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Law and biomedicine: Main risks, new approaches to regulation

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Abstract. Biomedical technologies have advanced rapidly in recent decades, impacting human nature itself and reshaping the surrounding social environment according to new principles. These developments carry significant implications for law and public policy, highlighting the importance of legal research in regulating biomedical innovation. This article explores the transformation of traditional legal principles in family and inheritance law, focusing primarily on surrogacy under the influence of reproductive technologies. The concept of biolaw is introduced as an integration of law and biomedicine, alongside the emerging interdisciplinary field of neurolaw, which studies how advances in neurobiology influence jurisprudence. Key areas of interaction between neurobiology and law include the development of judicial practice, legislative reform informed by neuroscience evidence, and shifts in the general theory and philosophy of law. Philosophical ideas about constructing future societies grounded in biomedical achievements – proposed by thinkers such as F. Fukuyama, E. Toffler, A. Bard, and J. Söderqvist – are discussed. The article highlights certain central public concerns: social control, biologically based hierarchies, renewed eugenics, and discriminatory practices. It identifies biomedical technologies with potential to fundamentally transform society, the emerging risks they pose, and possible legal ramifications. Examples discussed include the creation of artificial wombs and genome editing, both of which may have applications beyond biomedicine for broader social purposes. The article also points out gaps in Russian legal regulation and presents the results of a comparative legal study, culminating in general recommendations for improving Russian legislation.

Key words: legal regulation, neurolaw, ectogenesis, DNA, genomic technologies, CRISPR/Cas9

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Право и биомедицина: основные риски, новые подходы в регулировании

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Аннотация. Биомедицинские технологии, получив стремительное развитие в последние десятилетия, стали затрагивать саму природу человека, а также форматировать под новые принципы окружающую социальную среду. Эти процессы оказывают влияние на право и государственную политику, усиливая актуальность юридических исследований в области регулирования биомедицинских. Рассматривается трансформация традиционных правовых принципов в области семейного, наследственного права под влиянием репродуктивных технологий (наибольшее внимание уделено суррогатному материнству). Представлена концепция биоправа как результата интеграции права и биомедицины, а также новой области междисциплинарных исследований – нейроправа, в рамках которого изучаются возможности влияния достижений в области нейробиологии на юриспруденцию. Определены направления взаимодействия нейробиологии и права: формирование судебной практики; реформа законодательства на основе данных, полученных в области нейробиологии; изменения в общей теории и философии права. Представлены некоторые философские концепции построения общества будущего (Ф. Фукуямы, Э. Тоффлера, А. Барда и Я. Зодерквиста), основанные на достижениях биомедицины. Показано, что в центре общественного внимания находятся следующие потенциальные риски: установление социального контроля; ранжирование и иерархия на биологической основе; обновленная евгеника; дискриминационные практики. Выделены некоторые биомедицинские технологии, которые могут претендовать на принципиальные преобразования социума, возникающие риски, а также потенциальные правовые последствия. В качестве примера указывается на создание искусственной матки и геномное редактирование. Каждая из указанных технологий может быть использована в социальных целях (выходящих за пределы биомедицины). Обозначены пробелы в надлежащем правовом регулировании, которые характерны для российского законодательства. Проведено сравнительно-правовое исследование, на основе которого сформулированы общие рекомендации по совершенствованию российских правовых актов.

Ключевые слова: правовое регулирование, нейроправо, эктогенез, ДНК, геномные технологии, CRISPR/Cas9

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Introduction

Anthropogenic changes to the environment have produced significant effects, as evidenced by the intensity of public debate around climate change and reflected in international instruments and political initiatives addressing this issue. However, these environmental changes have generally not altered the biological essence of humans, leaving human nature essentially intact. This contrasts with the rapid development of biomedical technologies, which have drawn the attention of social scientists, including legal experts, because for the first time, human nature itself can be deliberately modified through targeted intervention.

The consequences of such innovations will affect numerous facets of social life, with law and the state often relegated to reactive roles. Early in this process, the boundaries of scientific creativity were tested primarily through a lens of almost unrestricted freedom, as reflected in Article 44 of the Constitution of the Russian Federation, which guarantees freedom of scientific creativity. Currently, the discourse is shifting toward imposing limitations and restrictions. In this context, jurisprudence occupies a critical position by defining the legal boundaries of permissible actions. This includes establishing regulations not only for medical professionals providing healthcare services but also for scientists conducting research, introducing permit requirements for certain developments and experiments, and setting penalties for violations.

Law and Modern Biomedicine: The state of the problem/Current challenges

Law itself is subject to change due to newly discovered technologies. For example, since the time of Justinian's Digest (Roman law), fundamental principles have been established that continue to influence current legislation: the mother is the one who gave birth; an absentee will not inherit; no one is punished for their thoughts. Although this list is not exhaustive, it demonstrates the profound impact biomedicine has had on jurisprudence. Consider some examples. Surrogacy has not only divided motherhood into three types – biological, genetic, and social (with further

possible fragmentation within these categories) – but it has also generated legal challenges that remain unresolved. A notable case involves children born to surrogate mothers in Russia for Chinese couples. Due to a perceived similarity between the legal regulation of this reproductive technology and the criminal offense of “human trafficking,” doctors from the European Surrogacy Center, LLC, received maximum prison sentences for operating commercial surrogacy programs¹. This case led to amendments in Federal Law No. 323-FZ of November 21, 2011, “On the Basics of Protecting the Health of Citizens in the Russian Federation”, which introduced restrictions on surrogacy participation for foreign citizens, as well as unmarried men and women.

Such legislative prohibitions are characteristic of the vast majority of countries. Moreover, the broad discretion of states in this matter has been upheld by relevant decisions of international courts. In particular, the European Court of Human Rights, in its judgment of July 8, 2014, in the case of *D. and Others v. Belgium* (Application No. 29176/13)², although it declared the case inadmissible due to its resolution by national courts, expressed its position that prohibitions and restrictions on children born through surrogacy programs abroad for couples in states where such technologies are prohibited are permissible, as these measure help prevents various crimes, including human trafficking.

The Grand Chamber of the European Court of Human Rights’ further addressed related issues in its January 24, 2017 decision in *Paradiso and Campanelli v. Italy* (Application No. 25358/12)³, which has intersections with the Russian Federation. In this case, an Italian couple used a surrogate mother in Russia but registered the child’s birth as their own. A subsequent investigation led to a criminal case against the couple on charges of forgery of civil status (Articles 489 and 567 of the Italian Criminal Code). Genetic testing showed no biological ties between the couple and the child. National courts prohibited the couple from asserting parental rights due to the absence of familial or legal connections. The European Court of Human Rights upheld the admissibility of such state measures. Of note is the opinion of Judge D.I. Dedov of the Russian Federation, who justified the illegality of the surrogacy arrangement by emphasizing that, for the first time, the Court prioritized fundamental values over formal discretion. The Court recognized that bans on private adoption and restrictions on surrogacy aim to protect children from illegal practices, including those amounting to human trafficking, which often occur alongside with surrogacy agreements.

Inheritance law has also been affected by new reproductive technologies, particularly in cases where an heir is born after the death of the testator. For example, in 2006, a child was born in Yekaterinburg via surrogacy to a deceased father who had cryopreserved his gametes during his lifetime. The grandmother acted as the client and

¹ Mashkin S. For children – not childish terms. Available at: <https://www.kommersant.ru/doc/6320759?ysclid=lri2zx9yd6291593546> (accessed: 12.12.2024).

² Bulletin of the European Court of Human Rights. 2014. No. 12.

³ Case of *Paradiso and Campanelli v. Italy*. Available at: <https://hudoc.echr.coe.int/eng#%7B%22itemid%22:%5B%22001-170359%22%5D%7D> (accessed: 12.12.2024).

later claimed to be the newborn's mother⁴. In 2021, the birth of a child using a frozen embryo in a surrogacy program was announced following the death of singer Yulia Nachalova in 2019⁵.

To prevent potential legal conflicts, several countries, including Germany and Italy, have banned posthumous insemination, while others have imposed time limits for claiming inheritance rights – some US states allow claims within two to three years following insemination after the testator's death. In the Russian Federation, despite recognizing the issue over 15 years ago, there remains no adequate legal regulation. The inheritance legislation (Part 3 of the Civil Code of the Russian Federation) has yet to be updated to address these developments.

Meanwhile, the concept of thoughtcrime, popularized by George Orwell's 1984, is becoming increasingly relevant in reality. The notion of "predictive justice," which is actively being implemented (the term is discussed in foreign literature, e.g., Rouvière, 2021, p. 101), extends far beyond assessing potential disputes based solely on prior judicial or administrative decisions. Similarly, "predictive policing" aims to prevent crimes before they occur. Between 2012 and 2014, algorithms were developed to assess crime risk relative to locations and potential victims, such as Predictive Policing (PredPol, Risk Terrain Modeling – RTM in the USA) and PreMap (Predictive Mobile Analytics for Police in Germany) (Mugari and Obioha, 2021). These algorithms rely on statistical data without attempting to identify perpetrators in advance; however, many scientists have expressed serious concerns about the potential risks (Hung and Yen, 2023). Further reflecting these concerns, courts in the Netherlands have banned the use of the System RiseCo Indicatie (SyRI) predictive algorithm, citing violations of privacy rights (Strikwerda, 2021).

Neuro-ID⁶ currently offers software products such as ID Orchestrator that generate recommendations on a person's *bona fides* based on individual behavioral characteristics, including facial expressions and body posture. The company's founders emphasize that final conclusions are derived from "behavior analysis and intent detection". Cognitec⁷, a company operating in a similar field, provides analysis of random person interactions. This enables the identification of individuals concealing their connections. Users of such services, including law enforcement agencies (to identify accomplices in cases such as terrorism) and large corporations (to detect fraudsters), frequently utilize products like FaceVACS-VideoScan.

A related development is the search for a "criminal gene", where DNA sequencing and biological characteristics are analyzed predisposition to criminal behavior. Courts are increasingly considering "behavioral genetic data" in both criminal and civil proceedings (Sabatello and Appelbaum, 2017). Notably, prosecution and defense often interpret the same generic data differently: prosecutors argue that it

⁴ A surrogate mother carried a child from a deceased father // *Komsomolskaya Pravda*. 2006. January 26.

⁵ Super learned about Yulia Nachalova's child, born after her death. Available at: https://super.ru/a/nachalova_rebenok (accessed: 12.12.2024).

⁶ Human Analytics for the Digital World. Available at: <https://www.neuro-id.com/> (accessed: 12.12.2024).

⁷ The trusted face recognition company since 2002. Available at: <https://www.cognitec.com/> (accessed: 12.12.2024).

suggests no possibility of rehabilitation and thus justify isolation, while defenses compare the presence of certain genotypes to legal insanity to challenge prosecution. High-profile US trials, such as those of Tony Mobley, Billy Joe Hall⁸, and Waldrup⁹, have centered on the issue of genetic predisposition to aggression, particularly in brutal murder cases.

Currently, these examples have not caused fundamental shifts in the global legal landscape. While biomedical technologies are spreading, their scale has yet to create significant risks or threats. This may particularly explain the cautious nature of Russian legal policies, with no significant federal laws in this domain. Such a minimalist regulatory approach grants some freedom to medical professionals and researchers. Simultaneously, ongoing advances in biomedical technologies and related fields are prompting deeper reflection on humanity's future, the nature of humans, and their biological essence. Emerging concepts will require legal codification, with law employing its full range of instruments – from incentives and protections to prohibitions and punitive measures – to ensure implementation. A feedback loop is developing: by influencing human nature and its core characteristics, biomedicine preordains changes in legal regulation. Social scientists agree that, in this dynamic, law often lags behind, merely reflecting existing realities, a tendency reinforced by law's inherent conservatism. Conversely, science, enriched by interdisciplinary connections, fosters promising new fields such as legal anthropology, biomedical law, neurolaw. These disciplines merit closer examination.

Neuroscience and Law

It should be noted that advances in biomedicine influence the very structure of law. In Russian jurisprudence, proposals for establishing a new field – biomedical law – were formulated relatively early (Sergeev, 2006). More recently, proposals have emerged advocating the development of biolaw (Mokhov, 2022), aligning with international trends that consider it a product of the integration of law and biomedicine, similar to bioethics (Vidalis, 2022). Furthermore, the process continues to evolve with the emergence of a new interdisciplinary field – neurolaw – which examines the potential impact of neuroscience advances on jurisprudence. In Russian scholarship, a direct link has been identified between biojurisprudence and neurolaw (Kravets, 2022). The interaction of neuroscience and law spans multiple areas:

1 The influence of Neuroscience on Judicial Practice. In many countries, brain scan evidence of individuals accused of crimes of varying severity increasingly affects sentencing decisions. Between 2014 and 2017, one pioneering figure was Kent Kiehl, a professor at the University of New Mexico, USA¹⁰, who secured grants to purchase mobile MRI units to scan the brains of young offenders. Kiehl also served as an expert in several high-profile cases involving “natural-born

⁸ Guy F. The Warrior Gene: Genetics and Criminology. Available at: <http://www.crimetraveller.org/2016/04/the-warrior-gene/> (accessed: 12.12.2024).

⁹ Hagerty B.B. Can Your Genes Make You Murder? Available at: <http://www.npr.org/templates/story/story.php?storyId=128043329> (accessed: 12.12.2024).

¹⁰ Kent A. Kiehl, Ph.D. Available at: <https://kentkiehl.com/> (accessed: 12.12.2024).

killers”¹¹. Initially, the connection between neuroscience and criminology was met with skepticism (Davis, 2014). However, there is no a gradual shift toward concepts such as “reintegrative justice,” which emphasizes rehabilitation over punishment; skepticism regarding the determinism of criminal behavior; and increased consideration of external risk factors influencing such behavior (Meynen, 2016). Continued evolution of legal practice in this direction could transform understandings of criminality, the causes of criminal behavior, and the penitentiary system as a whole. The number of court decisions recognizing neuroscience-informed perspectives is growing annually, exemplified by Australia’s dedicated Neurolaw Database¹².

2 Amending Legislation Based on Data Obtained in Neuroscience. One of the earliest examples of such legislative regulation is the French Law No. 2011-814 of July 7, 2011, On Bioethics¹³, which clarified provisions in the Public Health Code, the Civil Code, and other regulatory acts. Among the amendments, the French Civil Code was supplemented with Article 16-14: “Brain imaging methods may only be used for medical or scientific research purposes or in the context of a forensic examination”. Simultaneously, the Public Health Code authorized the Minister of Health to establish rules of good practice governing brain research. This provision allowed the use of anatomical (but not functional) brain imaging. However, the provision was met with criticism in scientific literature and the media. The main concerns included significant restrictions on individual autonomy (and the potential for personality modification), risks of discrimination, and skepticism toward neurodeterminism in legally assessing a citizen’s actions (Gkotsia et al., 2015). Due to such criticism, proposals to repeal the brain imaging regulations emerged as early as 2012. In 2013, the National Ethics Advisory Committee issued an official opinion on neurotechnology use, emphasizing that brain imaging data cannot replace a judge’s assessment within their competence¹⁴. In 2018, at the request of the French Government, a report on bioethics legislation changes was prepared, dedicating a section to neurolaw¹⁵. This contributed to the adoption of Law No. 2021-1017 of August 2, 2021, On Bioethics,¹⁶ which explicitly prohibits the use of functional brain tomography in forensic medical examinations.

¹¹ Gutowski Ch., Mills Brian St. Dugan gives 1st prison interview: “I could not stop” // *Chicago Tribune*. 2014. 13 Dec. Available at: <http://www.chicagotribune.com/news/ct-brian-dugan-serial-killer-interview-met-20141212-story.html> (accessed: 12.12.2024).

¹² Australian Neurolaw Database / https://neurolaw.edu.au/about_us (accessed: 12.12.2024).

¹³ Loi n° 2011-814 du 7 juillet 2011 relative à la bioéthique. Available at: <https://www.legifrance.gouv.fr/loda/id/JORFTEXT000024323102/> (accessed: 12.12.2024).

¹⁴ CCNE, 12 décembre 2013, avis n° 122, Recours aux techniques bio-médicales en vue de “neuro-amélioration” chez la personne non malade: enjeux éthiques. Available at: <https://www.ccne-ethique.fr/sites/default/files/2023-06/avis122.pdf> (accessed: 12.12.2024).

¹⁵ Étude à la demande du Premier ministre. Révision de la loi de bioéthique: quelles options pour demain? Étude adoptée en assemblée générale le 28 juin 2018 / <https://www.vie-publique.fr/files/rapport/pdf/184000450.pdf> (accessed: 12.12.2024).

¹⁶ Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique. Available at: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043884384> (date of access: 12.12.2024).

Another example of neuroscience influencing legislation is found in the 2014 Dutch Criminal Law Amendment, concerning the responsibility of young adults. The revised Article 77c of the Criminal Code¹⁷ permits judges to apply preferential provisions (typically reserved for those under 18) to offenders aged 18 and 23 if “grounds for doing so are found in the personality of the perpetrator or the circumstances under which the crime was committed”. Both prior to and after enactment, judges and legal scholars have cited brain research as the amendment’s basis (Schleim, 2020).

3 The Influence of Neuroscience on the General Theory and Philosophy of Law. This aspect is of particular relevance, as it raises philosophical questions that, in turn, lead to changes in the content or interpretation of fundamental legal principles. Since these principles form the foundation of the entire normative system, any significant modifications affect the entire sphere of law-making and law enforcement policy.

The growing impact of neuroscience – and other biological sciences – has contributed to the naturalization of normative science. This trend is increasingly integrated into modern risk frameworks and is encapsulated in P.D. Tishchenko’s concept of “biopower” (Tishchenko, 2001), where regulation is grounded in medical recommendations, and power acts as a conduit for ensuring healthcare objectives. These concerns are not new; Michel Foucault famously employed the term “biopower”, emphasizing that “the human race is the human species of the animal kingdom” (Foucault, 2011, p. 13). Foucault’s concept of biopolitics merges biological characteristics of human behavior with economic interests, creating a unified analytical framework (Foucault, 2010).

The growing popularity of behavioral economics, exemplified by its representative Richard Thaler – who received the Nobel Prize in 2017 – can be understood as a consequence of these ideas. Thaler and his colleague Cass Sunstein introduced the concept of libertarian paternalism (Thaler and Sunstein, 2017), which attempts to integrate economic theory with cognitive psychology (Thaler, 1985). Notably, the recommendations emerging from this school extend well beyond economics. First, they advocate a fundamental reform in public administration, envisioning the state as an “architect of choice” rather than imposing mandates. Second, they propose that “nudge” technology should be the primary societal tool, a strategy dependent on knowledge of human psychology and its biological foundations. Third, these principles imply that environmental and social transformations cannot occur without reforming key social institutions. Accordingly, Thaler and Sunstein identify education, healthcare, family relations, social insurance, and harm compensation as pivotal areas for future reform.

¹⁷ Wetboek van Strafrecht. Available at: https://wetten.overheid.nl/BWBR0001854/2024-01-01#BoekEerste_TiteldeelVIII_Artikel77g (accessed: 12.12.2024).

Legal Futurology and Modern Biomedicine

Many prominent futurologists have expressed their views on the impact of biomedical technologies on law and government, outlining their visions of the future of society. Francis Fukuyama predicted a “posthuman future” (Fukuyama, 2004), in which social hierarchy would be based on biological differences, following a transformation of the individual. Notably, Fukuyama sought to address these concerns through his participation in the Council on Bioethics, established under the U.S. President. His efforts to limit certain medical innovations were later criticized for causing the United States fall behind in several areas, contributing to the Council’s disbandment and the end of its activities.

Alvin Eugene Toffler envisioned biological control over all aspects of human life, including permissive mechanisms for childbearing based on parents’ genetic makeup, total artificial procreation, the rejection of the traditional family concept – replaced by family as a service benefit for top company managers – and human construction through DNA manipulation (Toffler, 2002).

A more pragmatic prospective is offered by netocracy, an ideology developed by A. Bard and J. Söderqvist (Bard & Söderqvist, 2005), which envisioned the emergence of a “new human race”. This transformation would be driven by genomic and reproductive technologies, including the ability to create a “biological carbon copy” of oneself – a form of biological immortality through reproductive cloning. However, after a peak in popularity, netocracy has lost its original meaning, and is now often equated with networked governance (Da Roit & Busacca, 2023), no longer advocating radical transformation.

Next, we will consider several biomedical technologies – highlighting reproductive technologies already mentioned – that have the potential to fundamentally transform society, along with associated risks and possible legal implications.

Among the first biomedical technologies worth mentioning is the creation of the artificial womb, given the significant progress achieved in this field. Between 2017 to 2022, over 300 lamb fetuses were successfully gestated in an artificial environment at the Children’s Hospital of Philadelphia. In September 2023, US Food and Drug Administration held its first consultation on the ethics and regulations of the Extra-uterine Environment for Newborn Development (EXTEND) device for human fetal use (Kozlov, 2023: 459). Parallel research is ongoing in Australia, Japan, the Netherlands, and Canada, each applying slightly different approaches to artificial gestation (Romanis, 2020).

The excitement surrounding this technology is partly speculative but rooted in its connection to the concept of ectogenesis – the artificial gestation and birth of a child. Coined in 1924 by J.S. Haldane, who predicted that by 2074 only about 30% of human births would occur via traditional means (James, 1987), ectogenesis has long been a science fiction theme, not always depicted positively. The emergence of this technology, however, marks the transition from fiction to potential reality.

There is also demand from some sectors for ectogenesis to become a modern form of human reproduction, heralded as a “moral imperative and a long-awaited result” (Khulbe et al., 2023: 618). Advocates suggest that ectogenesis could eliminate gender discrimination by depriving women of the exclusive role of childbearing – a capacity often framed as a stigma that restricts their rights and social life. This logic portrays child-rearing and housekeeping as gender stereotypes undermined when childbearing is provided as a service. It is argued that “technology will create a new kind of gender equality” (Cavaliere, 2020). Furthermore, artificial wombs could replace surrogacy, reshaping the availability and ethical landscape of reproductive technologies. While such developments would certainly shift social norms and family structures, the exact consequences remain unpredictable. Nonetheless, new values will likely emerge, altering family life even if the traditional nuclear family is not the primary target of these changes (Horn, 2020).

The expansion of artificial pregnancy capabilities may lead to new forms of social control. The initial euphoria of liberation could ironically turn into its opposite. For example, classifying pregnancies into “good” and “bad” categories might lead to coercion into ectogenesis, with the subsequent distribution of offspring into socially approved families. Scientific literature points out to a significant number of socially disadvantaged women who could be disproportionately affected. In some US states, pregnant women have been prosecuted for behaviors deemed harmful to the fetus, such as smoking or drug use. Notably, in 2003, the South Carolina Supreme Court, in *McKnight v. South Carolina*, recognized drug use during pregnancy as “conscious indifference to the rights of the child”, resulting in charges related to the child’s death¹⁸.

Many concerns remain premature as current artificial gestation is only partial ectogenesis, supporting fetal development from the 13th week onward. In countries concluding successful experiments, this technology is primarily regarded as emergency medical assistance rather than a social experiment. Nonetheless, legal challenges arise, notably regarding the definition of birth. The moment of birth, as defined in Russian Federal Law No. 323-FZ (2011), is the separation of the fetus from the mother’s body during childbirth. This definition underpins legal considerations such as whether a homicide has occurred. Artificial womb technology could alter this understanding, as birth may no longer be connected physically to the mother’s body (Hooton & Romanis, 2022). A fetus gestated in an artificial womb is not a newborn in the traditional sense as gestation remains incomplete, yet it is no longer dependent on the maternal body. This shift necessitates redefining birth and determining medical and legal criteria for transferring a fetus into an artificial womb. Whether these criteria will be strictly medical or influenced by social factors remains unresolved and rhetorical.

¹⁸ *McKnight v. South / Carolina*. Available at: <https://www.judicial.state.sc.us/opinions/display Opinion.cfm?caseNo=25585> (accessed: 12.12.2024).

Law and genome editing

The emergence of certain risks and threats is associated with the possibility of genome editing, which was long considered a medical experiment characterized by its exclusivity. This changed dramatically with the advent of CRISPR/Cas9 technology, which greatly simplified DNA manipulation, reducing both laboratory complexity and financial costs. The concept of “GMO humans” shifted from fantasy to reality when Chinese biophysicist He Jiankui announced in November 2018 the birth of gene-edited girls Lulu and Nana, who were edited using CRISPR/Cas9 to be immune to HIV infection¹⁹. He shared his ‘brainchild’ on YouTube, causing widespread controversy. This research was not entirely original; similar studies were conducted in the Russian Federation prior to China’s announcement. The Intellectual Property Court of Russia (case No. SIP-960/2019), for instance, denied a patent application concerning editing the human CCR5 gene to introduce delta32 deletion for HIV prevention – a decision influenced by legislation restricting patenting of genomic technologies. However, the denial of a patent does not imply the cessation of experiments in this domain.

A comprehensive review of scientific literature on legal challenges in genome editing highlights several major risks: the redefinition of family structures (Brokowski, 2018), the emergence of a “fertility industry” (Morrison & de Saille, 2019), potential delayed and unpredictable health harms (Benston, 2016), and the resurgence of eugenics (Ranisch, 2018). These risks include the misuse of genomic medicine for social selection, discrimination, citizen stratification. Privacy rights are particularly endangered, especially when DNA is decoded and manipulated, potentially requiring full biological disclosure. The “Pandora’s box” is exacerbated in the Russian Federation by a legal vacuum – Federal Law No. 86-FZ On State Regulation in the Field of Genetic Engineering Activity (1996) has had a controversial application history in humans. As of September 1, 2024, its limited applicability to gene diagnostics and therapy ceased, meaning that general medical practice laws now govern these areas. Notably, there remains no clear definition of human DNA, raising question as to whether editing mitochondrial DNA versus nuclear DNA is permissible, with varying implications for the legal and ethical status of the edited individual.

International legislation regulating genomic medicine has made significant progress, highlighting numerous gaps that still exist in Russian legislation. Many countries have established comprehensive laws, including:

– Germany: Law of November 21, 2011, on the Regulation of Preimplantation Diagnostics²⁰, and Law of July 31, 2009 on Genetic Testing²¹;

¹⁹ About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery As Single-Cell Embryos. Available at: <https://www.youtube.com/watch?v=th0vnOmFltc> (accessed: 12.12.2024)

²⁰ Gesetz zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG. Available at: <https://www.buzer.de/s1.htm?g=Pr%C3%A4implantationsdiagnostikgesetz&f=1> (accessed: 12.12.2024)

²¹ GenDG. Available at: http://www.biodeutschland.org/tl_files/content/positionspapiere/BIO_D_Position-Diagnostikgesetz.pdf (date of access: 12.12.2024).

- Spain: Law 14/2007 of July 3, 2007, on Biomedical Technologies²²;
- Norway: Act of May 12, 2003, on the Use of Biotechnology in Medicine, etc.²³;
- Japan: Law No. 85 of November 27, 2013, on the Safety of Regenerative Medicine²⁴.

These laws have been amended and supplemented multiple times. Additionally, many countries have developed criminal legislation to prevent the abuse of genomic technologies. For example, the French Criminal Code contains a special Section VI, titled Attacks on a Person Related to the Study of Their Genetic Properties or Identification by Means of Their Genetic Traits (Chapter VI of Book II), comprising six offenses. Furthermore, Section I of Book V, On Criminal Acts in the Field of Health, includes several provisions related to the use of genomic technologies.

Conclusion

Modern biomedicine has achieved results that allow it to influence key aspects of human life, from childbirth to the transformation of biological traits. Its potential – and in some cases, actual – capabilities are growing with each passing year, while access is becoming easier and more affordable. Just a few years ago, some technologies were considered exotic, shockingly expensive, and reliant on significant public resources. Today, they have become routine in many medical centers. For example, DNA sequencing, which at the start of the 21st century cost millions of dollars and required an international scientific consortium, is now offered by companies like 23andMe for as little as \$100. While such sequencing may not be comprehensive, it sufficiently addresses key medical needs by revealing individual biological characteristics. The resulting data, which reflects a person’s biological traits, holds privacy concerns and introduces new vulnerabilities.

This “biomedicine to the masses” approach is transforming society in ways that are not always positive. Until recently, law actively influenced innovation processes – whether by accelerating or hindering them, it rarely remained passive. Now, a unique phenomenon is unfolding: technology is reshaping the world at an accelerated pace, creating a new social reality to which law is still adapting. Political solutions are lagging behind the rapid formation of this renewed reality. Globalization adds further complexity: bans in one country can be circumvented by liberal policies in another, and the universal nature of biomedical technologies makes restricting their spread within national borders challenging. Consequently, many nations are promoting international initiatives to establish unified legal framework for the most ethically sensitive technologies such as cloning, genome editing, and eugenics. However, the lack of global consensus continues to hinder the adoption of these much-needed universal conventions. Noteworthy declarations include

²² Ley 14/2007, de 3 de julio, de Investigación biomédica / <https://www.boe.es/buscar/act.php?id=BOE-A-2007-12945> (date of access: 12.12.2024).

²³ Lov om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven). Available at: <https://lovdata.no/dokument/NL/lov/2003-12-05-100> (accessed: 12.12.2024).

²⁴ Act on the Safety of Regenerative Medicine. Available at: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000150542_00001.html (accessed: 12.12.2024).

the Universal Declaration on the Human Genome and Human Rights (1997)²⁵ and the UN Declaration on Human Cloning (2005)²⁶, but even these non-binding documents failed to gain unanimous approval.

The state seeks to fine-tune its own legislation regarding biomedical technologies. Most countries employ mechanisms of deconcentration of public power, where decisions on implementing biomedical technology in medical practice occur at the lowest level of governance. Subsequently, control may pass to professional medical corporations, ensuring efficiency and prioritizing bioethical expertise. A consensus has emerged on several issues reflected in industry regulations, including prohibitions on unethical experiments with human embryos (such as bans on the creation of chimeras), strengthening judicial roles in reproductive matters (e.g., preliminary court approval for surrogacy), prohibiting discrimination based on genetic characteristics, restricting DNA identification (including bans on secret testing), defining special human rights (like the right to ignorance in gene diagnostics, establishing national registries for reproductive and genomic technologies, and limiting the use of brain imaging results for non-medical purposes.

In the Russian Federation, there is an urgent need to deregulate biomedical technologies, as strict administrative barriers hinder research and practical implementation. The bureaucratic approval process under Federal Law No. 180-FZ of June 23, 2016, On Biomedical Cell Products, has effectively negated prior achievements. Although amendments in August 2023 aimed to simplify these procedures, the Law On the Basics of Protecting the Health of Citizens in the Russian Federation does not address genomic medicine's specifics or codify legal nuances of biomedical technologies.

1. Urgent legislative reforms in Russia should include revising the legal framework for assisted reproductive technologies – specifically, banning all forms of surrogacy; strictly limiting preimplantation genetic diagnostics to medical indications, establishing registers for such studies, and restricting access to authorized medical personnel and organizations; and allowing married couples access to artificial insemination with assessment protocols for the child's future care.

This decentralized approach to governance supports efficiency and ethical oversight by situating decision-making closer to the medical practice level while ensuring national legislative frameworks provide necessary limits and protection.

2. Supplementing the Law On the Basics of Protecting the Health of Citizens in the Russian Federation with specific provisions on genomic medicine. These provisions should define the limits of intervention in human DNA, restrict the creation of living chimeric organisms involving humans, guarantee privacy during genome sequencing, establish the legal framework for medical DNA databases, and limit the use of human genetic data for non-medical purposes. Additionally, the law should encompass emerging human rights recognized in foreign regulations, such as the right to an “open future” –

²⁵ Universal Declaration on the Human Genome and Human Rights. Available at: https://www.un.org/ru/documents/decl_conv/declarations/human_genome.shtml (accessed: 12.12.2024).

²⁶ United Nations Declaration on Human Cloning. Available at: https://www.un.org/ru/documents/decl_conv/declarations/decl_clon.shtml (accessed: 12.12.2024).

allowing adults to remain unaware of genetic tests results obtained during childhood unless directly related to their health – and the right to ignorance, which protects individuals from receiving unsolicited genetic information beyond the intended scope of testing.

3. Amendments to the Law On the Basics of Protecting the Health of Citizens in the Russian Federation are required to redefine the moment of birth. Currently, Article 53 does not address births by cesarean section. The development and use of artificial gestation technologies necessitate recognizing the acceptability of such technologies and defining the legal status of an unborn fetus maintained in an artificial environment.

4. The advancement of biomedicine and personalized medicine demand a thorough revision of healthcare legislation. Many countries have introduced specialized legal acts – biomedicine or bioethics laws – while Russian healthcare legislation remains fragmented, with many laws dating back to the 1990s and needing comprehensive modernization. Adopting a unified Public Health Code (name subject to discussion) appears optimal. Such a code would streamline healthcare workers' responsibilities, standardize law enforcement practices, and reduce contradictions in existing legislation. Furthermore, the Code could establish legal frameworks for innovations such as 3D bioprinting, biobanks (including DNA databanks), advanced therapeutic drugs, and gene therapy.

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