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Legal framework for gene editing in human genome "World's First Mutant twins by China"

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Abstract: A Chinese Scientist named He Jiankui in a secret experiment successfully edited the genome of twins. He debugged the human source code by removing the genetic door that cause HIV virus to enter functional unit of the body hence made the twins born after genome editing immune to it. Although, recently a lot of attention has been converged to the regulatory framework of gene editing involving humans in China, but those efforts have not ended up at any viable solution. The paper will address whether the legislation that specifically address the issue of Assistive Reproductive Technology research and Human Embryo Stem Cell research are sufficient and provide sustainable legal framework that is pertinent to the regulatory control of this research in China. The current legal framework based on Administrative Measures and Ethical Guidelines lack any solid penal law that accord penal liability for violation. These Measures and Guidelines do allow for the research on editing human genome but specifically prohibit the use of edited embryos, zygotes and genomes for reproduction purposes.
Keywords: Assisted reproductive technologies; human embryonic stem cell research; regulations; ethical review, genetically edited twins

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I. INTRODUCTION

Recently a biophysicist named He Jiankui from Southern University of Science and Technology in Shenzhen, edited the genome of two embryos in a secret experiment which came to public after the twin sisters named Lulu and Nana born with edited genome[1]. This is claimed as the first ever human born with its genome edited to avoid certain traits in subsequent growth to happen[2]. Germline gene editing or gene editing in gametes or reproductive cells make a permanent change to the reproductive cells that could be passed on to future generations[3]. It distinguishes from the use of gene-editing tools as therapies that correct genetic alterations in somatic cells in blood and other tissues[4][3].He Jiankui made this astonishing claim in a speech at the Second International Summit on Human Gene Editing, held in Hong Kong from 26-29 November 2018. In the Summit, while describing the details of his experiment, he told that he worked with eight couples of HIV-negative women and HIV-positive men out of which one dropped out later on. During the experiment, He's team injected the washed sperm along with CRISPR–Cas9 enzymes, into unfertilized eggs obtained from the corresponding men's partners. The process produced 22 embryos in total, of which successfully edited and sustainable embryos were 16. According to He's spokesperson, He implanted two embryos with modifications to CCR5in the woman, interestingly he used one embryo which also had an intact copy of the CCR5 gene. This pregnancy successfullygive birth to twins[5].

According to He's statement he tried to prevent the subsequent risk of HIV infection in the babies when their father was HIV positive[6]. A geneticist named Kiran Musunuru from the University of Pennsylvania said, He's presentation suggest that both copies of the CCR5 gene were disabled in one of the twins where other twin seems to have at least one working copy[7]. He claimed that the CCR5 is the gene responsible for contracting HIV, so by doing mutation in CCR5, the danger of contracting HIV reduced to manifold because of high resistivity for HIV virus and conclusively claimed the act as a savior of humanity from the curse of HIV[7]. However the mutation in CCR5 has other adverse implications which can affect the health in even worse way than the HIV affects [8]. After giving a brief introduction of the He Jiankui research, leaving the specific scientific details for biologists and geneticists, it is intended in this article to focus on the legal and ethical issued posed by this research and the regulatory framework of Chinese government to handle research on human gene editing.

China does not have a sustainable legal frame work that has the capacity to regulate the research involving human gene editing in case one transgress the boundries[9]. Although China has a centralized political system, but the provincial governments and the four municipalities have significant autonomy. National level

regulations for health biotech research often merely serve as general guidance, which are then interpreted and defined at a provincial level with significant flexibly[10]. This can result in significant variation in the implementation of regulatory standards. Activities related to health care, medical research and family planning are managed by the National Health and Family Planning Commission (NHFPC),formerly known as the Ministry of Health[11] and the China Food and Drug Administration (CFDA)[11]. Both, the NHFPC and the CFDA have branches at a provincial level. Although these institutions are accountable to their national counterparts, local interests and links with regional officials, scientists and companies can result in lenient enforcement of regulatory rules. As Warrell and his colleagues conclude in a Report of Medical Research Council (MRC) on China-UK bioscience collaborations, these local alliances and the vast territory of China make it "sometimes difficult for the national ministries to get accurate data about what is happening in remote regions, let alone to govern them" [12]. This situation seems still prevailing today observing the media reports of He's Experiment and the reaction of hospital involved in the process[5].

In case of He's experiment, the reason he presented to convince the community of geneticist as a noble quest to find a universal solution for HIV. Gene editing technologies may offer a powerful method to treat many human diseases, including sickle-cell anaemia, several forms of cancer, haemophilia, and HIV/AIDS [13]. QiuRenzong, A professor at the Chinese Academy of Social Sciences, specialist in bioethics, while speaking at the Hong Kong summit criticized He's work and declared it unethical, unjustifiable and unacceptable"[6]. He added there are other methods to prevent HIV. Prof Qiu said preventing HIV with gene editing is like "using a cannon to shoot a bird."In fact, all gene editing techniques are currently in developmental phases used in clinical researchspecifically focus on modifying the genetic material of somatic cells which does not affect sperm or eggs and impact future generations[14]. The experts working on gene editing technology in US and UK agreed that if gene editing technology need to apply on human genome, it should only be done to address "serious unmet needs in medical treatment, it has to be well monitored, well followed up, full consent has to be in place" [15]. He altered the genome and inseminated the women with that altered genome and born twins girls claiming it is permanent prevention of HIV but it does not conform to be a sustainable solution in medical terms.

Even before the speech of He Jiankui, the news was already made public and on 26 November, the NHFPC requested the Health Commission of Guangdong province [16] to investigate the matter stipulated with a condemning statement from Chinese Academy of Sciences, Chinese Society for Stem Cell Research and Genetics Society of China saying He's experiment "violated internationally accepted ethical principles regulating human experimentation and human rights law"[5]. Even the hospital mentioned in China's clinical trial registry[17]disowned the matter in a press release on 27 November refusing to accept the responsibility of granting approval for this experiment, rather question the credibility of the signature on the approval form[5]. The Chinese government ensured to resolutely dealt with the experiment in accordance with laws and regulations[18]. There is no any clear law that mark the penal limits available on this subject however certain guidelines are available which regulate the experiments with human germ cells. The Chinese Government strictly prohibits the genetic manipulation of human germ cells, zygotes, and embryos for reproductive purposes. There are guidelines and regulations issued by Ministry of Health which clearly state in the "Guidelines for Ethical Principles in Human Embryonic Stem Cell Research (2003)" (Hereinafter HESCr Ethical Guidelines) the protocol for research involving human genome and embryo stem cells [19].

The article addresses the topic from the legal perspective in which the author will intend to answer multiple questions relating to HeJiankui experimentation of germ line edited twins birth. The account about what he did is already given briefly in the literature review. Further body of article will pick the topic from the specific law governing the gene editing and related aspects, responsibilities of hospitals, research authorization and finally to the point where if any law allows for this kind of research, what prerequisites it demand to fulfill beforehand to get go with the later procedures of gene editing. The body consists of four parts, the first part elaborates the regulatory framework of the Chinese government that govern and address the research or other aspects involving editing and mutation in human genome. The second part address the ethical review which is a compulsory prerequisite of the government to proceed with the experiments, the third part narrate the possible legal consequences based on the examination of laws and regulations and the prospective outcome of liabilities for He's experimentation. The forth part address the He's experiments from the perspective of a successful breakthrough, and the moral and legal constellations which has the conclusive authority to proceed with this kind of research. The last part consists of conclusion and recommendations to develop a regulatory framework which has strong enforceability capacity to deal with such cases.

II. REGULATORY FRAMEWORK FOR GENE EDITING IN CHINA

There is no specific law or regulation available in China that address germline gene editing in human beings, however there are regulations that regulate the basic and preclinical research involving human genome[20]. The only regulatory instrument that addresses genome research directly including human gamete, embryo and germ line is – "Technical Norms on Human Assisted Reproductive Technologies 2003(ART

Technical Norms)" (人类辅助生殖技术规范)[21]. Other regulations that deal with the genetically modified cells are "Points to Consider in Human Somatic Cell Therapy and Gene Therapy Clinical Research" (人的体细胞治疗及基因治疗临床研究质控要点), issued by the Ministry of Health in 1993 and the "Guiding Principles on Human Gene Therapy Research and Product Quality Control" (人基因治疗研究和制剂质量控制技术指导原则) (hereinafter Guidelines) promulgated by the same body in 2003. Article 3.9 of 2003 ART Technical Norms states that: "医务人员不得实施以生育为目的的嵌合体胚胎技术 (The use of genetically manipulated human gametes, zygotes and embryos for the purpose of reproduction is prohibited)"[21]. This clause does at present effectively ban the clinical applications of genome editing in human reproduction. However, it allows for the use of genetically modified stem cells or reproductive tissues for research. It substantively regulates the donation and transfer of human gametes and embryos for use in basic and preclinical research. Together with the "Basic Standards and Technical Specifications of Human Sperm Banks (人类精子库基本标准和技术规范)" (which regulate the donation and reproductive and research use of sperm) the "Technical Norms on Human Assisted Reproductive Technologies (人类辅助生殖技术规范)" shape a limited space allowed for the research modifications of gametes or embryos in the basic or preclinical research. This limited space can be summed up in following five ways:

- By stipulating that ART institutions must set up ethics committees, and that these committees must review and approve the donation and use of human embryos for research.
- By restricting the use of embryos for research to super-numerous embryos derived from IVF, and by prohibiting the creation of IVF embryos for research only.
- By clarifying that with the informed and free consent, the embryos and gametes must be donated voluntarily.

This regulation is backed up by punitive measures which in case of violation by IVF clinics or ART centers can lose their license [12]. The Guideline also stipule that the buying and selling of human ova, sperm, embryos or fetal tissues is prohibited. This does also include the selling of genetically modified gametes and embryos, including the prohibition to patent genetically modified gametes and embryos. The "Administrative Measures for Assisted Human Reproductive Technologies 2001(ART Administrative Measures)"[21] which in article 13 stipulate the compulsory abidance of above mentioned 2003 ART Technical Norms [21]. The 2003 ART Technical Norms, in article 3.7 and 3.9, clearly mention prohibition of gene manipulation on human gametes, zygote and embryos for the purpose of reproduction[21].

A set of ethical guidelines which appears to be most relevant in this case are the "Guidelines for Ethical Principles in Human Embryonic Stem Cell Research" (HESCr Ethical Guidelines) [22]jointly issued by the China's Ministry of Science and Technology and the Ministry of Health in 2003. The article 6 of these HESCr Ethical Guidelines allow for research of gene editing in human embryo with certain restrictions.

According to article 6, stem cell research in human embryo shall be in compliance with the following behavioral norms[23]:

- "Where blastula is obtained from external fertilization, somatic nucleus transplantation, unisexual duplicating technique or genetic modification, the culture period in vitro shall not exceed 14 days from the day of fecundation or nuclear transplantation.
- Implantation of human blastula obtained and used in research as provided in the preceding paragraph into human or any other animal reproductive systems shall be prohibited.
- Combination of human germ cell with that of other species shall be prohibited."

According to the HESCr Ethical Guidelines, the development period of human embryos used in research is restrict to 14 days, and most importantly, such genetically modified embryos are strictly prohibited to be implant into animal or human body for the purpose of reproduction.

Tetsuya Ishii [20], a legal scholar, after comparison of regulatory framework of human gene modification in 39 countries, has introduced a distinction between "ban by guidelines" and "ban by legislation". According to Ishii, China has banned germ line gene modification under guidelines which are less potent and enforceable than laws [24]. This claim is true to some extent examining the enforceability potency of these regulations. The 2003 ART Technical Norms, 2003 HESCr Ethical Guidelines and 2001 ART Administrative Measures have the legal status of ministerial guidelines and not laws. Ministerial guidelines are very important for the governance of China's life and health science sector. Ministerial guidelines can either take the form of ethical guidelines (伦理指导原则) or ethical principles (伦理原则) or administrative measures (管理办法) sometimes also translated as "regulatory rules". Administrative measures, as defined in Articles 71 and 82 of the "Legislation Law of the People's Republic of China" (立法法) promulgated in 2000[25], are rules issued by ministries or other government bodies directly under the State Council. They are a source of legal norms in the Chinese legislation and are authoritative within the scope of the authority issuing them [26][27]. Administrative measures that address scientific or medical research and practice are binding for research institutions and hospitals, which are licensed by the NHFPC or the MOST to carry out these practices[12].

The 2003 HESCr Ethical Guidelines also stipulate that the research is subject to reviews by the ethics committee of researcher's own institution. According to article 9 of the 2003 HESCr Ethical Guidelines, hospitals and research institutions conducting research on human embryonic stem cells are required to establish institutional ethics committees that consist of research and executive personnel in the areas of biology, medical science, jurisprudence, and social sciences[23]. According to the 2003 ART Technical Norms, IVF clinics and ART centers must be authorized and certified by the NHFPC. After the research institute or hospital got the license, it became legally bound to submit documentation and annual reports to NHFPC[27]. On the authority of "Regulation on the Administration of Medical Institutions," issued by the State Council in 1993, if any ART center provides illegal services or offer services which are unauthorized and beyond the scope of license, the NHFPC has the authority to withdraw license and automatically shut the institute[27]. The 2001 ART Administrative Measures, in article 12 specifically prohibit the performance of ART by unauthorized institute or individual. Article 14 of the Administrative Measures also require informed consent, and in case any ethical issue involved must be submitted to the ethics committee for discussion[28]. In case of He's experiments, he operated secretly and by his own admission kept the project secret from the Southern University of Science and Technology, Shenzhen, where he was working at that time and has also obtained the ethical approval from Shenzhen Harmonicare Hospital. However, the hospital Medical Ethics Committee rejected his claim and said, they never met to discuss such a project[29], and that the signatures on He's approval form "are suspected to have been forged" [30]. Qin Suzhen, the director of the medical department in Harmonicare Hospital and the member of ethics committee said his signature should be on the form when his missing signature is synonymous to forgery in the document[31]. He personally inquired from one of his colleagues who had his signature on the application from to clarify the matter, but was surprised to know that his colleague also doesn't know anything about this experiment and deny signing on the form. According to Li Rong, a reporter of Southern News, in his report mentioned that the Shenzhen Municipal Health Planning Commission Medical Ethics Committee did not receive the project report, and the Health Planning Commission is currently verifying the matter[31]. A *prima facie* impression of the situation makes it a competent case of forgery. This can invoke provisions of criminal law for the forgery of documents but no conclusive appropriation can be made at this moment as the matter is still under investigation of respective authorities.

III. ETHICAL REVIEW OF BIOMEDICAL RESEARCH

China is determined to grasp the promise of regenerative medicine and has stirred the wave of germ line gene editing research nationwide. Even the germ line gene editing research is also supported by the national government. The Ministry of Science and Technology (MOST) plays a fundamental role in the formation and implementation of science and technology policy. The MOST, in collaboration with the China National Science Foundation (NSFC) allocate the majority of research funding in China[12]. In the NSFC, The Department of Life Sciences and the Department of Health Sciences are two main funding agencies for health biotech research. In the Thirteenth Five Year Plan (2016-2020), China's health biotech industry was defined as a 'strategic emerging industry', with genomic research, personalized medicine treatments and regenerative medical techniques as key research areas 'to cultivate strengths for future development'[32]. By October 2015, the NSFC had funded 57 projects involving CRISPR, including the first two studies that reported human genome editing in human embryos[33][34]. The complexity of human embryonic stem cell research generates situations which typical creates a trouble for regulators to deal with. Efforts are being made to increase the awareness and policy canvas with sound regulations to treat issues of human genome research. In an attempt to clean up the field, the NHFPC and China Food and Drug Administration (CFDA) issued the first "Notice on Printing and Disposing of Stem Cell Clinical Research Management Measures" (2015 Management Measures) [35]. Under the 2015 Management Measures, the research institutions are required to perform necessary registration, conduct initial ethical review, maintain and file record, reporting and supervision of the process, risk control and quality management throughout the whole process of clinical stem cell research[35].However the preconditions of ethical review in research involving human subjects is already mature. The Ministry of Health issued the "Notification on ethical review of biomedical research involving human subjects" (涉及人的生物医学研究伦理审查办法通知 [试行]) in 2007[19]. The Notice provides in detail the composition of independent ethics review committee at the level of a research institute or hospital, structure of committee, review mechanism and criteria for informed consent.

In 2016 the NHFPC further clarified the tasksand responsibilities of medical ethics review committees, by issuing the "Measures for the Ethical Review of Biomedical Research Involving Humans" (涉及人的生物医学研究伦理审查办法) (2016 Measures) [36]. The 2016 Measures introduce a much-needed oversight system for institutional research ethics review committees. It introduces a regional inspection system and when research ethics review committee fails to comply or violate existing norms, serious consequences can follow[11]. The 2016 Measures furnish the most detailed provisions, requiring thereby the research ethics review committees of health and medical institutions at different levels shall not be less than seven members, selected from experts in related fields including medicine, biology, jurisprudence, sociology, ethics, as well as members from general

public other than the employees of the respective institutions. Except for the NHFPC, no ministry or cabinet institution has a permanent ethics committee, and the administrative responsibilities for science and technology related ethical issues in specific areas still rest with the relevant departments of the government. [11].

IV. POSSIBLE LEGAL CONSEQUENCES

In light of above mentioned Chinese Laws and regulations, it may not be easy to determine exactly what legal liabilities He Jiankui, and his team or others working with him can face for producing a gene edited twin babies. His misconduct falls into three categories of liabilities namely; criminal responsibility, civil liability and administrative law. Indeed, they have violated the article 6 of 2003 HESCr Ethical Guidelines but the 2003 ethical guidelines prescribe no penalties for violations of these guidelines. The 2001 ART Administrative Measures in article 22 provides fine of up to 30,000 Chinese yuan for violation of measures by any medical institution. It also mentions the possibility of criminal prosecution in accordance with the Criminal Law. However, the 1997 Criminal Law[37] does not contain a specific crime such as creating gene-edited babies. Liu Lijie, a doctor of criminal law at China University of Political Science and Law and head of business management at Beijing Kyoto Law Firm said, if two babies who have received genetic editing cause serious illness or even death in the future, this will make He Jiankui criminally responsible[23]. In addition, Yao Fei, the chief lawyer of Sichuan Zhouyi Law Firm explained, implementing a genetically edited embryo development with express prohibition may violate the crime of endangering public safety in criminal law, because once a gene with great risks has been edited into the entire human gene pool, the entire human genome will face an unknown risk. At the same time, it may also be suspected of illegal medical practice or medical malpractice. At present, with the development of medical technology, the scope of medical protocol is becoming wider and wider. He Jiankui's research is difficult to define whether it is medical behavior or a dishonesty in scientific research. However, if the He Jiankui team is in the process of implanting the genetically edited embryo into the mother, as is clearly refused by the alleged hospital, the operator does not have the qualification of a medical practitioner, and his behavior cannot exclude the crime of illegal medical practice, but the specific situation needs to be determined according to further investigations by relevant departments and judicial organs" [38].

In terms of civil liability, if the parent who gave birth to the genetically edited baby and the medical institution where He Jiankui is located did form a medical contractual relationship, the parents of the infant had the right to informed consent. However, whether to pursue He Jiankui's civil liability is the right of infant parents and depends on their wishes. In addition to procedural issues, for the genetically modified twins themselves, based on the ethical controversy of their own life upon their birth, their personal dignity has been undermined, which is in violation of the Constitution, hence invoke the civil law liability on He regarding the violation of personal dignity, the protection of the interests of the fetus.

Finally, according to various regulations issued by the relevant state departments in China, He's behavior has been clear violation. However, these industrial regulations are not laws established by the legislature in the strict sense. They are mostly clear guidelines, but there are no penalties attached to them and the binding force is weak. It is more likely that He will be given administrative sanctions. The new "social punishment" in China which came in 2018 is limited to the "dishonesty in scientific research" (科研领域的失信行为)[39]. This case is still in the investigation phase and we will be able to mark a final penalty after the final report from the Guangdong Health Commission will come out.

V. NECESSITY FOR GENE EDITING IN HUMAN BEINGS

Germline cells or gene editing is restricted in almost all the countries. In Unites States, the Federal Drug Authority (FDA) treat and regulate the gene editing as biological drug or devise [40]. Doctors can carry out gene editing therapy to treat a disease caused by mutation in a single gene such as haemophilia, sickle-cell anaemia and several forms of cancer where the therapy only affects the patient [40]. The similar logic is put forward by He for expressing the reasons to carry out his experiments on Lulu and Nana. Although it is true to major extent that mutation in CCR5 can eliminate the subsequent danger of Contracting HIV [41]. But mere prevention of contracting HIV from one of the HIV positive parent does not provide a situation which compel any geneticist and especially physicist to carve out such a technique which in serious connotation and specific to its functional capacity is not necessary for HIV treatment at all. As Dr Richard Hynes said, altering genes to make people resistant to HIV is not a serious necessity because HIV–positive men do not infect embryos [15]. The virus that causes AIDS is present in the semen, which may infect the women. With proper precaution a doctor can inject a single sperm into an egg after washing off virus (semen fluid) from sperm before insemination [42,43]. In this case the efforts to prevent the subsequent danger of HIV is even lesser than gene editing and risk factor is also very low[43]. One could say that He's experiment may have been motivated by other underline motivations to get instant fame or publicity or maybe to get promotion in job which in the absence of culpability do compel an educationist or researcher to transgress his professional or ethical limits as evident in the past [44].

Culturally, China also provides a less problematic environment to carry out embryonic research partially because of recent one child policy. Since the Chinese people have reached a consensus that abortion is legal, in China, embryos are not typically treated as people[45]. In an interview by Dominique S McMahon, one Chinese expert stated, "When we draft our Guideline, we always need to think about our culture as well. For Chinese people, we have not so strong religious ideas about the [embryo]… This is not a person, we don't think so… so we accept" [46]. The government is dedicated to enhance the development capability of China in research and innovation but specifically in Human Embryonic Stem Cell research the legal framework is lagging far behind its required position. One holds no deterrence to mind the ethical boundaries when those boundaries don't actually base on the ethics of society and the statutory framework also mark no limitation point to invoke the liability. Giving the example of above mentioned regulatory measures, technical and ethical guidelines, there appears a lot of regulatory stipulations but nothing is backed by any legal authority or penal liability. Ethical context of imminent Chinese culture with its roots derived from society and fluid modernization, the idea of super human may well not seem absurd to try at the next step.Chengzhi Wang, an associate researcher of the Chinese Academy of Science has commented on the Internet: "Mankind never gives up the realization of their dreams. This can be seen with the increasing popularity of plastic surgery hospitals. Imagine that human embryonic genes could be edited without restrictions. Then, a variety of genetic diseases will be completely eradicated. But humans will not be satisfied with this, because humans also want to get"better genes." […] But if the Pandora box has been opened, the consequences may be unpredictable. We should not forget that there are always some crazy people in mankind. When they have mastered some resources, they follow the path of human nature" [27].

Just like the "absolute power corrupts absolutely," the persistence of similar non-cognizance of any act of human gene editing and further development of embryos to any mature human can cause unpredictable consequences. As Chen Guoqiang, a professor of biology at the School of Life Sciences at Tsinghua University states: "keeping in mind the vast and beneficial future implications of this technology, the first mature mutant human is a much-desired breakthrough. While this step may probably bring about some problematic effects and repercussions, every technology undergoes a period from premature to mature. Currently, many heritable diseases do not have well-developed treatments. This embryo gene editing is a possibility of exploration. But at present used embryos should not be allowed to grow beyond the embryonic stage. Scientific research is always risky. If it is forbidden, for fear of risks, then it is difficult for science to progress" [27].

VI. CONCLUSION

The experiment performed by HeJiankui is a one-time irregularity because the second time will not be a problematic case. Either it will become allowed for all or be banned for all as a crime. The second instance will be clearer in its legal nature. However, the first successful experiment of human birth with edited genome, though irregular in its procedural commitments and unethical in moral terms but became a spectacle for the whole world. It has open a new dimension for the scientists to proceed. This is the time for not only Chinese but the international community to reconsider and draft regulations and laws that can better deal the experiments of editing in human genome. Laws with effective punishment do offer deterrence to those who don't follow the rules. The 2003 HESCr Ethical Guidelines, 2003 ART Technical Norms, 2001 ART Administrative Measures, 2015 Management Measures and 2016 Measures launched by NHFPC, MOST and CFDA proposed a monitoring and review system of human embryonic stem cell research. Nonetheless, in the absence of effective liability and traceability system, Chinese human embryonic stem cell scientists and practitioners are free to perform any research to satisfy any underlying motive. There is a need to establish an International mechanism for transparency and ethical oversight of human embryonic stem cell research. The establishment of international regulatory authority and the formulation of international guidelines will push all countries to regulate and supervise stem cell research and therapies including China. Otherwise, as Stephen Hawking said, a new race of super-humans could develop from wealthy people to choose and edit their children's DNA.

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