoc.unesco.org/ark:/48223/pf0000233258>.

to the germ line and, consequently, shall introduce hereditary modifications which later may be passed over to further generations.

Therefore, the IBC insisted on introducing a moratorium on this particular procedure, and announced, "Interference with the human genome should be admitted only for preventive, diagnostic or therapeutic reasons and without introducing changes for further generations," the alternative will "jeopardize the inherent and, consequently, equal dignity of all people and will restore eugenics."

Despite the opinion of such an important organization concerning the protection of genetic dignity, the world still does not have a common ban on genetic manipulation with human embryos.

At present, the first internationally binding instrument in the sphere of biomedicine is the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, effective in 1999) ETS No. 164. Pursuant to Article 13 of the Convention, interference with the human genome aimed at its modification can be admitted only for preventive, diagnostic or therapeutic reasons, provided it does not introduce changes into the genome of the person's descendants. The Convention prohibits all forms of discrimination by genetic heritage and allows conducting genetic testing only for medical purposes. The Convention prohibits the use of technologies aimed at rendering medical aid to continue a person's family line, and choosing the gender of a future child, except for such cases where it is done to prevent inheriting some serious hereditary disease by the child. The Convention establishes rules of medical research listing specific conditions, especially in relation to people who are not able to express their consent to such research. It is prohibited to create human embryos for scientific purposes, and when a country allows research on embryos in vitro, it must ensure adequate protection of these embryos. Despite the importance of the provisions of this international instrument, only twenty-nine out of the thirty-five member states that signed the Oviedo Convention have ratified it so far. A large number of developed states actively involved in genetic research and experiments have not signed the Convention yet.¹⁹ Consequently, at the present time there is no common international instrument binding for a large number of states which would limit or prohibit activities on genetic modification of a human being.

¹⁹ The Convention has been signed but not ratified by Luxembourg, the Netherlands, Poland, Ukraine and Sweden; it has been signed and ratified by Albania, Bosnia and Herzegovina, Hungary, Greece, Georgia, Denmark, Iceland, Spain, Cyprus, Lithuania, Latvia, Norway, Portugal, Moldova, Romania, San Marino, Northern Macedonia, Serbia, Slovakia, Slovenia, Turkey, Finland, France, Croatia, Montenegro, Czech Republic, Switzerland and Estonia. It has not been signed by, e.g., Austria, Belgium, Ireland, Great Britain, Germany and Russia (data taken from the official website of the Council of Europe (Sep. 25, 2019), available at <https://www.coe.int/ru/web/conventions/full-list/-/conventions/treaty/164>).

1.3. Criminal Liability for Human Genome Editing

Some states do impose criminal liability for editing the human genome. Canada has formulated the criminal ban on gene editing in the following way (Sec. 5(1)(e) Assisted Human Reproduction Act 2004²⁰):

No person shall knowingly ... alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants.

The Act itself does not contain any sanctions.

The 1999 Israeli Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law declares the use of reproductive cells subject to deliberate germ line gene therapy for creation of a human being illegal. In particular, the law prohibits the following actions: (a) Human cloning – human reproductive cloning; (b) Using reproductive cells that have undergone a permanent intentional genetic modification (Germ Line Gene Therapy) in order to cause the creation of a person. The law provides for criminal liability in the form of imprisonment up to four years.²¹ The ban introduced in Israel is of a temporary character: initially, it was valid until 1 March 2009; however, its term was prolonged and now it is effective until 23 March 2020.

Under Section 5 of the Embryo Protection Act of the Federal Republic of Germany passed on 13 December 1990 (*Embryonenschutzgesetz*):²²

(1) Whosoever artificially alters the genetic information of a human germ line cell shall be punished by up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who uses a human germ cell with artificially altered genetic information for fertilization.

The Act contains elements of no fewer than twenty-eight crimes which to a certain extent are likely to affect the genetic dignity of a human being and human embryos: (1) creation of dual motherhood; (2) support of substituted motherhood; (3) creation and use of embryos for unrelated purposes, especially for scientific research; (4) bringing to a pregnancy by more than three embryos; (5) deliberate creation of extra embryos; (6) planning a gender of a future child; (7) deliberate artificial

²⁰ Assisted Human Reproduction Act (S.C. 2004, c. 2) (Sep. 25, 2019), available at <https://laws-lois.justice.gc.ca/eng/acts/A-13.4/section-5.html>.

²¹ Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 5758–1999 (Sep. 25, 2019), available at <http://www.hinxongroup.org/docs/Israel.html>.

²² Act for Protection of Embryos (the Embryo Protection Act) (Sep. 25, 2019), available at https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/E/ESchG_EN_Fassung_Stand_10Dez2014_01.pdf.

fertilization by the sperm of the deceased; (8) cloning; (9) creation of chimeras and hybrids; (10) artificial fertilization, transfer, conservation of embryos not by a doctor; etc.

The Criminal Code of the Federal District (Mexico) contains two provisions criminalizing any genetic intervention. Article 154 imposes imprisonment up to six years, disqualification or removal from office or occupation of those who manipulate human genes to change the genotype for purposes unrelated to, for example, elimination or suppression of a serious disease or condition. This provision also prohibits any genetic modifications for unlawful aims.²³ However, the Federal Criminal Code of Mexico does not provide for criminal liability for human genetic manipulation.

M. Araki and T. Ishii, researchers at Hokkaido University, have analyzed the international regulation of modification of human embryos.²⁴ They came to the conclusion that many countries prohibit modification of the human germ line gene. Twenty-nine out of the thirty-nine most developed states prohibit modification of germ line genes. The other ten states include nine states with a rather controversial legal status of such modifications (including Russia, the Republic of South Africa, Greece, Slovakia, Chile and Argentina) and the United States (with a special approach to regulating this question at the state level and at the federal level, where a temporary moratorium is in place).

China, India, Ireland and Japan prohibit human genome manipulation in the form of guidelines, which, as mentioned in the research by Araki and Ishii, can be rather easily changed and which have less binding force than laws.

For example, India does not have a specific law that would prohibit genome editing of germ lines. However, in 2017 the Indian Council of Medical Research (ICMR, a state organization accountable to the Health and Family Welfare Ministry) adopted National Ethical Guidelines for Biomedical and Health Research on Human Participants.²⁵ Under this Act, germ line therapy is prohibited under the present state of knowledge (p. 10.14.7). Additionally, eugenic genetic engineering is also prohibited, as we possess insufficient information at present to understand the effects of attempts to alter or enhance the genetic machinery of humans (p. 10.14.8).

²³ Código Penal para el Distrito Federal [Penal Code of the Federal District] (Sep. 25, 2019), available at <http://www.aldf.gob.mx/archivo-d261f65641c3fc71b354aaf862b9953a.pdf>.

²⁴ Motoko Araki & Tetsuya Ishii, *International Regulatory Landscape and Integration of Corrective Genome Editing into in Vitro Fertilization*, 12(1) *Reproductive Biology and Endocrinology* 108 (2014).

²⁵ Indian Council of Medical Research, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) (Sep. 25, 2019), available at https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf.

2. He's Case and Legal Regulation of Genetic Manipulation in China

2.1. Preliminary Remarks on the Legal System of China

First and foremost, it is necessary to make a few preliminary remarks on the system of sources of law in China to understand the importance of different legal documents. The legal system of China has several significant differences, the main one being a relatively small number of laws.

Laws (法) are passed by the National People's Congress (Parliament of the People's Republic of China) on most serious questions.

Rules (条例) are usually developed by ministries and approved by the State Council (Government of the People's Republic of China). It is noteworthy that due to the specific character of the legal system of China rules passed by ministries, in fact, have the same legal force as laws.²⁶

The guiding principles passed by different bodies play an important role in the management of different branches, especially in the sphere of health and science. Guiding principles can also be passed in the form of "Ethical Guides" (伦理指导原则), "Ethical Principles" (伦理原则) or "Administrative Measures" (管理办法), which sometimes are translated as "Normative Rules," "Instructions." The aim of administrative measures is to administer specific types of activities. As stipulated by Articles 71 and 82 of Act No. 31 on the Legislation of the People's Republic of China (中华人民共和国立法法) passed on 15 March 2000,²⁷ administrative measures are rules passed by ministries or other state bodies which are directly controlled by the State Council of the People's Republic of China. They are a source of legal norms and are binding for a ministry or a government body which passes them. Administrative measures concerning scientific or medical research and practice are binding for research institutions and hospitals with an appropriate license.

Another normative document is technical norms (技术规范) or technical standards (技术标准) aimed at securing the safety and efficiency of technologies. Like ethical guiding principles, they can be applied only when permitted by normative acts, laws and administrative measures. It is important to note that many normative or ethical guiding principles in China are introduced as "experimental," "temporary" or "preliminary." However, the temporary character of such a source does not make it non-binding.

²⁶ Трошинский П.В. Правовая система Китая [Pavel V. Troshchinsky, *The Legal System of China*] 44 (Moscow: IFES RAS, 2016).

²⁷ 中华人民共和国立法法释义 [Act on the Legislation of the People's Republic of China] 436 (Beijing: Legal Publishing House, 2015).

2.2. A Short Overview of Legal Regulation of Genetic Research and Experiments, Clinical Application of Genetic Technologies in the People's Republic of China

Though China is recognized as the world leader in the sphere of biomedical technologies connected with the human genome, China has not yet developed appropriate legislation in this sphere.²⁸ Priscilla Song states that it is the lack of legal regulation of biomedical research that is a triggering factor in the development of new medical and biological technologies in China.²⁹ Legal regulation in this sphere represented by a group of normative acts is not consistent.

1. *Act on Medical Practice (中华人民共和国执业医师法) of 26 June 1998*³⁰

Article 14 of the Act on Medical Practice states that doctors cannot conduct their professional activity without being certified. Furthermore, under Article 26 of the Act, doctors involved in experimental clinical treatment must receive the approval of the hospital and consent from the patient or his or her family.

2. *Rules on Managing Medical Institutions (医疗机构管理条例), Order of the State Council of the People's Republic of China No. 149 of 1 August 2005*³¹

Pursuant to Article 25 of the Rules, medical institutions shall comply with corresponding laws, rules and medical technical rules when conducting medical activities. Violations of medical technical rules are equivalent to violations of the Rules and may lead to liability and sanctions.

3. *Decision of the Ministry of Science and Technologies and the Ministry of Health of the People's Republic of China No. 460 of 24 December 2003 approved "Guiding Ethical Principles in Research of Human Embryo Stem Cells" (科学技术部、卫生部关于印发《人胚胎干细胞研究伦理指导原则》460号)*

This Act prohibits any research in the sphere of reproductive cloning (Art. 4) as well as selling and buying human gametes, a fertilized ovum, embryos and embryonal tissues. To research human stem cells three special rules are established:

- First, a blastocyst received by in vitro fertilization, the transfer of the somatic cell nucleus, parthogenesis or genetic modification shall not be cultivated for more than fourteen days from the moment of conception or the nucleus transfer;
- Second, blastocysts received in the above said ways cannot be implanted in the reproductive system of a human being or any animal;
- Third, human germ cells shall not be combined with germ cells of other types (Art. 6 of Decision No. 460).

²⁸ Tom Hancock & Wang Xueqiao, *China Set to Tighten Regulations on Gene-Editing Research*, Financial Times, 25 January 2019 (Sep. 25, 2019), available at <https://www.ft.com/content/a464bd9c-f869-11e8-af46-2022a0b02a6c>.

²⁹ Priscilla Song, *Biomedical Odysseys: Fetal Cell Experiments from Cyberspace to China* 7–8 (Princeton: Princeton University Press, 2017).

³⁰ 中华人民共和国执业医师法 [Act on Medical Practice] (Sep. 25, 2019), available at http://www.gov.cn/banshi/2005-08/01/content_18970.htm.

³¹ 医疗机构管理条例 [Rules on Managing Medical Institutions] (Sep. 25, 2019), available at http://www.gov.cn/banshi/2005-08/01/content_19113.htm.

However, the current rules in China do not prohibit the application of such technologies in relation to an adult person. In particular, to apply genetic modifications technologies (e.g. CRISPR-technologies) in relation to an adult person in China, it is necessary to obtain the approval of the Committee on Ethics of the hospital and the consent of the patient (Arts. 8, 9 of Decision No. 460). Due to the simplicity of such a procedure, technologies such as CRISPR-technologies are more often applied in China than in all other countries taken together.³²

4. *Instruction of the National Committee on Health and Family Planning No. 11 of 12 October 2016 “On the Order of Considering Ethical Questions Related to Biomedical Research of a Human Being” (涉及人的生物医学研究伦理审查办法, 第11号)*³³

This Instruction provides for ethical control over biomedical research of a human being by an independent committee on ethics which must be created in every medical institution. The lack of such control leads to administrative liability under Article 46 of the Instruction.

5. *“Administrative Measures for Clinical Application of Medical Technologies” (医疗技术临床应用管理办法) No. 18 of 16 March 2009³⁴ and No. 1 of 1 November 2018³⁵*

Article 41 of the 2009 Administrative Measures (effective at the time He was conducting his experiment) states that the medical institution has no right to apply a medical technology which has been rejected or prohibited by the Ministry of Health of the People’s Republic of China. The “Administrative Measures on the Application of Auxiliary Human Reproductive Technologies” (人类辅助生殖技术管理办法, established by the Ministry of Health of the People’s Republic of China No. 14 of 1 August 2001),³⁶ prescribe the possibility to apply such reproductive technologies which fully comply with the “Technical Norms on Human Reproductive Technologies” (人类辅助生殖技术规范³⁷); consequently, any genetic manipulation with human gametes, zygotes and embryos for reproductive purposes is prohibited.

³² Hancock & Xueqiao, *supra* note 28.

³³ 涉及人的生物医学研究伦理审查办法, 第11号 [Instruction No. 11 “On the Order of Considering Ethical Questions Related to Biomedical Research of a Human Being”] (Sep. 25, 2019), available at <http://www.nhc.gov.cn/fzs/s3576/201610/84b33b81d8e747eaf048f68b174f829.shtml>.

³⁴ 医疗技术临床应用管理办法 [Administrative Measures for Clinical Application of Medical Technologies] (Sep. 25, 2019), available at <https://baike.baidu.com/item/%E5%8C%BB%E7%96%97%E6%8A%80%E6%9C%AF%E4%B8%B4%E5%BA%8A%E5%BA%94%E7%94%A8%E7%AE%A1%E7%90%86%E5%A%9E%E6%B3%95>.

³⁵ 医疗技术临床应用管理办法 [Administrative Measures for Clinical Application of Medical Technologies] (Sep. 25, 2019), available at <https://www.sifc.com.cn/InsidePage/1000/38/8839.html>.

³⁶ 人类辅助生殖技术管理办法 [Administrative Measures on the Application of Auxiliary Human Reproductive Technologies] (Sep. 25, 2019), available at http://www.gov.cn/fwxw/bw/wsb/content_417654.htm.

³⁷ 人类辅助生殖技术规范 [Technical Norms on Human Reproductive Technologies] (Sep. 25, 2019), available at <http://www.zxxyy.cn/manage/detail/454.html>.

The 2018 Administrative Measures part with the blank description of legal regulation of the clinical application of new technologies. Article 4 states that clinical application of medical technologies must comply with scientifically substantiated principles, principles of safety, requirements of standards and ethics, and must be efficient and economical. Medical institutions that are not certain of the effectiveness and safety of a new technology to be applied cannot clinically apply it. Article 9 directly prohibits medical technologies if: (1) their safety and effectiveness are not clear enough; (2) there are serious ethical problems; (3) the application of a technology was prohibited earlier; and (4) new medical technologies are not clinically tested and proved.

2.3. What Criminal Charges Can He Jiankui Face?

First, He Jiankui can be suspected of committing a crime stipulated by Article 336 “Illegal Medical Practice” of the Criminal Code of China.³⁸ Under this rule, whoever conducts unauthorized birth control, reversal surgery, fake birth control surgery and pregnancy termination surgery, or removes birth control devices from the womb, and when the circumstances are serious, shall be sentenced to not more than three years of fixed-term imprisonment, criminal detention or control, and may in addition or exclusively be sentenced to a fine. Whoever causes serious harm to the health of patients shall be sentenced to not less than three years and not more than ten years of fixed-term imprisonment and a fine. Whoever causes the death of a patient shall be sentenced to not less than ten years of fixed-term imprisonment and a fine.³⁹

In accordance with the Clarification of the Supreme People’s Court No. 5 “On Separate Issues Concerning Specifics of Law Application When Trying Criminal Cases on Illegal Medical Practice,” adopted at the 1446th meeting of the Judicial Committee of the Supreme People’s Court on 28 April 2008 (最高人民法院^{关于}审理非法行医刑事案件具体应用法律若干问题的解释),⁴⁰ the illegal medical practice by people without medical qualification includes: (1) inability to acquire medical qualification or acquiring it by illegal means; (2) conducting medical activity when the certificate permitting the person to conduct medical practice has been revoked under the law; (3) inability to get a certificate to practice as a rural doctor and conducting medical activity in rural areas; and (4) other operations performed by a family obstetrician except for

³⁸ 庞九林. 贺建奎不是科学家而是罪犯应该立即对其采取强制措施 [Pang Jiulin, *He Jiankui Is Not a Scientist but a Criminal. Enforcement Measures Should Be Taken Against Him Immediately*] (Sep. 25, 2019), available at <https://zhuanlan.zhihu.com/p/50991327>.

³⁹ Criminal Code of the People’s Republic of China (Sep. 25, 2019), available at <https://www.fmprc.gov.cn/ce/cgvienna/eng/dbtyw/jdwt/crimelaw/t209043.htm>.

⁴⁰ 最高人民法院^{关于}审理非法行医刑事案件具体应用法律若干问题的解释 [Clarification of the Supreme People’s Court “On Separate Issues Concerning Specifics of Law Application When Trying Criminal Cases on Illegal Medical Practice”] (Sep. 25, 2019), available at <http://www.court.gov.cn/zixun-xiangqing-33031.html>.

child delivery. Aggravating circumstances include: (1) mild dysfunction of a patient and general dysfunction caused by damaged organs and tissues; (2) spread or risk of spreading and epidemic of infectious diseases of class A; (3) use of forged medicine, low quality medication or sanitary materials or medical goods which are not consistent with national standards, thus jeopardizing people's health; and (4) illegal medical practice has been twice punished by the Administrative Department of the Ministry of Health.

The given official interpretation by the court does not allow classifying the actions by He Jiankui as illegal medical practice. Firstly, the professor is an expert in the sphere of medical genetics. Secondly, all instances of manipulation were conducted by the medical staff in the medical center. Thirdly, medical intervention, in fact, concerned only the application of reproductive technologies to implant the embryo. Manipulation to edit a separate gene of the embryo is not a medical act itself and was conducted beyond the medical procedure, thus, in fact, being a scientific experiment.

Second, He Jiankui can be charged with the forgery of licensing documents granted by the Committee on Medical Ethics of the hospital where genetically modified embryos were implanted. Under Article 7 of Instruction No. 11 of the National Committee on Health and Family Planning of 12 October 2016 "On the Order of Trying Ethical Questions Related to Human Biomedical Research," one of the conditions necessary to conduct biomedical activity in respect of a human being is the establishment of an independent committee on ethics. In the opinion of the Chinese lawyer Pang Jiulin,⁴¹ if forgery of documents was committed to deceive the parents of the child and obtain some money, then He's actions can be classified as fraud (Art. 266 of the Criminal Code). But even if there was some degree of forgery in He's case, it must have been caused by those restrictions which concerned manipulation with the human embryo genome and not by money considerations. Thus, his actions fall under Article 280 "Forgery of Documents" of the Criminal Code. In accordance with this provision, whoever forges, alters, trades, steals, forcibly seizes or destroys officials documents, certificates or seals of state organs is to be sentenced to not more than three years of fixed-term imprisonment; when the circumstances are serious, the sentence is to be no less than three years but not more than ten years of fixed-term imprisonment.⁴²

Third, some actions may be classified as administrative offenses or neglect of official duty. Thus, Professor He can be charged with violations of Articles 33 and 35 of Instruction No. 11 of 12 October 2016 concerning the informed consent of a patient to perform medical intervention.

Though there are alternatives as to how to classify the actions committed by He Jiankui, Chinese law seems to lack special liability for illegal manipulation of the genome of a human being and other organisms. Professor at Beijing University Wang Yue thinks that He's case has become a watershed between ethical and juridical risks in the sphere of genetic research. Wang Yue considers He's actions to be a risk to the

⁴¹ Jiulin, *supra* note 38.

⁴² Criminal Code of the People's Republic of China, *supra* note 39.

safety of the gene pool of the whole of mankind, therefore he offers to introduce liability in criminal law for crimes committed with the use of new technologies. In his view, one of the factors contributing to the commission of He's actions concerned the fact that it was possible to clinically apply new medical technologies not on the basis of the license but by following the simplified registration procedure of a project. The scholar comes to the conclusion that control in this sphere must only increase. To make such control effective, it is necessary to find a balance between technological freedom and public safety.⁴³

Professor at the Criminal Law Institute of the Beijing Pedagogical University Peng Xinlin says that the genetic editing conducted by He Jiankui is scientific research, and though it violates the norms of medical ethics, it is not obvious that it should be classified as a crime. To make a violation of ethical rules a crime, we must see significant public damage and, secondly, such an action must be of a universal character (to be dangerous "by itself" without any additional conditions). Will babies born in such a way pose a threat to the society? He's case contradicts medical ethics, but it does not meet the universality requirement. Peng also mentions that different ideas on amending the legislation which appeared after He's declaration should be treated rationally and with caution.⁴⁴

Professor at the Chinese University of Political Science and Law and Director of the Centre of Legal Research in the health sphere Xie Zhiyun has called the experiment conducted by He Jiankui an insane adventure.⁴⁵ In his view, it is difficult to predict the implications of such an experiment and what we may face in the future in terms of ethics, evolution and human reproduction. At the same time, the importance of the very problem convinces Xie Zhiyun of the necessity to impose punishment in this case.⁴⁶

3. He's Case as a Factor Contributing to the Development of Genetic Justice in China and Other Countries

The process of developing and adopting amendments in the criminal legislation of China requires a lot of time and effort,⁴⁷ therefore the Chinese legislator is unlikely

⁴³ 赵汉斌. 面对“科学狂人”，法律应提前归位 [Zhao Hanbin, *In the Face of "Scientific Madman," the Law Should Be Returned to the Place in Advance*] (Sep. 25, 2019), available at http://www.xinhuanet.com/tech/2018-11/28/c_1123777358.htm.

⁴⁴ 黄海英. 基因编辑婴儿涉及哪些法律问题？专家全面解读 [Huang Haiying, *What Legal Issues Are Involved in Genetic Editing of Infants? Comprehensive Interpretation of Experts*] (Sep. 25, 2019), available at <https://tech.sina.com.cn/d/2018-11-28/doc-ihmutuec4251913.shtml>.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ See on criminal legislation in China: Сергеев Д.Н. Законотворчество в системе уголовно-правового регулирования // Вестник Пермского университета. Серия: Право. 2018. № 39. С. 125–133 [Danil N. Sergeev, *Law-Making in the System of Criminal Law Regulation*, 39 Perm University Herald. Juridical Sciences 125 (2018)].

to rapidly respond to the events in He's laboratory. While the experiment by He was not shown to be dangerous, the Chinese experience does show that the legal system is not ready to take measures against serious violations of medical and scientific research ethics. The Russian legal system seems also not to be ready for such situations. As in China, in Russia legislation does not consider actions to edit the human embryo and further implant it a crime even if parents are not aware of the genetic editing of their embryo. We observe that even when genetic intervention in the human genome is obviously illegal, such actions cannot be classified as crimes not only in China, but in most of the countries of the world.

The doctrine of Chinese criminal law differentiates two categories in the notion of a crime: the legislative concept of a crime and the judicial (law enforcing) concept.⁴⁸ An analogue to the legislative concept of a crime is the crime classification criteria existing in national and international criminal law.⁴⁹ The most important criterion of criminalization in Chinese doctrine is social harmfulness (public danger), which serves as the watershed between a crime and other offenses. The moment when the harmfulness of an action turns into a public danger is called the "initiation point." From the viewpoint of public danger, Chinese scholars are not unanimous concerning He's case. Indeed, looking at the general assessment of the scientific progress, we cannot with absolute certainty recognize the activity of human genome manipulation as a public danger.

At present, science does not possess reliable knowledge on the possible damage by such manipulation to an individual or the whole of humanity. By and large, the experiment conducted by He Jiankui pursues a publicly useful purpose to restore genetic immunity in the case of HIV. Additionally, to treat hereditary diseases and defects which once were incurable, genetic therapy is being actively developed. Methods of genetic therapy are now already applied in relation to an adult person and are a form of medical intervention into genetic information. The German Embryo Protection Act mentioned above is often criticized for excessive criminalization of twenty-eight actions with regard to embryos.⁵⁰ For this reason, we cannot recognize all possible manipulation of the human genome as activities that are public dangers. At the same time, a public danger does arise in human genome manipulation when: (1) the embryo genome is edited by means of genetic engineering technologies

⁴⁸ 王世洲。现代刑法学（总论）[Wang Shizhou, *Modern Criminal Law (General Part)*] 74–75 (Beijing: Beijing University Press, 2011).

⁴⁹ Верле Г. Принципы международного уголовного права: Учебник [Gerhard Werle, *Principles of International Criminal Law: Textbook*] 58 (Odessa: Feniks, 2011).

⁵⁰ Рёрихт А.А. Гюнтер Х.-Л., Таупиц Й., Кайзер П. Закон о защите эмбрионов. Günther H.-L., Taupitz J., Kaiser P. Embryonenschutzgesetz. Stuttgart: Kohlhammer Verl., 2008. 428 s. // Социальные и гуманитарные науки. Отечественная и зарубежная литература. Серия 4: Государство и право. Реферативный журнал. 2010. № 4. С. 104–107 [Alla A. Rerikht, Günther H.-L., Taupitz J., Kaiser P. *Embryo Protection Act. Stuttgart: Kohlhammer, 2008. 428 p.*, 4 Social Sciences and Humanities. Russian and Foreign Literature. Series 4: State and Law. Abstract Journal 104 (2010)].

with further implantation of the embryo in cases where the parents of the child are not aware of the nature of such intervention and its possible implications; (2) application of genetic therapy or any other transgenesis in relation to a person in cases where the person is not aware of the nature of the applied manipulation and possible implications of the applied technology.

As for other human genome manipulation, at present it is difficult to make a determination as to the obvious public danger. If one follows the principle of a “potential danger sufficient for criminalization of an action,” then it can have a negative impact on the development of biomedical technologies and genetic science on the whole. For this reason, at present, we do not see legal grounds to make He Jiankui criminally liable.

Should He’s experiment pose a risk to the life of Nana and Lulu born as a result of his experiment, and the risk be associated with the fact of genetic editing at the embryonal stage, then even on the basis of current criminal law the actions by He’s group may be recognized as criminally punishable.

On 26 February 2019, the Health Ministry of China published a project of the Rules on Administering the Clinical Use of New Biomedical Technologies (关于生物医学新技术临床应用管理条例⁵¹) for public discussion. As mentioned earlier, the Rules (条例) in fact are equal to the law in the hierarchy of sources of law in China. The adoption of the Rules will significantly increase the level of legal regulation of genetic research and manipulation. The project not only offers positive regulation of such matters, but also introduces liability. As the explanatory note to the project reads:

It is not possible to enforce legal norms due to ineffectiveness of sanctions imposed under current normative acts, therefore the project introduces sanctions for their violations. Such sanctions include warnings, offering time to remove such violations, fines, cancellation of a license, etc. In case of more serious violations, offenders will be subjected to criminal liability.⁵²

Though the explanatory note clearly states that offenders will be criminally liable for violations in the sphere of clinical use of new biotechnologies, the project itself does not impose any criminal rules. It is important to underline that there is no clear understanding of the sources of criminal law in China: alongside the Criminal Code, China has separate normative acts on criminal liability.

The Project offered by the Health Ministry of China divides new medical technologies into three groups of risk, introducing differentiated legal regulation for

⁵¹ 关于生物医学新技术临床应用管理条例 (征求意见稿) 公开征求意见的公告 [Announcement on Public Consultation on the Rules on Administering the Clinical Use of New Biomedical Technologies (Draft for Comment)] (Sep. 25, 2019), available at <http://www.nhc.gov.cn/yzygj/s7659/201902/0f24ddc242c24212abc42aa8b539584d.shtml>.

⁵² *Id.*

each type of technologies. New biomedical technologies of high risk are administered by the State Council of the People's Republic of China and are accountable to the managing bodies of health at the All-China level. This group includes technologies connected with genome editing, gene transfer, mitochondrial replacement, etc.; technologies of xenotransplantation and cloning; production of new organisms or biological products, including synthetic bacteria; the use of auxiliary reproductive technologies; and other research projects with high technical risks and difficulties which can have serious implications.

The section of the project on liability has a rather big volume and includes a group of different elements of administrative offenses with huge fines and states that,

In case of a serious violation, it will be tried under the rules of criminal liability.

Conclusion

He's case has caused many ethical and purely legal problems. If society closes its eyes to the necessity to resolve these issues today, and without delay, the result will be the accumulation of such problems.

At present, it is obvious that human genome editing can be carried out by research scholars "at their own risk," despite all legislative restrictions and the lack of normative legal acts. The lack of a common approach to the legal assessment of human genetic modifications at the international level (provided the human genome is declared the public domain of the whole of humanity) is compensated by the inconsistent regulation of different countries with quite different approaches: from relative freedom in questions of genetic experiments (Brazil, Russia, India, China and South Africa) to criminal bans (Israel, Canada and Germany). The lack of common approaches will trigger medical genetic tourism in those states which allow such experiments (including pre-implantation genetic editing) or to those states which close their eyes to such experiments.

Current criminal law is clearly not ready to assess the degree of danger of different areas of manipulation of the human genome as well as of other related actions, for example, in the sphere of genetic information exchange. In this connection, we find it reasonable to take a cautious approach to the necessity to criminalize such actions. We should prohibit obviously dangerous activities rather than limit ourselves by a general ban.

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References

Allers K. & Schneider T. *CCR5Δ32 Mutation and HIV Infection: Basis for Curative HIV Therapy*, 14 *Current Opinion in Virology* 24 (2015). <https://doi.org/10.1016/j.coviro.2015.06.007>

Araki M. & Ishii T. *International Regulatory Landscape and Integration of Corrective Genome Editing into in Vitro Fertilization*, 12(1) *Reproductive Biology and Endocrinology* 108 (2014). <https://doi.org/10.1186/1477-7827-12-108>

Berg P. et al. *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72(6) *Proceedings of the National Academy of Sciences* 1981 (1975). <https://doi.org/10.1073/pnas.72.6.1981>

Cyranoski D. *Russian Biologist Plans More CRISPR-Edited Babies*, 570(7760) *Nature* 145 (2019). <https://doi.org/10.1038/d41586-019-01770-x>

Loureiro A. & da Silva G.J. *CRISPR-Cas Converting a Bacterial Defence Mechanism into a State-of-the-Art Genetic Manipulation Tool*, 8(1) *Antibiotics* 18 (2019). <https://doi.org/10.3390/antibiotics8010018>

Song P. *Biomedical Odysseys: Fetal Cell Experiments from Cyberspace to China* (Princeton: Princeton University Press, 2017). <https://doi.org/10.23943/princeton/9780691174778.001.0001>

王世洲。现代刑法学 (总论) [Shizhou W. *Modern Criminal Law (General Part)*] (Beijing: Beijing University Press, 2011).

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