



Legal Regulation of Diagnostic Technologies in the Sphere of Human Reproduction: the Balance of Ethics and Law

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Abstract: The article analyzes the legal regulation of diagnostic technologies in human reproduction, focusing on non-invasive prenatal testing (NIPT). It examines the ethical and legal dilemmas arising from the introduction of this technology, including the balance between reproductive autonomy and non-directive counseling, the problem of “wrongful birth” and “wrongful life,” and the risks of eugenic selection and discrimination against persons with disabilities. Through a comparative legal analysis of the regulatory frameworks in the Russian Federation and some foreign countries, the study identifies distinct national models for balancing ethical principles and legal imperatives. The article highlights the progressive steps taken by the Russian Federation in providing accessible reproductive care, such as the inclusion of NIPT in state guarantees. The purpose of this article is to systematically evaluate the ethical-legal nexus of diagnostic reproductive technologies and to substantiate doctrinally sound pathways for enhancing national regulatory frameworks without compromising sovereign constitutional values.

Keywords: human rights; legal ethics; legal regulation; human reproduction; legal engineering; diagnostic technologies; non-invasive prenatal testing (NIPT); invasive prenatal testing (IPT); preimplantation genetic diagnosis (PGD); diagnostic reproductive technologies (DRT); comparative bioethics; constitutional values

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I. Introduction

The availability and rapid advancement of diagnostic technologies in human reproduction has fundamentally transformed traditional approaches to the diagnosis, prevention, and treatment of numerous hereditary human diseases. Concurrently, the medical application of genetic testing raises a number of ethical, legal, and social issues that require consideration and the development of approaches to address them in order to maximize the benefits of these new healthcare methods. The evolution of diagnostic reproductive technologies (DRT) — ranging from fundamental prenatal ultrasound screening to preimplantation genetic testing (PGT) and non-invasive fetal DNA analysis — has created unprecedented opportunities for assessing reproductive health and preventing hereditary diseases. However, the implementation of these technologies is associated with a complex set of legal and ethical issues that require a systematic approach. Non-invasive prenatal testing (NIPT), also known as cell-free fetal DNA screening, is a rapidly advancing technology that continuously expands its capabilities and offers new approaches to fetal medicine. According to some authors, NIPT

is at the “forefront of genomic medicine.” Since 2011, NIPT has been commercially available in more than 60 countries (Allyse et al., 2015). DRT have advanced rapidly over the past three decades, evolving from screening for single-gene disorders to complex polygenic risk assessment, non-invasive prenatal testing, and the integration of artificial intelligence into embryology laboratories (Frolova et al., 2012; Lebina et al., 2025; Simon and Rubio, 2017). Humanitarian ethics and law are the two primary regulators of the use of reproductive technologies for human reproduction.

NIPT offers several advantages over the traditional combined first-trimester screening, which includes ultrasound examination and serum markers. It can be performed earlier in pregnancy (from 9–10 weeks), it is considered more accurate in detecting common chromosomal aneuploidies, it has a lower false-positive rate and reduces the number of invasive tests that carry a small risk of miscarriage (Gil et al., 2015; Taylor-Phillips et al., 2016). Regulatory frameworks cannot ignore the ethical norms; humanitarian ethics and jurisprudence serve as the two primary, synergistic regulators of reproductive technologies. Ethical norms ensure a universal standard of judgment regarding the acceptability of medical interventions, mitigating risks associated with potential discrimination or eugenic selection. The goals and means of applying modern technological solutions in human reproduction encompass not only legal regulation, but also inevitably touch upon ethical parameters, which can be challenging to resolve. Universal ethical guidelines for the application of diagnostic technologies in human reproduction are essential as a factor embodying equal judgment in understanding what is acceptable and unacceptable, what is right and what is wrong. The central hypothesis of this study posits that a critical examination of the current legal and ethical frameworks governing NIPT reveals significant disparities between technological capabilities, societal expectations, and regulatory responsiveness. The purpose of this article is to systematically evaluate the ethical-legal nexus of DRT and to substantiate doctrinally sound pathways for enhancing national regulatory frameworks without compromising sovereign constitutional values.

II. Methodology

This study employs a comparative legal method and a systematic review of empirical literature to analyze regulatory frameworks and their impact on patient autonomy. The formal-legal method is applied to systematically interpret the normative framework of the Russian Federation governing DRT. This involved a detailed analysis of the Federal Law No. 323-FZ “On the Fundamentals of Health Protection of Citizens in the Russian Federation,” dated 21 November 2011 (as amended), subordinate acts of the Ministry of Health of Russia, and Decree of the Government of the Russian Federation No. 2188, dated 29 December 2025, which incorporated NIPT into the Programme of state guarantees of free medical care for the years 2026–2028. The comparative-legal method is employed to analyze the regulatory approaches to diagnostic reproductive technologies in Germany, the United Kingdom, France, the Netherlands, Belgium, and Japan. These jurisdictions illustrate contrasting ways of balancing reproductive autonomy, embryo protection, and the prevention of eugenic practices. The case-law analysis method is used to assess the practical application of legal norms and to illustrate liability for deficiencies in prenatal diagnostics. The interdisciplinary approach integrates insights from bioethics, medical sociology, and disability studies to provide a comprehensive understanding of the ethical and social dimensions of NIPT regulation.

III. Regulatory Framework for Prenatal Diagnostics in the Russian Federation

The rapid development of diagnostic technologies in human reproduction has raised fundamentally new questions for the legal system and bioethics. The Russian Federation has established a comprehensive legal framework for diagnostic reproductive technologies, grounded in the Constitution of the Russian Federation and Federal Law No. 323-FZ “On the Fundamentals of Health Protection of Citizens in the Russian Federation,” dated 11 November 2011. Current legislation defines the organization of medical care, licensing requirements, and the rights of

patients, creating a stable basis for the implementation of new technologies.

Diagnostic testing of pregnant women as well as the prevention and treatment of diseases and conditions, is considered medical care, requiring the use of specialized methods and complex medical technologies. Due to the Order No. 185n of the Ministry of Health of the Russian Federation, dated 11 April 2025, specialized medical care, including high-tech care, may be provided in medical and other organizations within the state, municipal (in the cases that state authorities of constituent entities of the Russian Federation transfer the authority to organize the provision of specialized medical care to local self-governments), and private healthcare systems. A medical organization should have a license to carry out medical activities, obtained in accordance with the legislation of the Russian Federation on licensing certain types of activities.

Diagnostic testing in the form of screening is a comprehensive examination of a specific category of pregnant women aimed at identifying specific pathologies. Screening is only the first step in assessing pregnant women, who, if positive, require further testing to establish a definitive diagnosis or rule it out. Screening is especially important in the first trimester of pregnancy, as it allows for the identification of women who require more targeted testing — this will help rule out or promptly detect serious pathologies.

By an appellate ruling of the Stavropol Krai Court No. 33-8852/2018, dated 20 November 2018, the non-governmental healthcare institution “Office Clinical Hospital at Mineralnye Vody Station of Joint Stock Company “Russian Railways” was awarded moral damages in the amount of 300,000 rubles (increased from 200,000 rubles awarded by the decision of the Mineralnye Vody City Court of Stavropol Krai). This was based on the fact that the medical organization limited itself to conducting a first-trimester ultrasound screening and did not refer the pregnant woman for additional testing. According to the plaintiff, these deficiencies in the provision of medical care to the pregnant woman led to the fact that congenital anomalies in the fetus were not detected on time, which is why she was deprived of the opportunity to terminate the pregnancy before 20 weeks. The birth of a child with severe develop-

mental disabilities (the child is considered disabled from birth and for life), as well as the difficult struggle for their life, causes severe emotional suffering for both the child and their entire family. Furthermore, the child's rehabilitation program requires significant financial investments from the family (for example, transportation costs to medical interventions, etc.), which are not reimbursed. During the trial, it was also established that the ultrasound screening was performed by a doctor who did not have the appropriate qualifications.

In accordance with the current legal regulation of diagnostic researches for pregnant women are carried out in the form of screening — prenatal (antenatal) screening. Due to the Order of the Ministry of Health of Russia No. 747n "On the Procedure for the Provision of Medical Care in the Profile of "Obstetrics and Gynecology," dated 19 December 2025 prenatal (antenatal) screening is carried out for all women in the following gestational periods: in the 1st trimester — 11 weeks 0 days — 13 weeks 6 days; in the 2nd one — 18 weeks 0 days — 20 weeks 6 days; in the 3rd one — 34 weeks 0 days — 35 weeks 6 days, an assessment of the antenatal development of the fetus is carried out (Clause 27).

The 1st-trimester screening evaluates fetal antenatal development to detect various fetal pathologies, including congenital and/or hereditary diseases, fetal malformations, and signs of genetic disorders. The physician also assesses the risk of chromosomal abnormalities, premature birth, preeclampsia, and fetal growth restriction. Ultrasound screening during 11–14 weeks of pregnancy assesses fetal antenatal development to identify chromosomal abnormalities, malformations, the risk of fetal growth restriction, premature birth, and preeclampsia (preeclampsia in multiple pregnancies). The results of the screening study are reflected in the screening ultrasound protocol.

At the same time, the physician conducts a study of plasma protein A (PAPP-A) in the blood serum and the level of human chorionic gonadotropin (free beta subunit) in the blood serum (free HCG) (hereinafter referred to as serum markers). At this stage, the plasma protein A (PAPP-A) in the blood serum of the pregnant woman and the level of human chorionic gonadotropin (free beta-subunit) in the blood serum (free — HCG) (serum markers) are also tested. Based on the re-

sults of this test, the woman can be assigned to one of three risk groups: 1) a high-risk group for giving birth to a child with chromosomal abnormalities of 1:100 and above; 2) an average-risk group — 1:101-1:1000; 3) a low-risk group — 1:1001 and below. Pregnant women from the 1st group — average-risk and the 2nd one — high-risk (except in cases where signs of a fetal malformation are detected based on the results of a 1st-trimester screening ultrasound) are recommended to undergo a non-invasive prenatal test — NIPT (determination of cell-free fetal DNA from the mother's blood).

NIPT has become widely used in clinical practice in Russia. However, scholars and experts raise ethical concerns regarding the use of NIPT based on the values of free choice, autonomy, and voluntary informed consent of women, avoidance of harm, as well as equality, justice, and inclusivity. On the one hand, NIPT can promote reproductive autonomy by giving women (parents) the opportunity to prepare for the birth of a child with a genetic disorder or to decide on an early termination of pregnancy. On the other hand, it can violate autonomy and freedom of choice if accurate and balanced information about the test and the conditions being tested for is unavailable, and they are unable to assess the risks of potential pathologies for the unborn child (Baranova et al., 2024, pp. 15–16). Experts point out that many women refuse to undergo screening tests due to lack of awareness, lack of knowledge, inability to assess the consequences, and also due to the high cost of the procedure (Zhuchenko et al., 2017, p. 12). Foreign experts see a certain risk in the reliability of test results, which can contribute to excessive anxiety in the expectant mother (parents) and the unnecessary use of invasive procedures (Gekas et al., 2016, p. 16; O'Keeffe and Doyle, 2025, p. 492).

NIPT is of particular importance for pregnant women, it has become widely used in clinical practice in Russia to diagnose chromosomal abnormalities of fetuses (Gnetetskaya et al., 2018). NIPT can detect an increased risk of the most common chromosomal abnormalities, primarily Down syndrome, as well as Edwards and Patau syndromes. More advanced versions of the test evaluate more complex anomalies, and NIPT can also determine the fetus's sex and, in some cases, the Rh factor.

Although, until 2026, it was provided on a paid basis and was not included in the state system of free medical care guarantees. Some regions of the Russian Federation financed this type of screening for pregnant women from their regional budgets. The Programme of state guarantees for the free provision of medical care to citizens for 2026 and for the planning period of 2027 and 2028, approved by Decree of the Government of the Russian Federation No. 2188, dated 29 December 2025, provides for the implementation of NIPT on a free basis. We believe that this legislative approach will facilitate the early detection of fetal abnormalities, which is clearly aimed at ensuring public health, consistent with the constitutional right of everyone to health protection and access to medical care, and consistent with the principles of health protection, primarily the observance of citizens' rights in the area of health protection and the provision of state guarantees associated with these rights, and the principle of access to high-quality medical care.

To ensure the quality of medical care, the order establishes qualification requirements for the physician and the organization performing this procedure. The assessment of antenatal fetal development during the first two diagnostic researches (at gestational ages of 11 weeks 0 days to 13 weeks 6 days and 18 weeks to 20 weeks 6 days) is performed by ultrasound specialists who have completed advanced training in ultrasound diagnostics in the sphere of ultrasound diagnostics of fetal development (prenatal screening). For the third diagnostic research, the pregnant woman is referred to a medical organization that monitors the pregnancy and is licensed to perform medical activities, including ultrasound diagnostic work (services). If the medical organization where the pregnancy is monitored does not have a license to carry out medical activities that include ultrasound diagnostic work (services), the pregnant woman is referred to the antenatal fetal care office (department) for prenatal screening in the third trimester.

Based on the results of the 1st-trimester screening, a geneticist and obstetrician-gynecologist may recommend additional research — invasive prenatal testing (IPT) for a pregnant woman in the following cases: 1) if signs of fetal malformations are detected; 2) if a high risk of giving birth to an infant with chromosomal abnormalities is established, 3) the risk of giving birth to an infant with chromosomal abnormalities

based on the results of a NIPT, as well as an increased risk of monogenic and/or chromosomal abnormalities in the fetus (based on the anamnesis), regardless of whether the 1st screening was performed. IPT is performed by using the following methods: chorionic villus sampling, placental biopsy; amniocentesis; cordocentesis.

Due to the result of IPT, if a severe somatic disease is detected that is included in the List of medical indications for artificial termination of pregnancy, approved by Order No. 736 of the Ministry of Health and Social Development of the Russian Federation, dated 3 December 2007, the woman is referred for the appropriate operation. In such a situation, it is important for the woman (parents) to understand the possible risks of developing a somatic disease, which influences her decision to terminate the pregnancy that is ensured by the explanatory activity of the physician (council of specialists) who are responsible for the health of the unborn child and mother. Due to the Order of the Ministry of Health No. 742n if chromosomal abnormalities, congenital and/or hereditary diseases, genetic disorders or developmental defects of the fetus are detected, the further tactics of monitoring the course of pregnancy are determined by a perinatal concilium.

Russian researchers note the fragmentation of legal regulation and the lack of a systematic approach to diagnostic reproductive technologies (Lapaeva, 2021; Nekoteneva et al., 2024). This fragmentation is particularly evident in the absence of a unified federal law specifically governing DRT, with crucial aspects scattered across various departmental acts and orders of the Ministry of Health. For instance, there is currently no federal law-defined basis or explicit list of cases in which a treating physician should refer a pregnant woman for screening tests; these relationships are predominantly regulated by sub-legislative acts. This creates ambiguity and potential inconsistencies in practice. We suppose that it would be appropriate to include provisions on the need to conduct screening tests for pregnant women, indicating the gestational period (in weeks and days) and a list of grounds for their appointment in Chapter 6 “Health Protection of Mother and Child, Family and Reproductive Health Issues” of the special Federal Law No. 323-FZ “On the Fundamentals of Health Protection of Citizens in the Russian Federation,” dated 21 November 2011.

An important ethical and legal aspect of screening is the legal nature of informed patient consent. According to Federal Law No. 323-FZ, a prerequisite for screening is the patient's signature of informed voluntary consent to medical intervention based on information provided by a healthcare professional. This information must be presented in an accessible form. An important characteristic of the information provided is its completeness and accuracy, including information about the consequences and risks of refusing screening. Information must be presented in an accessible form. An important characteristic of the information provided is its completeness and accuracy, including information on the consequences and risks of refusing screening tests.

According to the legal position formulated by the Constitutional Court of the Russian Federation in Resolution No. 1-P, dated 13 January 2020, the right to privacy also entails a state-guaranteed right to control one's own information and prevent the disclosure of personal, intimate information, including health information. Legislators are obligated to ensure that all third parties respect an individual's will in matters relating to their private life.

By giving consent, the patient does not expect a guaranteed therapeutic effect, but rather delegates to the healthcare organization the right to intervene in the sphere of bodily autonomy in order to obtain probabilistic data about their health. At the same time, the patient may not have a full understanding of the consequences of refusing to undergo the necessary diagnostic procedures, the capabilities of a particular type of diagnostics, the severity of their condition, etc.

The complexity of informed consent in the context of diagnostic testing stems from several factors: 1) *cognitive complexity of the information* — patients should understand the probabilistic nature of genetic testing results, distinguish between diagnostics and screening, and recognize the limitations of each method; 2) *emotional burden* — decisions about diagnostic testing and the interpretation of its results are made under time pressure and high emotional involvement; 3) *long-term consequences* — diagnostic results can influence decisions about continuing the pregnancy or choosing embryos for transfer, which has lifelong consequences for the unborn child.

The fundamental principle of legal regulation of diagnostic tests in human reproduction requires consideration of their intended purpose — ensuring the health of the unborn child and eliminating developmental pathologies and hereditary genetic diseases. Diagnostic methods for reproductive health care used for screening must be convenient, affordable, and sensitive enough to detect early stages when the patient is asymptomatic, without leading to overdiagnosis. Regulatory frameworks should ensure the accessibility of this type of screening for prospective parents, either by including it in the state's mandatory health insurance program or by reducing its cost.

IV. Regulatory Models for Prenatal Diagnostics and Embryo Status

The foundational issue determining the legal framework governing diagnostic reproductive technologies, particularly preimplantation genetic diagnosis, is the legal status attributed to the human embryo. As V.V. Lapaeva emphasizes, “it is necessary to develop a legal regime for in vitro embryo manipulation that ensures the necessary legal protection of the embryo by recognizing its special ontological status as a constitutional value for the common good” (Lapaeva, 2023, p. 4). According to the researcher, the status of the embryo can be considered from different positions — ontological, moral and legal, and approaches to understanding its moral and legal status are formed depending on the definition of the ontological status of the embryo. In this case, we do not have in view so-called embryonic models created for research purposes. This proposition reflects a broader doctrinal challenge: the legal system must simultaneously accommodate the embryo's biological potential, its moral significance, and the practical realities of biomedical innovation. Consequently, the legal status of the embryo cannot be reduced to a binary classification (subject v. object), but rather requires a differentiated and context-sensitive regulatory approach.

The legal status of the human embryo remains one of the most contested issues in biomedical law, reflecting divergent cultural, religious, and ethical traditions across nations. Across jurisdictions, the regulation of diagnostic reproductive technologies reveals not merely diversity

in legislative techniques, but the existence of distinct normative paradigms that structure the relationship between reproductive autonomy, human dignity, and the protection of potential life. These paradigms may be analytically understood as coherent regulatory models, each grounded in specific constitutional, ethical, and socio-cultural premises.

The German model represents a paradigmatic example of a dignity-centered regulatory framework. The legal status of the embryo in Germany is shaped by the Embryo Protection Act (*Embryonenschutzgesetz*, 1990), the Stem Cell Act (*Stammzellgesetz*, 2002), and the constitutional jurisprudence of the German Federal Constitutional Court (*Bundesverfassungsgericht*) interpreting the Basic Law (*Grundgesetz*). The Embryo Protection Act fundamentally prohibits any use of a human embryo that does not serve its preservation. Under the Act, it is a criminal offense to fertilize a human egg for any purpose other than initiating a pregnancy in the woman who produced the egg. This provision effectively prohibits the creation of embryos for research purposes and the use of embryos for scientific investigation.

Complementing this strict embryo governance, the German model for non-invasive prenatal testing (NIPT) is characterized by a cautious approach that balances reproductive autonomy with the constitutional principle of human dignity, enshrined in Art. 1 of the Basic Law. Since 2021, NIPT has been covered by public health insurance for pregnancies with an increased likelihood of trisomies 21, 18, and 13, without defining a numerical risk threshold; reimbursement is case-by-case, based on potential serious harm to the pregnant woman's mental health (Perrot and Horn, 2022). Publicly funded NIPT for T13, T18, and T21 is suggested, with a focus on individualized decision-making and increasing usage since its introduction. The German system does not define a numerical risk threshold. Instead, reimbursement is determined on a case-by-case basis, requiring a particular situation where the pregnancy and its consequences present a burden that could lead to serious harm to the pregnant woman's mental health (Perrot and Horn, 2022). The German debate emphasizes the woman's right not to know and her right to decline available tests, as well as the importance of providing balanced information that includes the perspectives of families raising

children with disabilities. A key feature of the German approach is the conceptualization of a potential conflict between the dignity of the unborn child and the dignity of the pregnant woman as an autonomous individual, a framing that reflects Kantian philosophical influences and post-war constitutional sensitivities (Perrot and Horn, 2022).

In contrast, the United Kingdom embodies an autonomy-oriented regulatory model, characterized by institutionalized flexibility and regulatory pragmatism. The Human Fertilisation and Embryology Act 1990 (as revised in 2008) and the oversight of the Human Fertilisation and Embryology Authority (HFEA) construct the embryo as a special legal entity subject to controlled use rather than absolute protection. This framework constructs the embryo as a special entity — neither a person nor a piece of property — subject to permitted uses under licensing oversight. UK legislation avoids conferring full personhood on embryos while prohibiting their treatment as mere property. The 1990 Act establishes that embryos may be used for licensed research purposes, but prohibits their use for unauthorized purposes, including reproductive cloning and sex selection except for medical necessity.

Regarding prenatal diagnostics, NIPT was introduced as a second-tier test within the NHS Fetal Anomaly Screening Programme, with access granted to women those combined first-trimester screening indicates a risk threshold of 1:150 or higher for trisomies 21, 18, and 13 (Perrot and Horn, 2022). NIPT was proposed for T13, T18, T21 screening in 2015 and officially implemented from 2018, available free for women with high-risk pregnancies, with a strong emphasis on accurate information and informed choice. The British debate places a strong emphasis on informed consent and non-directive counseling, reflecting an autonomy-focused approach. A 2017 report by the Nuffield Council on Bioethics highlighted concerns that the less invasive nature of NIPT could lead to routinization, potentially undermining informed decision-making (Perrot and Horn, 2022). Public discourse in England tends to favor the benefits of NIPT, while critical voices, including those from disability advocacy groups, have raised concerns about the devaluation of people with Down syndrome. However, these concerns have not substantively altered policy, as the value accorded to women's autonomous choice remains predominant (Perrot and Horn, 2022). From a

theoretical legal perspective, this approach aligns with the concept of contextual legal idealism where the law discerns principles that explain and justify existing legislative rules. The principle that best explains and justifies the approach in the UK legislation to the developing human is adherence to the proportional status position. The law grants increasing protection to the developing human according to legally relevant thresholds, such as preimplantation, implantation to 24 weeks, post-24 weeks, and birth. This principle is a direct implication of the Principle of Generic Consistency (PGC), which requires agents to act in accord with the generic rights possessed by all agents. Since the PGC is categorical and it is not strictly possible to know whether another is an agent, all others must be treated according to strict moral precaution. It follows that those others who display sufficient characteristics and behavior to be meaningfully treated as agents must be treated as possessing generic rights, while those who display only some of the characteristics and behavior expected of agents, such as a fetus, must be treated as possessing interest-rights to the generic needs. Where there is a conflict of duties, agent-behavers have full moral status and partial agent-behavers have lower moral status. This lower moral status is proportionate to the closeness to being an agent-behaver.

In the Japanese regulatory framework for human embryos is notable for its absence of comprehensive statutory law governing embryo research. Instead, governance operates through administrative guidelines and professional self-regulation, reflecting a cultural preference for flexible, consensus-based policy development rather than rigid legislative mandates. The Act on Special Provisions of the Civil Code (Act No. 76 of 2020) addresses parent-child relationships in assisted reproduction, but does not establish a substantive legal status for the embryo itself. Importantly, the Japanese jurisdiction lacks a unified “embryo protection law.” The definition of an embryo is contained in the Act on Regulation of Human Cloning Techniques (Act No. 146 of 2000) and defines it as cells that have the potential to develop into a human being. The embryo occupies an intermediate conceptual space — neither fully personified nor reduced to ordinary property — requiring respectful treatment without conferring rights equivalent to born persons. Recent scholarship highlights Japan’s proactive stance in developing

regulatory frameworks for stem cell-based embryo models (SCBEMs) (Sawai et al., 2025) in EMBO Reports document Japan's efforts to "take the lead in developing ethical and innovative guidelines" for SCBEM research, distinguishing these models from fertilized embryos while maintaining ethical oversight. Regarding NIPT, it was introduced in Japan in 2013, with uptake increasing since then. However, there is no comprehensive policy, and it is primarily offered out-of-pocket, making it expensive and mainly recommended for high-risk pregnant women.

Further differentiation emerges within European jurisdictions that have integrated NIPT into publicly funded healthcare systems, notably France, the Netherlands, and Belgium. Although these systems formally endorse reproductive autonomy, their practical implementation reveals significant variation shaped by institutional design and socio-cultural context.

In France, NIPT has been reimbursed since 2019 as a second-tier test for pregnancies with a trisomy 21 risk probability between 1:51 and 1:1000 following first-trimester screening (Perrot and Horn, 2022). NIPT was initially implemented for T21 and occasionally T13/T18 with public insurance support and expanded in 2020 to cover rarer aneuploidies via private labs, being free for high-risk pregnancies. The French regulatory framework explicitly states that "the woman is at the center of the system and makes all decisions regarding her pregnancy," emphasizing respect for autonomy. However, in practice, the French approach is characterized by a more protective stance, with greater emphasis on the content of information provided to women rather than on non-directiveness *per se*. The National Ethics Committee (CCNE) has expressed concerns about the commercial exploitation of genetic tests and the risk of leaving couples "alone and helpless" when confronted with non-validated tests (Perrot and Horn, 2022). Empirical studies confirm a degree of paternalism among French healthcare professionals regarding prenatal testing decisions. Criticisms of NIPT in France are notably framed in the language of "eugenics," "elimination," and "social eradication," with both religious and secular voices warning against the risk of widespread fetal selection. These critiques, while vociferous, have not prevented the integration of NIPT into public healthcare, but they reflect a societal unease with the potential normalization of ge-

netic selection that is less pronounced in the English context (Perrot and Horn, 2022).

Comparative empirical research on pregnant women's decision-making in the Netherlands and Belgium — both early adopters of NIPT as a first-tier screening test — further illuminates how country-specific contexts influence informed choice (Lannoo et al., 2023, p. 301). The Netherlands implemented NIPT as a publicly funded screening program in 2014 for high-risk pregnancies, and expanded it to all pregnant women in 2017, leading to high uptake rates and a decline in combined first-trimester tests. Despite geographical proximity and similar healthcare system structures, significant differences emerged. In the Netherlands, 83 % of women opting for NIPT made an informed choice (defined as a decision based on sufficient knowledge, value-consistency, and adequate deliberation), compared to only 59 % in Belgium (Lannoo et al., 2023, p. 299). Dutch women demonstrated higher knowledge scores (94 % v. 82 %), higher deliberation scores (87 % v. 70 %), and were more likely to report that they did not feel societal pressure to accept screening (88 % v. 77 %). Conversely, Belgian women were more likely to perceive those parents are judged by society for having a child with trisomy 21 (42 % v. 16 %) and were less positive about the quality of care and support available for children with trisomy 21 (23 % v. 62 %) (Lannoo et al., 2023, p. 299). These differences likely reflect variations in counseling modalities — the Netherlands mandates a standardized 30-minute counseling session with a certified provider, while counseling in Belgium is less structured — as well as divergent cultural attitudes toward disability and reproductive choice. Belgium was the first country to publicly reimburse NIPT as a first-tier screening test for all pregnant women, leading to a 52 % decrease in invasive procedures. The Belgian cohort also demonstrated a higher intention to terminate pregnancy in case of confirmed trisomy 21 (62 % v. 51 %), but a lower intention for trisomy 18 or 13 (73 % v. 80 %), suggesting potential gaps in understanding the severity of these conditions (Lannoo et al., 2023, p. 300).

Other European countries also present diverse regulatory landscapes. Denmark, for instance, saw NIPT become available as a screening option in 2013, with guidelines revised in 2017 to include it as a standard screening test for high-risk pregnancies. In Italy, NIPT was

incorporated into clinical use for T13, T18, T21 screening in high-risk pregnancies after a pilot study in 2016, though it is largely used in the private sector. Switzerland has seen increased NIPT use since 2012, with public funding since 2019 for limited medical reasons, while Slovenia offers NIPT only when invasive procedures are contraindicated, with public funding for such cases. Romania, notably, provides NIPT as a self-financed commercial option.

In the Russian legal system, the regulation of diagnostic reproductive technologies reflects an evolving and multi-layered approach grounded in constitutional principles and sectoral legislation. Researchers note that “an embryo *in-vitro* lacks viability and is therefore different from a fetus in the womb; however, it has the potential to develop life, which also distinguishes it from an object” (Lapaeva, 2021, p. 184). In this regard, scientists are reiterating the need for legislative recognition of the distinction between the status of an *in vivo* and *in-vitro* embryo, which meets the requirements of legal certainty (Dovnar, 2025; Frolovskaya and Bondarenko, 2025; Muravyova and Eliseeva, 2023; Plotnikova, 2022; etc.). The lack of a unified approach to determining the legal status of an embryo creates difficulties in regulating diagnostic procedures related to embryo biopsy for preimplantation genetic testing, cryopreservation and use of embryos for research purposes, and determining the fate of “excess embryos.” A new direction — bioethical constitutionalism has emerged in Russian legal doctrine, examining the impact of new biotechnologies on their implementation of human rights and the transformation of the concept of human rights itself (Kravets et al., 2023; Kravets, 2023; 2025).

Taken together, comparative analysis demonstrates that contemporary legal systems do not converge toward a single model of regulation. Instead, they articulate different configurations of fundamental principles — human dignity, autonomy, solidarity, and the protection of a potential life — each of which is institutionalized through specific legal mechanisms. At the same time, a degree of convergence can be observed at the level of general trends: the rejection of treating the embryo as a mere object, the recognition of the centrality of informed consent, and the increasing role of procedural safeguards in legitimizing reproductive choices. These shared elements suggest the gradual formation of a

transnational normative framework, within which national systems retain their distinct identities while responding to common technological and ethical challenges.

V. Ethical and Legal Dilemmas in Reproductive Diagnostics: Harmonization and Future Directions

The rapid integration of NIPT into contemporary healthcare systems necessitates a re-evaluation of the normative foundations underpinning legal regulation in the field of reproductive diagnostics. The complexity of this regulatory domain does not merely rest on the technological sophistication of diagnostic tools, but on the multidimensional nature of the values at stake, including reproductive autonomy, human dignity, the protection of potential life, and the principle of non-discrimination.

A central issue emerging across jurisdictions concerns the structural tension between reproductive autonomy and the requirement of non-directive counselling. While NIPT significantly expands the informational horizon available to prospective parents, thereby strengthening their capacity for autonomous decision-making, this expansion simultaneously generates risks of routinization. When screening becomes embedded in standard medical protocols, the voluntariness of consent may become formal rather than substantive. Consequently, the legal concept of informed consent must be interpreted not as a procedural formality, but as a substantive communicative process, requiring that patients are equipped to understand the probabilistic nature of genetic information, the limitations of testing, and the ethical implications of potential outcomes.

This leads to the recognition that autonomy in the context of reproductive diagnostics is inherently relational rather than purely individualistic. Decision-making is shaped not only by medical data, but also by social narratives surrounding disability, cultural expectations, and the perceived responsibilities of parenthood. Therefore, legal frameworks must ensure that counselling practices remain genuinely non-directive while also sufficiently informative, enabling a form of autonomy that is both informed and reflective.

A second major doctrinal challenge concerns liability for deficiencies in prenatal diagnostics, commonly articulated through the concepts of “wrongful birth” and “wrongful life.” The comparative analysis demonstrates that legal systems adopt differentiated approaches to these claims, reflecting deeper philosophical divergences regarding the valuation of life with disability. While claims for wrongful birth are increasingly recognized as a mechanism for protecting parental autonomy and compensating informational harm, the recognition of wrongful life claims remains far more contested due to the inherent difficulty of comparing existence with non-existence within a legal framework. This tension illustrates the limits of traditional tort law when applied to the domain of reproductive technologies and suggests the need for a more nuanced doctrinal approach that distinguishes between informational harm, reproductive choice, and the intrinsic value of human life.

A third area of concern relates to the potential for implicit forms of eugenic selection arising from the widespread use of highly sensitive screening technologies. Importantly, contemporary regulatory systems do not endorse eugenics in its classical, coercive form. However, the combination of technological capability, social expectations, and systemic incentives may produce conditions under which certain reproductive choices become indirectly normalized. The ethical discussion surrounding NIPT also involves the problem of societal pressure that pregnant women may experience. As the scholars note, even before the advent of NIPT, parents of children with Down syndrome faced questions about whether it “could have been avoided” (Liehr, 2024, p. 893). The widespread use of NIPT and high societal expectations regarding its reliability amplify this pressure, compelling women to undergo testing and, in the event of a positive result, to consider terminating the pregnancy. This societal dimension, alongside the inequality in NIPT accessibility due to its high cost and lack of universal public funding in many countries, underscores the necessity of developing legal and ethical frameworks that protect a reproductive choice from hidden forms of coercion and ensure equitable access to services (Liehr, 2024, p. 893). This phenomenon underscores the importance of embedding the principle of non-discrimination, particularly with regard to persons with disabilities, within the regulatory framework governing diagnostic tech-

nologies. The objective is not to restrict a reproductive choice, but to ensure that such a choice is exercised within a normative environment that affirms the equal value of all human lives.

In light of these challenges, comparative analysis reveals the emergence of distinct regulatory models that may be conceptualized along a spectrum. At one end lies an autonomy-oriented model, which prioritizes an individual choice and emphasizes non-directive counselling as the primary safeguard. At the other end lies a dignity-oriented model, which places greater weight on the protection of the unborn and seeks to prevent practices that may undermine the moral status of human life. Between these poles, hybrid models attempt to reconcile competing values through procedural safeguards, public funding structures, and differentiated access to testing based on medical indications.

The evolution of regulatory approaches suggests that no single principle can serve as an exclusive foundation for legal governance in this domain. Instead, an integrated normative framework is required — one that simultaneously accommodates autonomy, dignity, solidarity, and justice. Within such a framework, the role of law is not limited to permissive or prohibitive regulation, but extends to the structuring of conditions under which ethically responsible decision-making can occur. From this perspective, the development of diagnostic reproductive technologies should be understood as a catalyst for the refinement of legal doctrine rather than a challenge to its coherence. The task of the legislator and the legal scholar is to ensure that the normative architecture of regulation evolves in parallel with technological innovation, preserving the balance between individual rights and collective ethical commitments.

The introduction of NIPT and other diagnostic reproductive technologies gives rise to several profound ethical and legal dilemmas. First, there is a need to balance reproductive autonomy with the requirement of non-directive counselling. While NIPT can enhance autonomous decision-making by providing timely information that allows parents to prepare for the birth of a child with a genetic condition or to consider termination of pregnancy, inadequate or unbalanced information may undermine genuine autonomy (Baranova et al., 2024; Perrot and Horn, 2022).

Second, the problem of “wrongful birth” and “wrongful life” arises. Russian judicial practice, as illustrated by the Stavropol case, recognizes the right of parents to compensation for moral harm when inadequate diagnostics deprive them of the opportunity to decide on pregnancy termination in cases of severe fetal abnormalities. However, claims brought by the child (“wrongful life”) have not yet been recognized in Russian law, in contrast to certain European jurisdictions.

Third, there exist risks of eugenic selection and discrimination against persons with disabilities. Experts highlight concerns that the widespread use of NIPT, grounded in values of a free choice and informed consent, may nevertheless contribute to societal devaluation of lives with disabilities if counselling fails to adequately address issues of equality, justice, and inclusivity (Bowman-Smart et al., 2023).

Furthermore, the prevalence of false positives and negatives in NIPT necessitates careful interpretation and a robust follow-up. The global experience highlights the critical need for well-trained healthcare professionals and comprehensive, unbiased counseling to ensure informed decision-making. Cultural, religious, and socioeconomic factors significantly impact the acceptance and accessibility of NIPT, demanding tailored approaches to policy and funding.

VI. Conclusion

The development of diagnostic reproductive technologies, particularly NIPT, presents a dynamic landscape that continually challenges existing legal and ethical systems. Striking a thoughtful balance among reproductive autonomy, the prevention of hereditary diseases, and the protection of the rights of persons with disabilities is paramount. Comparative analysis reveals diverse approaches across legal systems, each reflecting their unique underlying values and priorities in navigating this complex terrain. The Russian legal framework is actively evolving, and to further strengthen its comprehensive approach and alignment with best international practices, several key areas offer significant opportunities for enhancement.

A crucial pathway for advancement lies in the development of a unified federal law dedicated to diagnostic reproductive technologies.

Consolidating existing regulations, currently found across various departmental acts and orders, into a single, comprehensive legislative instrument would provide greater clarity, consistency, and a more systematic framework for the field. Furthermore, clarifying the legal status of the embryo through explicit legislative recognition of the distinct considerations for *in vivo* and *in vitro* embryos is essential. This would move beyond binary classifications to provide a nuanced approach to regulating procedures such as preimplantation genetic testing, cryopreservation, and addressing the disposition of “excess embryos.” The standardization of genetic counseling practices is another vital step. Establishing mandatory, high-quality, and non-directive pre- and post-test genetic counseling standards would ensure that individuals receive comprehensive and accurate information. This includes detailed explanations of NIPT variants, the significance of fetal fraction, a clear interpretation of Positive Predictive Value (PPV), and the potential for false positives and negatives, all delivered by independent, qualified specialists. Building upon the existing foundation of including NIPT in state guarantees, enhanced accessibility and integration of NIPT into public health programs are crucial. This involves clearly defining which population groups and medical indications are covered by the state funding, thereby ensuring broad and equitable access to these valuable diagnostic tools. Finally, while directly addressing concepts like “wrongful life” may remain a subject of ongoing debate, exploring robust legal mechanisms to provide fair compensation for informational harm in cases of medical negligence is imperative. Such measures would uphold principles of accountability for healthcare providers and protect parental autonomy, reinforcing trust within the medical system.

By proactively addressing these areas, Russia can further advance its reproductive diagnostics landscape, ensuring responsible progress. This comprehensive regulatory paradigm should continue to balance individual autonomy with collective ethical commitments, ensuring equitable access and an informed choice within a framework that upholds human dignity and actively prevents discrimination against persons with disabilities. The ongoing development of a coherent and comprehensive regulatory approach, informed by comparative experience and

grounded in bioethical principles, is essential for ensuring both legal certainty and the enduring protection of human dignity in the context of rapidly advancing reproductive technologies.

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