

Legal Regulation of the Use of Human Genetic Information

--A Perspective on the Protection of Privacy

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Abstract

The rapid development of genetic engineering has brought many benefits to the world in the fields of biomedicine, energy and new materials, but it has also brought new challenges to the existing legal system. Focusing on risk prevention and the legal regulation of the confidentiality of human genetic information, this study proposes legal regulation of the confidentiality of existing human genetic information based on a comparative analysis of domestic and international jurisprudence. Based on an in-depth study of the legal mechanisms and experiences of the use of genetic information at home and abroad, combined with the jurisprudence within existing regulations and the impact of society on genetic information incidents, as well as the current discussions and research on the legal concept of genetic information privacy as an individual right in China, we will develop a system of procedural and substantive regulation of the use of genetic information as an individual right China's regulation of human genetic information as an individual right The system of procedural and substantive regulation of the use of human genetic information as an individual right aims to fill the gaps in the existing special law on the protection of the privacy of personal genetic information.

Keywords

Human genetic information; Genetic privacy; Boundary of rights; Legal protection.

1. Overview of Genetic Privacy

1.1. Genes and genetic rights

The term "gene" is derived from the phonetic translation of the English word "gene", which in biology is a collective term for a specific sequence of nucleotides in a DNA molecule (deoxyribonucleic acid) that has a genetic effect. The human gene is the most fundamental concept and basic unit of every human being, storing information on almost all life processes such as growth, development and apoptosis, and determining a person's physical appearance, health, growth and development, as well as personal and biological identity, resulting in a complex biological, legal, political and economic identity.

The study and application of the human genome has led to a new understanding of genetic rights as a result of the various rights and interests associated with human genes. Gene rights are a set of rights arising from the genetic information contained in genes, including primarily property, use, enjoyment, transfer and personal rights, including the right to genetic equality, the right to genetic privacy, the right to genetic property and the right to genetic patents. In this paper, genetic rights are classified as substantive personality rights, so we consider and study genetic personality rights as genetic rights from this perspective.

1.2. The concept and characteristics of genetic privacy rights

As part of the genetic rights of the human body, the boundaries of protection of the right to genetic privacy are constantly affected by the development of genetic technologies and the challenges of the era of big data. Genetic information obtained through genetic interventions on the human body belongs exclusively to the individual and contains unique genetic information in the form of specific genetic segments or mapping data. Genetic privacy, a cross-cutting area of genetic privacy protection, is also rich and varied.

(1) Complexity and diversity of content. In terms of the specific content of genetic privacy, genetic privacy comprises at least three rights: the right to physical privacy, the right to information privacy and the right to property privacy, which are interrelated and together are considered to constitute the entirety of genetic privacy.

(2) These rights are complex. They relate to genetic information, which is highly identifiable and whose biological characteristics can be easily detected. At the same time, an individual's genetic privacy is reproducible and heritable, affecting close relatives and even entire families, from which people cannot escape and which will remain with them throughout their lives.

(3) Self-determination. The exclusivity of a person's genes gives him the right to decide for himself whether to be informed of medical tests such as genetic sequencing, fertility tests, genetic screening and disease management, and whether to disclose them or request confidentiality to protect his rights and dignity.

2. Current Status of Genetic Privacy Protection in China

The application of genetic information is developing in the fields of science and technology, medicine and health, and biotechnology, and genetic information is being disclosed one by one, mainly in terms of privacy protection. For example, in the field of medicine, medical institutions in some parts of China now allow genetic testing of patients. Genetic testing involves analysing a person's genetic information to understand their physical and psychological state and to predict their risk of disease and health problems. However, as the right to privacy of personal genetic information is a new type of personal interest, it is currently under-protected under current Chinese law and there are a number of legal loopholes.

2.1. Legal definition of the right to privacy of personal genetic information

In China's existing laws and regulations, the concept of personal genetic information privacy is not clearly defined and is generally understood as a special kind of privacy. However, the lack of a clear definition of the right to privacy of human genetic information in China has led to many disputes over the application of the law in judicial practice due to different understandings of legal issues such as the elements of infringement of the right to privacy of human genetic information and the subject of tort liability.

The Civil Code combines the provisions on the "protection of personal data" with the right to privacy, which represents the rights of individuals, making it clear that the right to privacy and the right to protection of personal data are two parallel personal rights and interests. Article 1034 (3) of the Civil Code states that "the provisions on the right to privacy shall apply to personal data contained in personal data or, in the absence of such provisions, to the provisions on the protection of personal data". This is made clear in that provision. Thus, in the absence of a separate specific law on genetic rights, such as the Human Genetics Act or the Gene Technology Act, conflicts between different norms can arise in China.

2.2. The legal system is fragmented, hard to articulate between sectoral laws

At present, the scope of the protection of the privacy of human genetic information in China's relevant laws and regulations is limited to the Measures for the Administration of the Safety of

Genetic Engineering, the Measures for the Administration of the Collection, Removal and Trading of Human Genetic Resources, the Regulations on the Authorized Use of Human Genetic Resources Collection and Trading Units and other relevant administrative regulations. There are few other laws and regulations related to the protection of the privacy of human genetic information; therefore, the protection of the privacy of human genetic information in China is currently not uniform.

2.3. The protection and remedial system genetic information is not perfect

The rapid development of genetic technology has left many "legal loopholes" that need to be filled. Since 1993, China has introduced laws and regulations on genetic safety, such as the Essentials of Quality Control for Clinical Research on Human Somatic Cell Therapy and Gene Therapy, the Interim Measures for the Management of Human Genetic Resources, and the Measures for Ethical Review of Human Biomedical Research, which stipulate that personal information of subjects cannot be disclosed to third parties without permission. While there are provisions allowing for this not to be done and providing for adequate compensation and satisfaction for subjects, the positive impact on medical research has been very limited. However, the question of whether subjects can share in the positive property benefits of medical research is not addressed and the associated sanctions and remedies are unclear. For example, in a 2015 case where genetic material (samples) containing human genetic information was illegally taken out of China and genetic information leaked, the Ministry of Science and Technology only issued an administrative fine for "destroying the samples and rectifying the situation", with no specific fine and no accountability for those involved. The Ministry of Science and Technology only issued administrative penalties such as "destroy the samples and rectify the situation within a certain period of time" to the company.

3. Extraterritorial Models of Genetic Privacy Protection

3.1. US Data Privacy Laws

As the birthplace of privacy theory, the United States has been an early adopter of the right to genetic privacy and has adopted specific laws and regulations to protect this right. The US federal government and a number of states have passed specific laws to protect genetic privacy: the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Genetic Information Nondiscrimination Act of 2008 ("GINA"). The Genetic Information Nondiscrimination Act ("GINA") and the Americans with Disabilities Act ("ADA") were passed in 2008. "ADA" is among others. The privacy provisions of these laws govern the use and disclosure of patients' medical records and health information (including genetic information) by health care providers and their business partners. As the initial focus in the US was on the combination of personal and physical characteristics, genetic privacy is no longer isolated, but extends to the protection of genetic, health and developmental interests. In the US, genetic privacy covers information about an individual's physical characteristics, personal behaviour and physical disabilities, and does not allow the collection and sale of genetic information without consent.

The protection of genetic privacy in the United States is also reflected in the reasonable limitations on an individual's genetic privacy rights, which provide that human genetic privacy is a fundamental right protected by law with broad, strong and equal protection. Despite the apparent comprehensiveness of the system, the protection of genetic privacy is not systematic due to the complexity of the legislation, the difficulty of implementation, the difficulty of communication between the different statutes, the absence of a detailed scheme and a coherent system conditioned by precise provisions, the aim of the legislator being primarily to solve current personal problems. It is necessary to borrow dialectically from.

3.2. The EU's GDPR system

In 1995, the EU adopted the Directive on the Processing of Personal Data and the Free Movement of Persons, which formalised personal data as a right, and in 2018, the EU adopted the General Data Protection Regulation (GDPR), which protects the right to privacy as a fundamental human right, including personal life, physical condition and biological information. It covers all aspects and is of great importance for European countries and even the world. With a clear definition of genetic information, enhanced supervision of data users and protection of data subjects, the genetic privacy of individuals is protected in data undertakings and the protection of genetic privacy in the EU has been very effective.

Taking into account the experiences and shortcomings of other countries, Chinese lawyers should pay attention to the emergence of genetic privacy as a new type of law, encourage a revision of the Genetic Privacy Law, promote the legislative process of genetic privacy, and ensure that our laws and regulations can be harmonized with the rapidly developing society and economy.

4. How to Optimise the Protection of Genetic Privacy in China

4.1. Clarify the legal status of genetic privacy rights

Clarifying the legal status of genetic privacy and protecting it as a special civil right is an important way to address the current lack of legislation on the protection of genetic privacy in China.

Firstly, the characteristics of human genetic information as a personal interest should be clarified in the civil code so that human genetic information is not subject to different degrees of restriction and control depending on its source, content or purpose; secondly, human genetic information should be clarified as a new type of legal subject and given sufficient rights and interests; thirdly, the content and scope of protection of the right to privacy of human genetic information should be legislated. For example, it should be defined as the interests of natural persons, legal persons or other entities that are closely related to the human body, that may benefit it and that may be tolerated by society in the interaction between the human body and the environment.

4.2. Promote legislation that adequately protects the right to privacy

With the gradual proliferation of data and the computerisation of genetic information, privacy is becoming a reality. The complexity and diversity of privacy invasion issues, the technical nature of privacy invasion methods and the confidentiality of In addition to the invasion of personal privacy, there are also information platform service providers, government departments, enterprises or legal persons who can easily access and profit from big biological data, including personal genetic privacy information, through data collection and analysis. Therefore, it is necessary to formulate specific and operable legal rules to regulate research activities related to biological sample banks, promote the formulation of a genetic law, clarify the rights and obligations of the parties and research subjects, improve the procedures related to the collection, use and destruction of genetic information, and guide and control the government to sign agreements on the protection of samples and genetic information at various stages to protect legitimate rights and interests.

4.3. Prohibit illegal genetic testing

Genetic testing is a product of technological progress, but it can also infringe on citizens' right to privacy to a certain extent. To avoid invasion of privacy and social biosecurity problems caused by loss of genetic information, voluntary collection and taking of personal genetic samples for analysis, transfer and disclosure of genetic information without written consent,

illegal genetic testing and disclosure, strict control of the source of personal genetic samples, secret genetic testing, uninformed collection of genetic information and inappropriate disclosure of personal genetic information without knowledge.

4.4. Establishment of a reasonable opt-out mechanism

Considering that the properties and characteristics of human genetic information are complex and obvious, that the subject of genetic information is the genes involved, and that genetic information data constitute personal privacy, there is no doubt that the moral interests of holders of genetic information are protected, but there is no doubt as to whether property interests are included, including the dominant position of property interests, the scope of sanctions, the limits of rights, and how to justify and legitimise them through morality. There is still considerable disagreement. A comprehensive mechanism for the release of genetic information, from anonymisation to the destruction of samples, must therefore be established.

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