

A Study on Civil Law Regulations in Human Embryo Gene Editing: A Perspective from the Civil Code of the People's Republic of China

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ABSTRACT

The "He Jiankui gene-edited babies" incident not only drew strong criticism and condemnation from numerous scientists and scholars but also sparked discussions within the legal community regarding the legal issues involved in human embryo gene editing. The Civil Code of the People's Republic of China, which came into effect on January 1, 2021, introduced legislative provisions concerning human embryo gene editing within its section on personality rights, thereby strengthening legal regulation in this field. However, Article 1009 of the Civil Code presents highly general provisions on human embryo gene editing. Controversies persist regarding its legal attributes, conflicts of rights, and remedies, rendering it impractical to resolve all legal issues in human embryo gene editing through this single article. Human embryo gene editing involves fundamental rights such as right to life, the right to health for multiple parties, including research subjects and the parents of gene-edited babies. The inadequacy of relevant laws and regulations fails to address the significant ethical and biological risks posed by the rapidly evolving field of human embryo gene editing. Therefore, further refinement and improvement of legal norms governing human embryo gene editing play a crucial role in safeguarding the healthy development of this emerging gene-editing technology.

KEYWORDS

Human embryo; Gene editing; Civil regulation; Right to life; Right to health; Civil code

1 Introduction: Conflict and Balance in the Technical Governance and Legal Regulation of Human Embryo Gene Editing

1.1 Controversy Surrounding the "Gene-Edited Babies" Case

With the rapid advancement of science and technology, the world is undergoing unprecedented changes. An increasing number of emerging scientific and technological innovations are being widely applied in medical, biological, and other research fields. Among these, the ethical, technological, and health risks associated with human embryo gene editing technology have recently been extensively discussed and researched, gradually becoming a hot topic in the field of bioethics and science and technology. The application of this technology brings not only hope for sustaining life but also poses significant threats to human health and even the security of the global human gene pool. The "gene-edited babies" incident at Southern University of Science and Technology in 2018 sparked intense global controversy. He Jiankui and his team violated relevant legal regulations, crossed ethical boundaries in scientific and medical research, and privately conducted human embryo gene editing experiments, severely disrupting national medical management order. They were subsequently held criminally liable according to law. Some scholars have pointed out that "from a human ethics perspective, He's 'gene-edited babies' case severely undermines human dignity and the value of existence; from a societal standpoint, it risks creating new inequalities and leading to the alienation of humanity itself." Consequently, stringent legislative regulation of human embryo gene editing is of paramount importance.

1.2 Balancing Technological Advancement and Legal Regulation at the Civil Code Level

The "gene-edited babies" incident played a significant guiding role in the compilation of China's Civil Code. Influenced by this event, Article 1009 of the Civil Code's Personality Rights section added provisions on human embryo gene editing to address the risks posed by current scientific and technological advancements. The provision states: "Medical and scientific research activities involving human genes, human embryos, and related matters shall comply with laws, administrative regulations, and relevant national provisions. Such activities shall not endanger human health, violate ethical principles, or harm public interests." This provision demonstrates a strong emphasis on macro-level principles and general guidelines, without detailed specifications on specific application. In practice, this creates difficulties regarding the uncertain legal basis for subjects to exercise their rights. Beyond the Civil Code's provisions on this technology, Article 336 of the Eleventh Amendment to the Criminal Law of the People's Republic of China and Article 55 of the Biosafety Law (effective April 15, 2021) both introduce regulations concerning gene editing or human genetic resources. Additionally, administrative regulations and rules such as the Regulations on the Management of Human Genetic Resources and the Technical Specifications for Human Assisted Reproductive Technology contain relevant provisions. Examining the rules established in Article 1009 of the Civil Code reveals several issues: First, the provisions of the Civil Code to some extent contradict the objective of safeguarding private rights. Second, there is insufficient protection for the freedom of scientific research. Third, most administrative regulations governing human embryo gene editing technologies have relatively low

legal hierarchy, and the overlap between public law and judicial law leads to functional confusion among different branches of law. Finally, the broad scope of the Civil Code's provisions readily generates significant uncertainty in practical application. When other legal norms are less effective and rules take precedence, the operational scope of this clause becomes severely limited. This paper analyzes human embryo gene editing issues through the lens of Civil Code applicability, dissecting emerging rights implicated by gene editing in the context of technological advancement, and exploring the avenues for rights enforcement when parties suffer harm.

2 Legal Challenges Facing Human Embryo Gene Editing Technology under the Civil Code

2.1 The Dual Nature of the Technology Itself: Risks of Human Embryo Gene Editing Technology

Gene editing, also known as genetic engineering, finds extensive applications in biology, medicine, and other fields. This technology "can be understood as recombinant DNA, where scientists precisely modify the genome or transcriptomic products to achieve targeted gene segment knockout or insertion, similar to cutting techniques in computer programming." Depending on research objectives, "human embryo gene editing technology is typically categorized into three types: preventive, therapeutic, and enhancement." While human embryo gene editing research holds significant promise and potential, it involves risks to human genetic material, life, health, and dignity. Key concerns include uncertainties from misuse of technology, genetic risks, safety concerns, lack of demonstrated necessity, and breaches of ethical boundaries. Article 1009 of the Civil Code stipulates that human gene technology activities must not violate ethical norms, reflecting the influence of ethical risks on legislation. On one hand, individuals born through human embryo gene editing technology are highly susceptible to genetic discrimination in real life, with their related rights and interests in daily life easily violated. On the other hand, if gene editing technology develops without any restrictions, the potential for significant risks and technological monopolies could exacerbate social polarization. Therefore, to ensure this technology better serves and benefits humanity, implementing mandatory legal regulations is of paramount importance.

2.2 The Legitimacy and Urgency of the Civil Code's Regulation on Human Embryo Gene Editing

Article 1009 of the Civil Code stipulates: "Medical and scientific research activities involving human genes, human embryos, and related matters shall comply with laws, administrative regulations, and relevant national provisions. Such activities shall not endanger human health, violate ethical principles, or harm public interests." Regarding the adverse effects of human embryo gene editing technology and safeguarding the interests of affected parties, this regulation represents not only a prudent consideration of the public interest for both the nation and society—both in the present and for future generations—but also a protection of the private legal rights of the involved subjects. With the introduction of the concept of "human genes" in the "gene clause," whether born natural persons or unborn or soon-to-be-born life forms, all may directly seek legal remedies for harm suffered in prior human gene editing experiments. "Regulating human embryo gene editing activities within the Personality Rights section incorporates relevant scientific and medical research into the scope of private law. This approach not only upholds personal dignity but also significantly safeguards the health rights, right to life, and other personality rights of those involved. It further advances and guides subsequent legislation, refines the legal framework for human embryo gene editing, and strengthens the modern governance functions of the Civil Code. However, it is noteworthy that "while the Civil Code's inclusion of medical and scientific activities involving human genes and embryos will generate systemic effects, such research inherently involves both public and private law issues, and civil liability alone has limited scope. Relying solely on the Civil Code cannot ensure the orderly conduct of these activities nor fully regulate them. Coordinated efforts and collaborative regulation across multiple departments are essential."

3 Normative Structure and Interpretive Analysis of the Civil Code's Regulation on Human Embryo Gene Editing

3.1 Applicable Norms for Collaborative Regulation

According to the Civil Code, medical and scientific activities involving human genes, human embryos, and related matters must comply with laws, administrative regulations, and relevant national provisions. This provision offers clear guidance to researchers engaged in human gene editing for scientific and medical purposes. In specific case applications, other normative legal documents should also be considered in light of the circumstances. At the level of fundamental principles, this expression can be understood as the principle of strict adherence to law. Given the scope of enumerated laws and regulations, it demonstrates both specialization and comprehensiveness, allowing for interpretive reference to unregulated behavioral patterns within the existing regulatory framework. Some scholars contend that "the freedom to conduct human embryo gene editing research is a subordinate concept to the fundamental right to scientific research freedom enshrined in the Constitution. It falls under the civil law concept of freedom of action and constitutes a legally protected subjective right." Given the high safety and ethical risks associated with this technology, coupled with its technical immaturity, the potential harmful consequences of its practical application and research are particularly

concerning. However, since such activities hold significant positive implications for public welfare, human life, and physical health, they should not be comprehensively prohibited. It is necessary to preserve a certain scope and space for scientific research freedom.

3.2 Prohibitive Norms of Definitive Regulations

Beyond providing guidance through analogous application for scientific and medical activities involving human genes and embryos, the Civil Code explicitly establishes prohibitions through determinate norms: actions must not violate ethical principles or harm public interests. This aims to "confirm specific behavioral patterns already clearly defined by existing legal provisions through other rules." The importance of definitive norms is self-evident. However, even the definitive norms of the Civil Code remain insufficient to regulate human gene editing practices and activities, failing to resolve all legal issues arising from the application of this technology. Therefore, given the current scarcity of relevant laws, the relatively low hierarchical status of regulations, and legislative lag, the aforementioned situation cannot be improved in the short term. Consequently, "even after relevant laws, administrative regulations, and national provisions become relatively complete, the three fundamental bottom lines—human health, ethics and morality, and public interest—remain indispensable."

4 Systemic Limitations of the Civil Code in Regulating Human Embryo Gene Editing Technology

4.1 Ambiguity in Defining the Subject Matter: Uncertain Legal Attributes of Human Genes

China's existing legal norms do not define the legal nature of human genes after embryo gene editing, and academic circles hold diverse views on this matter. The property rights theory posits: "Once genes are separated from the individual, they acquire the functions and value of property, meeting the legal criteria for being treated as objects and thus qualifying as objects of rights." Some scholars advocate the personality rights theory, arguing that "genes can only function optimally within the human body to sustain life. Even when separated from the body, they retain the genetic code of that organism and remain closely linked to the individual's personality interests, including dignity, health, and privacy." Based on this, some scholars propose using "legal subjecthood and its volitional capacity" as the determining criterion, arguing that the legal attributes of human genes vary depending on different circumstances. This perspective can be summarized as the typology distinction theory. Regardless of which of these three views is analyzed individually, they still face limitations imposed by legal principles—such as the prohibition against commodifying human body parts—and issues like uncertainty in rights attributes due to the conflation of subjective and objective standards.

4.2 Insufficient Rights Protection: The Absence of Genetic Rights in the Civil Rights System

Violating relevant civil legal provisions constitutes both the prerequisite for bearing civil legal liability and the basis for civil subjects to seek civil remedies and protection of civil rights. Analyzing the relevant provisions of Article 1009 of the Civil Code reveals its strong macro-level and broad nature, which easily disrupts the balance between exercising rights and fulfilling obligations. The requirement to "comply with laws, administrative regulations, and relevant state provisions" typically involves matters under administrative management, bearing little relation to the protection of private rights under civil law. In the "gene-edited babies" incident, He and others were not held liable under civil law. Under the semantic framework of "harming human health," where violations of the aforementioned provisions do not result in damage to private rights, civil remedies are unnecessary. In such cases, treating regulatory violations as infringements on private rights would constitute excessive protection of private rights.

5 Systematic Pathways for Improving Civil Law Regulation of Human Embryo Gene Editing

5.1 Clarifying the legal Attributes of Human Genes

Existing theories—personality rights theory, property rights theory, and typological distinction theory—each have their merits. Integrating the strengths of these three approaches, some scholars propose a dual-rights theory, arguing that "while human genes are indeed imbued with the sacred and inviolable dignity of personality, under the premise of biotechnology development and deepening medical research, the personality ethics of human genes also conceal an inalienable property interest." "Only by confronting the composite interests of personality rights and property rights inherent in human genes can we effectively establish corresponding dual protection mechanisms." Considering the inherent personality and property attributes of human genes, the need for adequate remedies for relevant parties, and theoretical feasibility, the author proposes adopting a dual-attribute theory for the legal nature of human genes. Human genes inherently possess dual attributes of personality rights and property rights. Therefore, the dual-attribute theory aligns more closely with reality, better accommodates the development of the times and technological progress, and establishes two distinct legal avenues for rights remedies and protection for entities involved in human gene editing activities. This approach facilitates the construction and refinement of corresponding rights protection systems and frameworks.

5.2 Refining the Regulatory Framework for Related Civil Rights Protection Systems

Existing legal norms do not explicitly stipulate genetic rights. Legal codification of genetic rights is a practical necessity to balance rights and obligations and promote the sound development of human embryo gene editing technology. "Genetic rights constitute a cluster of rights composed of various sub-rights, with each type containing distinct sub-rights. Genetic rights will continue to evolve and expand with practical development." Among the numerous applications of gene editing technology, human embryo gene editing is the most compelling, riskiest, and most controversial. Given the inadequacy of legal norms for gene editing within the civil legal system, it is imperative to address public concerns, safeguard the rights of relevant parties, and meet the practical demands of contemporary social development. This necessitates prioritizing and elaborating on specific rights related to genetic rights, including the right to informed consent, genetic privacy rights, genetic autonomy rights, and rights to benefit sharing. "The right to informed consent refers to the right of a gene provider to fully understand their genetic information, decide whether others may use it, and seek damages for violations of their genetic rights." This approach facilitates researchers' fulfillment of disclosure obligations while ensuring the principle of autonomy is integrated throughout genetic editing activities. "Although genetic privacy rights resemble existing civil privacy protections, they fundamentally differ by incorporating the unique attributes of modern genetic technology, necessitating distinction from traditional privacy concepts. Genetic autonomy primarily refers to an individual's right to self-determination regarding their genetic information." The establishment of genetic autonomy rights can achieve a balance between respecting natural persons' autonomy and advancing scientific and technological development, while also facilitating the protection of gene-related information. The creation of benefit-sharing rights is significant for mitigating conflicts between gene providers and researchers, thereby promoting social fairness and justice.

6 Conclusion

The advancement of human embryo gene editing technology presents unprecedented challenges to China's civil law while continuously driving innovation and development in civil law theory. Article 1009 of the Civil Code, as the core provision regulating human embryo gene editing, establishes fundamental principles and baseline rules, thereby delineating legal boundaries and red lines for technological advancement. However, the existing regulatory framework still faces limitations in areas such as ambiguous characterization of the subject matter, inadequate rights protection, and challenges in remedial pathways. Building upon the Civil Code's provisions concerning gene editing, subsequent legislation should further clarify the legal status of human genes and embryos and establish a system of genetic personality rights. This will foster a more systematic and comprehensive regulatory framework for human embryo gene editing under civil law, providing stronger institutional support for safeguarding the development of emerging technologies and protecting human life and health rights.

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