Legal Bases of Preimplantation Diagnostics in Russia and Abroad (A New Look At The Human Rights System)

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Abstract

The article shows the influence of modern assisted reproductive technologies on the content of basic human and civil rights and freedoms. The prospects for liberalizing preimplantation genetic testing are considered as an example. It is emphasized that the Russian legislation is completely silent about this technology, bringing regulation to the level of bylaws and approved clinical recommendations. An example of establishing a legal regime for preimplantation genetic testing in the European Union countries (France, Germany, Norway) is presented. In each country, it is the laws that determine the conditions and basic procedure for using preimplantation diagnostics. Restrictions have been introduced, according to which such diagnostics are used exclusively for medical purposes if there is a real risk of developing a congenital incurable disease in the unborn child, who is infected with artificial insemination. In conclusion, recommendations for improving the Russian legislation are presented.

Keywords: legal genomics, preimplantation genetic testing, assisted reproductive technologies, artificial insemination, human rights, regulation.

1. INTRODUCTION

Assisted reproductive technologies (ART) are firmly embedded in our lives, changing many basic human rights. Thus, cloning technology (if applicable to humans) extends the right to recognition of legal personality by providing it with a genetic copy of the individual. Surrogacy changes the principle that came to us from Roman law – "the mother is the one who gave birth", besides introducing differences in the concept of mother, dividing it into genetic and biological, adding to this list also a potential oocyte donor. Rapid development of genomic technologies, which resulted in the possibility of editing the genome of the unborn using a relatively simple CRISPR/Cas9 (*clustered, regularly interspaced, short palindromic repeats) model.*

Preimplantation gene diagnostics takes its place in this series of short stories (PGD is a term used abroad, but in Russia it is more often used differently – preimplantation genetic testing, which should be considered as identical concepts), a single concept that combines all types of analysis of hereditary germ cell material carried out before their implantation in the uterine wall. The emergence of threats of updated eugenics, which aims this type of testing not only to identify genetic anomalies, but also to implement the principles of genetic hygiene, leads to the consolidation of serious restrictive measures in many countries

2. METHODS

The study used the comparative legal method, methods of description, interpretation, theoretical methods of formal logic, as well as private scientific methods: legal-dogmatic and the method of interpretation of legal norms.

3. RESULTS AND DISCUSSION

3.1. Legal regulation of preimplantation genetic testing in the Russian Federation

In the Russian Federation, the implementation of LRT is based on Article 55 of Federal Law No. 323-FZ dated November 21, 2011 "On the fundamentals of public health protection in the Russian Federation", which allows artificial insemination, surrogacy, cryopreservation of germ cells and some other methods of reproduction. At the same time, the Law is absolutely silent about preimplantation genetic testing (PGT) mentioned in the bylaw – Order of the Ministry of Health of the Russian Federation dated July 31, 2020, No. 803n "On the procedure for using assisted reproductive technologies, contraindications and restrictions to their use". But even in this case, there is only indirect confirmation of the validity of testing. Paragraph 10 stipulates that among the indications for IVF (in vitro fertilization) programs, one of the indications is a hereditary disease, "for the prevention of which preimplantation genetic testing is necessary." In the form of informed voluntary consent for medical intervention with the use of ART and artificial insemination also have a phrase with a person's request for PGT. For more details, the PGT procedure is described in the Clinical Guidelines (protocol of treatment) "Assisted reproductive technologies and artificial insemination" (sent by letter dated March 5, 2019 from the Ministry of Health of the Russian Federation No. 15-4/I/2-1908). However, this document is an instruction for doctors, the main issues should be resolved in the law, namely: its admissibility, conditions, forms of control, registration of each case. The Russian legislation sees the PGT as a standard procedure that does not carry risks and threats. This is indirectly by the National Strategy for Women 2017-2022, approved by the Order of the Government of the Russian Federation dated March 8, 2017. 410-p, indicating the expansion of GTP in the framework of improving access to health care for women and girls.

There is also no mention in the Federal Law dated July 5, 1996. No. 86-FZ "On state regulation in the field of genetic engineering". Initially, it did not apply to the application of genetic engineering methods to humans, but in 2000 a landmark addition was made to article 1 (which defines the scope of the Law), according to which gene diagnostics and gene therapy in relation to humans falls under its regulation.

In Russian legal science, there is a wary attitude to the limitlessness of urban settlements, characterized by debatable from an ethical point of view (Vasilyev et al., 2020). It is indicated that the use of PGT in conjunction with CRISPR/Cas9 allows editing the human genome for various purposes (Benston, 2016; Tuzhilova-Ordanskaya & Akhtyamova, 2021). The commercialization of the sensitive medical field is increasing, and so much so that a new field can be represented – "commercial genomics" (Doronina et al., 2020). In addition, in 2017, an international research team from the Oregon Health and Science University in Portland (USA) published successful results of correcting a genetic defect that causes severe hereditary heart muscle disease as part of germ-line therapy at the earliest stages of human life during artificial insemination (Ma et al., 2017).

A. V. Maleshina cites some North American states as a negative example, where it is allowed to advertise PGT not in order to detect genetic diseases, but to solve the issue of the unborn child's gender, which may be dictated by the desire to "balance the family" (Maleshina, 2017). Such liberalism contributes to the development of reproductive tourism, although it is justified not so much by any purposefulness, but by public attention to everything that will limit the artificial termination of pregnancy (Bayefsky, 2016).

E. E. Bogdanova develops the gap in Russian legislation in this area, considering that such a regulatory defect could lead to discriminatory risks. Further to this point: Article 3.1 of the Federal Act dated November 24, 1995 No. 181-FZ "On the social protection of disabled persons in the Russian Federation" declares the inadmissibility of discrimination on the basis of disability, which is in accordance with article 3 of the United Nations Convention on the Rights of Disabled Persons (adopted by General Assembly resolution 61/106 dated December 13, 2006).

Detection of diseases in PGT will lead to the rejection of embryos, and therefore to the impossibility of their development into a fetus and subsequent birth. If the PGT is completely free, the culling can be based not only on the presence of a serious genetic disease (which in itself is considered by many experts to be a controversial definition) but also the presence of mutations that are likely to lead to possible serious diseases in the future. So, in medicine, it has been determined that mutations in the brca1 and brca2 genes are a genetic factor of cancer - breast cancer in women. The symbol of preventive mastectomy has become Angelina Jolie, who gave her act public publicity (Jolie, 2013). E. E. Bogdanova. said: "the Recognition of the birth of a child is wrongful (incorrect) in essence means the recognition by government that can be legally assess: whether people with physical disabilities their place in society; whether it's functional limitations are substantial enough to admit that it was preferable not to be born" (Bogdanova, 2021). This position is consistent with many international

assessments. T. S. Petersen notes: "And the use of PGD will lead to increased injustice, stigmatization and discrimination against people with disabilities" (Petersen, 2005). T. M. Crane believes that the solution to the ethical dilemmas that arise when regulating access to PGD is not even to restrict access to certain tests and technologies, but to create a targeted policy in which the medical community dictates that women should avoid pregnancy that leads to the birth of children with a genetic disease. This, in turn, may lead to the recognition of such behavior by a woman who burdens society with children with certain genetic conditions as egoism (Krahn, 2011). R. Collier agrees with him (Collier, 2012).

There is another problem – a change in the nature of informed voluntary consent for any medical intervention, the mandatory receipt of which is explicitly indicated in article 20 of the Federal Law "On the Basics of Public Health Protection in the Russian Federation". At the same time, the health professional should provide information in an accessible form about the goals, methods of providing medical care, the risk associated with them, possible options for medical intervention, its consequences, as well as the expected results of providing medical care. DNA decoding prior to the birth of a child provides a likely prognosis for the child's future life. The medical worker is thus assigned an unusual function to carry out "scientific divination" on the topic of the probability of occurrence of certain diseases and conditions, the presence of potential opportunities (and vice versa, their absence). A certain euphoria that is present from the achievements that are made public by geneticists can force you to make a decision about continuing the course of pregnancy, based on the likely prognosis. Their actual implementation will depend not only on the genome of the child, but also on the social factors that will surround human development. Such a dilemma will be faced by parents, and in the context of an increasing search for comfort in their personal lives, it can lead to making a decision based on supposedly "altruistic" motives – to make life easier for their unborn child. Thus, the parents will decide the child’s fate for themselves (Romanovsky & Romanovskaya, 2021). In this case, the separation of diagnostic and social criteria will be very problematic.

3.2. Legal regulation of prenatal gene diagnostics in the European Union

Biomedical technologies in France were actively developed in the late 90s of the last century. A certain impetus in the emergence of basic legal acts in the field of biomedicine was given by the political decision of the President of France F. Mitterrand on the establishment of the National Advisory Committee on Ethics and Life Sciences and Health Care (https://www.ccne-ethique.fr) (Decree of the President of France dated February 23, 1983 No. 83-132 "On the establishment of the National Advisory Ethical Committee on Life Sciences and Health"). The formation of a platform for public discussions and the development of professional solutions on complex ethical issues still affects the development of a unified policy in this area.

The first document adopted in France in the field of biomedicine should be considered the Law dated July 29, 1994 No. 94-654 "On donation and use of elements and products of the human body, procreation with medical care and prenatal diagnostics" (https://www.legifrance.gouv.fr), although it was preceded by serious public debate, which continued after its adoption (Ray, 2001). Already in this document, among the key areas of innovative medicine, subject to special regulation was the reference to prenatal gene diagnosticsy and the use of its results in prognostic medicine (Menezo, 2004). Subsequently, when health legislation was clarified and bioethics acts were adopted (in 2004, 2011, and 2021), preimplantation gene diagnostics was not excluded from the scope, but was subject to additional details. A distinction was also made between prenatal gene diagnostics (primarily non-invasive) (Duguet & Boyer-Beviere, 2017). Moreover, article 511-20 of the French Criminal Code establishes criminal liability for conducting prenatal diagnostics without obtaining the permission specified in the Public Health Code (2 years in prison and a fine of 30,000 euros, article 511-20). The basic approach is that PGD is exclusive in nature.

Germany has a long-standing Embryo Protection Act - Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG) (http://www.gesetze-im-internet.de). It should be noted that it has rarely been amended (the last time was in 2011), which allows many authors to characterize it as conservative, and the German situation with embryo protection is "unique and contradictory" (Krones & Richter, 2004). In addition, the German legislator followed the path of adopting independent laws regulating certain areas of biomedicine that affect the status of the embryo, but with amendments to the Law on Embryo Protection. Such acts include: The Law on the Regulation of Preimplantation Diagnostics (Gesetz zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG (https://www.buzer.de/)), thanks to which Section 3a appeared in the Embryo Protection Act. The adoption of the law was preceded by a federal court decision that acquitted the gynecologist who conducted such studies in relation to couples during the implementation of ART (Bettina Bock von Wülfingen, 2016).

The general rule is based on the fact that preimplantation diagnosis is a criminal offense, for which a prison sentence of up to three years or a fine is provided. Only in cases of high risk of serious hereditary diseases to the offspring due to genetic predisposition women, from which the ovum, or men, from which, the sperm, or both of them, with the written consent of the woman, which occurred egg "cells of the embryo can be studied *in vitro* on the basis of risk of this disease in accordance with the generally accepted standards of medical science and technology, to intrauterine transfer". It is also possible to perform preimplantation diagnostics with the written consent of the woman from whom the egg originated, in order to determine serious damage to the embryo, which is highly likely to lead to stillbirth or miscarriage.

The law sets out the conditions for preimplantation diagnosis:
- conducting consultations (providing information and giving recommendations on the medical, psychological and social consequences of genetic testing of embryo cells) with a woman;
- approval of the ethics committee in the center that can perform preimplantation diagnostics;
- diagnostics can only be carried out in specialized centers and only by a qualified doctor;
- mandatory documentation of all stages.

The Federal Government prepares a report on the experience of preimplantation diagnostics every four years. Based on the submitted documentation and anonymous data, the report contains the number of events held annually, as well as their scientific assessment.

Legislation of Norway is an example of strict regulations regarding the regulation of biomedical technologies, which focus on the Norwegian Biotechnology Act of 2003 (full name - "Law on the Use of biotechnology in Medicine, etc.") (https://lovdata.no). It was preceded by Law No. 56 dated August 5, 1994 "On the use of biotechnologies in medicine" (https://lovdata.no). In Norway, preimplantation diagnostics can only be performed for medical reasons in the case of probable transmission of a severe hereditary disease to the newborn, when the participants in the ART program (one or both) are carriers of a severe monogenic or chromosomal hereditary disease. It is forbidden to carry out genetic modification of the embryo. The medical organization submits a full report to the Ministry of Health and Medical Services on the implementation of diagnostics. The Ministry establishes additional rules for conducting the examination, establishes a list of indications for diagnosis;
– special requirements are imposed on the organization that implements regulated biomedical technologies (it is planned to submit a regular report on its activities).
It should be noted that Norwegian legislation consistently follows the path of introducing additional bans in the field of genetic technologies. For example, the main restrictions on preimplantation diagnostics were introduced after 2016. Discriminatory risks of expanding preimplantation diagnostics, as well as prenatal gene diagnostics, are constantly discussed in the professional environment (Johannessen et al., 2017). In the same year, medical professionals were prohibited from notifying relatives of a patient's genetic disease without their consent, which is generally supported by the medical community (Von Krogh et al., 2016). The scope of information that should be provided to the patient during genetic studies has been expanded (Prescott, 2016).

It should also be noted that a different stance aimed at liberalizing PGA rules is gaining ground in the countries of the European Union. Accusations in advertising "children under order" are considered false. Practice shows that couples going to PGA make informed choices related solely to medical purposes (Braude et al., 2002).

4. SUMMARY

A comparative legal study has shown that very complex issues that are subject to comprehensive public discussion do not find their legislative consolidation in the Russian Federation. This conclusion is primarily applicable to preimplantation genetic testing. Caution is not caused by the technology itself, but by the social prospects that can become a reality with the full liberalization of this technology. Practice confirms this conclusion. The US experience shows that in addition to detecting serious genetic diseases, in the absence of restrictions, medical clinics at least offer a choice of the gender of the unborn child.

5. CONCLUSIONS

To address the identified gaps, it is necessary to amend Federal Law No. 323-FZ dated November 21, 2011 "On the Fundamentals of Public Health Protection in the Russian Federation" and Federal Law No. 323-FZ dated July 5, 1996, No. 86-FZ "On state regulation in the field of genetic engineering". It is necessary to determine the target basis of PGT, introduce restrictions for clinics participating in ART programs, and also fix the obligation to maintain a report on each PGT procedure and submit it to the relevant ministry.

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