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EDITORIAL

Dear Readers and Authors,

Significant changes have taken place in the life of our Journal. Since 2022, Kutafin Law Review (KuLawR) has joined the Scopus database. This is an undoubted recognition of the increased quality of the Journal, which, inter alia, demonstartes considerable contribution of the Editorial staff. Moreover, the Journal was highly appreciated by the experts due to the high quality and content of the manuscripts submitted for publication. A relatively young journal has already acquired regular readers both in Russia and abroad. I would like to say a special word of gratitude to the members of the Editorial Board and especially to invited reviewers for their integrity and insistance on high standards of academic publications.

Today, a year after the journal started publishing four issues a year we can admit with confidence that the aforementioned changes in the format of the journal, the frequency of publication of new issues, as well as the editorial policy have shown success. From now on, the objective of the Journal team will be to comply with the latest trends in the development of both world and domestic scientific periodicals. It turned out to be a successful decision to publish thematic issues that reflect the very essence of the title of the journal — Review. The four issues were devoted to the topics of biolaw, cyber law, megascience and legal education and they reviewed if not of all branches of law, then, in any case, they helped to give a broad view of the topics where the most interesting and significant changes are taking place.

Today, a year later, we return to the biolaw issues discussing bioethics on the pages of this issue. The forthcoming issues of Journal will reflect on the topics of technologies in law, legal novels and human rights. We hope we will remain interesting and attractive for our readers and will continue to provide a platform to all authors having received significant results in these fields and wishing to make them public.

Sincerely yours,
Vladimir I. Przhilensky

Dear Readers and Authors,

For the second year in a row, the journal Kutafin Law Review (KuLawR) has become a thematic platform for conceptual images, discussions and doctrinal conclusions on the problems of law and bioethics in the field of genomic research and the application of genetic technologies. In this continuity and sequence of scientific connections, the tendency of the emergence of a new tradition of Russian legal science on the formation of responses to global technological conclusions of the external environment is clearly manifested. We are grateful to the representatives of legal science, bioethics, genetics and medicine for the valuable research, the results of which they posted on the pages of the journal. The interdisciplinary field of Lex genetica, in its empirical basis, needs such inter-disciplinary assessments.

We are waiting for old friends of our Journal and new authors in 2023!

Maria V. Zakharova,
Invited Editor

RESEARCH ARTICLES

DOI: 10.17803/2313-5395.2022.1.19.003-038

Legal Regime for the Protection of Genetic Information of Indigenous Peoples and Local Communities in International Law

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Abstract: The present study aims at providing an idea that the protection of genetic and genomic information of indigenous peoples and local communities should be legally established at universal and regional levels. There is a trend in many countries towards the disappearance of rare nations and peoples representing genetic diversity. In the case of the collection, processing, storage, transmission of data in the application of artificial intelligence take further action to ensure cybersecurity, develop ethical guidelines and confidentiality requirements for collection and processing genomic and genetic information on the health of indigenous peoples and local communities bearing in mind the provisions of the United Nations Declaration on the Rights of Indigenous Peoples (2007) and the International Convention on the Elimination of All Forms of Racial Discrimination (1965). Although human genes are not covered by the Convention on Biodiversity (1992), it should be applied by analogy in the case of the protection of the "genetic" heritage of mankind. The research uses general scientific and special cognitive techniques wherein legal analysis and synthesis, systemic, formal-legal, comparative-legal, historical-legal and dialectical methods are applied. The author calls on the international community to recognize indigenous genetic information from medical research as the common heritage of mankind and to establish special legal responsibility of present generations for the future of mankind at the universal level. The author of the article notes the importance of prevention the development of racial and ethnic weapons against a certain population group and to prevent the commission of the crime of "genomocide" against indigenous peoples and local communities

and to comply with biosafety measures in conducting scientific research and obtaining certain genetic information, to preserve the uniqueness of the biocode of the nations and peoples inhabiting our planet.

***Keywords*:** biosecurity; cybersecurity; indigenous peoples; genetic information; genomic sovereignty; biocolonial approach; genetic heritage of mankind; UN Sustainable Development Goals

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Contents

I. Introduction

Over the past 30 years, human genetics has made impressive progress in reconstructing the history of a population[1] and determining what genes make a person predisposed to a particular disease.[2] Interest in

[1] As well as answering questions about heritage, population history research can be useful for health research. In 2009, genetic epidemiologist Marlo Moeller and her colleagues at Stellenbosch University in South Africa teamed up with Brenna Henn, a population geneticist at Stanford University, to study the genomes of South African people with a Khesan ancestry. They hoped to find out why people with this background are more susceptible to TB than other groups.

[2] For example, scientists from the Medical Genetics Research Centre found out that in both ethnic groups, hypotrichosis, a congenital disease in which a person has much less hair than expected, is common in the Chuvash and Mari ethnic groups. This disease is caused by a mutation in a small area of the LIPH gene located on the third chromosome. In addition, another hereditary disease, lethal infantile osteopetrosis, is common in both peoples. Available at: https://ria.ru/20190417/1552774350.html?in=t [Accessed 24.01.2022].

genetics has grown rapidly in recent years from population geneticists,[3] molecular anthropologists, genetic epidemiologists and paleontological researchers.[4] A few prominent examples can be mentioned to illustrate this point. For example, in 2017, the first ancient DNA laboratory was established in India with the objective to find out how different populations relate to each other genetically. DNA samples from members of the Havasupai tribe (Havasu 'Baaja, "people of turquoise water") in Arizona were gathered to investigate diabetes. A US researcher, Dr Katrina Klaw of the University of Washington, D.C. was wondering why American Indians and Alaska Natives (Iñupiat) absorbed nicotine faster than people of other ethnic backgrounds. The study compared the DNA of Inupiat ancestors in Alaska with DNA of modern people to study the genetic history of the population. Geneticist Tsosie on Diné and Navajo Nations from Vanderbilt University in Nashville (Tennessee, USA), working with a group of Turtle Mountain Chippewa Indians (Turtle Mountain) in North Dakota, researching genetic factors that might explain why in the community some women are more susceptible to preeclampsia during pregnancy[5] than others. In British Columbia,

[3] A striking example is a study by the International Paleogenetics Group, which studied 48 samples of remains of people who lived from three to six thousand years ago in the North Caucasus and compared them with the DNA of other peoples, establishing their kinship with American Indians, indigenous peoples of Siberia and the inhabitants of southern Europe. Thus, genome analysis of the famous Maikop culture, which occupied the territory from the Taman Peninsula to Chechnya, revealed a kinship with the Indians and contemporary Siberian ethnic groups. The Yamnaya culture, which lived in the eastern Caucasian foothills, was genetically linked to the ancient peoples of South and Southeast Europe and their contemporary descendants. Available at: https://www.nature.com/articles/s41467-018-08220-8 [Accessed 24.01.2022].

[4] According to a report by scientists from the Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences and the University of Pennsylvania (USA), North American Indians and Southern Altai peoples are related. Their common ancestor lived in the Altai 15–20,000 years ago. Experts have compared more than a hundred genetic markers inhabitants of the Northern and Southern Altai, Mongolia and southern Siberia, and also the Indians of North America. As the experts note, "the Altai and Indians are closest to each other in terms of the frequency of the relevant mutations in the genome. Available at https://www.cell.com/ajhg/fulltext/S0002-9297(11)00549-0 [Accessed 24.01.2022].

[5] A complication of pregnancy that develops after 20 weeks' gestation characterized by high blood pressure and increases the risk of cramps and preterm birth.

collaborative research effort on excess cardiac mortality in Gitxsan First Nation have led to the discovery of a gene combination that contributes to an increased propensity for arrhythmia, and sudden death being an extended interval syndrome of QT. In New Zealand, gout research was conducted in consultation and collaboration with the Maori tribe, Ngāti Porou through its health care provider the Ngāti Porou Hauora Charitable Foundation. That resulted in the identification of genetic variations associated with high levels of uranium in serum in the case of gout and evidence that gout is hereditary. This knowledge has not only improved diagnosis and treatment, but, more importantly to the tribesmen, have de-stigmatized gout as a disease arising from hereditary genetic factors, not as a result of a bad lifestyle.

Such active tribal research is conducted with members of indigenous peoples of African and Latin American origin, local communities in Mexico, New Zealand and Canada, there studies of the Inupiat people of the Arctic Slope in Alaska, the Navajo nation in the United States, and local communities in Hawaii, San communities in Southern Africa, and research on the formation history of some South Asian populations (Phillips, 2019). State recognition of the existence of certain peoples through DNA tests becoming increasingly relevant in state practice (Arnaiz-Villena *et al.*, 2017; Blakemore, 2019), there are precedents for the acquisition of nationality through DNA testing of biomaterials to establish a biological/legal bond ("right to citizenship").[6] However, experts point to the abuse of DNA samples without indigenous people consent. In one notorious story, researchers from the University of Arizona took DNA samples from members of the Hawasupai tribe in Arizona in the 1990s for diabetes research, but later used samples without tribal consent to investigate schizophrenia and patterns of mixing and migration. In 2010, the Hawasupai people won a $ 700,000

[6] A group of Telugu-speaking people who live in a small village near Guntur in Andhra Pradesh (about 50 families in the village) practice Judaism, and most of them can read and write Hebrew. The researchers believe the community members come from the tribe of Ephraim, one of the ten lost tribes of Israel, and hope that DNA analysis of the members will help them be recognised as Jews. According to researcher Jacoby, some 200 people who gave blood samples now want to know their origins.

lawsuit (Harmon, 2010) and the university was forced to return all DNA samples collected. Indigenous genomes are interesting in their unique variability. New genotype and phenotype relationships found in small isolated groups used to develop personalized medicine. According to researchers, the problem should be approached considering the fact that the project "Diversity of the Human Genome" makes it clear to participants in various sectors of the market that the benefits of the Big Data Economy and genome information is available due to the indigenous peoples of Central and South America (Fox, 2020). There is a huge disproportion in the health of indigenous peoples due to persistent bias including in research work. And personalized medicine is not going to help. Researchers simply cannot publish the study because the results could be detrimental to the indigenous community. That is probably why most genome research is focused on people of European origin. A recently published analysis showed that as of 2018, only 22 % of persons involved in general genomic association research[7] are of Non-European origin. People of African and Latin American descent and indigenous peoples together accounted for less than 4 % of participants, indicating a lack of diversity of sufficient genetic worldwide research. For example, according to the United Nations,[8] 370 million people in over 90 countries consider themselves as indigenous peoples representing humanity in all its diversity but what unites them all is that they are the most isolated, discriminated against, endangered and often the poorest communities around the world. Although indigenous peoples make up 5 % of the world's population, 15 % live in extreme poverty.

[7] Indigenous and non-indigenous scientists are trying to stop the cycle of separation. In 2011, Ripan Malhi, a molecular anthropologist at the University of Illinois at Urbana-Champaign, started a Summer Internship for Indigenous Peoples in Genomics (SING). The annual week-long course is taught primarily by Indigenous educators and allows people from Indigenous communities, including college and tribal university students, to learn about genomics and discuss its uses and abuses. The workshop was originally funded by the US National Science Foundation and the University of Illinois; it is now supported by the NIH.

[8] The Indigenous Peoples' Major Group for Sustainable Development (IPMG) website. Available at: https://indigenouspeoples-sdg.org/index.php/english/ [Accessed 24.01.2022].

II. General Provisions

The terms "indigenous peoples" (*in Spanish* pueblos indígenas, marginalized populations) and "local congregations/communities/ population" (*in Spanish* comunidades campesinas) need more careful study by specialists in international law, as in the legal literature the terms "ethnic minorities" (ethnical minorities; minority ethnic groups, indigenous and other marginalised populations, indigenous tribes, *in Spanish* minorías) and "First Aboriginals" (Native Nations, First Nations), which creates further confusion in the legal understanding (Saul, 2002; Abashidze and Sheremet, 2021). International indigenous justice (Wardana, 2012)[9] is currently emerging. The term "bio-colonial" (Worlds, 2019) is also used by foreign colleagues to inventory the collection of genetic information from indigenous DNA samples. Data sovereignty of indigenous peoples, the concept of "genomic divide," the concept of genetic division and genetic map, indigenous genetic self-determination and the concept of digital colonization in relation

[9] *See:* Jurisprudence of the European Court of Human Rights Regarding Indigenous Peoples: O.B. and Others Against Norway, O.B. & Others, App. No 15997/90, Eur. Comm'n H.R. Dec. & Rep., at 8–9. Könkäma and 38 other Saami Villages v. Sweden, App. No 27033/95, Eur. Comm'n H.R. Dec. & Rep. (1996), Halvar From Against Sweden, Johtti Sapmelaccat RY and Others Against Finland, The Muonio Saami Village Against Sweden; Hingitag 53 Against Denmark, Handolsdalen Sami Village and Others Against Sweden, Chagos Islanders Against United Kingdom. Jurisprudence of the Inter-American Court of Human Rights Regarding Indigenous Peoples: Kichwa Indigenous People of Sarayaku v. Ecuador, Merits & Reparations, Judgment, Inter-Am. Ct. H.R. (ser. C) No 245 (June 27, 2012); Indigenous Communities of the Xingu River Basin in Para v. Brazil, Inter-Am. Comm'n H.R., Apr. 11, 2011, (PM 382/10); Salvador Chiriboga v. Ecuador, Reparations and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 222 (Mar. 3, 2011); Xákmok Kásek Indigenous Community v. Paraguay, Merits, Reparations, and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 214 (Aug. 24, 2010); Saramaka People v. Suriname, Preliminary Objections, Merits, Reparations, and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 172 (Nov. 28, 2007); Sawhoyamaxa Indigenous Community v. Paraguay, Merits, Reparations and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 146 (Mar. 29, 2006); Yakye Axa Indigenous Community v. Paraguay, Inter-Am. Ct. H.R. (ser. C) No 125 (June 17, 2005); Moiwana Community v. Suriname, Preliminary Objections, Merits, Reparations and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 124 (June 15, 2005); Mayagna (Sumo) Awas Tingni Community v. Nicaragua, Inter-Amer. Ct. H.R. (ser. C) No 79 (Aug. 31, 2001); IACHR, Report No 96/03, Case 12.053, Maya Indigenous Communities of the Toledo District (Belize), October 24, 2003.

to indigenous peoples, and the right to return[10] to one's home country are a vivid proof.

For example, the Maori have adopted the Treaty of Waitangi[11] which enshrines traditional values and rights of indigenous peoples to the protection of data important to them in modern digital systems; the document establishes the obligation to consult with Maori and indigenous peoples at all levels of policy, legislation and development of any systems that contain Maori data, including the use of artificial intelligence to avoid inadvertent bias and negative consequences.

In particular, indigenous peoples and local communities are a vulnerable category in international human rights law and it is vital to uphold the requirements of confidentiality, voluntariness and legal and obtaining the legal written consent[12] of participants in genetic research, protecting the personal data of those involved, their rights to participation and representation in research bodies, and the collective rights of indigenous peoples to genetic resources as set forth in international instruments.

The goals enshrined in the 2030 Agenda for Sustainable Development (resolution 70/1, adopted by the UN General Assembly in 2015)[13] provide an unprecedented opportunity to guarantee indigenous peoples participation. Indigenous knowledge on topics such as community resilience and the environment, for example, can be used in achieving the goals (Anisimov and Gulyaeva, 2021). For example, for the first time, the law of the sea[14] will provide legal protection for indigenous and local

[10] Application No 35622/04, Chagos Islanders v. the United Kingdom, ECHR Decision of 2012.

[11] The Treaty of Waitangi. Available at: https://www.taiuru.maori.nz/maori-data-sovereignty-and-digital-colonisation/ [Accessed 24.01.2022].

[12] In 2016, Suzman, who worked with San communities in southern Africa for nearly 30 years, led a workshop to develop a standard process for obtaining consent to research for two specific groups. After a two-day discussion of genomic research, community leaders told Suzman that they did not understand genetics and would prefer to have a trusted person to negotiate for them to participate in the study.

[13] Transforming our world: the 2030 Agenda for Sustainable Development UN General Assembly. 2015. 21 October. UN Doc. A/RES/70/1.

[14] Specialised international access and benefit-sharing instruments in the context of Article 4, paragraph 4 of the Nagoya Protocol CBD/SBI/3/14 of 13 July 2020, pp. 12–13; UNEP. UNEP/CBD-SBSTTA/11/11, Par. 44 of 22 July 2005. Available

communities (Anisimov and Gulyaeva, 2021) traditional knowledge of marine genetic resources at the universal level, as well as a specific mechanism to control stakeholders' access to this knowledge. The fact that indigenous traditional knowledge falls within the definitions of intangible cultural heritage raises the question of the overlap between the scope of the future Agreement and the 2003 Convention for the Safeguarding of the Intangible Cultural Heritage.[15]

Moreover, genetic information and data, as well as relevant marine and biotechnological information are the subject of intellectual rights, which falls within the purview of WIPO. Accordingly, it is strange to see a simplification of the definition of MGM in the Revised Draft, which is formulated along the lines of the definition of genetic material in the Convention on Biological Diversity and does not contain any reference to maritime zones or corresponding exemptions. As the omics sciences and genomics in particular, evolve, large volumes of complexly organized data (*Big Data*) are accumulating, leading to a close interaction of advocacy mechanisms with bioinformatics and biostatistics.[16] The Genome Aggregation Database (GnomAD),[17] used mainly as a reference tool to interpret sequencing data and understand variants associated with disease on a global scale, is not subject to generalization. The GnomAD genetic database does not include the

at: https://www.cbd.int/doc/meetings/sbstta/sbstta-11/official/sbstta-11-11-en.pdf [Accessed 09.08.2021]; United Nations. Sustainable Development GOALS. Goal 14: Conserve and sustainably use the oceans, seas and marine resources. Available at: https://www.un.org/sustainabledevelopment/oceans/ [Accessed 24.01.2022].

[15] Convention for the Safeguarding of the Intangible Cultural Heritage adopted on 17 October 2003 by the General Conference of the United Nations Educational, Scientific and Cultural Organization. Available at: https://www.un.org/ru/documents/decl_conv/conventions/cultural_heritage_conv.shtml [Accessed 24.01.2022].

[16] The European Bioinformatics Community for Mass Spectrometry. Available at: https://eubic-ms.org/ [Accessed 24.01.2022].

[17] The Genome Aggregation Database (GnomAD) is a resource developed by an international coalition of researchers to aggregate and harmonize exome and genome sequencing data from a wide range of large-scale sequencing projects and provide aggregated data for the wider scientific community. Available at: https://gnomad.broadinstitute.org/ [Accessed 21.01.2022]. The v2.1.1 (GRCh37/hg19) dataset available on the official website includes 125,748 exome sequences and 15,708 whole-genome sequences of unrelated individuals (humans) sequenced in various disease-specific genetic and population genetic studies.

indigenous population of the planet, and therefore, the results may be misleading or even detrimental to the rights of these groups. Without taking into account the biological data of the indigenous peoples of the world, the success of genomic medicine can be called into question. For this reason, worldwide efforts are under way to establish a BVDs genetic database[18] for previously excluded populations, recognizing that both affiliated policies and science infrastructure are needed. Without that, the success and benefits of genomic medicine are disproportional. It should be highlighted that in North America, China and Europe, a scientific project involving geneticists called the *Human Genome Diversity Project* ("Diversity Project"/"Project"/"HGDP") has been initiated to try to create a collection of indigenous genetic material from all over the world (Greely, 1997; Cavalli-Sforza and Cavalli-Sforza, 1995, pp. 258–259; Cavalli-Sforza *et al.*, 1997).

With the development of genomic technology and genetic engineering, nations are seeking new ways and methods to ensure the biosafety of both the individual and society as a whole. There is a growing global awareness of the need for effective protection of constitutional and civil human rights through scientific research and its subsequent applications.

Alongside the purely legal issues, genomic research raises a number of general *socio-ethical and moral conflicts*. After all, the undeniable benefits of the research in question are often fraught with potential risks to human and public health, the environment and the ecology. The bioethical aspects and moral dilemmas of genetic screening have now come to the fore: protection of confidentiality of data or disclosure for biosafety; personal choice or coercion of members of the public; voluntary or mandatory screening; and discrimination and stigmatization on genetic grounds such as Cold Winters Theory. There is a need to develop effective ethical and legal ways of dealing with the challenges posed by the introduction of genetic-based personalized medicine technologies into the clinic. Here it is important to respect the bioethical principle of justice, combined with the classical principle of

[18] Background variant databases (BVDs) for genetic diagnosis across the globe. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7193324/ [Accessed 24.01.2022].

"do no harm" by unnecessary knowledge about one's genome (Furrow *et al.*, 2013).

In doing so, information derived from genetic data should not be used to harm or discriminate against individuals, families or groups in both clinical and non-clinical spheres, including employment, insurance, access to social inclusion and opportunities to increase general well-being (European Commission, 2004, p. 26).

One example of genome research is a study of the Nuu Cha Nult people in British Columbia, Canada, whose blood samples were originally collected in order to understand the cause of the high morbidity and severity of rheumatoid arthritis. Instead, DNA was used to study human migration and retroviruses. Another equally striking example is the controversial study of the "warrior" gene conducted on Maori in New Zealand, which, based on a relatively small sample, were said to be more likely that the assumed higher frequency of the monoamine oxidase gene variant, as was previously the case, related to the aggressive behavior of the non-indigenous population which explains the aggressive behavior of some Maori.

This research has been widely condemned for reinforcing unjustifiably negative stereotypes of Maori as inherently violent. Attention should be drawn to the observance in indigenous genetic research of the 1965 Convention on the Elimination of All Forms of Racial Discrimination, which enshrines the basic principle of international law that all human beings are equal, that all States shall work to eradicate racial discrimination, that is to say, any distinction, exclusion, restriction or preference based on race, color, descent, or national or ethnic origin having as its purpose or effect the destruction or impairment of the rights of persons belonging to indigenous peoples, and that it shall be applied in the case of indigenous peoples.

Biological and medical research, biotechnological developments have led to impressive achievements in the field of health care. However, these achievements raise ethical issues that affect the protection of human rights and dignity in the field of genetics, transplantation of organs, tissues, cells and embryos, the creation of national and personalized biobanks,[19] use of modern technologies in the creation

[19] A biobank is a type of biorepository, a specialized repository of biological materials for scientific and medical purposes, accompanied by information about them (Smirnova, 2013).

of databases on health, *etc.* In this context, not only positive legal regulation is developing but also topical public discussions about the so-called "genetic responsibility."

The moral concept of "genetic responsibility" (GR) is relatively young in EU law and has been associated with a progressively increasing sense of responsibility ("responsibilisation") in the health care field (Leefmann, Schaper, and Schicktanz, 2017). It emerged within the framework of discussions on genetic testing in the 1970s, to promote reproductive positive eugenics and to imply a collective responsibility towards future generations to avoid inheriting diseases (Lipkin and Rowley, 1974, pp. 93–100), a term coined by scientists Lipkin and Rowley.

In addition, the phenomenon of "responsibility" has many conceptual and historical meanings in bioethics (Schicktanz and Schweda, 2012, pp. 131–145). In the 2000s, this concept of "genetic responsibility" was closely linked to the development of the concept of the influence of biopolitics and the genetic approach on the individual's perception of himself ("genetic thought style") and thus on the socio-political sphere of his action (Lemke, 2006, pp. 83–91; Denisenko and Trikoz, 2020).

International instruments and existing European regulations recognize everyone has the right to know his or her own medical and genetic information and the right not to know. However, the professional community of doctors, employers and common laymen do not always agree on this problem of "genetic responsibility." Most are leaning towards the "calm" version of ignorance as opposed to the "responsible" knowledge.

Not long ago, a comparative study was conducted among German and Israeli residents on their moral attitudes towards "*genetic responsibility*." Three main aspects of this responsibility were examined: personal responsibility, responsibility for loved ones, and the responsibility of society towards its members. Ethnocultural differences in the responses of German and Israeli respondents showed serious differences, and a moral conflict was identified between the right to confidentiality and the moral obligation to disclose genetic information to relatives (responsibility for relatives). There was also a disagreement on the more personal issue of the right not to know genetic information

about oneself combined with the duty to know and make a responsible decision (personal responsibility). In summary, the study showed that the moral assessments of the Israelis were more oriented towards the public interest, while the Germans expressed an attitude towards the rights and interests of the individual in their assessments (Raz and Schichtanz, 2009).

The collection, processing, use, research, storage and transmission of genetic information about the world's indigenous peoples and local communities, and the subsequent application of the data acquired, constitute an invaluable contribution to knowledge of the history of human evolution and human capital. Nevertheless, it must be understood that the collection, processing, use and storage of such data have potential risks for the exercise and observance of human rights and fundamental freedoms, and respect for human dignity.

It should be emphasized that there is an emerging need for independent international centers of expertise and commissions to verify the ethical and legal aspects of genomic research and the confidentiality of this information obtained from DNA samples from indigenous peoples and local communities around the world. It is very likely that in the near future international jurists will question the need for international legal regulation of such universal health biobanks (Yastrebova and Gulyaeva, 2021) in order to preserve the common heritage of humanity.

Therefore, establishment of a single global registry — a databank of genetic information on the health of indigenous peoples has to be registered with the United Nations General Secretariat by analogy with the law of outer space and the law of the sea.

III. UN Sustainable Development Goals and the Rights of Indigenous Peoples and Local Communities

The goals enshrined in the UN 2030 Agenda for Sustainable Development (UN General Assembly resolution 70/1) include an essential component such as the full protection of indigenous peoples' rights. The UN Permanent Forum on Indigenous Issues[20] was established within

[20] The Permanent Forum and the 2030 Agenda. Available at https://www.un.org/development/desa/indigenouspeoples/focus-areas/post-2015-agenda/

ECOSOC to actively participate in the 2030 Agenda for Sustainable Development and to oversee that indigenous peoples' rights[21] are implemented first, follow up and review the Agenda itself. As a subsidiary body of ECOSOC, the Permanent Forum contributes substantially to the thematic reviews of the Sustainable Development Goals. Over the years, the UNCSD Permanent Forum has made several recommendations concerning indigenous peoples' conservation priorities, first in the framework of the Millennium Development Goals, then in the so-called Post-2015 Agenda negotiations, in the 2030 Agenda and the Sustainable Development Goals adopted on 25 September 2015.

For example, among the experts is the creation of research infrastructure on indigenous lands, which would allow the extraction of genetic technology "from the obscura" and ensure the transparency of projects. There are also plans to establish an independent genetic research institute, a network of research centers in various indigenous communities with independent biobanks, computing clusters and scholarship programs.

The recent report of the 16th session of the Permanent Forum on Indigenous Issues[22] includes a special section with recommendations related to the 2030 Agenda, based on extensive dialogue and discussion with the participants of the 16th session of the Permanent Forum, including indigenous peoples, Member States, UN specialized agencies and other stakeholders. The main recommendations address the following issues:

— paying due attention to indigenous peoples' rights and the UN Declaration on the Rights of Indigenous Peoples in the implementation of the 2030 Agenda;

— establishment of consultative platforms for IPs, and voluntary inclusion of IPs in national reviews at the HLPF;

the-sustainable-development-goals-sdgs-and-indigenous/recommendations.html [Accessed 24.01.2022].

[21] Indigenous Peoples and the 2030 Agenda. Available at: https://www.un.org/development/desa/indigenouspeoples/focus-areas/post-2015-agenda/the-sustainable-development-goals-sdgs-and-indigenous.html [Accessed 24.01.2022].

[22] United Nations Permanent Forum on Indigenous Issues Report on the sixteenth session (24 April to 5 May 2017) Recommendations Specifically Pertaining to the 2030 Agenda adopted by the Permanent Forum on Indigenous Issues.

— disaggregation of data according to indigenous identifiers and inclusion of appropriate indicators for IPs, in particular related to secure land tenure.

The recommendations of the 15th session reflect the implementation of the commitments set out in the 2014 World Conference on Indigenous Peoples' Outcome Document (*World Conference on Indigenous Peoples' Outcome Document*), in which Member States committed to give due consideration to all rights of indigenous peoples when developing the post-2015 development agenda (*paragraph 37*) and generally to work with indigenous peoples to disaggregate data, as appropriate, or conduct surveys and use holistic indicators of indigenous peoples' well-being to address the situation and needs of indigenous peoples and individuals in particular the elderly, women, youth, children and the disabled (*paragraph 10*).

To implement the recommendations, the Secretariat of the Permanent Forum on Indigenous Issues (Division for Social Policy and Development, Department of Economic and Social Affairs) organized an "Expert Group Meeting on Indigenous Peoples and the 2030 Agenda" in October 2015. At the meeting, the experts proposed specific indicators for indigenous peoples' development and how they should be reflected in the review and follow-up of the 2030 Agenda.

The officially published document "**ABS is Genetic Resources for Sustainable Development**"[23] on the UN website notes the impact of the Nagoya Protocol on Access and Benefit Sharing (ABS) and the importance of national ABS laws/policies for achieving the Sustainable Development Goals (SDGs). In particular, the legal framework targets the private sector, researchers, indigenous peoples and local communities from 27 countries to develop innovative products that contribute to the UN SDGs.

This report highlights that genetic resources are accelerators of the 2030 Agenda for Sustainable Development. Genetic resources contribute

[23] This paper deals with biodiversity and how traditional knowledge, science, technology and human ingenuity can be used to develop new products from genetic resources. Witnesses and sustainability advocates provide personal perspectives on the implications of new discoveries in biology, including reflections on key challenges and how to overcome them. Available at: https://www.undp.org/publications/abs-genetic-resources-sustainable-development [Accessed 24.01.2022].

to poverty reduction (Goal 1), food security (Goal 2), good health and well-being (Goal 3), gender equality (Goal 5), innovation (Goal 9) and life on earth (Goal 15). In addition, stories of biological discoveries are excellent examples of national and international partnerships (Goal 17). The chapters are written by experts and practitioners from governments, private companies, research institutes, indigenous peoples, local communities and UNDP.

As a result of indigenous peoples' active participation in the 2030 Agenda process, the final resolution "Transforming our world: the 2030 Agenda for Sustainable Development" (A/RES/70/1) mentions indigenous peoples six times, and three times in the political declaration; two of the targets under Goal 2, Eradicate Hunger (target 2.3) and Goal 4, on education (target 4.5), and one in the follow-up and review section, which calls for indigenous peoples' participation.

In addition to explicit references, many of the Sustainable Development Goals and related targets are relevant to indigenous peoples. Moreover, the comprehensive structure of the 2030 Agenda contains many elements that can help to articulate indigenous peoples' development concerns. Importantly, human rights principles and standards are clearly reflected in the 2030 Agenda (A/RES/70/1, para. 10). Moreover, the overall focus of the 2030 Agenda on reducing inequalities is of particular importance for indigenous peoples, who are almost always disadvantaged compared to other segments of the population.

The global indicator framework that will measure progress towards the 17 Sustainable Development Goals (SDGs) includes two indicators that are specific to indigenous peoples (indicator 2.3.2 and 4.5.1) and several other indicators relevant to indigenous peoples, in particular indicator 1.4.2 and 5.a.1 on land rights. Moreover, there has been much emphasis on the need to disaggregate data, as advocated for, inter alia, by the UN Permanent Forum on Indigenous Issues. The list of global indicators states that "SDG indicators should be disaggregated, where relevant, by income, gender, age, race, ethnicity, migration status, disability and geographic location or other characteristics in accordance with the Fundamental Principles of Official Statistics." The

Statistical Commission agreed the global indicator framework in 2017 as a voluntary and country-driven tool, but work on it is still ongoing and will be adjusted as necessary in the coming years. At this stage, indicators are being developed at the national and regional levels.

The primary responsibility for implementation, review and follow-up lies at the national level, as outlined in A/RES/70/1. Globally, the High-Level Political Forum (HLPF) is the main UN platform for oversight of follow-up and reporting. **Indigenous peoples have attended both meetings of the HLPF in order to include indigenous voices, priorities and concerns**. The HLPF will meet once a year under the auspices of the Economic and Social Council and every four years under the auspices of the General Assembly.[24]

In "**Countering Injustice in Genomic Science"** (Guglielmi, 2019, pp. 290–293), researchers call genomics "inclusive," working with communities that have been ignored or abused. A prime example is the case of a Pacific coastal resident in southern Mexico who decided to trace his ancestry back to the sixteenth century, believing himself to be Afro Mexican. The group is not officially recognized as an ethnic minority by the Mexican government, so members of the community cannot receive government funding for cultural programs. Members of the group have turned to geneticists to find answers to their questions.

Building trust and long-term partnerships with communities is not easy, and many in the field are still struggling to understand how to achieve scientific goals and respect cultural sensitivity. Geneticists are concerned that some still view indigenous peoples as guinea pigs rather than research partners, an egregious approach that Native Hawaiian anthropologist Keolu Fox describes as "*biocolonial*."

To date, there has been a lack of reliable data and information on indigenous peoples, as well as biopiracy and misuse of their traditional knowledge and cultural heritage. These are the problems that were addressed in the process of drafting and negotiating the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). Paradoxically, even with the onset of the global "information revolution,"

[24] Resolution A/RES/70/299 adopted by the General Assembly on 29 July 2016. Follow-up and review of the 2030 Agenda for Sustainable Development at the global level (A/70/L.60). Available at: https://documents-dds-ny.un.org/doc/UNDOC/GEN/N16/241/59/PDF/N1624159.pdf?OpenElement [Accessed 24.01.2022].

these problems persist in many countries where indigenous peoples live. The United Nations Permanent Forum on Indigenous Issues at its first and second sessions[25] (2002, 2003) has already recognized that a key problem facing national and international bodies is the lack of disaggregated data on indigenous peoples.

The lack or scarcity of information on the territory and numbers of indigenous peoples, on how individual and collective rights are being realized, is directly linked to the weakness of the policies of governments and inter-governmental bodies in formulating and realizing the rights of indigenous peoples. Several expert meetings and forum meetings have produced recommendations on how data on indigenous peoples can be collected and disaggregated, and on how and which indicators should be used to measure the implementation of the Sustainable Development Goals, with respect to the realization of indigenous peoples' rights.

Data should be collected to measure compliance with indigenous peoples' rights to access and ownership of lands, territories and resources; how their participation in decision-making and control over their own development processes is progressing; what kind of control they can exercise over data and knowledge; and what discrimination and exclusion they face with regard to their social, economic and cultural rights.

United Nations forums have emphasized that indigenous peoples should control data and that their effective participation in data collection and research should be ensured. Moreover, the resulting data should be available for their use in policy formulation, planning, and monitoring and evaluation. Unfortunately, there is still a long way to go before such data collection and disaggregation is done in most countries outside Canada, Australia, New Zealand, the USA and some Latin American countries.

A common concern raised by governments is the lack of financial and technical resources to undertake this task. Another unfounded fear, repeatedly expressed by some governments, is that creating disaggregated data could exacerbate discrimination and that differentiating data could lead to conflict. Such concerns should not be used to deny indigenous

[25] United Nations Permanent Forum on Indigenous Issues at its first and second sessions (2002, 2003).

peoples their right to self-determination (Article 3 of the UNDRIP), which is the freedom to choose their political status and freely pursue their economic, social and cultural development. This right necessarily includes guarantees that the data and information collected by or with them reflects their past and present realities and provides the basis for their aspirations for autonomous economic, social and cultural development. *The concept of data sovereignty* is linked to indigenous peoples' right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as their right to maintain, control, protect and develop their intellectual property over them.

The emergence of a global information revolution and related new technologies can be a double-edged sword for indigenous peoples. If indigenous peoples control how data and knowledge will be generated, analyzed and documented, as well as disseminated and used, positive results can be achieved. Collecting and disaggregating data on indigenous peoples and documenting and transferring their knowledge to younger generations can be facilitated. They can be the main beneficiaries of the use of data, their knowledge and their cultural heritage (Kukutai and Taylor, 2016).

However, if indigenous peoples lose control due to the lack of existing laws and policies recognizing their rights and regulating the behavior of institutions and individuals involved in the collection and dissemination of data and knowledge, marginalization, inequality and discrimination will persist. Respect for their right to obtain their free, prior and informed consent before the data collection and dissemination is crucial to prevent this.

As more businesses and organizations have adopted cloud-based data storage models, this raised concerns about the security and confidentiality of data stored abroad, as well as the legal framework and principles of confidentiality to which these data are subject, including the data problem.

It should be recalled that there are small indigenous peoples in Europe, although not as well-known as the indigenous peoples of the Americas as well as other parts of the world. Like all Europeans, various international instruments guarantee certain human rights to these

peoples but the right of such peoples to live a traditional way of life in Europe is not well established. For complex socio-historical reasons, complaints by indigenous community peoples in Europe are often ignored and communities are not often able to obtain a substantive resolution before the bodies of the European Convention on Human Rights. The lack of substantive resolution of these complaints in Europe stands in stark contrast to the practice of the Inter-American Court of Human Rights (IACHR), where cases affecting indigenous peoples are regularly heard and decided. As a result, the rights of indigenous peoples in the Americas are better and better established (Ruozzi, 2011), while in Europe such rights are hardly mentioned. However, this difference between the European and inter-American systems is not insurmountable, and the Council of Europe can learn from the inter-American human rights system how to defend the rights of indigenous representatives.

There are very few indigenous communal peoples left in Europe today, such as the Saami in Scandinavia, and various indigenous communal peoples in Siberia and northern Russia (Vakhtin, 1994, 2019).[26] These groups are small in number, compared to those in South and Central America, where there are now over 800 distinct indigenous groups. The small number of indigenous communal peoples in Europe[27] is the main reason that minority rights protection in Europe concentrates on the more linguistically and religiously distinct communities. The difference in the number of cases concerning indigenous communal peoples between the ECHR[28] and IACHR[29] can be explained by the size

[26] In Russia, they, among others, include the Samoyeds, Yakuts, Khantis, and the Manysis. Indigenous Peoples of the North.

[27] G. & E. v. Norway, App. No 9278/81, 35 Eur. Comm'n H.R. Dec. & Rep. 30 (1983).

[28] ECtHR jurisprudence on indigenous peoples: O.B. and Others Against Norway, O.B. & Others, App. No 15997/90, Eur. Comm'n H.R. Dec. & Rep., at 8–9. Könkäma and 38 other Saami Villages v. Sweden, App. No 27033/95, Eur. Comm'n H.R. Dec. & Rep. (1996), http://hudoc.echr.coe.int/app/conversion/pdf/?library=ECHR&id=001-3390&filename=001-3390.pdf&TID=THkbhnilzk; Halvar From Against Sweden; Johtti Sapmelaccat RY and Others Against Finland; the Muonio Saami Village Against Sweden; Hingitag 53 Against Denmark, Handolsdalen Sami Village and Others Against Sweden; Chagos Islanders Against United Kingdom.

[29] IACHR's jurisprudence in relation to indigenous peoples: Kichwa Indigenous People of Sarayaku v. Ecuador, Merits & Reparations, Judgment, Inter-Am. Ct. H.R.

of the population concerned. However, the significant differences in decisions in such cases are not so easily explained. Of the few cases submitted to the ECtHR and the European Commission of Human Rights, almost all were rejected at the stage of determining admissibility on the merits. The complaints did not get to the merits.

IV. International Legal Recognition of Indigenous Peoples' Somatic Rights in Processing of Genetic Information

In contemporary international human rights law, everyone has the fundamental and inalienable right to respect for his or her dignity, uniqueness, uniqueness and non-discrimination on the basis of genetic heritage. The European legal system has established the fundamental principles of bioethics: *respect for dignity, autonomy, integrity, good faith, vulnerability, free and informed consent, responsibility and justice*. Russia has also launched a genetic technology development program from 2019, which runs until 2027, with plans to create full genomic portfolios of up to 250,000 DNA samples by 2024.

The Universal Declaration on the Human Genome and Human Rights[30] recognizes the special status of human genetic data as being confidential since they can be predictive of genetic predispositions

(ser. C) No 245 (June 27, 2012); Indigenous Communities of the Xingu River Basin in Para v. Brazil, Inter-Am. Comm'n H.R., Apr. 11, 2011, (PM 382/10); Salvador Chiriboga v. Ecuador, Reparations and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 222 (Mar. 3, 2011); Xákmok Kásek Indigenous Community v. Paraguay, Merits, Reparations, and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 214 (Aug. 24, 2010); Saramaka People v. Suriname, Preliminary Objections, Merits, Reparations, and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 172 (Nov. 28, 2007); Sawhoyamaxa Indigenous Community v. Paraguay, Merits, Reparations and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 146 (Mar. 29, 2006); Yakye Axa Indigenous Community v. Paraguay, Inter-Am. Ct. H.R. (ser. C) No 125 (June 17, 2005); Moiwana Community v. Suriname, Preliminary Objections, Merits, Reparations and Costs, Judgment, Inter-Am. Ct. H.R. (ser. C) No 124 (June 15, 2005); Mayagna (Sumo) Awas Tingni Community v. Nicaragua, Inter-Amer. Ct. H.R. (ser. C) No 79 (Aug. 31 2001); IACHR, Report No 96/03, Case 12.053, Maya Indigenous Communities of the Toledo District (Belize), October 24, 2003.

[30] Universal Declaration on the Human Genome and Human Rights adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organization. Available at: https://www.un.org/ru/documents/decl_conv/declarations/human_genome.shtml [Accessed 24.01.2022].

concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data. Furthermore, it is interesting to note that such data may have a significant impact on the family, including offspring, and in some instances on the whole group, extending over generations; because they may contain information the significance of which may not be known at the time of collection of biological samples; and because they may have cultural significance for individuals or groups.

The generation of somatic rights is regulated by a number of international legal instruments, among which the most important are the following:

— Convention for the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine, adopted by the Council of Europe in 1997;

— Resolution 2001/39 of 26 July 2004 on "Genetic privacy and non-discrimination";

— Resolution 2003/69 of 25 April 2003 on "Human rights and bioethics";

— United Nations Declaration on Human Cloning, which was adopted by the United Nations General Assembly in 2005.

This international instrument has received worldwide support from the international community and has also influenced Member States using it in the development of their legislation, regulations, norms and standards, as well as codes of ethics and guidelines. The provisions of the Declaration state that international and regional instruments, national laws, regulations and ethical texts relating to the protection of human rights and fundamental freedoms and to respect for human dignity as regards the collection, processing, use and storage of scientific data, as well as of medical data and personal data, shall be based on this instrument.

Since the development of innovations today often requires the use of the full diversity of genetic resources, one of the central issues in the current debate is the need to expand the requirement for patent disclosure. There has always been some tension between patent law and biodiversity law, which has often been a source of disagreement.

The Convention on Biological Diversity defines "genetic resources" as "genetic material of actual and potential value" and "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity."[31] The latter expression is generally understood to mean that the material must contain DNA (deoxyribonucleic acid) and RNA (ribonucleic acid).

In 2013, the United States Supreme Court ruled that genes cannot be patented since DNA is a product of nature.[32] The decision of the United States Supreme Court declared the previous patents null and void making previously patented genes available again. The debate is evolving against the backdrop of the hesitancy of individual states to recognize the significance of the moral and ethical conflict in patenting, which boils down to the following dilemma: one party to the conflict advocates patents and sees this right as protecting intellectual property and ensuring further development of science, while the other party raises concerns about patenting natural objects and respect for the fundamental principles of dignity and integrity of persons.

WIPO developed the Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge,[33] which is a technical study of the current legal and practical issues surrounding the patent disclosure of information on genetic resources. The study identifies specific disclosure requirements for genetic resources and traditional knowledge:

1) define the legal status of genetic resources and traditional knowledge, the requirement of legality on mutually agreed terms);

2) disclosure of the origin and/or source of genetic resources and traditional knowledge;

3) a statement of due diligence in which the applicant reports compliance with all applicable legal requirements for access and utilization of genetic resources.

[31] Article 2 of the UN Convention on Biological Diversity of 05.06.1992. Available at: https://www.un.org/ru/documents/decl_conv/conventions/biodiv.shtml [Accessed 24.01.2022].

[32] US Supreme Court says human DNA cannot be patented. Available at: https://www.bbc.com/news/world-us-canada-22895161 [Accessed 24.01.2022].

[33] Patent disclosure requirements for genetic resources and traditional knowledge. Main issues. Second edition. 2009. Available at: https://www.wipo.int/edocs/pubdocs/ru/wipo_pub_1047_19.pdf [Accessed 24.01.2022] (In Russ.).

However, it should be noted that human genetic resources are excluded from the scope of application of the UN Convention on Biological Diversity. Such an exclusion is also provided for in the patent disclosure requirements of national legal systems.

On the one hand, the expansion of genomic research and the novelty of the methods used has given a powerful impetus to the development of medical and other scientific research, the diagnosis and treatment of diseases, and the identification of evidence in criminal proceedings. On the other hand, the rapidity of research on the human genome has given rise to a number of problems associated with the specifics of the subject of legal regulation in this area. Since the genome, as a global phenomenon, affects the interests of all mankind and has a special nature of regulation of information obtained in the course of genomic research, the subject of legal regulation in this area is also heterogeneous and constantly subject to transformations. Firstly, the subject under consideration includes relations that directly affect the conduct of genomic studies and their subsequent implementation in various social spheres. Secondly, it includes relations related to the obtaining and further use of information on the human genome (Kalinichenko, 2020).

The rapid progress in genomic developments (genetic editing and gene engineering, genomic testing and genomic registration, genomic screening and monitoring) has also generated ethical problems, which have some peculiarities. First, genomic research involves risks to human life and health. It is important to note that there are particularly acute questions about editing the genome at the embryonic stage. Secondly, any experiments on an individual's genome will affect not only the individual subject, but also their descendants, which also requires special precautions to be taken. Lastly, ethical problems often arise in cases where human genome research is conducted for scientific rather than clinical purposes, that is, research is not directed towards crucial human goals (Yudin, 1998, pp. 242–243).

The regulation of genomic research is primarily aimed at protecting human rights, at carrying out safe activities, and at protecting intellectual property. However, so far there has been no centralized, uniform approach to the regulation of this sphere at the universal level.

The first international document regulating the ethical side of the issue of human research (including research in such spheres as genetics and medicine) was the Nuremberg Code of 1947, which had a recommendatory character. The Code, adopted at the conclusion of the Nuremberg trials,[34] is considered to be the first set of rules that established ethical guidelines and standards for research and experimentation on humans (Siliyanova, 2014, p. 85). The Nuremberg Code, for example, made voluntary consent obligatory for medical and other types of research on human subjects. The subject of the research must be recognized as competent to do so and must be informed of all aspects of the research to be conducted (Yudin, 1998, 36–362). In this way, the principle of free and informed consent, which was first enshrined in the Nuremberg Code, has become one of the key documents in bioethics[35] in subsequent years.

Another document of great influence on bioethics is the Declaration of Helsinki of the World Medical Association (1964)[36] that also has a recommendatory character. This document, unlike the Nuremberg Code, allows for consent to medical research on human subjects, even when the subject is declared incompetent. In this case, consent must be obtained from the legal representative of the subject (Article 28). The 1964 Declaration of Helsinki also established the most important bioethical principle — that the rights and interests of the research subject must take priority over the aims and purposes of the research (Article 8).

Specific provisions of the International Covenant on Civil and Political Rights[37] adopted by the United Nations General Assembly in

[34] A major trial (1945–1946) where the main war criminals of World War II were convicted.

[35] A field of interdisciplinary research aimed at solving ethical problems that have arisen as a result of scientific research.

[36] The Declaration of Helsinki of the World Medical Association, 1964. (Revised 19.10.2013). Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects [Accessed 05.03.2021].

[37] International Covenant on Civil and Political Rights, 1966. Available at: https://www.un.org/ru/documents/decl_conv/conventions/pactpol.shtml [Accessed 24.01.2022].

1966, also address the bioethical side of the research on human beings. This paper emphasizes that it is prohibited to perform medical and other experiments on human beings without their free consent (Art. 7).

Thus, it may be concluded that long before human genome research was actively pursued, bioethical foundations have already been laid for regulating the safety of scientific experiments on human beings and their biological samples. Although the 1947 Code of Nuremberg and the 1964 Declaration of Helsinki of the WMA are nonetheless only recommendatory in nature and pertain primarily to research for medical purposes, they were nonetheless a significant step in the history of bioethics, and all subsequent documents on the subject have been adopted with them in mind. As for the 1966 International Covenant on Civil and Political Rights, it already constitutes an element of international law, thereby establishing provisions for the patient's free consent.

The UNESCO Declaration of 1997 equates the human genome with "the heritage of humanity" (Art. 1) that cannot be "a source of revenue" (Art. 4). Articles 5 to 9 of this Declaration outline the fundamental rights of the persons concerned. These include a mandatory prior careful assessment of the risks and verification of the intended results, the right to free and informed consent (that can also be obtained from others within the framework of national legislation), the right to non-discrimination, the right to confidentiality of the genetic information provided and, in the event of harm, the right to compensation. However, the UNESCO Declaration of 1997 envisages the possibility of limiting the principles of confidentiality and consent where there are "very serious reasons" which are not explained. By analogy, for example, with the 1964 Declaration of Helsinki, the 1997 UNESCO Declaration also states that human rights and freedoms prevail over scientific goals (Art. 10). One of the characteristics of the 1997 UNESCO Declaration is that the person concerned has the right to accept or refuse to be informed of the results and consequences of genetic analysis (Art. 5), that is to say, a person's right to be ignorant.

The instrument is consistent with and supports the objectives of the Convention on Biological Diversity and the Nagoya Protocol, and is not inconsistent with those objectives, including with regard to the

following aspects: (a) consistency with the conservation and sustainable use objectives of biodiversity; (b) fairness and equity in benefit sharing; (c) legal certainty in relation to access to genetic resources or traditional knowledge associated with genetic resources, including, as appropriate, prior informed consent and benefit sharing; (d) full and effective participation of relevant indigenous peoples and local communities; (e) contribution to sustainable development arising from internationally agreed goals; (f) other general principles of law, including good faith and efficiency.

The provisions of the United Nations Declaration on the Rights of Indigenous Peoples[38] are important in this regard: "all peoples contribute to the diversity and richness of civilizations and cultures, which constitute the common heritage of humankind." Furthermore, Member States need to recognize the urgent need to respect and promote the inherent rights of indigenous peoples based on their political, economic and social structures as well as on their cultures, spiritual traditions, histories and philosophies, especially their rights to their lands, territories and resources. Also noteworthy is the need to respect indigenous peoples' knowledge, culture and traditional practices that contribute to sustainable and equitable development and appropriate care for the environment. Thus, Article 2 of the Declaration stresses that "Indigenous individuals and peoples are free and equal to all other peoples and individuals among them and have the right to be free from any kind of discrimination in the exercise of their rights, in particular discrimination based on their indigenous origin or identity." Article 31 of the Declaration states: "Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their

[38] United Nations Declaration on the Rights of Indigenous Peoples, adopted by General Assembly resolution 61/295 of 13 September 2007.

intellectual property over such cultural heritage, traditional knowledge and traditional cultural expressions." As can be seen from the text of the Declaration, indigenous peoples are granted a special legal regime for the protection of rights and freedoms.

Attention should also be drawn to the draft Recommendation on the Protection and Use of Health-Related Data.[39] The document provides for the importance of adopting a legal framework for the processing of health data. According to the drafters, the Guidelines should provide a common international legal basis for minimum standards for the protection of health-related data, enshrine legal provisions at the national level, and be a point of reference for the ongoing debate on how the right to privacy can be protected in the context of cross-border transfers of health data in combination with other human rights. According to the text of the submitted draft, "genetic data" means all personal data on a person's genetic characteristics that are either inherited or obtained during prenatal development, since they result from analysis of a biological sample of the person concerned, in particular chromosome, DNA or RNA analysis or any other element that provides equivalent information.[40] In working on the draft, two questions arose for the experts: (a) should non-genetic information revealing genetic information, such as family history, be included in the definition? (b) should data on somatic tumor mutation, which may not necessarily be considered an acquired characteristic of the individual, be specified. It is noteworthy that "before any data processing, individuals should be informed of the possibility of **not receiving information** about

[39] Draft Recommendation on the Protection and use of health-related data T-PD (2017)03. Mandate of the United Nations Special Rapporteur on the Right to Privacy — Task Force on Privacy and the Protection of Health Data the importance of a legitimate basis for data processing of health-related data. The Consultative Committee of the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data. Available at: https://rm.coe.int/draft-recommendation-on-the-protection-and-use-of-health-related-data/1680943beb [Accessed 24.01.2022]. Council of Europe, Committee of Ministers, Recommendation No R(97)5 on the Protection of Medical Data (Feb. 13, 1997). Available at: http://hrlibrary.umn.edu/instree/coerecr97-5.html [Accessed 24.01.2022].

[40] Draft Recommendation on the Protection and Use of Health-Related Data. Available at: https://rm.coe.int/draft-recommendation-on-the-protection-and-use-of-health-related-data/1680943beb [Accessed 24.01.2022].

the results, including any incidental findings. The wish not to receive such information may, in exceptional circumstances, be restricted, as provided for by law, in such cases where the doctor has a duty of care or where it is in the public health interest to do so. A person's wish to remain ignorant of a diagnosis or prognosis should be respected, except where this poses a serious risk to the health of third parties. The information that the data subject has a right to know under this provision does not extend to unverified research results, where in an objective assessment granting access could be misleading." The text of the draft is currently being worked on.

Nevertheless, from a scientific and technical point of view, various human genetic materials, including specimens from indigenous peoples, could be used in, or form the basis for, patented inventions. Therefore, some national and regional laws and regulations address the issue in terms of patent disclosure. A prime example is Section 8(b) of the Patents Act No 9 of December 5, 1967 (as amended in 2016), which provides as follows: "Where the invention relates to or involves the use of biological material derived from the human body, the patent application shall include information as to whether the person from whom the biological material was obtained has given his consent to its use under the Biobank Act No 12 of 21 February 2003."

According to the Preamble of Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, a distinction is made between biological material of human origin and biological material of plant or animal origin and applicants are encouraged to obtain prior informed consent from the person who submitted such material:

"(26) Where, however, the invention is based on, or involves biological material of human origin, the person from whose body such material was taken should, when filing the patent application, be able to give free and informed consent, subject to the provisions of national law."

V. Conclusion

The author concludes that the relevance of genetic research on indigenous peoples' DNA in the world is growing. The technological revolution makes it necessary to speak of the importance of protection

of personal data in indigenous DNA research in cyberspace, the non-return to eugenics and the necessary adoption of common international ethical and legal standards. The author draws attention to possible future violations of somatic rights in the creation of national and personalized biobanks, genomic sovereignty of individual nations and peoples. There is an urgent need for States and private corporations in the conduct of their business to comply with UN SDGs 2030 and respect the rights of indigenous peoples and local communities as recognized. At present, international law regulates genomic research on the basis of international soft law, which, first of all, relates to the specificity of the subject matter of the area in question. The concept of soft law includes prescriptions by public authorities, which are not legally binding but are social regulators. Soft law plays an important role, as often not only directs the legal discourse, but also provides the framework for strong rules.

The regulation of genomic research is primarily aimed at protecting human rights, at carrying out safe activities, and at protecting intellectual property. However, so far there has been no centralized, uniform approach to regulating this sphere at the universal level.

The establishment of specialized committees to develop international standards for the control of genomic research, as well as the preparation of documents regulating the safety of this research, is carried out at the universal level within the framework of such international organizations as the United Nations (UN), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the United Nations Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the World Health Organization (WHO) and others.

The basic principles for the regulation of research in the field of the human genome are laid down in universal international documents that ensure the protection of human rights, such as, for example: Universal Declaration of Human Rights of 10.12.1948; UN International Convention on the Elimination of All Forms of Racial Discrimination of 21.12.1965; UN International Covenant on Economic, Social and Cultural Rights and on Civil and Political Rights of 16.12.1966; UN Convention on the Elimination of All Forms of Discrimination against

Women of 18.12.1979; UN Convention on the Rights of the Child of 20.11.1989 (Dubov and Dyakov, 2019, p. 129).

The author therefore proposes that States draft a Convention on the prohibition of racial and ethnic weapons. The author concludes that it is necessary to define as an international crime (crime of "genomocide"[41] against indigenous peoples) any illegal actions with the use of modern biotechnology and genetic engineering methods, committed with the intention to destroy, fully or partially, any national, ethnic, racial or religious group as such. For example, in its application to the International Court of Justice in the Nuclear Weapons case, Australia pointed out that the use of biological weapons[42] would violate "fundamental general principles of humanity."[43] Indigenous individuals must not be subjected to any act of genocide or any other act of violence, and genetic research must respect all internationally guaranteed rights and freedoms, as well as biosecurity measures. Although human genes are not covered by the Convention on Biodiversity,[44] it should be applied by analogy in the case of the protection of the "genetic" heritage of mankind.

The author points to the need to address the legal vacuum in terminology regarding the concept of "indigenous peoples" and to the importance of making contact, obtaining indigenous consent for genetic studies and ensuring that the tribe is adequately represented in project

[41] A new type of genocide defined as the following unlawful acts: (a) killing members of such a group; (b) causing serious bodily or mental harm to members of such a group; (c) deliberately creating living conditions for a group calculated to bring about its physical destruction in whole or in part; (d) measures calculated to prevent births within such a group; (e) forcibly transferring children from one human group to another. *See* Convention on the Prevention and Punishment of the Crime of Genocide, adopted by UN General Assembly Resolution 260 (III) of 9 December 1948. Available at: https://www.un.org/ru/documents/decl_conv/conventions/genocide.shtml [Accessed 24.01.2022].

[42] Biological (bacteriological) weapons are the first category of WMD to fall under the universal prohibition that has become a peremptory norm of international law.

[43] Australia, Oral pleadings before the ICJ in the Nuclear Weapons case (ibid, § 79).

[44] 1992 UN Convention on Biological Diversity. Available at: https://www.un.org/ru/documents/decl_conv/conventions/biodiv.shtml [Accessed 24.01.2022].

publications on genetic studies. Genetic epidemiologists point out that it is crucial to be cautious about making results public on sensitive issues such as migration and population mixing (Marzeca, 2017).

Indigenous health on a global scale is determined by the intergenerational effects of colonization and the persistence of unjust social practices and policies of violence, institutional discrimination and racism. Examples of ethical violations (for instance, forced sterilization, act of genocide, gender-based violence, discrimination, and torture) in the history of genomic research and the lack of specific policies and specific governance bodies for indigenous genomic data reflect centuries of colonization, raise legitimate concerns and reluctance of some indigenous communities to join genomic research projects. Health inequalities hamper efforts to address health issues specific to indigenous peoples. The challenge is to ensure equitable conditions for the participation of indigenous people in genomic research and health care. Therefore, indigenous peoples' ability to have access to genomic tools for diagnosis and to have choices in this scientific space is crucial.

It is a serious concern that Indigenous Peoples currently do not have equitable access to health services and resources, to geneticists, and to genomic and genetic research. Furthermore, proponents of genomic medicine should learn from the stories of genetics/genomics among indigenous peoples and think about what is needed to provide the benefits and opportunities of genomic science. The model of such research should be changed with respect for indigenous peoples, their ancestors and future generations.

In addition, researchers have noted the lack of due consideration for indigenous communities, which is reflected in the lack of indigenous scientists, genomic researchers, medical geneticists, genetic counselors, practitioners and staff in research organizations, as well as in the editorial boards of scientific publications. Such capacity is needed to lead genomic research and clinical trials on fair terms.

The most important international instrument in the field of genomic research to date is the Universal Declaration on the Human Genome and Human Rights,[45] adopted on 11 November 1997 under the

[45] Universal Declaration on the Human Genome and Human Rights, 1997. Available at: https://www.un.org/ru/documents/decl_conv/declarations/human_genome.shtml [Accessed 24.01.2022].

auspices of UNESCO. The 1997 UNESCO Declaration stresses the need for international cooperation in the field of genomic research in order to meet the ethical and legal challenges posed by scientific research. This Declaration has been reflected in many regional and national legislations.

It should be emphasized that the principles of international instruments are based on the values of humanism and individualism, *i.e.*, the interests of the individual prevail over the interests of society and science. To date, the activities of international governmental and non-governmental organizations are based on the following key principles: 1) respect for human dignity and the right to privacy and confidentiality of genetic data; 2) principle of informed voluntary consent; 3) principle of equality, non-discrimination and fair treatment; 4) prior assessment of risks, results and benefits of research; 5) promotion of international cooperation in the field of genomic development; 6) protection of genetic material of future generations, environmental protection and biodiversity; 7) prohibition of financial gain from research findings.

In this regard, the author of this study calls for the genetic research of DNA samples of indigenous peoples and local communities to comply with international human rights standards, as set out in international instruments and based on the principles of justice, democracy, respect for human rights, non-discrimination and good faith. The author recalls that indigenous peoples have collective rights that are essential to their existence, well-being and full development as peoples. The establishment of a single international regulatory framework and the formulation of an explicit policy by each State that together would balance the potential benefits and risks of genomic and post-genomic technologies. Thus, already at this stage, humankind recognizes the need to move from soft law in regulating the safety of genomic research to the law itself.

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International Legal Framework for the Application of Genetic Technologies: Main Features and Issues Open for Discussion

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Abstract: The objective of the present article is to determine the specific characteristics of the established international legal framework for the application of genetic technologies and to identify general guidelines that influence states' policies in this area.

Genetic technologies evolve rapidly, raising a number of ethical and legal issues and directly affecting human rights. At the universal level, there is still no international treaty containing uniform rules in this field. At the regional level, the experience of the Council of Europe deserves further study. National approaches to the legal regulation of applying genetic technologies differ since States retain a great deal of discretion in regulating these issues.

Though the Council of Europe Member States enjoy a margin of appreciation in regulating the use of genetic technologies, a number of common distinctive features underlying the international legal framework in this area can still be singled out. These are informed consent, prohibition of reproductive human cloning, prohibition of germ line modification with certain exceptions. They arise primarily from the Oviedo Convention, the Protocols thereto and the ECtHR practice. Soft law documents adopted at the UN, UNESCO and the Council of Europe contribute to the process of their formation, too, but to a lesser extent. The efforts undertaken at the European and universal level shape modern international legal regulation in the field and set up the course of action for States to follow.

Keywords: genome; genetic technologies; bioethics; biomedicine; human rights; informed consent; genetic testing; human cloning; UN; UNESCO; Council of Europe; ECtHR

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Contents

I. Introduction

Genetic technologies are developing very rapidly and the scope of their application is expanding. Undoubtedly, the efforts of the United Nations (UN) and the United Nations Educational, Scientific, and Cultural Organization (UNESCO) aimed at regulating their application have borne some fruit. However, the documents developed by them at the universal level are not legally binding and constitute only the initial guidelines for humanity that faces the obvious need for international legal regulation of such new phenomena as genome research and the use of genetic technologies. At the regional level, the Council of Europe tries to resolve difficult issues that arise in the process of interaction between biomedicine and human rights and eliminate contradictions between ethical considerations and international law. The European Court of Human Rights (ECtHR) functioning under the auspices of the Council of Europe, has already established a notable practice of considering individual complaints on various aspects of the genetic technologies use.

Applying genetic technologies directly affect human rights and raises many legal and ethical issues. The range of these legal questions is fairly broad. Some of these problems would be considered in this article: the need to comply with appropriate ethical and legal standards in all research involving human beings; ensuring equal access to using genetic technologies in the context of the right to health; observing current prohibitions in the use of genetic technologies and searching for the answers what prohibitions are necessary and effective.

II. Regulating the Application of Genetic Technologies at the Universal Level

There is a number of international legal acts in the field of intellectual property protection that touched upon certain aspects of the applied use of genetics, namely the Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO World Copyright Convention of 6 September 1952 (both of them were revised in Paris on 24 July 1971), the Paris Convention on the Protection of Industrial Property of 20 March 1883 (revised on 14 July 1967), the Budapest Treaty of the World Intellectual Property Organization (WIPO) on the International Recognition of the Deposit of Microorganisms for the Purposes of the Patent Issuance Procedure of 28 April 1977, the Agreement on Trade Aspects of Intellectual Property Rights (TRIPS), contained in the annex to the Agreement on the Establishment of the World Trade Organization of 15 April 1994, as well as in the UN Convention on Biological Diversity of 5 June 1992.

Over time the UN and its specialized agencies such as the UNESCO and the World Health Organization (WHO) started to regulate the use of genetic technologies and establish ethical principles that underlie the process more specifically. The UNESCO elaborated the Declaration on the Human Genome and Human Rights in November, 1997 and the Universal Declaration on Bioethics and Human Rights in October, 2005. In March, 2005 the UN General Assembly adopted the United Nations Declaration on Human Cloning. In 2016, International Ethical Guidelines for Human Health Research were developed jointly by the WHO and the Council for International Organizations of Medical

Sciences (CIOMS), an international non-governmental organization (NGO) that represents the biomedical scientific community.

The Universal Declaration on the Human Genome and Human Rights,[1] adopted by the UNESCO General Conference on 11 November 1997, contains provisions concerning the human genome and its treatment, human rights in the context of genetic research, conditions for scientific activities, implementation of the above-mentioned provisions.

In section A "Human dignity and the human genome," the human genome is declared the heritage of humanity. It forms the basis for the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity (Article 1). The Declaration establishes everyone's right to respect for their dignity and human rights, regardless of genetic characteristics, thereby introducing the prohibition of genetic discrimination (Article 2). Article 3 recognizes the possibility of mutations in the human genome due to its evolving nature: the potentialities contained in the human genome manifest themselves differently depending on the influence of natural and social environment. Article 4 bans receiving financial gains from the human genome. One should pay attention to the fact that the human genome should not serve as a source of financial gains only "in its natural state," therefore we can conclude that the human genome if modified, can still become a source of financial enrichment. In addition, a ban is introduced in respect of receiving financial gains from the genome in its natural state, but not from the entire genomic turnover or any manipulations with the genome. Thus, it is worth emphasizing that the 1997 Universal Declaration on the Human Genome and Human Rights addresses the issues of genomic turnover and manipulation with genomes in a rather liberal way.

The provisions of Section B enshrine human rights in the use of the individual's genome. Article 5 deals with some procedural issues of genome research, in particular, it covers issues of the prior, free and informed consent, control over research, as well as exceptions

[1] Universal Declaration on the Human Genome and Human Rights, 11 November 1997. UNESCO Legal Instruments. Available at: https://www.ohchr.org/en/instruments-mechanisms/instruments/universal-declaration-human-genome-and-human-rights [Accessed 10.02.2022].

to these rules for the direct health benefit. Article 6 deals with genetic discrimination and its prohibition. Article 7 declares that the confidentiality of genetic data must be protected by law. Article 8 declares a right of a person to just reparation for any damage sustained as a direct and determining result of an intervention affecting his or her genome. The formulation in Article 8 raises questions of whether the human genome is viewed as a part of the human body or as an object of scientific research. Most probably, this article should be interpreted restrictively. In other words, the direct and determining impact can only take place in situations when the genome is considered a part of a person. Article 9 declares that within the bounds of public international law and the international law of human rights, limitations on the rights to confidentiality of information about genetic data and the procedure for obtaining informed consent may be imposed.

Section C deals with various issues of human genome research. Article 10 declares that no research and no research applications concerning the human genome, in particular in the fields of biology, genetics, and medicine, should prevail over respect for human rights, fundamental freedoms, and human dignity. Similar provisions were laid down in the acts of international NGOs, in particular, in the 1964 Helsinki Declaration of the World Medical Association "Ethical Principles for Medical Research Involving Human Subjects."[2] Article 11 states that practices that are contrary to human dignity shall not be permitted. However, it is not specified whether research or production practices are meant precisely. "Reproductive cloning of human beings" is cited as a specific example. Though this type of cloning of human beings is expressly prohibited, cloning for research purposes or for obtaining any biomedical products is hypothetically allowed. This is another confirmation of the liberal approach that guided the process of elaborating the Universal Declaration on the Human Genome and Human Rights back in 1997. We believe that this prohibition should bear a comprehensive character: any activity with the human genome

[2] Helsinki Declaration "Ethical Principles for Medical Research Involving Human Subjects", adopted in Helsinki in June 1964. World Medical Association. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [Accessed 10.02.2022].

that contradicts human dignity is unacceptable. Article 12 declares such principles of human genome research as the principle of availability of benefits from advances in biology, genetics, and medicine for all and the principle of freedom of research, which is an integral part of freedom of thought.

Section D indicates conditions for the exercise of scientific activities in this field. Article 13 declares that public and private science policy-makers should bear particular responsibilities in this respect. What is meant here is "meticulousness, caution, intellectual honesty and integrity" in carrying out genetic research. Articles 14, 15, and 16 characterize the role of the State in human genome research. States are obliged to undertake the following actions:

1) foster the intellectual and material conditions favorable to freedom in the conduct of research on the human genome and consider the ethical, legal, social and economic implications of such research, based on the principles set out in this Declaration;

2) provide the framework for the free exercise of research on the human genome with due regard for the Declaration principles, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health;

3) recognize the value of promoting at various levels the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised;

4) seek to ensure that research results are not used for non-peaceful purposes.

Section E proclaims priority support for individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character (Article 17) and also covers some international cooperation issues (Articles 18 and 19). Sections F and G contain provisions on promotion and implementation of the 1997 Universal Declaration on the Human Genome and Human Rights.

Summing up, one should bear in mind that the 1997 Declaration on the Human Genome is one of the few international legal acts regulating the use of genetic technologies. The Declaration highlights a number of issues, such as the prohibition of genetic discrimination, procedures for genome research and obtaining informed consent, the

participation of ethics committees, the need to support individuals and groups of the population most vulnerable to genetic diseases as well as issues of international cooperation. The authors of this document could have further elaborated on the issues of manipulations with the human genome in light of their ethical acceptability, the legal status of the human genome, the functioning of ethical committees. In the 1964 Helsinki Declaration "Ethical principles of conducting medical research involving human subjects," many of the issues mentioned above had been laid down in a more detailed way.

In the fall of 2001 France and Germany made an appeal to the UN General Assembly to develop a new global regulatory instrument, more precisely an international convention against the reproductive cloning of humans.[3] On 8 March 2005, the UN General Assembly adopted the United Nations Declaration on Human Cloning[4] that is often characterized as a purely political declaration — "as a way of emphasizing the degree of compromise reflected in the text and also as a way of minimizing its normative value" (Arsanjani, 2006, p. 164). It does not directly prohibit human cloning, including for reproductive purposes. Its main goals were to draw the attention of the public, the international scientific community and governments to the problems of bioethics and to promote the development of national legislation to regulate stem cell research. In paragraph (a), the 2005 UN Declaration on Human Cloning calls on Member States to take "all measures necessary to protect adequately human life in the application of life sciences," which can be interpreted broadly even as a ban on abortion. In paragraph (b), States are called upon to prohibit "all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life." In paragraph (c), Member States are further "called upon to adopt the measures necessary to prohibit the

[3] Legal Committee calls for Working Groups on human cloning, better protection for UN, related personnel; other texts also approved. UN General Assembly Sixth Committee. GA/L/3199, 19 November 2001. Available at: https://www.un.org/press/en/2001/GAL3199.doc.htm [Accessed 11.02.2022].

[4] United Nations Declaration on Human Cloning, UN General Assembly Resolution 59/290, annex. 8 March 2005. United Nations Digital Library. Available at: https://digitallibrary.un.org/record/543570 [Accessed 11.02.2022].

application of genetic engineering techniques that may be contrary to human dignity." In paragraph (e), Member States are also "called upon to adopt and implement without delay national legislation" to bring into effect all the aforementioned provisions.

The UN General Assembly adopted the text by a vote of 84 in favor to 34 against, with 37 abstentions. During the negotiations at the UN on the possibility of human cloning, the states were divided into two groups. They held different views on cloning issues due to their predominant religious and ethical traditions (Arsanjani, 2004, pp. 151–157). Both groups were in favor of an unconditional ban on reproductive cloning of humans. However, the group of industrialized countries (France, Germany, Belgium, China, India, Japan, Russia, Singapore, South Korea, United Kingdom) pointed to the need for international legal regulation of stem cell research and therapeutic cloning, while the states supported by the Holy See, including the group of Latin American countries led by Costa Rica, the United States and European Catholic countries such as Italy, Portugal, Spain, were in favor of a comprehensive ban on all forms of cloning.[5] The problem of "chimeric experiments"[6] remained completely unresolved in the UN Declaration on Human Cloning. In this process human cells are implanted into organisms of other biological species, and it is not known whether the appearance of human-like consciousness, emotions and cognitive abilities would be possible.

In October 2005, UNESCO returned to the issues of international legal consolidation of the interests of the individual, society, and the State in the field of medicine based on the norms of bioethics and adopted the Universal Declaration on Bioethics and Human Rights.[7] The Bioethics Declaration consists of four sections: general provisions, application of the principles, promotion of the Declaration and final provisions.

[5] General Assembly Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37. United Nations. Available at: https://www.un.org/press/en/2005/ga10333.doc.htm [Accessed 12.02.2022].

[6] The term "chimera" in ancient Greek mythology was used to denote a fire-breathing monster with a lion's head, a goat's body and a dragon's tail.

[7] Universal Declaration on Bioethics and Human Rights, 19 October 2005. UNESCO Legal Instruments. Available at: http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html [Accessed 13.02.2022].

The principles that should guide any medical research are set out in the sections "General provisions" and "Application of the principles." The following principles are proclaimed as fundamental in the Declaration: human dignity and human rights, priority of the individual's interests and welfare over the interest of science and society (Article 3), the right balance between benefit and harm in applying and advancing scientific knowledge, medical practice and associated technologies (Article 4), the need to respect personal autonomy (Article 5), prior, free and informed consent of the person concerned (Articles 6–7), non-discrimination and respect for human rights (Articles 9–11), cultural diversity and pluralism (Article 12), solidarity and cooperation (Article 13), the highest attainable standard of health as one of the fundamental rights of every human being (Article 14), protection of future generations, the environment, biosphere and biodiversity (Articles 16–17) and others. Article 16 contains a principle, according to which due regard should be given to the impact of life sciences on future generations, including on their genetic constitution. Such provisions are characteristic of acts regulating environmental protection, for example, the UN Declaration on the Human Environment of 1972, the Rio Declaration of 1992, the Convention on Biodiversity of 1992, *etc*. Most likely this principle should be interpreted as an indication of the need for precaution in order to prevent the negative consequences of an intervention in the genome of living beings and as an instruction to carry out further research to alleviate the fate of people suffering from genetic diseases.

The section "Application of the principles" gives an understanding of how the principles set out in the 2005 Declaration should be implemented in practice. The Declaration brings up the issues of establishing independent, multidisciplinary and pluralist ethics committees (Article 19), previously mentioned in the 1997 UNESCO Declaration on the Human Genome and Human Rights, the need to address bioethical issues in decision-making (Article 18), *etc*. The provisions of Article 21 of the Declaration on transnational activities in health research deserve attention and further reflection. With the intensive development of transnational ties at the end of the 20th century — beginning of the 21st century, certain practices of transnational medical activity have

developed, creating a risk of violations of bioethical norms. Scientific research in this area can be carried out in countries with a low level of legal protection of their citizens. The provisions of Article 21 are aimed at reducing the risk of such abuses by making States responsible for ensuring the compliance of their professionals with bioethics standards in all cases when such activities are "undertaken, funded or otherwise pursued in whole or in part" by the State. Along with the requirement to comply with an appropriate level of ethical review in transnational medical practice in all States involved in such activities, the Declaration on Bioethics proclaims the need for transnational health research to be responsive to the needs of host countries. This indicates the intention of the authors of the Declaration on Bioethics to protect developing countries from exploitation by developed countries. In addition, the Declaration contains provisions on the need for interstate cooperation in the dissemination of useful research results and combatting bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials. To be able to take follow-up actions, the UNESCO will seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC) (Article 25).

The UNESCO Declaration on the Human Genome and Human Rights of 1997 and the Universal Declaration on Bioethics and Human Rights of 2005, as well as the United Nations Declaration on Human Cloning of 2005 laid some international legal foundations for the subsequent use of genetic technologies. However, a number of burning questions remained unanswered. The legal status of the human genome was not determined with full certainty. Manipulations with the human genome did not receive an assessment in the light of ethical considerations. Legally binding bans of the reproductive cloning of humans and "chimeric experiments" were not introduced. Some of these gaps were subsequently filled in the process of international legal regulation at the regional level within the framework of the Council of Europe.

III. Regulating the Application of Genetic Technologies at the Council of Europe Level

For a long time the Council of Europe has been discussing, to varying degrees, the use of genetic technologies and related aspects in the context of ensuring human rights. This is evidenced by various publications of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe prepared by expert groups (Le Bris, Knoppers, Luthera, 1997, pp. 1368–1369).[8] In 1982, the Council of Europe became the first regional organization that initiated consideration of the concept of human dignity in the context of genetics, noting that "the rights to life and to human dignity protected by Articles 2 and 3 of the European Convention on Human Rights imply the right to inherit a genetic pattern which has not been artificially changed."[9]

In 1985, efforts in this direction were institutionalized, and under the leadership of the Committee of Ministers, the Ad Hoc Committee of Experts on Bioethics (CAHBI) responsible for interstate interaction on these issues was founded. In 1992, it became the Steering Committee on Bioethics (CDBI).[10] The Steering Committee on Bioethics has carried out extensive work concerning various legal aspects of human genome research and provided important information concerning the legal implications of their impact on human rights (Jónatansson, 2000, p. 33).

In 2012, as a result of reorganization of intergovernmental bodies of the Council of Europe, the Steering Committee was transformed into the Committee on Bioethics (DH-BIO, hereinafter referred to as the Committee)[11] and it was subordinated to the Steering Committee

[8] Compendium of texts of the Council of Europe on bioethical matters. Available at: https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ [Accessed 20.02.2022].

[9] Council of Europe Recommendation 934(1982) on Genetic Engineering, 26 January 1982. Available at: https://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=14968&lang=en.

[10] Information document concerning the DH-BIO. Available at: https://rm.coe.int/inf-2021-2-info-doc-dh-bio-e/1680a2cfbb [Accessed 14.02.2022].

[11] Council of Europe Resolution CM/Res(2011)24 on intergovernmental committees and subordinate bodies, their terms of reference and working methods, 9 November 2011. Available at: https://rm.coe.int/ref/CM/Res(2011)24 [Accessed 15.02.2022].

on Human Rights (CDDH).[12] Currently, the Committee performs the following functions:

— fulfilling tasks in the field of ensuring human rights when applying the achievements of biology and medicine;

— developing the Draft Additional Protocol concerning the protection of human rights and dignity of persons with mental disorder with regard to involuntary placement and involuntary treatment;

— monitoring the implementation of the Strategic Action Plan for 2020–2025 with a special focus on human rights issues arising from new technologies, such as neurotechnologies;

— studying ethical and legal issues arising in connection with the development of genome editing technologies in connection with Article 13 of the Convention on Human Rights and Biomedicine, *etc*.[13]

The Committee meets at least two times a year at the headquarters of the Council of Europe. These meetings are attended by representatives of all 47 Member States of the Organization. In addition, representatives of observer States (Canada, Japan, Mexico, the USA and the Vatican), the European Union, WHO, UNESCO, OECD and a number of other organizations can participate in the meetings of the Committee without the right to vote. The Committee carries out its work by issuing various resolutions, recommendations, guidelines and reports. The documents in the field of legal aspects of the use of genetic technologies include Recommendation No R(90)13on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling of 1990, Recommendation No R(92)3 on Genetic Testing and Screening for Health Care Purposes of 1992, Recommendation No R(94)1 on Human Tissue Banks of 1994, Recommendation No CM/Rec(2016)8 on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests of 2016, Recommendation

[12] Committee on Bioethics (DH-BIO), Information document concerning the DH-BIO, 16 March 2021. Available at: https://rm.coe.int/inf-2021-2-info-doc-dh-bio-e/1680a2cfbb [Accessed 15.02.2022].

[13] Committee on Bioethics (DH-BIO), Information document concerning the DH-BIO, 16 March 2021. Available at: https://rm.coe.int/inf-2021-2-info-doc-dh-bio-e/1680a2cfbb [Accessed 15.02.2022].

No CM/Rec(2020)5 on the quality and safety of tissues and cells for human application, *etc.*[14]

Since 1992, the Steering Committee on Bioethics has been actively working on a draft framework convention "establishing common standards for human protection in the context of the development of biomedical sciences."[15] Thus, the most significant result of the activities of the Steering Committee on Bioethics is the development and adoption within the Council of Europe of the first and, in fact, the only international treaty in the field of ensuring human rights in the use of genetic technologies — the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 1997 (hereinafter — the Oviedo Convention).[16]

The Oviedo Convention reflects the consensus that existed at the time of its adoption on various issues of applying the achievements of medicine and technology to humans (Knoppers, Le Bris, 1991, pp. 329–361). It establishes the principles of human rights protection in the implementation of medical activities, as well as a number of norms regarding the use of genetic technologies in this context. In general, the Oviedo Convention contains general principles that were later developed in more detail in its additional Protocols.

In accordance with the Oviedo Convention, human interests should be above the interests of the science or society, in connection with which a number of prohibitions are established in the field of bioethics, medical

[14] Compendium of texts of the Council of Europe on bioethical matters. Available at: https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ [Accessed 16.02.2022].

[15] Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 1997. Available at: https://rm.coe.int/168066caa2 [Accessed 16.02.2022].

[16] Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164), 4 April 1997. Available at: https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164 [Accessed 16.02.2022].

research, obtaining consent for medical intervention, the right to privacy and information, the human genome and the removal of organs for transplantation. In particular, in the field of the human genome, the Oviedo Convention prohibits all forms of discrimination based on a person's genetic heritage, permits only predictive genetic tests for medical purposes. According to Article 13 of the Convention, genetic engineering is permitted only for preventive, diagnostic or therapeutic purposes and only if it does not entail any modification in the genome of any descendants. As a rule, the Convention also prohibits the use of genetic technologies for the purpose of choosing the sex of a child.

As noted in the academic literature, the Oviedo Convention has become a model, a reference tool for the European Union, as well as the UNESCO and the WHO in matters of legal regulation of bioethics and the use of genetic technologies (Lwoff, 2009, pp. 1374–1377). At the same time, the object of regulation of the Convention divided the experts into two groups. The conservative-minded group focuses on the respect for human dignity and the inadmissibility of weakening ethical principles that can lead to the deterioration of moral standards. The liberal part of the expert community insists that people are constantly changing their environment in order to survive and provide a better standard of living, which involves some degree of risk. However, in their opinion, the mere probability of undesirable consequences should not exclude the possibility of using genetic technologies that help the humanity to survive (Jónatansson, 2000, pp. 35–36). Thus, the adoption of the Convention was the result of a compromise, the consequence of which is the inclusion of categories that are broad and vague to some extent, leaving freedom for national discretion. Nevertheless, there is an emphasis in the text of the Convention towards a "precautionary," conservative approach.

Largely, this was the reason for the delay in the ratification procedure of the Convention by the Member States of the Council of Europe. The entry into force of the Convention on 1 December 1999 was preconditioned only by the maximum understated requirement for the number of ratifications required for this, up to five. After more than

20 years after the Oviedo Convention was drafted, 29 States ratified it, 7 States (including Italy, Sweden and Ukraine) signed it, but did not ratify, and 11 States (including the UK, Germany, Austria and Russia) did not even sign it out of 47 Member States of the Council of Europe.[17]

To date, four protocols have been adopted to the Oviedo Convention:

1) the Additional Protocol on the Prohibition of Cloning of Human Beings of 1998 that entered into force in March 2001 (ratified by 24 States);[18]

2) the Additional Protocol on Human Organ and Tissue Transplantation of 2002 that entered into force in May 2006 (ratified by 15 States);[19]

3) the 2005 Additional Protocol concerning Biomedical Research that entered into force in September 2007 (ratified by 12 States);[20]

4) the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes that entered into force in July 2008 (ratified by 6 States).[21]

It should be noted that in accordance with Article 29 of the Oviedo Convention, the European Court of Human Rights (ECtHR) may issue advisory opinions on legal issues concerning its interpretation. However, the provisions of the Oviedo Convention have not been developed in the judicial practice of the ECHR.[22] The Court referred to the norms

[17] Chart of signatures and ratifications of Treaty 164. Available at: https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164 [Accessed 17.02.2022].

[18] Chart of signatures and ratifications of Treaty 168. Available at: https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=168 [Accessed 17.02.2022].

[19] Chart of signatures and ratifications of Treaty 186. Available at: https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=186 [Accessed 18.02.2022].

[20] Chart of signatures and ratifications of Treaty 195. Available at https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=195 [Accessed 18.02.2022].

[21] Chart of signatures and ratifications of Treaty 203. Available at https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=203 [Accessed 20.02.2022].

[22] European Court of Human Rights. Vo v. France (GC), No 53924/00, 8 July 2004; Lambert and Others v. France (GC), No 46043/14, 5 June 2015; Vo v. Italy (GC), No 46470/11, 27 August 2015; Lopes de Sousa Fernandes v. Portugal (GC),

of the Convention in a number of cases, using previously expressed approaches to interpretation. Thus, in its judgment in *Vaux v. France* in 2004, the ECtHR confirmed the position of the Steering Committee on Bioethics and noted that the content of the word "everyone" in Article 1 of the Oviedo Convention, due to the lack of a unified approach, each State defines in its national legislation.[23] Similarly in another case in a partially overlapping and partially dissenting opinion, J. Paulo Pinto de Albuquerque referred to the explanatory note of the Steering Committee on Bioethics and indicated that the purpose of Article 3 of the Oviedo Convention, guaranteeing equal access to health care of appropriate quality "is not to create individual rights which every person can refer to in the judicial processes against the State, but rather, prompting the latter to take the necessary measures in the framework of its social policy to ensure equal access to health services."[24]

The content of the Convention and Protocols is criticized, in particular, in connection with the restrictions imposed on embryo research (Ponomareva, Kosilkin, and Nekoteneva, 2019, pp. 5408–5415), the prohibition of inherited genome editing (Boggio, Romano and Almqvist, 2020, pp. 201–236; Sykora and Caplan, 2017, pp. 1871–1872), human cloning and related aspects (McDaniel, 1998, pp. 543–581), that are discussed in more detail in the subsequent sections of this study. However, it can be stated that the experience of the legal regulation of the use of genetic technologies within the Council of Europe through specially established intergovernmental bodies and expert groups, as well as normative and regulatory acts developed on the basis of their recommendations, with the current level of scientific knowledge, meet modern requirements in the field of human rights protection.

No 56080/13, 19 December 2017; Vavřička and Others v. The Czech Republic (GC), No 47621/13 and 5 others; 8 April 2021.

[23] European Court of Human Rights. Vo v. France (GC), No 53924/00, 8 July 2004.

[24] European Court of Human Rights. Lopes de Sousa Fernandes v. Portugal (GC), No 56080/13, 19 December 2017.

IV. Specific Human Rights Issues in the Application of Genetic Technologies

IV.1. Informed Consent in Genetic Research and Treatment

The principle of informed consent underlies the concept of personal autonomy; it is based on the ability and right of a person to make an independent choice and expresses one of the aspects of the human right to privacy. Any medical intervention, including genetic intervention, regardless of whether it is of scientific or therapeutic nature, can be carried out only with the consent of the patient or the person participating in the medical study. Article 5 of the Oviedo Convention contains a provision on the need for voluntary informed consent to a medical intervention. It is important to note that, unlike the 1947 Nuremberg Code[25] and the 1964 Helsinki Declaration "Ethical Principles for Medical Research Involving Human Subjects" — the first documents that enshrined the principle of informed consent, the Oviedo Convention states that the need to obtain such consent is no longer limited to the conditions of a medical experiment, but extends to any medical intervention. Informed consent presupposes that a person receives relevant information in advance about the purpose and nature of the intervention, as well as about its consequences and risks, and can freely withdraw his consent at any time.[26]

In the world practice of using genetic technologies, the case of Jesse Gelsinger that occurred in 1999, is widely known. 18-year-old Jesse was ill with a rare genetic disease. When the doctor informed that clinical trials in the field of gene therapy aimed at treating this disease in children were conducted, Jesse decided to take part in clinical trials and gave his consent. The study of new methods of gene therapy led to the death of the patient. During the investigation, the US Food and Drug Administration found out that the researchers did not tell Jesse about serious side effects in previous patients and that two laboratory monkeys died from similar gene manipulations. If he had been properly

[25] The Nuremberg Code, (1947). British Medical Journal, 7070 (313), p. 1448.

[26] Article 5 of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (SED No 164). Oviedo, 4 April 1997.

informed about these problems, he could have refused to participate in the study and stayed alive. Serious violations of the principle of informed consent (failures in the informed-consent procedure) were revealed, despite the fact that formally a participant in clinical trials gave his consent to the trial of gene therapy. This case greatly influenced the organization of research in the field of gene therapy (many studies were stopped or taken under serious state control), and it resulted in the more detailed elaboration of the requirements for informed consent in different countries.

At the moment, in many jurisdictions, the requirements for the information to be provided to persons giving their informed consent are quite clearly formulated. For example, in the USA, the requirements for the form of expression of consent are defined in detail in §§ 50.25, 50.27 of Title 21 of the Code of Federal Regulations.[27] In Russia, the procedure for giving informed voluntary consent to a medical intervention and refusal to a medical intervention is approved by the Order of the Ministry of Health of the Russian Federation.[28] Voluntary informed consent in relation to children has its own characteristics. The general approach is that the consent to the treatment of the child, including the use of genetic technologies, is given by the parents.

This procedure is illustrated in *Glass v. United Kingdom*[29] considered in the European Court of Human Rights. The child was hospitalized several times with a respiratory system disease. There were disagreements between the hospital staff and Ms. Glass about the methods of child's treatment in the event of a crisis — whether to conduct intensive therapy or not. In one case, doctors believed that the child was in a near-death state, and in order to reduce pain, they injected diamorphine against the mother's wish. In addition, "Do Not Resuscitate" order was included in the child's medical card without the

[27] Sec. 50.25, 50.27. Title 21. Code of Federal Regulations. Available at: https://www.ecfr.gov/cgi-bin/ECFR?page=browse [Accessed 01.05.2021].

[28] Federal Law No 323-FL of 21.11.2011 "On the basics of protecting the health of citizens in the Russian Federation", Rossiyskaya Gazeta, No 263, 23 November 2011.

[29] European Court of Human Rights. Glass v. the United Kingdom, No 61827/00, 6 March 2004.

knowledge of his mother. There was a serious conflict between doctors and family members of the child. The child survived.

The ECHR held that imposing the course of treatment on a child, despite the constant objections of the mother, was an act of interference in the exercise of the child's right to respect for his private life. The fact that the doctors dealt with a crisis situation for the child's life did not justify the fact of such an intervention. The Court noted that at the initial stages of the applicant's conflict with the hospital, the hospital administration did not attempt to resolve this conflict by resorting to judicial intervention. The burden of the initiative to resolve the conflict at the threshold of the next crisis of the patient lay on the hospital administration. Instead, doctors used the limited time available to them in that situation to try to impose their point of view on the mother. The Court considered that the decision of the medical authorities to ignore the objections of the mother of a minor patient about the proposed treatment in the absence of permission from the judicial authorities led to the violation of Article 8 of the Convention.

At the same time, there are situations when the doctors' actions against the will of the parent or the legal representative of the child were recognized as permissible. In *Jehovah's Witnesses in Moscow v. the Russian Federation*[30] the ECtHR pointed out that the provision of the Russian legislation[31] in force at the time of the case that the decision of parents to refuse treatment provided to a child in order to save his life can be overcome by a court decision that protects the rights of the child.[32]

The situation of saving a patient's life may be directly related to gene therapy. Thus, one of the most expensive medicines in the world,

[30] European Court of Human Rights. Jehovah's Witnesses of Moscow v. Russia, No 302/02, 10 June 2010.

[31] Paragraph 3 of Article 33 of the "Fundamentals of the Legislation of the Russian Federation on the protection of citizens' health" (approved by the Supreme Court of the Russian Federation on 22 July 1993 No 5487-1), Vedomosti of the Congress of People's Deputies of the Russian Federation and the Supreme Council of the Russian Federation, 19 August 1993. 33, Article 1318. The document became invalid on 1 January 2012.

[32] European Court of Human Rights. Jehovah's Witnesses of Moscow v. Russia, para. 137.

Zolgensma®, is a gene therapy drug developed for the treatment of patients with spinal muscular atrophy, and it is used to treat children under 2 years old (Zolgensma® is a prescription gene therapy used to treat children younger than 2 years old with spinal muscular atrophy. Some countries implement policies for free provision of such expensive drugs for the treatment of severe hereditary diseases.

It can be concluded that the decision on a medical intervention in relation to a minor, who in accordance with the national legislation does not have the right to make such a decision independently, lies with his parents (legal representatives). At the same time, in cases requiring medical personnel to respond immediately in order to save a child, when a parent (legal representative) prevents it, doctors can act at their discretion after applying to the court.

Consent may be required not only in cases of treatment or participation of a person in biomedical research, but also when using his genetic material by third parties: by medical, scientific institutions or family members, spouses, partners. Thus, in *Evans v. United Kingdom*[33] the Court considered the legality of the prohibition to use embryos by one partner — the carrier of genetic material — without the consent of the second partner. Natalie Evans suffered from the ovarian cancer. Before the removal of the ovaries, she and her partner D. resorted to *in vitro* fertilization. The resulting embryos were placed in storage. The couple's joint relationship did not work out. D. withdrew his consent to the use of embryos since he did not want to become the genetic father of the applicant's children. According to the national law, the embryos had to be destroyed. Natalie Evans was deprived of the opportunity to ever have her own, genetically native children.

Expressing sympathy for the applicant, the ECtHR found no violation of Articles 2 (right to life), 8 (right to respect for private and family life) and 14 (prohibition of discrimination) of the European Convention on Human Rights. One of the criteria for the Court's making of such a decision was a clearly formulated rule in national law on the consent of the partner, with which Ms. Evans was acquainted before the

[33] European Court of Human Rights. Evans v. the United Kingdom (GC), No 6339/05, 10 April 2007.

fertilization procedure. Absence of the spouse's consent to the use of embryos containing his genetic material prevented the applicant from becoming a mother, which undoubtedly affected her right to privacy protection. However, the Court declared that the notion of a "private life" incorporates the right to respect for both the decisions to become and not to become a parent.[34] The Court concluded that, given the lack of a European consensus on this point, the fact that the domestic rules were clear and brought to the attention of the applicant and that they struck a fair balance between the competing interests, there was no violation of Article 8 of the Convention.[35]

Voluntary informed consent is a prerequisite for a person to participate in a genetic examination, to undergo genetic testing or treatment. Informed consent is not just a document signed by a patient or his legal representative; it is a procedure that requires compliance with certain criteria.

IV.2. Genetic Diagnostic Technologies and Reproductive Rights

Despite the rapid development of technologies, patients' access to genetic technologies is not always open, it is provided, restricted and prohibited by national legislation. Genetic testing technologies allow carriers of serious genetic diseases to avoid transmitting the disease to their future children, make it possible to detect fetal development pathologies in time and make an informed decision about maintaining or terminating pregnancy, help doctors to determine pregnancy follow-up or treatment strategies. Prenatal (antenatal), in particular pre-implantation genetic diagnostics (testing/screening) allow parents to ensure the protection of reproductive rights and, as a consequence, the right to health and the right to respect for private and family life.

Prenatal testing may be offered to women during pregnancy to determine if the fetus has a possibility to be born with a genetic condition or a birth defect. Performing prenatal testing may be useful in

[34] European Court of Human Rights. Evans v. the United Kingdom (GC), para. 71.

[35] European Court of Human Rights. Evans v. the United Kingdom (GC), para. 92.

determining different options for the pregnancy or special management of the pregnancy and delivery to improve the outlook for the baby (Genetic Alliance, 2009). Preimplantation genetic testing (PGT) is an early form of prenatal genetic diagnosis where abnormal embryos are identified, thereby allowing transfer of genetically normal embryos (Parikh, Athalye, Naik and Naik, 2018, pp. 306–314).

Let us turn to the ECHR jurisprudence concerning access to prenatal genetic diagnosis. In cases related to reproductive health, the ECtHR quite often refers to the concept of a "broad margin of discretion" of States.[36] Due to the lack of a pan-European consensus on such sensitive issues as reproductive rights, States can use wide opportunities for legal regulation in this area. Despite this, the Court quite often recognizes a violation of rights related to reproductive health on the part of the participating States. In some cases, national legislation is applied (or not applied) in such a way that it leads to a violation of the right to privacy. In others, the national legislation itself is so vague or contradictory that its application naturally leads to a violation of human rights in the reproductive sphere.

In *R.R. v. Poland*[37] the medical staff deliberately refused to conduct timely genetic tests for a woman pregnant with a third child, even though the fetus was suspected of having a serious genetic defect. After considerable delay, the examination took place. By the time she received the results confirming that the foetus was suffering from Turner Syndrome, it was too late for R.R. to have a legal abortion under Polish law. The Court found a violation of Article 3 (prohibition of inhuman and degrading treatment) of the Convention as the applicant, who was in a very vulnerable position, had been humiliated and "shabbily" treated. The determination of whether she should have had access to genetic tests, as recommended by doctors, was marred by procrastination, confusion and lack of proper counselling and information. The Court concluded that the authorities had failed to comply with their positive obligations to secure effective respect for the applicant's private life

[36] European Court of Human Rights. Parrillo v. Italy (GC), No 46470/1, 27 August 2015, para. 180.

[37] European Court of Human Rights. R.R. v. Poland, No 27617/04, 26 May 2011.

and that there was therefore a breach of Article 8 (right to respect for private and family life) of the Convention.

The case of *A.K. v Latvia*[38] is quite similar to the previous one. The applicant was 40 years old at the time of pregnancy. Under domestic law she should have been treated as a patient with a high-risk pregnancy. The applicant claimed that her gynaecologist had failed to ensure that she would have an antenatal screening test. She gave birth to a daughter with Down's syndrome. Relying on Article 8 (right to respect for private and family life), A.K. alleged that she had been denied adequate and timely medical care in the form of an antenatal screening test which would have indicated the risk of a genetic disorder in the foetus and would have allowed her to choose whether to continue the pregnancy. The Court stated that the cumulative effect of the failings identified was that the domestic courts did not properly examine the applicant's claim that she had not received medical care and information in accordance with domestic law in a manner sufficient to ensure the protection of her interests. Consequently, there was a violation of Article 8 of the Convention in its procedural aspect.[39]

Despite the broad discretion in cases related to reproductive health, in *Costa and Pavan v. Italy*[40] the Court recognized the inconsistency of Italian national legislation in the regulation of preimplantation diagnostics and the use of assisted reproductive technologies, which led to human rights violations. The applicants were healthy carriers of cystic fibrosis and they had a child with the disease. Before having any more children, the applicants sought access to medically-assisted procreation techniques so they could have the embryos screened prior to implantation. In Italy, however, medically-assisted procreation was available only to sterile or infertile couples or where the man had a sexually transmissible viral disease, and the embryo screening (or pre-implantation diagnosis) was prohibited. The Court discovered that Italian domestic law lacked consistency: on the one hand, it prohibited the screening of embryos, a technique that made it possible to select

[38] European Court of Human Rights. A.K. v Latvia, No 33011/08, 24 June 2014.

[39] European Court of Human Rights. A.K. v. Latvia, para. 94.

[40] European Court of Human Rights. Costa and Pavan v. Italy, No 54270/10, 28 August 2012.

only those not infected with cystic fibrosis for implantation, on the other hand, it permitted the abortion of a foetus infected with the same disease. The applicants did not have an opportunity to use pre-implantation diagnosis and *in vitro* fertilisations. The only option they had was to conceive a child naturally, make a prenatal testing and terminate pregnancy in case of discovering the foetus development abnormalities. The Court concluded that there had been a violation of Article 8 of the Convention.

In cases where artificial insemination and termination of pregnancy for medical reasons are permitted in national legislation, prenatal diagnostics should not be prohibited, which makes it possible to make a decision on keeping or terminating pregnancy if a fetal defect is detected.

IV.3. Human Cloning and Germ Line Modification Prohibition

Genetic technologies are developing so fast that law falls behind with responding to these changes. Nevertheless, in modern conditions, there are still certain restrictions and prohibitions in the use of such technologies that can be considered quite justified. Thus, it is forbidden to carry out reproductive human cloning and edit the germline in such a way that the change becomes hereditary. We will attempt to find out what acts constitute the international legal framework regulating human cloning and germline modification and identify national approaches to the regulation of these issues.

The possibility of human cloning is both an ethical and a legal problem: you can never know for sure what consequences may be brought about by the interference in the natural process of human creation. Prof. Paul A. Kalinichenko notes that “from a legal point of view, human cloning conflicts with a number of the most important rights of the individual, with the right to human dignity and the resulting right to the integrity of the individual. There is no need to even talk about the legal problems that the appearance of a human clone will lead to. The first problem will be the question of whether a human clone will be a subject of law, and if so, whether its legal personality will coincide

with the legal personality of the original. A colossal legal puzzle will be provoked by the settlement of relations between the original personality and his clone, at least in terms of identity identification (who is who), succession, family relations, *etc*." (Kalinichenko, 2002, pp. 45–48).

There are two types of cloning, namely: reproductive and therapeutic. Reproductive cloning refers to artificial reproduction in laboratory conditions of a genetically exact copy of any living being (Dolly the sheep, born at the Roslin Institute in Edinburgh, is an example of the first case of such cloning of a large animal). Therapeutic cloning is carried out for medical purposes (embryo development is limited to a period of 14 days; the embryonic cells formed during this time can later turn into specific tissue cells of individual organs: heart, kidneys, liver, pancreas, *etc*. and be used in medicine for the treatment of many diseases).

Reproductive cloning is prohibited in many countries at the legislative level (Lo, Parham and Alvarez-Buylla, 2010, pp. 16–20). Moreover, such a prohibition is enshrined in international legal instruments. Carmel Shalev, an academic lawyer and ethicist, who specializes in health, medicine, biotechnology and human rights, wrote, "A ban on cloning constrains two important liberties: freedom of reproduction and freedom of science. The essence of liberty is that it may not be constrained, except to protect the liberty of another person or a strong public interest. Proposed justifications to prohibit reproductive cloning are based primarily on concern for human dignity and the moral status of the human embryo" (Shalev, 2002, pp. 137–151).

Reproductive cloning is prohibited by such international instruments as the Universal Declaration on the Human Genome and Human Rights of 1997 (Article 11 of the Declaration states that "practices contrary to human dignity, such as human reproductive cloning, are not allowed"), the United Nations Declaration on Human Cloning of 2005, the Additional Protocol to the Convention on the Protection of Human Rights and Dignity in Connection with the Application of Advances in Biology and Medicine concerning the Prohibition of Cloning of Human Beings (SED No 168) (hereinafter the Protocol on the Prohibition of Cloning). The Protocol establishes an absolute prohibition on human cloning. Article 1 of the Protocol on the Prohibition of Cloning states,

"Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."

The preamble of the Protocol on the Prohibition of Cloning emphasizes that "the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine," human cloning can give rise to "serious difficulties of a medical, psychological and social nature." The Protocol on the Prohibition of Cloning is mandatory for its participants. It is the only binding international treaty banning reproductive cloning. It entered into force for 24 States of the Council of Europe. Russia is not a party to this international treaty.

Though there exist only one international treaty and several declarative acts prohibiting reproductive cloning, such a prohibition is contained in many national laws (at least 50 countries) (Matthews, 2009, p. 20), including Russia. In countries where the prohibition is not explicitly established, as a rule, this issue is not settled at all. At the same time, it will be difficult to find a State that has directly allowed such a practice at the legislative level. In general, there is a consensus between countries on the issue of reproductive cloning: it is either prohibited or not regulated at the national level.

Despite the fact that the Protocol on the Prohibition of Cloning has entered into force for a small number of States, and not all States have an outright prohibition concerning such activities, the provision on the prohibition of human reproductive cloning exists as an *opinio juris*. This statement is supported by the existence of a large number of countries that enshrined a prohibition on reproductive cloning in their legislation, the absence of opposing opinions of States on this issue, and the existence of a number of international recommendation acts indicating inadmissibility of human reproductive cloning.

At the same time, the regulation of therapeutic cloning differs significantly from one jurisdiction to another. There is no ban on therapeutic cloning at the international level, and there are no strict restrictions for this activity, which means that States retain ample opportunities to address this issue at the national level in accordance

with social and scientific priorities, as well as cultural, religious, ethical characteristics of individual countries.

International acts do not explicitly prohibit therapeutic cloning. The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (SED No 164) in Article 18 establishes that "where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo." The UN Declaration on Human Cloning calls for prohibiting "all forms of human cloning in as much as they are incompatible with human dignity and the protection of human life." The phrase "all forms" can also be attributed to therapeutic cloning, but "human dignity" and "human life" in many European countries are protected since the moment of birth rather than at the stage of embryonic development. In the Inter-American Human Rights protection system, where the beginning of life is determined by the moment of conception, an embryo created and maintained *in vitro* and not implanted into a woman's body is not recognized as a "human being."[41] In this regard, the ambiguous provisions of the UN Declaration on Human Cloning that need interpretation, can hardly be applied in matters of therapeutic cloning permissibility.

The issues of therapeutic cloning are not regulated in many jurisdictions, national laws do not contain either a direct prohibition or permission for such activities, *e.g.,* Denmark, India, China, Finland, South Korea (Matthews, 2009, p. 20). Russia can also be classified as a country where there is no unambiguous regulation of therapeutic cloning. Although the existing Federal Law No 180-FL of 23.06.2016 "On Biomedical Cell Products" partially regulates the issues of therapeutic cloning, due to substantive, technical and legal imperfections, it does not provide legal certainty in this area. There are States where therapeutic cloning is prohibited along with reproductive cloning, despite the fact that the purpose of such cloning is not to create a human being identical to another. Such prohibition exists in Austria, Italy, Canada, Latvia, Lithuania, the Netherlands, France, Switzerland. At the same time, in

[41] Inter-American Court of Human Rights. Artavia Murillo et al. v. Costa Rica. Judgment of 28 November 2012.

some States, therapeutic cloning is directly permitted and regulated in legislation. Such countries include Belgium, Great Britain, Spain, Saudi Arabia, Singapore, Sweden (Matthews, 2009, p. 20). In addition, many States have the rule that allows research involving human embryos up to the 14th day after fertilisation (the stage of development equivalent to the time of completion of embryo implantation), which allows to achieve both practical and ethical goals. At the same time, there are discussions about increasing this period up to 28 days in order to expand scientific opportunities (Appleby and Bredenoord, 2018).

The conclusion is that the analysis of existing legislation on cloning in different jurisdictions indicates strong evidence of state practice and *opinio juris* supporting the prohibition of reproductive cloning. At the international level, there are no legally binding documents prohibiting therapeutic cloning. States enjoy a wide margin of appreciation to determine regulation in this area.

Another prohibited action refers to germline modification. Most countries with the legal framework for the regulation of biomedical developments either prohibit or severely restrict the use of human germline editing technologies (Isasi, Kleiderman and Knoppers, 2016; Araki and Ishii, 2014). The prohibition is enshrined in the Universal Declaration on the Human Genome and Human Rights and the Oviedo Convention. Under Article 13 of the Oviedo Convention, "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants." The Parliamentary Assembly of the Council of Europe highlighted in its Recommendation 2115(2017), "Deliberate germline editing in human beings would cross a line viewed as ethically inviolable."[42]

The Oviedo Convention has entered into force in only 29 of the 47 Council of Europe Member States. Countries have different opinions of the regulation proposed by the Oviedo Convention. The United Kingdom did not sign the Convention because it was considered too restrictive, on the contrary, Germany deemed it too permissive.

[42] Parliamentary Assembly of the Council of Europe in Recommendation 2115 (2017). The use of new genetic technologies in human being. Text adopted by the Assembly on 12 October 2017 (35th Sitting). Available at: https://assembly.coe.int/ [Accessed 25.02.2022].

The EU regarded germline gene modification as conflicting with the fundamental values of the European legal order. In the words of the Preamble of the "Biotech Directive" (1998), there is "a consensus within the Community that interventions in the human germline and the cloning of human beings violate 'ordre public and morality'." Correspondingly, Article 6 of the Biotech Directive excludes from patentability "processes for modifying the germline genetic identity of human beings" and "processes for cloning humans" (Van Beers, 2020). Due to the fact that at the moment no country authorizes direct editing of the germline, taking into account the acts of soft law and the Oviedo Convention, it can be stated that editing the germline is prohibited. However, researchers and States differ in their opinions on this issue more than on the issue of reproductive cloning.

In 2020, the CRISPR Journal published the results of the research on germline editing regulation in different countries. Scientists identified five counties where germline modifications are prohibited with some exceptions: these are Belgium, Colombia, Italy, Panama, United Arab Emirates (Baylis, Darnovsky, Hasson and Krahn, 2020, pp. 365–377). For example, in Belgium "germline genome editing is permitted for corrective purposes (meaning elimination or correction of genetic diseases), if approval of the local ethics committee and the Federal Commission on scientific research on embryos *in vitro* is obtained" (Pennings, 2020, pp. 266–280). The official statement of the Chinese scientist He Jiankui about the birth of children with the edited DNA in 2018 represents a vivid illustration of the weakness of this prohibition. In the Report of the Second International Summit on Human Genome Editing where this statement was made, the actions of the scientist were assessed as irresponsible and failing to conform to international norms (The National Academies of Sciences Engineering Medicine, 2018). It is reported that He Jiankui was sentenced in China to 3 years in prison. Nonetheless, it is obvious that the announcement of the birth of children with the modified DNA attracted even a greater interest of scientists and certain countries to the development and application of new genetic technologies. One would like to hope that the existing national and international legal mechanisms will develop together with technologies and it will prevent their uncontrolled and unsafe use.

V. Conclusion

The UNESCO Declaration on the Human Genome and Human Rights of 1997 and the Universal Declaration on Bioethics and Human Rights of 2005, as well as the UN Declaration on Human Cloning of 2005 defined initial contours of international legal regulation for the use of genetic technologies. However, a number of vital problems, such as the lack of certainty in defining the legal status of the human genome, the absence of legally binding bans on the reproductive cloning of humans and "chimeric experiments," no legal consolidation of ethical principles regulating manipulations with the human genome, to name a few, were not resolved. Some of these lacunae were filled later on as the process of international legal regulation of these issues continued at the regional level within the framework of the Council of Europe.

The Oviedo Convention and its additional Protocols specified the principles of human rights protection in carrying out medical activities and applying genetic technologies. Despite the fact that the Oviedo Convention and the Protocols thereto entered into force for a comparatively small number of countries, they have become a reference standard for the legal regulation of bioethical issues and the use of genetic technologies carried at the UNESCO, WHO and the European Union.

Informed consent is a fundamental principle that protects human rights in the circumstances of genetic treatment or in a situation when individuals are engaged in genetic research. This principle is not only enshrined in the Oviedo Convention but also reflected in the European Court of Human Rights jurisprudence. The ECtHR interpretation of this principle sheds light on how countries should apply it. The ECtHR is also a major instrument in protecting reproductive rights, including the situations of access to genetic diagnostic technologies.

The analysis of the existing national legislation on cloning in different countries indicates strong evidence that the state practice and *opinio juris* supporting the prohibition of reproductive cloning have been formed, but within the Council of Europe states enjoy a great deal of discretion in regulating therapeutic cloning. Germline modifications are prohibited by the Oviedo Convention and the soft law, but *de facto*

legal regulation in this field is a developing process and it is hard to predict what positions on these issues would be taken by various countries in the near future.

In conclusion, one can single out the following main features that constitute the basis of today's international legal framework regulating the application of genetic technologies:

— the prohibitions of reproductive human cloning and germline modifications have been firmly established;

— informed consent has become a feature of fundamental importance in the field under study;

— at the regional level, the Council of Europe plays a significant role establishing its guidelines in the sphere of biomedicine and human rights. At present they are laid down in the Oviedo Convention and the Protocols to it, as well as in the ECtHR jurisprudence and the soft law provisions on the use of genetic technologies (such as ensuring the protection of the embryo where law allows research on embryos *in vitro*; the recognition of the fact that prenatal genetic diagnostics should not be prohibited if artificial insemination and termination of pregnancy for medical reasons are permitted in national legislation, *etc.*). The prohibitions and restrictions mentioned above set the limits of what is legally permissible at the global and the European level. Apart from this, the Council of Europe Member States keep enjoying a wide margin of appreciation in determining their national approaches to regulating such a sensitive sphere as the application of genetic technologies.

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Rejecting the Medical Model of Disability in Belarusian Sports Law: A Long Way to Nowhere?

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Abstract: The article deals with the Belarusian legislation and international legal acts in order to answer the question whether the rejection of the medical model of disability is implemented in Belarusian sports law. The author studies the concept of a disabled person, models of disability and legal regulation of adaptive sports from the point of view of sports law and human rights. It is proved that despite the declaration of non-discrimination of persons with disabilities, the problems associated with the medical model of disability remain very relevant in Belarus. The Belarusian legislation uses the concept of formal equality, but it is supplemented by victimization of disability and objectification of persons with disabilities. The emphasis is shifted to the charity nature of medical care, which brings us back to the medical model. The article argues the importance of adopting a Draft Law on Adaptive Physical Culture and Adaptive Sports to eliminate the existing shortcomings of the legal regulation of sports for persons with disabilities. The author also emphasizes that equalization of opportunities in sports should be defined much wider than providing sports facilities, ensuring equal conditions and opportunities for the development of adaptive movement in relation to the conditions and opportunities for the development of non-disabled sports and non-disabled physical culture. Equalization of opportunities should include a freedom of adaptability as a key category and one of the basic principles of the adaptive movement.

Keywords: disabled person; person with a disability; medical model of disability; social mode of disability; Belarus; sports law; adaptive law

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Contents

Introduction

Medical model of disability is considered to be outdated as it does not meet modern human rights standards. In recent decades, other models of disability (such as the social model) have been established in international acts. The Belarusian legislation does not lag behind the trends and also declares the rejection of ableism and stigmatization of disability. It aims to protect human rights of persons with disabilities; however, a detailed study of domestic acts reveals that the real situation is quite different.

The problems of sports law for persons with disabilities are particularly acute, which is due to the fact that sports law and human rights of people with disabilities are considered to be two different areas. For a long time, the concepts of "disabled persons" and "sports" were regarded incompatible, so the sports law did not exist for people with disabilities either in theory or in practice.

Significant changes in this area began at the end of the 20th century with high achievements of Belarusian disabled athletes. For the first time the representatives of Belarus took part in the Paralympic games as a separate team in 1994 in Lillehammer. Since this year, Belarusian athletes with disabilities have been constantly participating in international competitions, winning hundreds of medals annually.

Significant achievements of Belarusian athletes with disabilities especially contrast with the shortcomings of legal regulation. To improve the situation, the Parliament adopted a number of laws regulating human rights of disabled persons. However, the medical model of disability, remaining in people's minds, continues to have a negative impact on legal instruments and their application in sports law. Being "the world's largest minority" (Stein and Lord, 2010) disabled persons stay one of the most vulnerable social groups in Belarus.

The article proves that improvement of the situation is possible through the consistent rejection of the medical model of disability, which implies not only declarative provisions, but effective mechanisms to protect Belarusian athletes from ableism and stigmatization, provided for in the Draft Law on Adaptive Physical Culture and Adaptive Sports (APCAS).

I. Materials, Methods and Questions

The article is based on the analysis of domestic Belarusian legislation on sports rights of persons with disabilities and its comparison with the provisions of international law.

Domestic legislation includes such key acts as the Constitution of the Republic of Belarus, general legal acts (the Law on Physical Culture and Sports (2014), *etc.*), the Law on Prevention of Disability and Rehabilitation of Persons with Disabilities, PDRPD (2008) as a special act on rights of persons with disabilities and two draft laws. The Draft Law on the Rights of Persons with Disabilities and their Social Integration (RPDSI) is analyzed as an act which is fully updated and is expected to be adopted in the near future. The Draft Law on Adaptive Physical Culture and Adaptive Sports (APCAS) is studied as more relevant to sports law and one of the few acts developed with the participation of associations of disabled people. However, the Draft Law APCAS is at the early stage of its adoption. Commissions of the Parliament of the Republic of Belarus have repeatedly discussed its provisions, but the need to adopt such a law is now called into question. Some authorities say that the necessary regulations are either already included or will be included in the legislation in the near future. The

Draft Law APCAS is studied in the context of the importance of its adoption in protecting human rights of athletes with disabilities.

Among the international acts analyzed are the Universal Declaration of Human Rights (1948) and the International Covenant on Economic, Social and Cultural Rights (1966). They were ratified by Belarus. Acts specifically devoted to the rights of persons with disabilities are the Declaration on the Rights of Mentally Retarded Persons (1971), the Declaration on the Rights of Disabled Persons, DRDP (1975), the World Programme of Action Concerning Disabled Persons, WPA (1982). After the United Nations Decade of Disabled Persons 1983–1992 and the adoption of the Standard Rules on the Equalization of Opportunities for Persons with Disabilities by the United Nations General Assembly, SREO (1993) the disability policy "gained momentum at the international level" (Favalli, 2018, pp. 517–538), however, most of the acts are not ratified by Belarus.

One of the most important acts of the recent decades is the Convention on the Rights of Persons with Disabilities, CRPD (2006). It does not establish new rights for persons with disabilities, but indicates ways to implement universally recognized human rights for persons with disabilities. Eighty-one states and the European Union signed the CRPD at its opening ceremony. It is "the highest number of opening signatures recorded for any human rights treaty" (Report of the Secretary-General as to the Status of the Convention on the Rights of Persons with Disabilities and the Optional Protocol, 2007). The Republic of Belarus became the 160th country to sign it.

Despite the non-ratification of some international acts by the Republic of Belarus, their provisions may be applied according to part 1 of Art. 8 of the Constitution. It says that the Republic of Belarus recognizes the priority of generally recognized principles of international law and ensures that legislation complies with them. In practice, there is a problem in recognizing a provision as a generally recognized principle of international law. However, this problem is not very relevant to the article, since the provisions are studied in the context of their adoption into domestic legislation.

The article analyzes the wordings and general notions in international and domestic acts in order to define whether domestic legislation

fully covers and protects the rights of persons with disabilities in sports. The author examines the concept of a disabled person, models of disability and legal regulation of adaptive sports from the point of view of sports law and human rights and argues that the problems of the medical model of disability remain very relevant in Belarus.

In the article, the terms "a person with a disability," "a disabled person," "a person with impairments," "a person with special features/ characteristics" are used as synonyms, but the author fully supports the concept of the primacy of the person and the rejection of ableism and objectification of persons with disbilities.

II. Medical Model of Disability is Gone, Isn't It?

The concept of "a disabled person" is changing over time and adaptable to the understanding of the main characteristics of disability. It is used in different international and domestic acts and cannot be recognized as a single one. To a large extent, the definition is related to a general model of disability.

The early approaches to regulating disability are now combined into the *medical model* (sometimes it is called biologistic or organicist (Domínguez and Luna, 2019, pp. 77–90). It "locates disability within individuals" (Marks, 2009) and looks at disability "as a defect or a disease that needs to be cured through medical intervention" (Rehabilitation International, "UN Convention on the Human Rights of People with Disabilities: Ad Hoc Committee Seventh Session — Daily Summaries," 2006). Medical treatment is not necessarily emphasized in the definition, since it can only refer to the presence of a medical problem. Also, medical definition may emphasize the presence of a general medical issue rather than a problem. The most significant feature of the medical model is that it leaves the problem in a person, placing a negative emphasis on disability. In addition, it objectifies a person with disabilities as a person who needs special help and care.

For example, the Declaration on the Rights of Disabled Persons (DRDP) says that the term "a disabled person" means any person "unable to ensure by himself or herself, wholly or partly, the necessities

of a normal individual and/or social life, as a result of deficiency, either congenital or not, in his or her physical or mental capabilities" (p. 1). This definition focuses on the medical aspect, viewing it as the cause of the problems of a person with disability. In addition, it introduces the concept of normality and normal life, thus fixing the characteristic of abnormality for a person with disability.

The problem of "normality" (Ganterer and More, 2019, pp. 160–173), "normal" and "pathological" bodies (Campbell, 2009, p. 2), ableism and stigmatization of disability remains acute, despite the prohibition of *discrimination*. The Universal Declaration of Human Rights says that "all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood" (Art. 1). Art. 2 declares that "everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind." Analyzing the similar provisions of the European Convention on Human Rights Fredman marks that the list of discrimination grounds is "a product of its time. On the other hand, it is non-exhaustive" (Fredman, 2016, p. 273). It provides "a list of such grounds which includes other status" (Arnardóttir, 2014, p. 648). Discrimination ground of disability "has been elevated by the European Court of Human Rights to the level of suspect discrimination grounds" (Arnardóttir, 2014, p. 649).

The recognition of disability as a discriminatory ground presupposes the rejection of the medical model of disability. Social, historical and legal evolution transformes the understanding of disability from a medical problem to "one that is defined by the complex interaction between the impairment of an individual and the sociopolitical environment" (Vanhala, 2015). Rejection of the medical approach is usually associated with the adoption of the WPA (Kayess and French, 2008, pp. 1–3).

Modern Belarusian legislation also declares the rejection of the medical model. According to the Law PDRPD, disability is a social insufficiency caused by health disorders (Art. 1). Disability is recognized as a social problem, not a medical one. However, elements of the medical model still remain in the legislation. For example, Art. 47 of the Constitution says, that citizens of the Republic of Belarus are guaranteed the right to social care in the event of illness, disability and

other cases. On the one hand, this provision is a manifestation of social protection, but on the other hand, it stigmatizes and objectifies disabled persons. Disability is matched with the disease and is recognized as a sufficient reason for social care.

To eliminate such problems, Mabbett suggests using different definitions of disability in different spheres of social policy. "Within each sphere, definitions of disability are based on relevant comparisons which determine who should be recognized as disabled for the purposes of the policy" (Mabbet, 2005, pp. 215–220). However, despite the fact that persons with disabilities may need special facilities, they should be always treated as full members of society. In the absence of any additional legal circumstances, such persons are full-fledged subjects of law and legal relations. It is symbolic that the Declaration of Madrid (2007), which became the outcome of the Expert Group Meeting in Madrid "Making it work: civil society participation in the implementation of the Convention on the Rights of Persons with Disabilities," ends with the words "Nothing about us without us." Undoubtedly, disabled persons should not be viewed as "objects instead of partners and leaders" (Arstein-Kerslake *et al.*, 2020, pp. 413–414). Thus, a single non-discriminatory approach to disability is more appropriate.

III. Equality and Rejection of the Medical Model

Rejection of the medical model raises a problem of *formal equality*. "The central premise of formal equality — the disregard of difference — is particularly problematic in a disability context... If the rights of human beings are the rights of all human beings, then it follows that these rights should also be the same for all human beings" (Mégret, 2008). For example, the Declaration on the Rights of Mentally Retarded Persons says that the mentally retarded person has, to the maximum degree of feasibility, the same rights as other human beings (p. 1). According to Art. 22 of the Constitution of Belarus everyone is equal before the law and has the right to equal protection of rights and legitimate interests without any discrimination.

In contrast to formal equality, *substantive equality* is proposed. It attempts to compensate for disadvantage and requires "alteration

of the norm to better reflect human diversity" (Kayess and French, 2008, pp. 1–34). The concept of diversity "claims the right to the full recognition of the dignity of these group of people, as they are just one possible expression of many diversities that, nowadays, are recognized in a positive way in our society" (Díaz and Ferreira, 2010, pp. 298–292).

Diversity involves rejecting the concept of normality and accepting the fact that a normal person is a theoretical model that cannot exist in reality. Diversity theory gives people the opportunity to have their own characteristics, while preserving equal dignity and rights, as guaranteed by the Universal Declaration of Human Rights and other instruments. For example, the CRPD expands the notion of personhood and requires more inclusive recognition of what it is to be human. "In relation to Article 12, it requires recognition of a pluralism of minds" (Arstein-Kerslake, 2017).

C.-M. Panaccio defends the validity of formal equality arguing its sufficiency (Panaccio, 2020, pp. 213–218), however, this applies more to the European legislation, where "formal EU equality law has always supported substantive equality and has gradually been mobilized to further substantive equality aims" (Vos, 2020, p. 64). In relation to Belarusian law the idea of adding substantive equality seems more reasonable, "efforts directed toward achieving formal equality should not stand alone without similar efforts to achieve substantive equality" (Burns, 2009, p. 23). Treatment of persons with disability equally requires specific recognition and accommodation of their difference.

Therefore, sports law substantive equality requires providing special care and it should be provided without stigmatization and objectification of persons with disabilities. According to the SREO the principle of equal rights implies that "the needs of each and every individual are of equal importance, that those needs must be made the basis for the planning of societies and that all resources must be employed in such a way as to ensure that every individual has equal opportunity for participation" (p. 24). The WPA establishes as one of its goals not only equal rights but "the equalization of opportunities for people with disability" (part 4). According to it, "Member States will assume responsibility for ensuring that disabled persons are granted equal opportunities with other citizens" (point 108). "Member States

will undertake the necessary measures to eliminate any discriminatory practices with respect to disability" (point 109).

According to the Rule 11 of SREA states will take measures to ensure that persons with disabilities have equal opportunities for recreation and sports. They will "initiate measures to make places for recreation and sports, hotels, beaches, sports arenas, gym halls, *etc.*, accessible to persons with disabilities." Such measures will encompass support for staff in recreation and sports programmes, "including projects to develop methods of accessibility, and participation, information and training programmes."

To set the substantive equality and equal opportunities, the Draft Law RPDSI contains several provisions on non-discrimination. Art. 7 prohibits direct and indirect discrimination, insult by action and denial of reasonable accommodation. However, the Draft Law RPDSI does not contain specific mechanisms for implementing these norms in adaptive sports. In fact, while declaring the rejection of the medical model and discrimination, the Belarusian legislation does not provide for mandatory implementation of these provisions. As a result, elements of the medical approach and discrimination remain in certain areas of sports law for disabled persons (medical, rehabilitation and others).

IV. The Right to Health or the Duty to Be Healthy

Since the Constitution declares the Republic of Belarus as a social state (Art. 1), the legislation pays much attention to medical rights of persons with disabilities. International law also addresses this issue. The right to health, which is considered in this article as a synonym to the right to health protection, is proclaimed by the Universal Declaration of Human Rights according to which "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services" (para. 1, Art. 25). The International Covenant on Economic, Social and Cultural Rights obliges "the States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (Art. 12).

According to Rule 2 of the SREO effective medical care to persons with disabilities is to be provided. “States will ensure that persons with disabilities are provided with any regular treatment and medicines they may need to preserve or improve their level of functioning” (point 6). That includes “working towards the provision of programmes run by multidisciplinary teams of professionals for early detection, assessment and treatment of impairment, which could prevent, reduce or eliminate disabling effects.” Such programmes will ensure “full participation of persons with disabilities and their families at the individual level, and of organizations of persons with disabilities at the planning and evaluation level” (point 1). States will also ensure that persons with disabilities are provided “with the same level of medical care within the same system as other members of society” (point 3).

Thus, international instruments assume that the right to health care is a human right. This implies a close relationship between the right to health and other human rights. However, in the Belarusian legislation, the emphasis is shifted to the charity nature of medical care, which brings us back to the medical model of disability (sometimes called the charity model). In particular, the Law on Health Care does not contain any principles related to the protection of human rights (Art. 3 and others).

According to the Constitution, citizens of the Republic of Belarus “are guaranteed the right to health protection, including free treatment in public health institutions. The state creates conditions for medical care that is accessible to all citizens” (Art. 4, 5). These provisions establish the right to free medical care and set fairly high standards in this sphere. Their implementation in sports law is regulated by the Law on Physical Culture and Sports. The Law pays much attention to health protection of persons involved in sports. According to para. 2 of Art. 70, medical support for athletes and other individuals engaged in physical culture and sports consists of medical services, including medical examinations, medical monitoring of health, and medical assessment of the adequacy of physical activity to the state of health.

In bylaws, under the influence of the medical model of disability, these high medical standards are transformed into a promise to prevent deterioration of health. Since a person with a disbility is considered in

the context of the disease and its treatment, people with disabilities are allowed to be involved in sports only if it is not risky for their health condition. A person with disability ceases to be a subject of law, cannot make independent decisions about his/her life, becoming an object that is to be protected.

According to the current system a doctor cannot allow a person with certain diseases, the list of which is very long, to participate in competitions or classes in sports clubs. Specialists involved in medical support become responsible for the health of athletes. To reduce legal risks, doctors often do not give permission to novice athletes with disabilities to have physical activities. The right to health goes from being a legal benefit to being a restriction and discrimination.

The existence of a similar problem is noted by different authors. They emphasize the discriminatory nature of this situation: "Participants who deviate from the able-bodied norm are constituted as 'impaired,' 'immoral,' 'supercrip,' 'unproductive,' '(un)reproductive'... or as objects of care" (Sanmiquel-Molinero and Pujol-Tarrés, 2020, p. 550).

To overcome unequal opportunities of athletes, the Draft Law APCAS declares independence of sports rights from medical permission to be engaged in sports (Art. 4). Besides, the Draft Law provides a number of protective procedures: examination by medical commissions, the right to choose a doctor, the recommendation character of some medical reports (Art. 18, 24, 29 and others). These provisions become the implementation of the rejection of medical model of disability. They restore the right to sports and the right to health as elements of human rights, rather than human responsibilities. Besides, these provisions may encourage children's adaptive physical culture and sports, since this is the area where the strictest boundaries and the most urgent need for physical culture exist.

V. Is Rehabilitation a Right or a Pain?

The right to medical care and the elimination of restrictions in implementing the right to sport for persons with disabilities contribute to the establishment of the right to rehabilitation. Being an important aspect of human rights of people with disbilities, rehabilitation is

sometimes even defined as a paradigm of the medical model. Based on health-disease parameters "the rehabilitation paradigm centred on disabled individuals, as they were understood to be suffering the consequences of a disease, trauma or health condition: this justified the aim of rehabilitating people so they adapt to their environment" (Domínguez and Luna, 2019, p. 78).

This approach has also an inverse relationship: rehabilitation is considered primarily in medical context, which is very narrow. On this issue, Rehabilitation International and the International Disability Caucus even "were of the view that habilitation and rehabilitation should be dealt with in a separate provision from the right to health because the placement of both in proximity to health risks reinforcing the medical model of disability… Rehabilitation has more to do with education than health" (Lawson and Beckett, 2020). This approach can hardly be called completely fair, since rehabilitation includes a wide variety of aspects, including medical ones.

According to the DRDP, disabled persons have the right to medical and social rehabilitation, vocational training and rehabilitation, aid, education, counselling, placement services and "other services which will enable disabled persons to develop their capabilities and skills to the maximum and will hasten the processes of their social integration or reintegration" (p. 6). The SREO defines the term "rehabilitation" as a process aimed at "enabling persons with disabilities to reach and maintain their optimal physical, sensory, intellectual, psychiatric and/or social functional levels, thus providing them with the tools to change their lives towards a higher level of independence." It says that rehabilitation "may include measures to provide and/or restore functions, or compensate for the loss or absence of a function or for a functional limitation" (para. 23 of the introduction).

Thus, rehabilitation is assumed to include medical rehabilitation (consisting of rehabilitation therapy, reconstructive surgery, *etc.*), social and professional rehabilitation, helping a person with disabilities to orient or reorient professionally (in case of loss or significant restriction of work skills), get professional education and find a job, adapting to the work environment. Psychological rehabilitation is also an important part of it (Razuvaeva, Gut, Lokteva and Pchelkina, 2019) as well as

other types of rehabilitation. In particular, sexual behavioral aspects of rehabilitation are researched (Blockmans, 2019, pp. 170–179; Reel and Davidson, 2018, pp. 35–48).

Such a broad understanding of rehabilitation covers not only the adaptation to new living conditions, but also the adaptation to the features acquired at birth (*i.e.*, habilitation). This approach does not allow us to take into account the specifics of rehabilitation and habilitation areas, as it unifies the set of adaptation measures offered to disabled people and often reduces their effectiveness. The DRDP declares that disabled persons have the right to psychological and functional treatment, including prosthetic and orthetic appliances. However, habilitation is much wider being related to persons with developmental disabilities that are present from an early age as therapeutic, social and other measures aimed at adapting them to existing living conditions.

Since many international and domestic acts assume that rehabilitation includes habilitation, this issue cannot be considered as resolved unambiguously. At the insistence of representatives of associations of the disabled persons, the Draft Law APCAS defines "habilitation" and "rehabilitation" as different concepts. It says that both physical rehabilitation and habilitation of disabled people aim restoration, correction or compensation of impaired, lost or temporarily lost body and other functions of persons with disabilities by using special instruments and methods of adaptive physical culture and adaptive sports (Art. 1). However, habilitation and rehabilitation may require different conditions, activities and measures (Art. 16).

Practice convincingly proves that social, mental and physical rehabilitation and habilitation of persons with disabilities are impossible without physical activity and social communication, which can be provided by training and participation in physical culture and sports events. That is why the Draft Law APCAS also distinguishes between active rehabilitation and habilitation as a set of activities with the use of physical culture and sports, aimed at ensuring self-service, maximum independence in everyday life, integration and social activity of persons with disabilities (Art. 1). The issues of active rehabilitation and habilitation of persons with disabilities, being closely related to the right to sports, are regulated in detail in the Draft Law APCAS (Art. 34–41).

Since the Draft Law APCAS has not been adopted yet, a problem of objectification of disabled people remains. The medical model of disability understands rehabilitation as a practice that is "done to" rather than "done with" the collaboration of the patient (Shakespeare, Cooper, Bezmez and Poland, 2018, pp. 61–72). In this context the right to sports for rehabilitation purposes becomes the duty of a disabled person to engage in special physical exercises. This approach also allows causing pain, discomfort, other kinds of physical and psychological pressure on the "rehabilitation object," which of course is unacceptable in any humane society.

VI. Adaptation of a Person with Disability or Adaptation of Society?

The problem of objectification is partly related to the establishment of high requirements for the rehabilitation process. The Sunberg Declaration adopted by the World Conference on Actions and Strategies for Education, Prevention and Integration (1981) underlines the importance of rehabilitation and integration of disabled persons, steps being taken to ensure that every person receives support and assistance that might be needed to reduce the handicapping effects of disability, "in order to bring about the maximum possible integration of disabled persons and enable them to play a constructive role in society." Arguing for these provisions, Rakhmatov says that people with disabilities "with appropriate training, are considered to be able to provide for their own existence, *i.e.*, not to be a burden" (Rakhmatov, 2016, p. 7).

In this context, the right to rehabilitation becomes a duty to stop being "a burden" and start playing "a constructive role in society" through rehabilitation. This approach not only objectifies a person with disability, but also becomes an example of ableism. We believe that persons with disabilities, regardless of their capacity and activity, should never be considered in the context of "burden or not a burden," being full members of society, capable of versatile and full realization of their potential.

Rehabilitation and habilitation of disabled people are carried out not only when having physical trainings or taking part in competitions,

but also when working as coaches, coordinators, sports judges. According to Rule 3 of the SREO, "persons with disabilities and their families should be encouraged to involve themselves in rehabilitation, for instance as trained teachers, instructors or counsellors." Discrimination in labor relations is prohibited in Belarus (Art. 14 of the Labor Code), but in practice this provision meets a number of challenges. Disabled persons complain that new sports facilities provide infrastructure for disabled athletes, but not for managers or coaches with disabilities. This is largely due to the lack of legislation requiring the participation of representatives of associations of persons with disabilities in the design and construction of public buildings and structures.

To eliminate such a gap, the Draft Law ACPAS declares accessibility of sports facilities for training and participation in sports and entertainment events for disabled persons as one of the principles of legal regulation of adaptive movement (para. 1 of Art. 2). Its implementation is provided by the organization of building, renovation and maintenance of sports facilities (Art. 6, p. 1), ensuring the availability of all sports facilities for classes, work and participation in sports and entertainment events for people with disabilities (Art. 5, p. 1), public supervision of compliance with the requirements of regulatory and technical documents for creating a barrier-free environment (Art. 7, p. 4).

Thus, an important aspect of rehabilitation can be recognized as the rehabilitation of society itself, the change in victimizing attitudes towards persons with disabilities. Disability creates a need for adaptability (the ability to adapt to special conditions), and it requires an effort not only from a disabled person, but from other people, society and the authorities. "This generally requires investment by lawmakers, employers, service-providers, *etc.* to alter the environmental barriers that act as mechanisms of exclusion" (Vanhala, 2015).

Adaptability extends to different areas and includes a wide variety of measures involved in economic, social, political, technological, legal and other relations. With regard to sports the following key concepts of adaptability are included in the Draft Law APCAS.

Adaptive sports are an integral part of sports that have developed in the form of a special theory and practice of preparing people with disabilities for sports competitions and participating in them for the

purpose of physical rehabilitation, habilitation, social adaptation and integration, forming a healthy lifestyle and achieving sports results on the basis of creating special conditions, including communication conditions.

Adaptive physical culture is a type of physical culture, a field of activity that represents a set of spiritual and material values created and used by society for the physical development of persons with disabilities, which contains a set of effective means of rehabilitation and habilitation, social adaptation and integration, health promotion and contributes to the harmonious development of the individual.

Adaptive sports movement (adaptive movement) as a form of social movement aims to promote the development of adaptive physical culture and adaptive sports, the achievement of physical and spiritual perfection by persons with impairments, and the strengthening of international cooperation in the field of adaptive physical culture and adaptive sports.

Thus, the goal of the Draft Law ACPAS (Preamble) and the adaptive sports movement is to equalize opportunities in sports. The WPA defines the equalization of opportunities as "the process through which the general system of society, such as the physical and cultural environment, housing and transportation, social and health services, educational and work opportunities, cultural and social life, including sports and recreational facilities, are made accessible to all" (Objectives, Background and Concepts). However, we believe that equalization of opportunities in sports should be defined much wider than providing sports facilities, ensuring equal conditions and opportunities for the development of adaptive movement in relation to the conditions and opportunities for the development of non-disabled sports and non-disabled physical culture.

Equalization of opportunities should include a *freedom of adaptability* as a key category and one of the basic principles of the adaptive movement. The freedom of adaptability means that persons with disabilities have the right to engage in adaptive physical culture and accessible types of adaptive sports in the direction corresponding to their characteristics, as well as to engage in physical culture and sports with non-disabled persons. Each person with disabilities has the right

to independently decide whether to train, participate in competitions and other events or not. He/she can choose whether to do it within the framework of general (non-disabled) physical culture (sports) or adaptive physical culture (sports).

The last provision is especially relevant in Belarus where the development of the Paralympics, the Deaflympics, the Special Olympics and other kinds of professional sports movement for disabled persons do not have such active support from the government and public organizations as the Olympics. The bonuses and rewards granted to athletes in adaptive sports are still several times less than those of non-disabled athletes. At the same time, some of the athletes in adaptive sports (for example, some of the deaflympians) express their readiness to participate in competitions on an equal basis with non-disabled athletes.

Discrimination on the basis of disability, including a possible violation of the right to adaptability, cannot be considered as permissible, therefore the freedom of adaptability should be recognized as one of the principles of adaptive sports movement. There is no such provision in the current legislation of the Republic of Belarus, but it is provided for in the Draft Law APCAS (Art. 2).

VII. Human Diversity and Diversity of Adaptability in Sports

Rejection of stigmatizing provisions gradually transforms the concept of disability into the concept of special features. It assumes that each person is unique and has specific features, but in some cases these features require additional efforts to adapt.

In practice, it causes the need to list what features (impairments) require special attention and regulation. For example, the Convention on the Rights of the Child (1989) refers to mentally and physically disabled children (Art. 23.61). The Declaration on Social Progress and Development (1969) also takes into account physical and mental disabilities (Art. 11, par. C).

The Law PDRPD as well as the Draft Law RPDSI offers a broader list of impairments and defines a disabled person as a person “with

persistent physical, mental, intellectual or sensory impairments that, when interacting with various barriers, prevent a full and effective participation in society on an equal basis with others" (Art. 1). Restriction of a person's life activity is expressed in the complete or partial loss of the ability or ability to perform self-service, movement, orientation, communication, control over the behavior, as well as engage in work.

The definition in the Draft Law APCAS is even wider. It says that health conditions or impairments do not necessarily prevent, and also may interfere with the full and effective participation in society. This definition is fully consistent with Article 1 of the CRPD.

Besides, to avoid stigmatization the Draft Law APCAS does not use the word "disability" in definitions. It mentions "a person with impairments in the functions of the musculoskeletal system, vision, hearing, intelligence and other functions as a person with physical, mental, intellectual or sensory characteristics, including: a person with diabetes; a person who has undergone a transplant; a person who has had cancer; a person who has or has had other persistent health disorders that require the creation of special conditions for the development (achievement) of results in physical and sports training that are commensurate with the results of persons who do not have these characteristics" (Art. 1).

The list of impairments is not exhaustive in the Draft Law APCAS, since many features (for example, albinism (Mswela, 2018, pp. 1–37)) are still debated as grounds for disability. The boundaries between the concepts of sickness and disability also "remain blurred" (Favalli and Ferri, 2016, pp. 5–35). In this case, the essential fact is that health conditions or impairments prevent or may prevent the full and effective participation in society. Special features of a person are only objective circumstances that do not affect someone's personal characteristics.

Variety of special features assumes a non-exhaustive list of possible directions of adaptive movement. Currently, the sports movement for disabled persons in Belarus is coordinated and managed by the Paralympic Committee of the Republic of Belarus, the Belarusian Sports Federation of the Deaf Persons, the Belarusian Committee of Special Olympics, *etc*. These organizations are not connected and often do not

interact with each other, because, despite the general principles, their activities are very specific.

The Belarusian legislation either does not regulate different directions of adaptive sports, or does it with general provisions. For example, athletes with visual impairments need some assistance of leading athletes. However, the Belarusian legislation does not regulate the work of leading athletes, which puts them in a vulnerable position, limiting opportunities for business trips, participation in competitions, receiving social payments.

The Draft Law APCAS was prepared with the participation of different Belarusian sports associations of persons with impairments and it aims to fill the gap. According to Art. 3, adaptive movement includes the following directions:

— the Paralympics that develop adaptive physical culture and adaptive sports for people with disorders of the musculoskeletal system, other physical features, including visual features;

— the Deaflympics that develop adaptive physical culture and adaptive sports for people with hearing disabilities;

— the Special Olympics that develop adaptive physical culture and adaptive sports for people with mental disabilities;

— other areas that develop adaptive physical culture and adaptive sports for people with disabilities, including the Dia-direction for people with diabetes; the transplant direction for people who have undergone organ transplantation; the Onco-direction for people who have had cancer, *etc.*

The principles of adaptability are applied to all possible types of disability. A non-exhaustive list makes legal regulation more flexible. However, each direction of adaptability assumes its own characteristics and special needs. The Draft Law APCAS pays much attention to the specifics of each of the key areas of adaptive movement. It regulates in detail such issues as the legal status of leading athletes, sports and medical classification, special judges, *etc.* (section 4, 5).

Thus, the current legislation of the Republic of Belarus and the existing Draft Law RPDSI correspond to international acts in the field of non-discrimination of athletes with disabilities. However, they do not provide specific ways to implement these provisions in different

spheres of adaptive sports. The adoption of the Draft Law APCAS will help to reduce discrimination by creating effective ways to ensure equal opportunities for athletes.

VIII. New Models and Definitions of Disability: Are You Ready?

Modern society offers many models of disability to replace the medical one. The most well-known is social model. It focuses on the fact that the problems rise not from a person and his or her impairment, but from the interaction between a person and the setting in which the person lives. Quinn and Flynn describe "the shift from civil rights approaches to locating disability rights within a broader theory of social justice" (Quinn and Flynn, 2012, p. 26). Besides, disability studies scholars "refer to this transformation as the shift from the medical or charity model of disability to the social or human rights model" (Shakespeare and Watson, 2002).

The human rights model focuses "on the inherent dignity of the human being and subsequently, but only if necessary, on the person's medical characteristics" (Quinn and Degener, 2002, pp. 13–14). The human rights model is considered to be a separate model or a part of the "social and human rights model of disability" (Lawson and Beckett, 2020). Perlin says, that "the human rights approach to disability endorses a social model of disability" (Perlin, 2013, p. 469). Besides, human rights and the social model are sometimes used as synonyms (Kanter, 2003, p. 241), but more often are separated as the initial and improved models (Degener, 2017, p. 31) or as complementary models (Lawson and Beckett, 2020).

Other models are also discussed. For example, Swain and French argue the affirmative model as "essentially a non-tragic view of disability and impairment which encompasses positive social identities, both individual and collective, for disabled people grounded in the benefits of lifestyle and life experience of being impaired and disabled" (Swain and French, 2000, pp. 569–582). Gabel and Peters explore resistance theory recognizing that "resistance appears to exist throughout all paradigms at play in disability studies while it is rarely explicitly addressed" (Gabel and Peters, 2004, p. 570).

The new theories do not absorb, but rather complement each other, defending the rejection of ableism, discrimination and objectification of disabled people, arguing for the social causes of disability and creating a foundation for the protection of human rights of disabled persons. Every new model emphasizes some aspects of non-discrimination, so all of them may gradually be supplemented. For the formulation of the concept of disability it is not the difference in theories that is important, but their overall contribution to the rejection of the medical model of disability.

Modern approach to disability leads to the softening of context and terminology. There is a discussion in English about the difference between "a disabled person" and "a person with disability." Reasons for preferring the terminology of "people/person with disabilities" are advanced by proponents of "person/people first" language (Titchkosky, 2001, p. 125), according to which the reference to a person should be situated before reference to his/her characteristics.

The Belarusian legislation uses a term that can be translated into English as "a person with disability" (a "person first" model). However, non-involvement of people with impairments in the preparation of draft laws leads to the appearance of outdated and even offensive terms in the legislation. For example, the Law PDRPD can be literally translated into English as "the Law on Prevention of Invalidity and Rehabilitation of the Invalids." It was adopted in 2008, and even back then such terminology was considered completely inappropriate.

The preparation and discussion of the Draft Law APCAS with the representatives of associations of persons with impairments showed the severity of the problem. It was recognized that even the term "a person with disability" can hardly be considered totally non-discriminating. The concept of disability implies that a person is not able to do something, while a person with special characteristics has the same abilities as any other one. It is true that "adaptive sports for people 'with impairments' are social activities in which, 'athletes with impairments' are no more people with disabilities, but people with 'abilities'" (Marcellini, 2018, pp. 94–104).

Representatives of various associations of people with impairments emphasize the need for new terminology, so the Draft Law APCAS uses

the term "a person with special characteristics or impairments in the functions of the musculoskeletal system, vision, hearing, intelligence and other functions (person with impairments)." This definition represents a new level of non-discrimination for the Belarusian legislation, since it means the rejection of stigmatization and it establishes a medical model in determining a person with impairments. However, the relevant terminology is still not well-developed, so there may be some issues with its implementation. It is clear that the terminology should become the subject of special scientific research and will be improved along with changes in the approach to disability and models of disability.

Conclusion

Modern legislation rejects the concepts of "normality" and "a normal person," since they are a manifestation of stigmatization of disability and ableism. A medical model that leaves a disability within the individual is also considered outdated. However, the rejection of the old approaches meets in practice a number of obstacles.

The Belarusian legislation uses the concept of formal equality, but it is supplemented by victimization of disability and objectification of persons with disabilities. As a result, in the context of sports law the right to health is transformed into a duty to maintain the level of health, and the right to have rehabilitation and habilitation is transformed into a duty to use it to improve the medical indicators of a person with impairments. Thus, a person with a disability becomes an object of care and protection, deprived of his/her own will and legal personality.

The Draft Law APCAS suggests using a new model of disability and a non-discriminatory approach to legal regulation of adaptive sports. It introduces a completely new approach to the Belarusian legal terminology that implies the rejection of ableism. The Draft Law APCAS enshrines the freedom of adaptability, active rehabilitation and habilitation, it regulates different areas of adaptability, and provides mechanisms for the implementation of the right to sport as a manifestation of human rights. The adoption of the Draft Law APCAS may become an important step to protect human rights of athletes with disabilities.

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ARTICLES

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Genetic Ombudsman: The Need for and Concept of Functioning in terms of New Measures of Legal Freedom

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Abstract: The purpose of this article is to describe the need for establishment of the institution entitled "genetic ombudsman" — a new body in the field of human rights protection — in the Russian Federation. The paper addresses the following issues: (1) the role of the ombudsman as an institution acting as a guarantor of democratic freedoms and the value of human life; (2) historical development and the process of becoming the ombudsman; (3) the need to create the institution of the genetic ombudsman during the era of Industry 4.0 (digital society); (4) factors that influence the society's demand for the establishment of the aforementioned institution; (5) the main goals and objectives of the genetic ombudsman (legal, economic, medical). This research allowed for the possibility not only to highlight the importance of the genetic ombudsman in the context of the political and legal reality but also to identify existing gaps in the normative regulation. In this article, based on the key provisions of the theory of competence, the author attempted to conceptualize the activities of the genetic ombudsman, describe characteristics of this institution, and summarize areas for further research. In the course of this study, logical, comparative legal and formal methods were used.

Keywords: genetic ombudsman; genetic education; actors; information; Industry 4.0; digital transformation; genomic technologies; freedom; interdisciplinarity

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Contents

I. Introduction

Nowadays legal reality takes the route of forming interdisciplinary development. This process challenges not only jurisprudence but also legal practice. It is all connected with the nature of the legal matter itself: the law is supposed to be the regulator of social relations, the beginning of civil society development.

People's lives become more complicated, new social institutions appear, people begin to study the environment and affect it like never before. There is a need to obtain special knowledge for the implementation of previously unknown types of human activities. This will affect the behavior regulators.

"The change of social guiding line system and needs determined the necessity of respective changes in all aspects of social life. The law, which role in society's life is rising, also changes. Reflecting the urgent social needs, the law, on the one hand, is forced to 'adapt' to the changes taking place, and on the other hand, it itself acts as a tool through which the necessary transformations can be carried out most quickly and efficiently" (Rasheva and Gomonov, 2006).

Due to modern trends, the scope of legal regulation is constantly expanding thus covering more and more different spheres of human life. These general theoretical provisions are shifted to questions concerning legal activity, the problem of human rights protection and the specialization of lawyers.

II. The Need for "Genetic Ombudsman"

Previously a cycle of works linked to questions of genetic and legal education has been written. The first article revealed the measure of freedom of the subject of law determining the mode of data use as in the case of genetic information (Voronin, 2019); the second dealt with the measure of freedom of the subject-addressee of genetic education in the context of its content (Voronin, 2020); the third analyzed the work of genetic and legal education executors and how the success and effectiveness of genetic and legal education directly depends on its executors and those having the particular knowledge in the respective field (Voronin and Sakhipgareeva, 2021).

On November 18th, 2021, a round table on the topic "Genetics and Law: The Challenge of the Time 2020–2030" was held at Kutafin Moscow State Law University (MSAL), organized by the Chamber of Young Legislators under the Federation Council with the participation of the expert community of the country's leading universities (The Chamber of Young Legislators under the Federation Council, 2021). The author of this paper performed as a moderator of this event.

The senator, the first deputy of the chairman of Federation Council of the Russian Federation Committee of social politics, coordinator of Chamber of Young Legislators of the Russian Federation Alexander Varfolomeev, addressing the participants, said that "in today's work we have to account the possibility of developing the concept of genetic and law awareness and education of the public, creating the institute of 'genetic ombudsman' in our country" REC Digital Education, (2021).

Thus, given the previous publications and the recommendations formulated during the roundtable discussion the author aims at conceptualizing the function of a genetic ombudsman.

III. Development of the Ombudsman Institute: Specialization Trend

Over several decades, the ombudsman institute has taken a special place in the life of the country and society. By becoming an inseparable part of democracy, it plays an important role in the evolution of law culture and solidifying legal consciousness among public.

The importance of such a profession is shown in effective and timely protection and advocacy of people, whose rights and interests were infringed and violated.

A significant factor influencing the strengthening of the law and order and the formation of well-being is the presence of such a body in the country.

The history of the ombudsman institution originates in Sweden during the absolute monarchy. At the very beginning of the development of the institution, its duties were mostly limited to monitoring the activities of the judicial institutions, whose actions subsequently had to be reported to the King. However, gradually the powers of the ombudsman began to expand and very soon began to extend not only to the judicial power, but also to the executive power such as the administration of the king. 1809 became the turning point in history of Sweden, when the ombudsman left the king's service and became under Sweden parliament — Riksdag control. From that moment on, he was obliged to submit an annual report on his work on monitoring the administration, justice, as well as religious organizations (Gil-Robles, 2004).

It is necessary to address the fact that two positions were formed at that time: 1) the Chancellor of Justice, who remained under the jurisdiction of the King and was listed as a public official; 2) the ombudsman of Justice, accountable to the body that elected him, but at the same time independent in carrying out his activities. Later, in the second half of the twentieth century, in connection with the development of the economy, social and spiritual spheres, it was decided to differentiate the ombudsmen by type of activity: for example, one is responsible for social issues; the second solves issues in the field of finance, *etc.*

The next important stage in the dissemination of the ombudsman institution is the two world wars of the twentieth century. After their conclusion, people realized that a real democracy could be built only if the priority of human rights prevails over state interests. In turn, to achieve this the government must provide a full and stable system of containments and guarantees, under which the population will be able to feel stability and security.

However, the correlation and differentiation of public and private interests is always a difficult task. Another French writer Claude Adrien Helvetius wrote that "interest is a powerful and universal incentive that moves people, luring them to vice, then to virtue" (Protopopova, 2008).

In order to maintain a balance between private and public interests, law and order in the world, and peaceful settlement of disputes, society and the state need impartial and independent mediators who are always able to resolve the conflict, to come to the aid of those whose rights are infringed. A person who could take on such duties and responsibilities is the ombudsmen. The meaning of his work is to protect the helpless and support those in need while carrying out their duties, they should be guided not by greedy and selfish motives, but by compassion and love.

Regardless of the variety of names, the essence and directions of such work is brought to the maintaining of law and order, supervision of government agencies actions and human rights protection.

Therefore, turning to history, one can see that the expansion of the institution of ombudsman is primarily "a response to the request of society, which needs to increase guarantees of human and civil rights and freedoms and new tools for their implementation in the living space" (Council of Europe. Protection, Promotion and Development of the Ombudsman Institution, 2020, p. 10).

At the same time, it is interesting to note the experience of French-speaking Canada. According to Professor Garant from the Laval University of Quebec, people of this province have never really felt an urgent need for an ombudsman, and only since 1966, when the party came to power, promising to establish this institution in its program. And gradually climate for its emergence began to change to be more favorable (Gil-Robles, 2004).

Today, in most countries of the world, there is an ombudsman institution or its analogues. Depending on the historical past, linguistic differences, traditions, *etc.*, this position may be called differently: Commissioner for Human Rights (Russia), European Commissioner for Human Rights (European Union), Commissioner for Human Rights of the Republic of Azerbaijan (Azerbaijan), *etc.*

Despite the large number of administrative and judicial bodies, whose job is to promptly resolve conflicts, many people still feel oppressed and defenseless. Due to the fact of limited funds, long hearing time of the case or simply the lack of knowledge of certain means of protection, many people do not want to start lengthy, sometimes devastating litigation, so in the process of human evolution the ombudsman institute was developed as one of the methods of protecting their own rights. At this moment, this institute is an effective indicator of government's system of human rights protection.

Now, the legal status of the Commissioner for Human Rights in the Russian Federation is regulated by the following acts: The Constitution of Russia and Federal Constitutional Law No 1-FCL of 26.02.1997 "On the Commissioner for Human Rights in the Russian Federation."

In regards to the position of the Commissioner for Human Rights in the Russian Federation, the Constitutional Court of the Russian Federation also expressed its position: "The Commissioner for Human Rights in the Russian Federation is a constitutional body established to ensure guarantees of state protection of citizens' rights and freedoms, their observance and respect by state bodies, local self-government bodies and officials."[1]

Similar opinion has been expressed by the Supreme Court of the Russian Federation: "...as follows from the provisions of law, the Commissioner for Human Rights in the Russian Federation and his working staff are a state body established to ensure guarantees of state protection of citizens' rights and freedoms, their observance and respect by state bodies, local self-government bodies and officials. The

[1] The Ruling of the Constitutional Court of Russian Federation of 21.12.2004 No 437-O "On refusal to accept for consideration the complaint of citizen Andrey A. Khoroshenko for violation of his Constitutional rights by the provision of paragraph 3 of Article 20 of the Federal Constitutional Law 'On the Commissioner for Human Rights in Russian Federation'". Legal reference system "ConsultantPlus" (In Russ.).

Commissioner is independent and unaccountable to any state bodies and officials in the exercise of his powers."[2]

It is also important to notice a Federal Law No 48-FL of 18.03.2020 in the source system "On Human Rights commissioners in constituent entities of the Russian Federation," which aimed at ensuring and fulfilling human and citizen rights on federal and regional level.

In addition, it is important to draw attention to the fact that in Russia there are ombudsmen in other areas other than the Commissioner for Human Rights:

1) President's commissioner for the protection of entrepreneurs' rights in Russian Federation (Federal Law No 78-FL of 07.05.2013 "On Commissioner for the Protection of Entrepreneurs' Rights in the Russian Federation");

2) Commissioner for the rights of consumers of financial services (Federal Law No 123-FL of 04.06.2018 "On Commissioner for the Rights of Consumers of Financial Services");

3) President's commissioner of rights of the child (Federal Law No 501-FL of 27.12.2018 "On Commissioner for Rights of a Child in the Russian Federation");

4) In 2013 the President voiced the idea of creation the position for commissioner for the rights of physically challenged.[3]

Considering the digital transformation of society and the problems of such transformation, it is important to notice the work of digital ombudsman, whose societal institution was established in 2021.[4] For example, if a person faced cyberbullying, fakes or lost their personal data in results of criminal activity, they will have the ability to contact digital ombudsman and their team for help.[5]

[2] Review of judicial practice of the Supreme Court of Russian Federation No 3 (2016) (approved by the Presidium of the Supreme Court of Russian Federation on 19.10.2016). Bulletin of the Supreme Court of Russian Federation. May 2017. No 5 (In Russ.).

[3] Experts assessed the necessity of the ombudsman for physically challenged people in Russian Federation. Available at: https://ria.ru/20130329/929979230.html [Accessed 15.01.2022] (In Russ.).

[4] *See:* Youth digital ombudsman — the first digital protector of Russian youth. Available at: https://youthombudsman.ru/ [Accessed 11.01.2022] (In Russ.).

[5] *See:* Youth digital ombudsman — the first digital protector of Russian youth. Available at: https://youthombudsman.ru/ [Accessed 11.01.2022] (In Russ.).

These institutions were not formed for the sake of complicating the bureaucratic system of the state and additional difficulties. The need for the ombudsmen in these areas was associated with the current agenda of the time and the challenges of society.

For example, due to difficult economic situation in the country, the post of the President's commissioner for the protection of entrepreneurs' rights was established to overcome administrative barriers and the pressure of unqualified state employees and corruption offenses.

As an example, illustrating the "narrow" functions of the ombudsman, we can refer to foreign experience, in particular German. Article 45-b of the Basic Law of the Federal Republic of Germany establishes: "For the protection of fundamental rights, the Bundestag commissioner of defense is appointed as an auxiliary body of the Bundestag in the exercise of parliamentary control. Details are regulated by federal law."[6]

The main task of the military ombudsman in Germany is the protection of military personnel who are as full and full-fledged citizens of their country as ordinary residents. As part of the job, the commissioner of defenses of the Bundestag has the right to demand from the Federal Ministry of Defense, as well as from other official authorities, to inform him and provide information and opportunity to study the case materials at any time. In addition, the German military ombudsman has the right to visit any unit of the Bundeswehr (armed forces of the Federal Republic of Germany) at any time without prior notification.[7]

"Among the specialized ombudsmen the Health Ombudsmen (in the UK at the level of England, Wales, Scotland and in the USA); ombudsmen for the supervision of correctional institutions (in the USA in Minnesota); prison ombudsmen (in the states of Oregon, Alaska, Hawaii, Iowa, Nebraska, Connecticut, Maryland, New Jersey, New York, Ohio, South Carolina, Wisconsin, Michigan in the USA) should be named" (Trifonov, 2020, p. 119).

[6] Basic Law of the Federal Republic of Germany. Availble at: https://www.btg-bestellservice.de/pdf/80201000.pdf [Accessed 11.01.2022].

[7] *See*: Commissioner for Military Affairs. Available at: https://www.bundestag.de/resource/blob/582058/761c6bcad25367ddaca07a33d3e167aa/flyer_wehrbeauftragter_ru-data.pdf [Accessed 11.01.2022].

Today the society actively begins to live in Industry 4.0 era. As a result, the humanity will be faced with new challenges and threats. The characteristic of 21st century can be described as such: the increase of amount of information (BigData; the volume of data is rising in geometrical progression), the development of molecular chemistry and bio nanotechnology, general digital transformation, and the increase of interdisciplinary knowledge relevancy.

This approaching era is the time of large-scale opportunities and equally significant threats. It will be the world where interaction between virtual and physical systems will be a common thing. All crucial changes in economy, technological and social spheres during forth industrial revolution will lead to necessary changes of the system of law.

Advancing changes of law is not a want, but a necessity since there are growing numbers of new unregulated social relations. In general, one can speak about transformation of the measure of freedom of juridical entity, but generalization of this process on general theoretic level is still needed to be done. And the problem that is being examined is one of the most important sections of such transformation linked to digitalization of social and humanitarian knowledge and its use. In fact, the need in digital and genetic ombudsmen is a new measuring law practice empiricism. During the creation of such institutions, the competences and place of this structure in the system of social relations will be expected to be defined.

Within the framework of genetic progress "one of the new socio-legal receiving institutional registration in the legal system is genetic data and personal genetic information, about genetically modified organisms. At the same time, the problem itself is not new. The freedom of genetic scientists in the field of scientific knowledge has been closely monitored by the state and society for more than 80 years. But in the conditions of the new reality, this freedom began to acquire a kind of 'individual immersion'" (Voronin, 2020, p. 16).

Legal regulation often lags behind the rapid evolution of science and technology, resulting in many gaps and conflicts in law that cannot be resolved in a timely manner.

In part, this process is somewhat natural, but it acquires new accents in a changing world. Thus, law is always directed at social relations, which in general are the basis of the system of law itself; in

many ways, both the content and the structure of law are determined by the state-power will and the legal policy that specifies it (Voronin, 2016, p. 119). What is important here is that the content of public relations is changing, previously humanity did not know such a large amount of information about the health of a particular person, it was impossible to carry out genetic correction and therapy, to influence other important spheres of life; there is a new emphasis between the private and public in human activity. Quite a lot of examples can be given based on the analysis of information about the development of society and the state in the context of the COVID-19 pandemic (Sinyukov and Mokhov, 2021).

"In the USSR, there was no legal regulation of genetic research, and there was no uniform measure of law in relation to problems of genetic nature, in modern Russia they have not developed up to now either, and therefore the most important is the conventional regulation of the institute of genetic research, as well as sectoral regulation at the domestic level" (Voronin, 2019).

Since humanity is not yet ready to fully enter the new era, the state will have to find solutions to problems and create all conditions for the transition between eras to be painless for the population and law and order to be preserved.

IV. The Concept of Genetic Ombudsman Functions

The following paragraph offers the concept of genetic ombudsman to improve legal system in Russia and to reduce risks and negative consequences.

To prove the need of establishing the role of special advocate one would like to focus on the following parts of analysis of the institute that is being studied:

1. factors that influence the need of creation of genetic ombudsman institution;

2. the purposes of genetic ombudsmen and problems that they solve;

3. genetic ombudsman as the main executor and guarantee of genetic and legal education;

4. genetic ombudsman or effective advocate for violated human rights.

IV.1. Factors that Contribute to the Need for Genetic Ombudsman

Even though heredity discussions were conducted earlier, the first research of biological patterns that determine the translation of features from parents to offsprings were conducted by Gregor Mendel in the Czech Republic in the 19th century (Agafonov, Belousov and Vypkhanova, 2022, p. 9).

More than one hundred years later genetic science has made an impressive leap forward. Nowadays scientists discuss the possibility of diagnosing predisposition to genetic illnesses.

"The changes in legal regulation of public relationships are dictated by their own development in different areas of life. The legal regulation of genetic research is the problem that was defined not to appeal to legal volition. This problem is faced due to scientific and medical progress" (Voronin, 2019).

At this time parents can have the screening made for genetic abnormalities which can be transferred to the offspring. This procedure allows future parents to prepare themselves for future challenges and avoid any negative consequences in time. Without a doubt these results in biotechnology sphere can cause not only society's approval but also suspicions and fears.

On November 17th, 2021 the President of the Russian Federation held a meeting in relation to genetic technology development in Russia. During this meeting its participants examined the process of carrying out the federal scientific program for genetic technologies development until 2027. They also discussed financial support of research in genetic sphere, methods of drawing in economic sector into genetic technology development in agriculture, medicine, and industrial microbiology.

During the event, the Head of the State emphasized that "it is necessary to clearly define the limits of permissible use of genetic technologies. We are talking not only about modern legal regulation, but also about compliance with ethical standards: they must be understood and recognized by researchers and businesses and, crucially, accepted by society, enjoy the trust of people. Of course, the most important topic is genetic information, and first we need legislative mechanisms

that will ensure the rights of citizens, regulate the issues of obtaining, using, and protecting genetic data of a person and his family, including future generations."[8]

And now, the country has clearly formed a request to notify the population and familiarize them with the progress in the field of biotechnological industries, as this directly affects us and our loved ones.

It is worth recalling the case of the Chinese scientist Jiankui Xe. He was sentenced to three years in prison and a fine of 3 million yuan (about 430 thousand dollars) for an illegal experiment with the birth of twins from genetically modified embryos.[9] Violating ethical norms and relying only on their own feelings, the doctor has conducted experiments on the embryos and mislead the patients. The procedure was unacceptable because the subjects believed that it was carried out legally. However, it turned out that all the documents confirming the alleged legality of the experiments turned out to be a fake. This indicates the need to create a legislative material that would act as a reliable regulator of such legal relations. However, the urgency of the issue lies in the need to create legal material based on which people's rights will be ensured and in ways of informing people about it.

During the creation of legal materials, the legislator must pay attention to the fact that most people live in the state of limited and imperfect possession of information. Legal regulation often cannot achieve its purposes because of that. The reason is that most of affected people would not see any effects. It is important that socially important information that influences people's behavior was effective and achieved its goals for the good for society. The rapid growth of social media platforms and emergence of new channels of information that are less transparent and obvious compete with traditional official forms of information distribution.

[8] The meeting on the development of genetic technologies. Available at: http://www.kremlin.ru/events/president/news/67119 [Accessed 15.01.2022] (In Russ.).

[9] Chinese scientist was sentenced to 3 years in prison for creating the genetically modified children. Available at: https://tass.ru/proisshestviya/7445829 [Accessed 15.01.2022] (In Russ.).

To overcome the phenomenon of limited possession of information the combined use of official and unofficial channels is needed. It is logical to divide information distribution about genetics into two types: official (governmental facilities) and unofficial (social media content creators).

With all of this going on, a genetic ombudsman will manage both channels as one entity. Thus, it would be possible to achieve the principle of objective truth, independence, and protection of human rights as much as possible since the main mission of the genetic ombudsman is to represent and protect the interests of the population.

IV.2. What Goals does the Genetic Ombudsman Have

The protection of genetic data. As stated earlier one of the primary goals of genetic ombudsman is their duty of protecting the genetic data of a human.

Today biomedical research makes it possible to diagnose diseases at an early stage and to carry out timely prevention. However, most people are afraid that the results of the tests that they have done in the doctor's office may be used later for illegal purposes.

It is not a secret that genetic information allows the doctors to learn a lot about a patient, but it also provides data about the family and genealogy. The possession of such knowledge can lead to fraudulent crimes and invasion of privacy.

Genetic certification, the formation of a large database of genes and conduction of experiments raises doubts in society about their future safety. Soon there may be a problem in the fields of insurance and lending. People will be discriminated against based on their health status.

For example, "in Estonia, in 2000, in order to protect individuals from discrimination, insurers were prohibited from collecting genetic data about insured people and individuals applying for insurance. Insurance agencies were prohibited to require the clients to provide tissue samples or DNA descriptions. It was banned to establish different insurance conditions for individuals with different genetic risks and develop preferential rates and to restrict the definition of insurance cases" (Suvorova, 2019).

However, of particular concern is the fact that a unified legal concept of genetic information has not yet been formed in Russia, its legal status has not been determined. Despite the large number of opinions and points of view on this matter, lawyers, doctors and other specialists have not formed a common position on this issue.

Thus, one of the main tasks of the genetic ombudsman and his team will be to determine the legal status of genetic data, as well as its boundaries.

Jurisdiction purposes. It has long been no secret that for the last thirty or forty years, criminologists and law enforcement agencies have been actively using genetic fingerprinting in the exercise of their functions for a long time.

During this time, DNA data banks have been formed in different countries, which contribute to the investigation of crimes: Fichier National Automatise des Empreintes Genetiques (FNAEG) in France; The National DNA Database (NDNAD) in the UK; Combined DNA Index System (CODIS) in the US.

A similar system exists in Russia. According to Federal Law No 242-FL of 03.12.2008 "On State Genomic Registration in the Russian Federation," a federal database of genomic information (FBoGI) was created in 2009 in our country. This repository contains genomic information obtained due to mandatory and voluntary state genomic registration.

In accordance with article 3 of the said Law, the following people are subject to mandatory state genomic registration: 1) convicted and serving a sentence of imprisonment for committing grave or especially grave crimes, as well as all categories of crimes against sexual integrity and sexual freedom of the individual; 2) unidentified people whose biological material was seized during investigative actions; 3) unidentified corpses.

Voluntary registration is carried out in accordance with the procedure separately established by law based on a person's written will.

The main problem in conducting such examination is the issue of storing unique genetic data. What should the authorities do if, after taking tests, it turns out that people were not involved in a crime? Let's

turn to the case of "S. and Marper v. the United Kingdom,"[10] considered by the European Court of Human Rights. The essence of the dispute was that the minor applicants, who had not been convicted, asked the police to remove their DNA samples and fingerprints from the database. However, neither the police nor the judicial authorities agreed to satisfy their demands, referring to the fact that: 1) such materials were in limited access; 2) an expanded database provides huge advantages in the fight against crime.

After considering the dispute, the Court came to the following conclusion: "the comprehensive nature of the right of retention applied in the applicants' case violated the fair balance of competing public and personal interests, and in this respect the respondent State went beyond the acceptable limits of discretion. That means that the storage of personal data constituted a disproportionate interference with the applicants' right to respect for their privacy and could not be considered necessary in a democratic society."[11]

Thus, given the special importance of public relations regulated by criminal law, the constant search for a balance between private and public interests, the task of establishing public order, it is necessary that such relations be under additional and enhanced supervision of a person who not only has the necessary knowledge for this, but also has the appropriate competence.

Economic goals. Today, the use of genetic technologies in the economy has become the main trend that allows you to optimize production, increase productivity and profit. The increase in the population and growth of its needs forces manufacturers to constantly find new ways to create their products. The use and implementation of genetic technologies in industrial biotechnology reveals the possibilities of extracting a large range of chemical substances and biomaterials

[10] European Court of Human Rights. Case of S. and Marper v. the United Kingdom. Grand Chamber. Applications nos. 30562/04 and 30566/04. Judgement. Strasbourg. 4 December 2008. Available at: https://rm.coe.int/168067d216 [Accessed 15.01.2022].

[11] Information about the ECHR ruling of 04.12.2008 on the case "S. and Marper v. the United Kingdom" (complaints No 30562/04, 30566/04). Bulletin of the European Court of Human Rights. 2009. No 4.

from renewable material, which can significantly improve traditional production.

In addition, there is a question about the nutrition of the population. Since the amount of fertile land is getting smaller, the soil does not have time to undergo the restoration procedure and get enough of the necessary trace elements, products containing GMOs have entered human life.

The ambiguous attitude towards GMOs has generated a lot of controversy. Rospotrebnadzor has banned the import of products from China that contain genetically modified corn.[12] Despite restrictions, research in this area is still going and now you can often buy goods containing GMOs.

The production and sales of such products is directly related to public and private interests, the balance between which is designed to be established by genetic ombudsman.

Preservation, maintenance, and protection of biological collection. To this day, there are no legislative concepts of bioresource collections or at least biological collections in Russian Federation. There are no special laws dedicated to bioresource collections. There are only separate mentioning in other Federal laws, such as "On the Animal World," "On Specially Protected Natural Territories," "On Biomedical Cell Products." Since it is obvious that the legislative framework is mosaic and incomplete, that creates many problems. There are also acts of ministries and departments, but they regulate only certain issues in this area. The acts of the departments are mostly more technical than legal.

In addition, there are currently no acts defining the status of biological collections. There is a separate question about the use of the current legislation to collections, to biobanks (for example, warehouse storage norms). There is no clear list of organizations that keep those collections, there is no understanding of their jurisdiction. These are museums, zoos, educational organizations and bioresource centers that do this in other countries. In Russia, these are probably collective use

[12] Russia has banned the import of corn noodles and crisps from China due to GMO in them. Available at: https://www.rbc.ru/rbcfreenews/6163ce8f9a794713ad5df641 [Accessed 15.01.2022] (In Russ.).

centers and unique scientific installations. Their legal status is also not fully defined.

The related issues of customs regulation, the procedure for collecting, accounting, and storing samples, the scope of use of existing biological collections, the replenishment of collections, the procedure for exchanging samples have not been resolved.

It is obvious that Russian Federation needs special legal regulation for bio collections at the level of federal law. The person who will assist the standard-setting activities, monitor the progress of work, and actively contribute to solving this problem should be the genetic ombudsman as the main performer of genetic education and human rights activist.

V. The Comprehension of Genetic Ombudsman Work: Conclusion of the Article and an Intermediate Conclusion for the Development of the Basics of Functioning

All the above make us conceptualize the activities of the genetic ombudsman based on a functional approach. At the same time, it is important to determine the main activities of the genetic ombudsman. From theory of law point of view, it is necessary to pay attention to such issues as its competence (officially/unofficially it may be an element of civil society, the presence of financing apparatus), the limits of discretionary powers and institutional design in general.

Based on the basic elements of the theory of competence, the possible jurisdiction of the genetic ombudsman can also be considered including "a) normative goals; b) subjects of reference as legally defined spheres and objects of influence; c) authority as a guaranteed measure of decision-making and action" (Tikhomirov, 2001).

In this paper, the clusters of issues that the author considers the most urgent for the protection of the genetic ombudsman have been investigated. Here are the key provisions of a possible legally formalized concept of a genetic ombudsman in the Russian Federation.

The main purpose of the genetic ombudsman's work is to protect human rights in the use of genetic information, the use of biological and genetic technologies, including those related to the decoding and

editing of the human genome, the use of genetic information about a person for jurisdictional, scientific, medical, economic, and other purposes, as well as the protection of social, scientific, medical, and other public institutions associated with these rights.

— Thus, the following issues should be the subjects of such genetic ombudsman:

— The use of genetic information by different subjects of law, legal protection.

— Protection of rights in genetic research, experiments, clinical trials and medical analyses and other medical interventions related to the invasion of the human genome.

— Issues of legality and safety of the use of products, raw materials and other goods obtained using genetic technologies.

— Issues of legal protection of valuable for human genetic and associated bioresource collections, genetic data banks.

— Assistance in the protection of human rights, the implementation of jurisdictional activities, including matters of the legality of genetic examinations.

— Protection of people suffering from genetic diseases, including the security of specialized medical care and medicines.

— Issues of genetic legal education, and cooperation within the framework of protectionism of genetic human rights.

VI. Conclusion

The paper considered the needs of introducing the institution of genetic ombudsman, the main stages of formation and preconditions for the narrowly focused specialization of such a human rights advocate, the basic conceptual provisions that are important for its introduction into political and legal reality were outlined.

The complexity of the detailed regulation of genetic ombudsman is associated with the still emerging regulatory material, the so-called "Lex genetic" field. This further intensifies the need to accelerate the development and adoption of the concept of genetic ombudsman, as well as to strengthen the educational component in this matter. In the subsequent work, it is planned to investigate a possible interdisciplinary

educational standard of abilities for such human rights advocate, which is largely associated with the introduction of certain qualification requirements for the future genetic ombudsman.

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Bioethics for Genomic Medicine: Responsibility to Family or Responsibility for Disclosure

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Abstract: Disclosure of patients' genetic information to their families is a central bioethical topic in genomic medicine. The issue of disclosure to family is often associated with a balance between patients' autonomy and confidentiality and beneficence of their relatives. Communicating patients' genetic risk profiles back to their family members gives them an opportunity to benefit from additional testing, screening and prevention of potential disorder, so that bioethicists have offered a several models of communication with families. There is no unified definition of the term "family" in bioethics or health law, although the concept of "family" has an important position in the history of private law. There are many ambiguities about such issues as "What does 'family' mean?", "How can communication about genetic risks be placed in a framework of family responsibilities?". The analysis of several cases in genomic medicine carried out in the article allows us to delve into ethical, administrative, and legal details of these issues in genomic medicine. Notions of "disclosure to family," "intrafamilial disclosure," "family dynamics" and "the best interests of the child" are discussed in the article in this regard. Various models of disclosure are grounded in different concepts of family and family relations. If we consider the health professional's duty to warn of risks to be the duty to help family members with exercising their autonomy, the health professional is responsible to family and is not responsible for consequences of disclosure. The notion of relational autonomy (based on recognition of mutual obligations of family members) begins to be discussed in law and bioethics, however, it still lacks the ethical underpinning. The further research could be aimed at developing the ethical concept of dependency in family relations.

Keywords: bioethics; relational autonomy; confidence; genetic counselling; genetic information; disclosure to family; familial information; family dynamics; collective agent; family decision-making

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Contents

I. Introduction

In the last two decades, the family perspective of genetic testing has become a subject of discussion in bioethics and health law. Many books and articles are devoted to the tension between patients' autonomy and potential benefit of family members. Debates about balancing between patients' confidentiality and interests of family members are getting more intense. Few basic bioethical and legal concepts were revised due to bioethical discussions and court decisions. The English Court of Appeal supplemented the concept of a doctor-patient relationship by adding the notion of the "potential patient" which is defined as a person who may benefit from results of genetic testing (Gilbar and Foster, 2018). Thus, the concept of individual autonomy was replaced by relational autonomy. This approach tends to consider a human as a social being influenced by and dependent from others, first of all, from family.

The so-called "family covenant model" of genetic counselling considers family as an important part of the decision-making process. Family becomes a third party in doctor-patient communication. This

trilateral dialogue allows us to define the boundaries of the patient's individual autonomy (Doukas and Berg, 2001). At first glance, the decision of the Court of Appeal has a similar logic with the family covenant model. The former implies sharing of the patients' autonomy between family members, while the latter considers family as a major actor in a dialogue along with the patient. Both of them raise such questions as "What is family?", "What definition of the term 'family' can help us solve the problem of family-relevant genetic findings?".

Family law and health law usually deal with family issues and family relationships. Family can also be a significant collective, social, and legal entity. This entity can be represented by one or several individuals while it can be composed of more people. These two perspectives, namely "family as a context of relationships" and "family as a participant of relationships" are not easy to combine. Their difference is relevant for the issues of confidentiality, autonomy, understanding of a legal entity (How is family constituted as a collective entity?) as well as for the issue of data ownership. Is genetic information personal or "familial" data? Can anonymized results of genetic tests be shared among family members as a scientific information generated in a lab?

Another dimension of the family problem is an inversion of dependency. Before "the birth of clinics," patients were dependent from family care. At present, genetic patients control family-relevant information, so that their relatives are dependent from their willingness to share it.

Genetic information is a gift and a curse at the same time (Reynolds, 2020). On the one hand, it helps people to cope with many diseases. On the other hand, it imposes responsibility. Such responsibility can be a part of moral duty of supporting the others' autonomy, *i.e.,* the health professional is responsible to patients' relatives (individuals who do not have enough knowledge to make their own decisions). Furthermore, such responsibility can be grounded in the risk-benefit ratio, *i.e.*, the health professional is responsible for sharing the genetic information to people at risk, as this act can potentially protect their health.

The controversy between patients' autonomy and beneficence of members of their families is not the sole framework for addressing the legal and ethical issue of disclosure of genetic information. The

autonomy and beneficence can be opposed to each other. For instance, the autonomy of family members or autonomy of a family as a collective entity can be opposed to the patient's autonomy. It is unlikely that the issue can be solved by determining whose autonomy is more important. Beneficence of a patient and health professional based on trust and confidentiality can also be opposed to beneficence of family members.

The conflict between Kantianism and utilitarianism has lasted more than two hundred years. This ethical dilemma is particularly relevant for addressing the issue of disclosure of genetic information. We can consider the notion of "family" from different perspectives based on the chosen line of reasoning (*e.g.,* autonomy or beneficence). On the one hand, family can be regarded as a collective entity having its own interests. On the other hand, the notion of family placed in the ethical and legal context can be viewed as a normative concept. Family presupposes a certain type of relationship, *i.e.,* a hierarchy of legal and moral responsibilities and opportunities. The issues related to family boundaries and other characteristics of family arise in both deontological and utilitarian contexts but can be addressed differently.

These issues were central in various ethical and legal concepts. The next section of the article presents the opinion of Russian historians and philosophers on the notion of family. The third section analyses bioethical aspects of disclosure of genetic information to the patient's family. The fourth section explores two ethical and legal cases related to the aforementioned issues. The article concludes with considerations for the understanding of a bioethical principle of autonomy extending beyond Kant's ethics.

II. Family in Russian History and Philosophy of Law

The notion of family was central in ethics, political philosophy, history, and philosophy of law. Even Aristotle considered family as a primary form of social relations (Aristotle, 2006). Much later, scholars began to define family as an independent entity of social and legal relations. M.F. Vladimirsky-Budanov (2005), a Russian legal historian of the second half of the 19th century, suggests that the consideration

of the individual as the main subject of private law is a result of the historical development of the system of legal relations.

"The concept of a person as a subject of private law, which seems so simple today, is the result of long-term efforts of history. Initially, there were public unions (e.g., family, tribal, communal, state unions) formed by the mixture of public and private principles; a physical person was not defined at that time" (Vladimirsky-Budanov, 2005, p. 437).

At the same time, Vladimirsky-Budanov considered the evolution of subjects of private law as one of the key tasks of the history of Russian law. Russian historians and philosophers of law of the second half of the 19th century generated discussions on the legal significance of family. A more active interest in this issue was caused by disputes between Westerners and Slavophiles.

The discussions on the role of peasant families in shaping the moral and political characteristics of the Russian population at that time deserve significant attention. These discussions were not only about the nature of family as a social and legal entity but also about its boundaries.

I.M. Tyutryumov, a prominent lawyer of the 19th century, believed that family is an association with a shared household. Family is primarily characterized by the community of property and property interests (Tyutryumov, 1881, p. 43). By contrast, S.V. Pakhman, a well-known legal scholar, claimed that the peasant family community was united on the basis of family ties (Pakhman, 1879, p. 12). At the same time, the interaction of family members unrelated by blood takes place according to the models of interaction between parents and children or brothers and sisters.

The discussion on the origins and foundations of family relationships taking place at that time may be relevant to the consideration of the role of family in the regulation of medical genetics. The main ethical issues in this field are connected with the discrepancy between the degree of consanguinity and the nature of the social connection. Although family communities discussed by historians could include a significant number of people who were distantly related to each other, positive law had been limited to the concept of a nuclear family even before the

revolution. G.F. Shershenevich, a lawyer of the 19th–20th centuries, states that "Family…is a union of persons related by marriage and persons descended from them" (Shershenevich, 1915, p. 253). At the same time, children are no longer considered members of the family upon reaching the age of majority.

Thus, there have been two sides of the issue of defining family in the history and philosophy of law. On the one hand, it is crucial to draw the boundaries of family as a community of individuals. On the other hand, it is also important to mention the nature of the relationship between family members and determine their duties in relation to each other. The development of genomic medicine has revealed another dimension of this issue. For centuries, family doctors have dealt with intra-family relationships, but the subject of their care was an individual, a family member, or a combination of such individuals (*e.g.,* in case the whole family got the flu). A genetic counselor treats each family as a single entity. He/she makes a diagnosis on the basis of the family history of the disease and the genetic risks which he/she determines as being relevant for the family and its descendants.

Nowadays, the transformation of the doctor-patient relationship is the object of bioethical regulation. This will be discussed in the following sections. At the same time, it cannot be said that the understanding of family as a subject of law has remained an object of historical study only. An analysis of the legal relations that arise in case of the assignment of pensions for the loss of breadwinner showed that the subject of these relations is family (Astrakhan, 1962, p. 153).

Such terms as "family interests" and "family protection" are used in modern law (Tarusina, 2020, p. 23). However, the understanding of family may differ in both cases. Each particular family has its own interests as a social and legal entity. For example, these interests may include housing improvement in connection with the birth of children. A group interest is not limited to increasing the amount of living space per family member. Conventionally, the family's interest does not imply buying two one-room apartments but living together in a three-room apartment. At the same time, it cannot be said that this family interest is expressed by all members of the family (*e.g.,* newborns or young

children do not have this interest). However, parents and relatives express their interest for the sake of all family members.

The term "protection of family" is often used in the sense of "protection of traditional family relations, that is, relations based on a marriage which is understood as union of a man and a woman." This is not the only possible interpretation of this term but it clearly demonstrates differences in the understanding of family. In this case, the object of protection in the first place is not a specific family or its unity but the interpretation of family with an ideal image of family relations. This understanding is based on the structure of mutual rights and obligations that arise within the framework of certain social (family) relations. Mutual obligations of family members are not limited by their legal nature. Rather, law forms the boundaries beyond which one can speak of the destruction of family. Thus, laws contain criteria for finding grounds for deprivation of parental rights or recognizing a marriage union as being fictitious. There is no statement of the essence of the relationship between spouses or between parents and children in written law (Tarusina, 2020, p. 25). Civil lawyers who deal with this kind of cases are often forced to rely on ethical concepts of mutual respect for spouses and proper care for children (Tarusina, 2020, p. 25).

With some reservations, we can say that the notion of "family protection" should be introduced in medical genetics especially in relation to cases of informing family members about hereditary risks. That is, a family member who received information from a medical geneticist about existing hereditary diseases should take care of the health of his/her relatives and share information that is relevant to them. At the same time, a genetic counselor always deals with the "interests of the family," their real boundaries and strategies for collective understanding, or vice versa, their ignorance of medical problems.

III. Bioethical Issues of Medical Genetics: "All in the Family"

A typical bioethical collision faced by a medical geneticist deal with the issue of informing the relatives of a patient about their possible diagnosis. This collision is usually considered as a conflict between the patient's autonomy (the right to preserve medical confidentiality)

and beneficence of relatives, family members. The ethical dilemma is that following two of the four basic bioethical principles (the principle of beneficence, non-maleficence, autonomy, and justice) imposes mutually exclusive moral obligations on the health professional and the entire healthcare system. The patient can disclose information about his/her health according to the principle of autonomy, while the principle of beneficence implies duty of care for people at risk. This bioethical collision can also be represented as a tension between a particular family as a subject of care and the image of family relations, the structure of people's moral obligations towards each other. At the same time, this structure seems to be similar to the kinship system for a medical geneticist.

Issues of family decision-making and family interests were addressed within the frameworks of medical humanities and evidence-based medicine (Siminoff, 2013). Medical genetics adds two more tightly connected dimensions to this problem. The first dimension deals with rethinking the concept of family. The second dimension relates to genetic ancestry testing. While laws in many countries tend to use more and more inclusive notion of family, the progress in medical genetics inclines courts and general public to handle with biological meaning of family. More than twenty years ago, Canadian courts considered that right to know one's own genetic heritage is based primarily on medical reasons (Caulfield, 2000). In these cases, the courts never referred to a specific disorder or even to a way of using genetic data. This phenomenon was called the "genetization" of the family (Caulfield, 2002).

Medical genetic testing sometimes influences family health history. Five years ago, Australian bioethicists discussed a very representative case.

Jordan's case

Jordan, a middle-aged paramedic, bought a direct-to-consumer genetic test kit. The result showed that she had an increased risk of Alzheimer's disease. This risk was detected because she carried the specific variant of the APOE gene. The test also showed that 25 % of Jordan's genetic inheritance is determined to be East Asian. She was surprised as she thought that all her grandparents had European roots.

The crux of the problem is that people with East Asian roots have higher risks of Alzheimer's disease if they carry this specific variant of the *APOE* gene (Mason, 2017). Therefore, the uncertainty of possible disease progression coincided with the uncertainty in ancestry estimation. Jordan realized her responsibility to inform her relatives about possible risk. However, it might not be necessary as there is no approved method to minimize the risk. Moreover, she did not know who to inform.

Therefore, family issues are the core aspects of bioethical regulation of medical genetics. Even though problem statements do not usually contain the word "family," they are closely linked to the normative understanding of the structure of family relationships and social subjectivity of each particular family. In Canada, France, Australia, the USA, and the UK, laws, directives and recommendations on intrafamilial communication of hereditary breast and ovarian cancer frequently contain the term "family" but rarely explain its meaning. Thus, three out of four main difficulties in interpreting these documents are related to the questions: "who should be considered as family?; why should patients inform their family members; and how should health professionals be involved in this process?" (Nycum, Avard and Knoppers, 2009).

The remaining fourth question concerns the definition of ethically and legally important characteristics of genetic data as well as the amount of data that can be disclosed to relatives by a patient. The patient has a moral responsibility for disclosing the aforementioned data. The next section of the article shows how the ethical and legal definition of genetic data is linked to the structure of relationships between the patient, his/her family members, the health professional and the genetic laboratory. We will also explore the definition of family boundaries and the structure of family relationships.

The normative (ideal) structure of a traditional family and the structure of a "biological family" may differ significantly. Informing the spouses of patients by a geneticist who deal with the "biological family" is of clinical importance only when it comes to planning the birth of children. However, a traditional nuclear family is usually understood as a union of a man and a woman based on marriage. The survey of

patients of geneticists of the reputable American Mayo Clinic showed that the majority of respondents (97 %) were ready to share the results of genetic testing with their spouses or partners. 92.2 % of patients planned to inform at list one adult child about the result of the genetic test, 86.2 % of respondents would inform at least one sibling, and 70.3 % of patients intended to inform at least one parent. In total, almost 3,000 people who took a comprehensive test to determine hereditary cancer risks were interviewed (Finn *et al.*, 2021). It can be assumed that the information about health risks is mainly relevant for parents. However, patients preferred to inform, first of all, their spouses, that is, people who were not genetically related to them. This can be explained by the difference in the degree of responsibility of relatives for the possible care of a person with cancer. It is more likely that spouses will take on this responsibility, but not the elderly parents.

A biosocial model of family has been used in bioethics for a long time (Gilbar, 2005). According to this model, social relationships and biological (genetic) ties can substitute each other. Many European guidelines have broadened the notion of family, recognizing that genetic tests are of interest to the extended family, including legal relatives. Their recommendations qualify sharing information with legal relatives as "intrafamilial disclosure." The US guidelines do not contain the definition of family, although there is a mention of "disclosure to family" (Black *et al.*, 2013, p. 205).

Authors of medical and bioethical recommendations suggest two ways of understanding family. For some, the disclosure of genetic information is addressed to family as a full-fledged stakeholder. This stakeholder may be represented by one or more people who receive information about the results of a genetic test, diagnoses, and risks, but these results affect the whole family. The health practitioner cannot interfere in the structure of intra-family interactions, since this would undermine the autonomy of both the consulted individuals and family as a whole. Another understanding of family is that the health practitioner's actions are aimed at maintaining the normative ("ideal") structure of interaction between family members.

Thus, the understanding of the real subjectivity of family may prevent the doctor from informing the patient's relatives about the

results of a genetic test. The basic understanding of "disclosure to family" is that the absence of a ban on going to the doctor with a family member. According the abstract structure of family, a healthcare professional can take real steps towards "intrafamilial disclosure."

We should also mention one aspect that may not be obvious to people who are not familiar with genomic medicine in the United States. There is a difference in approaches to communication between family and clinical geneticists or genetic counselors. For instance, clinical geneticists hold medical degrees such as MD and have completed one or two year residency training. Genetic counselors are non-medical health-care professionals who help patients and their families to understand their genetic risks and options for genetic testing. In European countries, this profession is gradually being integrated into the system of medical genetic care, but there are different ideas about its place in this system and about the necessary professional training (Paneque *et al.*, 2017). The ethical and legal nature of relationships with patients and their families is similar for clinical geneticists and genetic counselors. However, clinical geneticists focus rather on the clinically significant consequences of disclosure or non-disclosure of information about genetic risks. Genetic counselors are also concerned about the health of the patient's relatives, but they are much more immersed in the emotional context of family interaction (Dheensa *et al.*, 2016). In this regard, the improvement of the so-called "family dynamics" due to transparency in relations between relatives can be an important ethical decision-making factor. Genetic counselors, weighing the risks and benefits of disclosure, may consider their efforts to inform the patient's family members as actions aimed at strengthening family relationships.

However, the image of the scales on which the healthcare professional weighs the risks and benefits encourages us to adopt a utilitarian logic to the problem. Dheensa *et al.* (2016) illustrate the results of their systematic review of the arguments clinical geneticists and genetic counselors turn to when making disclosure decisions by using a picture of scales. In this situation, the "patient autonomy" does not necessarily have a deontological character, it can be considered as a rule utilitarian argument. That is, the obligation to respect the autonomy of the patient and maintain medical secrecy is not a part of

the moral responsibility of the doctor towards the patient. Compliance with these obligations from the perspective of rule utilitarianism is a social convention that brings the greatest benefits in the long run. That is why the factors of autonomy and privacy should be taken into account. Thus, the bioethical principle of autonomy becomes an integral part of the principle of beneficence, and this refers to the comparative weight of different benefits, namely medical and social ("family dynamics," "privacy," *etc.*).

Discussions on disclosure to family and intrafamilial disclosure can also be presented through the lens of deontology. From a utilitarian point of view, healthcare professionals are responsible for patients' and their relatives' health. From the point of view of medical responsibility, healthcare professionals are responsible to patients and their families. Although Dheensa *et al.* (2016) use the wording "responsibility to," the main arguments in their article are mainly related to "responsibility for." At the same time, within the framework of the deontological conflict, patients and their families are not necessarily the subjects which geneticists and genetic counselors are responsible to. The collision is that there is a difference in responsibility to a) a particular patient's family, represented at the doctor's appointment by patients, and possibly their relatives; b) family in the normative sense (*i.e.,* having a certain type of "family dynamics," and capable of collectively "managing hereditary risks"). The second type of healthcare professionals' and genetic counselors' responsibility refers to the society as a whole, which has certain ethical and legal norms. For example, the situation when a traumatologist identifies injuries on a patient's body that may indicate domestic violence could cause him/her to violate medical confidentiality. That is, the doctor may, contrary to the prohibition of a capable patient, provide details of his/her condition to law enforcement agencies. From a moral perspective, such an act of the doctor can be considered as being aimed at protecting the family, suppressing actions that contradict the normative understanding of family relations.

IV. Cases Scrutinized

The difference between "responsibility to" and "responsibility for" was highlighted in the discussion between Anneke Lucassen and Angus Clarke on two ethical and legal cases (Lucassen and Clarke, 2021). Anneke Lucassen has a background in the molecular genetics and now she is Chair of the British Society for Genetic Medicine. Angus Clarke is a clinical geneticist working both as a professor and as consultant in the All Wales Medical Genomics Service.

They have outlined their positions in their previous debate. Angus Clarke considers genetic information to be personal. Anneke Lucassen argued that it is a potentially familial information that can and, in some cases, should be shared with relatives who might be at risk (Lucassen and Clarke, 2007). However, they both agree that a patient has no right to veto intrafamilial use of genetic information generated by the genetics diagnostic laboratory. This information can be used to alert the relatives that could be at risk. Besides, information about the type of pathogenic mutation can be used for the benefit of blood relatives (Lucassen and Clarke, 2021).

Lucassen and Clarke suggest that both situations are acceptable, but each of them offers its own rationale for this. Lucassen believes that genetic data understood as family information should be available to all family members. That is, these data, in a sense, belong to the whole family. Clarke claims that data belongs to the genetic laboratory and health service in general. There are no privacy considerations that can be so strong to "override the health service's duty of care to the relatives" (Lucassen and Clarke, 2021, p. 1).

It was mentioned in the previous section that the issue of the nature of genetic data is also a family issue for ethics of medical genetics. Blood relatives have common fragments of the genome and, with certain probabilities, can be carriers of the same genetic variants. In a certain sense, the family history of diseases is the evidence of these data. It allows the geneticist to formulate a hypothesis about certain genetic variants. The genetic data are generated only in the course of molecular biological diagnostics (genome sequencing, PCR). Genetic data are not given to family as a family tree memory.

The question is which analogy of genetic data will be more fair and transparent. On the one hand, a photo of a family holiday can also be taken by a photographer, but it belongs to the family as a renewing group of people. Even after the death of the participants of the holiday, the photo will continue to be a part of the collective memory of the community of their descendants. On the other hand, information about risk groups and ways to measure and minimize this risk belongs to the health system. Information about the diagnoses of specific patients and pathogenic genetic variants found in them is used by this system in the same way as the data of population genetic studies. In the context of the health care system, the most important information is the information about certain medical risks for a group of "individuals A" and not about the health data of "patient A." The boundaries of this group and the type of risks are determined by the bloodline and diagnosis of the patient.

Therefore, the question is how separable genetic data are from private medical information. In order to answer this question, Lucassen and Clarke provide a fairly typical clinical scenario.

John's scenario

John has familial adenomatous polyposis (FAP) confirmed through mutation testing. For John's three children (aged 10, 13, and 15 years), each has a 50 % chance that they have inherited the condition and would then benefit from regular gastrointestinal surveillance for polyps and tumours. The information to be made available is (1) the diagnosis… and (2) its potential implications… (3) it is important for any genetics laboratory testing the relatives to have access to the molecular information about John's APC gene mutation, in order that they can target testing… Channels (of family communication) may be disrupted by poor relationships, geographical distance or for a variety of other reasons such as not wanting to be the bearer of bad news… (Lucassen and Clarke, 2021, p. 2).

Lucassen and Clarke agree that the best option is to convince John to divulge the information himself. However, if he cannot do this, the healthcare professional should try to contact a general practitioner who can invite the patient's relatives to an appointment and inform them of the risks (in order to do this, their full names and dates of birth are required) (Hyer *et al.*, 2019). According to Lucassen and Clarke, the

strength of the moral obligation to inform family members depends on the severity of the disorder, possible interventions and proximity of relatedness of the relative (Lucassen and Clarke, 2021, p. 3).

All this reasoning does not take into account the age of John's children whose health is important. Hundreds or thousands of adenomas typically start to develop in the adolescence. In this regard, it is recommended to offer predictive genetic testing to children between 12–14 years of age (Hyer *et al.,* 2019). As both Lucassen and Clarke discuss disclosure in British legal realities, it is worth noting that the National Health Service considers it possible to take informed consent from persons under 16, "if they're believed to have enough intelligence, competence and understanding to fully appreciate what's involved in their treatment" (NHS website). The father's and mother's refuse to give a consent can be overruled by court "if treatment is thought to be in the best interests of the child" (Hyer *et al.*, 2019).

Lucassen and Clarke do not mention whether healthcare professional activities in John's case go against conventional notions of autonomy. First of all, children receive information about possible genetic risks contrary to the prohibition of the father. Secondly, the father may not consent to genetic testing of minors. Lucassen believes that disclosure with a help of a general practitioner would not violate the confidentiality of John's diagnosis. However, there is a possibility that the father would not agree to do genetic screening. In order to solve this issue, the perspective should be changed from bioethical to judicial. The construct "best interests of the child" presupposes the completion of those actions in relation to the child that would be taken within the framework of the normative image of family relations but are absent in reality. At the same time, there are at least nine versions of the normative justification for the cancellation of parents' decisions regarding the health of their children in the world legal practice. The construct of "best interests" is only one of these nine principles. Thus, parental decisions can be overruled due to respect for children's autonomy (McDougall and Notini, 2014).

The second scenario, considered by Lucassen and Clarke, relates to the issue of the relationship between consequentialist and deontological principles in bioethics. It concerns non-disclosure of information about

the risk of Huntington's disease by physicians to the pregnant daughter of a patient who has been diagnosed with it. This case received a lot of publicity due to the ABC case. Lucassen argues that "being unable to exercise reproductive autonomy is akin to not being offered a medical intervention to influence the course of a disease" (Lucassen and Clarke, 2021, p. 3). She also mentions the possibility to separate father's clinical diagnosis and information about genetic risk. Communicating with the daughter, doctor could only mention that visible father's symptoms may be explained by genetic factor (Lucassen and Clarke, 2021).

V. Conclusion. Autonomy, Dependency Relations and Epistemology of Family Decision-Making

At the level of bioethical and legal regulations, the solution to the problem of disclosure may be to separate private clinical information from genetic data. The latter can be recognized as either simply belonging to all family members, or being at the disposal of the health service, which is obliged to act on the basis of respect for the autonomy of all family members or their beneficence. However, the focus on autonomy implies broader disclosure powers. The ABC case showed that it is important to not only prevent the development of the disease but also have a right to make decisions based on the most complete information about one's genetic risks. Such obligations of the health service arise outside of family relationships. Information about the genome of a person and the influence of genetic characteristics on his/her health can be significant for people who are not related to the person's bloodline (*i.e.,* for those who may have similar de novo mutations).

If we consider genetic information as family data, it is necessary to understand the property of the collective entity that possesses this data. It can be represented as a group subject based on the equality of family members whose ethical position is the sum of equally weighted individual preferences or ideas about duty. In this case, we are faced with difficulties and paradoxes similar to the Condorcet paradox. According to it, collective preferences can be cyclic, even though the preferences of individual voters are not cyclic. The preference cycle described by the paradox is much more likely to occur in small groups than in

large communities (Tangian, 2000). The difficulties of epistemological formalization of collective decision-making (the emergence of a group subject) clearly illustrate the obstacles to legal and bioethical formalization. Family is not the sum of individual autonomies. At the same time, the autonomy of the patient as a family member and the autonomy of the rest of the family cannot be placed on different scales.

The desire of healthcare professionals not to participate in disclosure of genetic information can be motivated by considerations of duty — observance of medical secrecy — from an ethical point of view. Accepting this considerable challenge, experts in the field of bioethics and law have made significant efforts to reconstruct the concept of autonomy. These attempts have led to the development of the concept of relational autonomy, according to which any person is always inscribed in a system of social ties that imply, among other things, the existence of ethical obligations to family members and other people and groups, as well as identification with certain communities (linguistic, ethnic, religious, *etc*.) (Herring, 2014). This concept finds its application in the field of family law, the decision on the ABC case, and medical law (Gilbar and Foster, 2018). This decision can be interpreted as a recognition that healthcare professionals are included in the system of intra-family obligations and begin to share the responsibility of the patient to the family.

However, the positive meaning of the concept of relational autonomy remains unclear. It can now be described as an element of criticism of the classical, Kantian concept of autonomy and a demonstration of its limited applicability. It is may be possible to add the ethical component to the meaning of this concept due to the development of the views regarding dependency as a fundament of autonomy of one of the greatest ethicists of the 20th century, MacIntyre (MacIntyre, 2001). Such an ethical conception may not begin with the notion of freedom to make rules for oneself, but with a relationship of mutual dependency. According to MacIntyre, the fundamental ethical relationship can be seen primarily in the dependence of the child on the mother. In this regard, the clarification of the normative image of the family and family relations is not one of the aims of bioethical regulation but its basis.

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Conversations about Hard and Soft Lex Bioetica in the Context of Grand Challenges of the External Environment

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Abstract: The paper is the result of a multidimensional comparative study of the ratio of hard to soft *Lex Bioetica* application on the modern legal map of the world. In terms of methodology, the study was based on both general and special methods of cognition. The formulation of the doctrinal approaches to the issue of *Lex Bioetica* would be impossible without a comparative analysis carried out within the framework of interdisciplinary (comparison of the legal doctrine with the related spheres of knowledge, such as philosophy and sociology), cross-branch (comparative analysis of the approaches used in comparative law, philosophy and theory of law as well as in branch legal disciplines), cross-border (comparison of different national legal systems with each other and with international law provisions), as well as chronological (historical comparative analysis) approaches. Application of the sociological method and the legal modeling method allowed identifying the social foundations of *Lex Bioetica* evolution existing in the global legal practice, and outlining the potential ways for the reform of the Russian system in this regard. The study also relied on synergistic research. The synergistic method allowed modelling the evolutionary picture of *Lex Bioetica* on the legal map of the world. The general conclusion with regard to the evolution of *Lex Bioetica* in Russia is presented in the form of a scientifically substantiated thesis stating that, in addition to developing *Lex Bioetica* at the integration level of cooperation (primarily in the Eurasian space), the Russian Federation needs to bring the bioethics-related discourse to the level of hard *Lex Bioetica*.

Keywords: legal system; bioethics; Russian; foreign (non-Russian); evolution; hard law; soft law

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Contents

I. Introduction

The current condition of societies and states is characterized as a time of grand challenges in the global science and research (Przhilenskiy, 2020, pp. 1–17). In regulatory practice, grand challenges are defined as "a set of problems, threats and opportunities objectively requiring a response from the state, the complexity and the scale of which do not allow solving, eliminating or implementing them solely by increasing resources."[1] Such challenges include external and internal factors identified based on an analysis of significant changes in the sphere of science and technology and creating "significant risks for the society, the economy, and the public administration [government] system."

The grand challenges of the external environment, existing at the intersection of humanities and natural sciences require interdisciplinary approaches and solutions.

[1] Decree of the President of the Russian Federation No 642 of 01.12.2016 "On the Science and Technology Development Strategy in the Russian Federation". Collection of Legislation of the Russian Federation (2016), 49, Art. 6887 (In Russ.).

One of the efficient responses in current conditions includes synthetic regulatory frameworks, *i.e.*, *Lex Bioetica*.

The evolution of social relations, as well as the enhanced abilities of modern science and technology, represent new evolutionary growth points for modern bioethics. In current conditions, bioethics can provide expert assessment and reconcile different (sometimes competing) value paradigms and worldviews, thereby ensuring social acceptance of innovations in biomedicine (Vorontsova *et al.*, 2021, p. 12).

This study examines the Russian and non-Russian practices in order to explore the possibilities of biotic solutions to the grand challenges of the external environment in the sphere of medicine. The background describing the emergence and evolution of bioethics (II) will serve as a general starting point for the study. This will be followed by an assessment of hard *Lex Bioetica* based on the French legal experience (III), as well as of the prospects for hard and soft *Lex Bioetica* implementation in the Russian Federation (IV).

II. Bioethics: A Concept and Evolution

The term *"bioethik"* was first forged by German pastor Fritz Jahr (Jahr, 2013) in 1927. However, fundamental research on this issue materialized almost half a century later, and was related to the work by Van Ressekaer Potter entitled *Bioethics: bridge to the future* (Potter, 1971). He saw bioethics as a combination of biological (*bios*) and humanitarian (*ethos*) elements. Potter turned out to be the key figure for the history of bioethics associated not only with the emergence of "bioethics" as a term, but also with a remarkable paradigm shift towards the so-called "global bioethics," which became the embodiment of a new look at the whole set of issues associated with life as a biological phenomenon. When introducing the term "global bioethics," Potter proceeded from the fact that a new stage in the history of ethical thought had begun, since all the known forms of ethics had already exhausted themselves. He saw bioethics as an interdisciplinary, humanitarian and biological approach to the phenomenon of survival, as a focus on the issues of living matter. In his opinion, the global dimension of bioethics consisted in focusing on at least three levels of organization

of the living — the organizational level, the population level, and the biospheric level — instead of just one. Thus, Potter conceived global ethics as a broad ethical approach to the issue of existence of not only human beings, but other living beings as well (Mikhel, 2018, p. 42).

A premise for the emergence of bioethics was the crisis in ethics that took place in mid-20th century. On the one hand, it was due to the fact that philosophical ethics (as metaethics) ceased to be seen as a teaching (theory) meant for practice due to the fact that the theoretical concepts of morality developed by it were so abstract that it was difficult to apply them to real-life situations (Apresyan, 1995, pp. 10–11).

The emergence of Russian bioethics can be traced back to the end of the 1980s. The interaction between Russian bioethicists and their foreign counterparts from Europe, Canada, the USA, and Japan started in early 1990s. One of the first contacts was devoted to the discussion of the ethical issues arising in connection with the launch of the international Human Genome Project. An important role in the development of bioethics in Russia was played by the introduction of a mandatory course in this discipline for students of medical and pharmaceutical higher education institutions in 2001. Russian bioethicists are playing an increasingly prominent role in the development of international regulatory documents. They took an active part in the work on such documents as the UNESCO Universal Declaration on the Human Genome and Human Rights (1997), and the UNESCO Universal Declaration on Bioethics and Human Rights (2005). In course of the latter document preparation, a regional UNESCO workshop was held in Moscow in January 2005, some recommendations of which were reflected in the final text of the Declaration (Petrov and Yudin, 2008, pp. 387–394).

In modern publications, bioethics is defined through the prism of philosophical and interdisciplinary approaches:

— Bioethics is a relatively young, multidisciplinary field of learning drawing on many established academic disciplines, such as philosophy, jurisprudence, sociology, and others (Thiele, 2001).

— Bioethics has become thoroughly internationalized in the past 30 years, and while one of the factors that has enabled it to travel is the dominance of the English language (and hence, up to a point, English-

language ways of doing things like philosophy), the influence of other philosophical traditions is increasingly important (Ashcroft, 2015).

— Bioethics and the clinical ethics case analysis approach presented herein may help the psychotherapist to formulate and achieve the goal of every professional (Spees, 2002).

One of the key paradigms, which is indispensable for understanding bioethics, is the paradigm of transdisciplinarity. Professor Elena Grebenshchikova made a very good point in this respect saying that "the need to solve — sometimes literally on the verge of life and death — critical moral dilemmas demonstrated the insufficiency of the expert opinion of medical professionals, pointing to the need of supplementing professional competence with knowledge that goes beyond the disciplinary sphere" (Grebenshchikova, 2010, p. 79).

Indeed, the prefix "trans" implies going beyond ("across," "through") disciplinary boundaries with the purpose of looking at the problems of life, the living world. At the same time, transdisciplinarity is not opposed to the discipline-specific models of knowledge, but complements multidisciplinary and interdisciplinary approaches with a study of the dynamics generated by the interaction of several levels of reality, which implies the fundamental complementarity of each of the forms of knowledge and, therefore, the need for a common methodology (Nicolescu, 2009).

Thus, the so-called dimensional knowledge (3D, 4D, *etc.*) is formed, which can become an efficient doctrinal basis for a social response to the global challenges of the external environment. Following the maxims of transdisciplinarity, we do not cross out the vector of knowledge generation set by Kant in his work entitled *The Conflict of the Faculties* (1798). On the contrary, we complement it. The medieval concept of universities, consisting of one lower faculty (philosophy) and three higher faculties (theology, law, and medicine), was replaced by a differentiated model of a research university.

The paradigms of *transdisciplinarity* and *interdisciplinarity* in this study allow considering bioethics, among other things, as the sum of deontological imperatives and the regulatory framework emerging in connection with the latest achievements of biology and medicine.

In its turn, the intersection betyween the purely bioethical and purely legal at the base of bioethics (in the constructive model of mathematician Leonhard Euler) produces the phenomenon of *Lex Bioetica*.

The dialectic of a universal viewpoint and a local viewpoint on the essence of bioethics-related issues can be observed in *Lex Bioetica*. For instance, the deontological imperatives of *The Nuremberg Code* have the nature of universal maxims; on the other hand, the boundaries of the proper and permissible behavior in certain aspects of the legal regulation of modern embryology are of a national (state, country-specific) nature. For instance, most countries of the world proceed from the precautionary principle with regard to embryo manipulation. At the same time, the UK assumes a unique and extremely liberal position in this regard. In 2016, the UK Human Fertilization and Embryology Authority approved the first experiments on human genome editing. Licenses for this type of activity allow experiments on human embryos before they reach 14 days (during the first 14 days after fertilization).

In terms of the source base for *Lex Bioetica*, there is a clear dominance of soft law at the integration law level. In particular, such documents include the UNESCO Universal Declaration on the Human Genome and Human Rights (1997), the UNESCO International Declaration on Human Genetic Data (2003), the UNESCO Universal Declaration on Bioethics and Human Rights (2005), and the ECOSOC Genetic Privacy and Non-Discrimination Resolution (2004) (Zakharova, 2021b, p. 30). The fundamentally unique interstate formation is a notable exception to this general vector. For instance, the genomic sovereignty of the member states is not absolute (there is already established regulation in EU law that influences the provisions of national law) (Kalinichenko and Nekoteneva, 2020, p. 75).

At the state level, the elements of hard *Lex Bioetica* are fragmentary rather than systemic. Unique experience in this regard is demonstrated by France with its decisive step toward the adoption of a dedicated Bioethics Law (1994). What are the origins, the main features, and social consequences of the adoption of this law?

III. Solid Ground for Hard Lex Bioetica in France

One of the first major public debates on bioethics in France took place in connection with the so-called case of Amandine (the first French IVF child). In course of the IVF, the doctors found several embryos in the test tube. After they transplanted two or three of them, the question about the fate of the remaining — so-to-speak, "extra" — embryos arose: are we allowed to freeze the embryos? This, inevitably, gave rise to another question: what is an embryo? The President of the Republic charged the newly created (in 1983) Bioethics Committee with the task to resolve these issues. Following a discussion, the Committee arrived to the conclusion that the embryo was a "potential human being [person]" and, therefore, it was inadmissible to do whatever you like with this potential human being.

Thereafter, for almost a decade, the matters of resolving bioethical issues in France were limited to the level of the so-called pure bioethics without any elements of hard *Lex Bioetica*.

The discussion about the vectors of resolving bioethics-related issues gained a new momentum in France in early 1990s. In the lecture delivered on 3 October 2018, within the framework of the Mediterranean Ethical Space conference in Marseille, Jean-François Mattéi, former French Minister of Health and the lead speaker with regard to this law in the French Parliament, when retrospectively talking about the development of this law, noted the following:

"When the Prime Minister asked me to make a report in order to demonstrate the need for adopting the legislation, especially with regard to embryo research, I went to the UK. My UK colleague was surprised: 'But why are you asking me about the embryo? We never touch the embryo.' Then I asked her why there was a 14-day rule in the UK. She told me that the embryo exists only starting with the 14th day. Before that, it is considered to be a pre-embryo on which actions can be performed. In pragmatic terms, since the embryo is needed for research, the concept of pre-embryo was defined. When I asked: 'Why 14 days?' she explained that within the period of up to 14 days the embryo can split in two [twinning can occur], and, therefore, cannot be considered as 'one' person. In France, such an argument is unacceptable. After that,

I went to Germany where I asked my interlocutor why the measures taken in this regard are restrictive and everything is prohibited. He replied that, because of what was going on in Germany during the war, there was a risk of getting headlines like *'They are reverting to their old habits!'* the next day. In short, Germany prohibited everything so as not to be accused of falling back into the old ways. I thought that such a viewpoint on the situation could not be suitable for France, either. Then, I went to Spain, where I asked why in a country of Catholic culture like Spain, everything is allowed. I was told that after thirty years of Francoist power and the influence of Opus Dei, the country is aspiring to freedom" (Mattéi, 2019, p. 11).

The 1994 Bioethics Law was adopted on 1 July 1994. From the point of view of legal technique, the Bioethics Law is replete with numerous references to major codes, in particular, the Civil Code of the French Republic, the Criminal Code of the French Republic, and the Public Health Code of the French Republic, which, in connection with the adoption of this law, were amended by adding new norms and (or) by modifying the previously existing provisions (Zakharova, 2021a, p. 20).

According to the legislator, the main objectives of the aforementioned law adoption were as follows: improvement of life, protection of individual and family values, as well as protection of the rights of children. Each of the aforementioned general humanitarian values acquired a narrowly focused meaning in the Law. For instance, improvement of life was considered within the context of establishing the principles of organ and tissue transplantation; protection of the rights of the individual and the family — within the context of a ban on eugenics, cloning; or establishing the measures for the organization of reproductive medicine. Protection of the rights of children also had a narrow focus. In particular, the legislator determined the rights and obligations of the parents in the event of artificial insemination. The Law establishes the following key provision in this respect: "If a pregnant woman is inseminated by a donor, her partner, who gave his consent to this insemination, becomes the father of the child, without being able to evade the obligation of paternity due to the fact that the child was not conceived with his own sperm." Other key provisions of the Law include the following:

1. The issues of organ and tissue transplantation. In particular, the law points out that it is impossible to take organs from a deceased person without verifying that they have not registered a refusal to provide their organs and tissues for transplantation in the relevant registry. Anonymity and a free-of-charge nature of donation must also be confirmed.

2. The sperm donation principles: anonymity and free-of-charge basis.

3. The basic provisions with regard to the protection of patients' personal data in the sphere of epidemiology and public medicine (Zakharova, 2020, p. 30).

The Law development has undergone several stages of evolution with the general vector being of a pro-liberal nature.

In 2004, the law was revised in order to clarify and supplement its provisions. For instance, the legal regulation of pre-implantation diagnosis was expanded. In many respects, these amendments were driven by the emergence of such a phenomenon as "savior sibling." At that time, wide coverage in the media was given to the achievements of the US researchers who twice managed to cure a child affected with a fatal genetic disease after conception and birth of a histocompatible sibling without this disease using *in vitro fertilization*. This allowed extracting the savior sibling's bone marrow and transplanting it in order to cure the affected child. The revision also expanded the possibilities for organ donation from one living person to another subject to consent.

In 2011, the legislation on bioethics underwent another reform. The changes included abolition of the condition of "having lived together for at least 2 years" for those wishing to resort to assisted reproductive technologies; as well as — in order to address the shortage of sperm donors — abolition of the requirement for donors to have children, and permission to use donor's gametes up to ten times instead of five. As for prenatal diagnosis, the practice of single examination was discontinued in favor of screening as common practice. In order to expand organ donation, paired donation was permitted. In addition, also in 2011, the Oviedo Convention was ratified.

The latest reform in the French legislation regarding bioethics took place with the adoption of the Law of 2 August 2021. However, it was initiated much earlier in 2019. The reason for such a long passage of the bill through the labyrinths of the legislative machine was connected with the so-called "legislative shuttle" — numerous procedures for agreeing/approving the text between the chambers of the Parliament, as well as other government authorities (such as the Constitutional Council of the French Republic, and the Council of State of the French Republic).

This reform essentially became the most large-scale, resonant and liberal as compared to the previous reforms of the Bioethics Law. Undoubtedly, the broadest discussion was brought about by the new provision of the Law regarding the expansion of the list of the subjects of law entitled to resort to the technological opportunities offered by IVF. By the time when the Law was adopted, several European countries had already stepped on the path of liberalization of IVF use. In ten European countries (Portugal, Spain, Ireland, the UK, Belgium, Holland, Luxembourg, Denmark, Sweden, and Finland), IVF has been allowed for same-sex couples and single women. In 7 countries (Estonia, Latvia, Croatia, Bulgaria, Greece, Cyprus, and Hungary), IVF is allowed for single women, but not for same-sex couples. On the other hand, in Malta and Austria, IVF is allowed for same-sex couples, but not for single women.

In France, the relevant permission mechanism for married couples (including same-sex couples) as well as single women was codified in Article 1 of the Law Amending the Bioethics Law, which resulted in modification of Article 2145-5 of the French Public Health Code.

Other noteworthy provisions of the latest reform regarding bioethics are the issues of regulating the procedure for using computer algorithms in medical diagnosis (Article 17 of the Law on Amending the Bioethics Law). In the latter case, we see that the subject-matter domain (scope of application) for hard law in the sphere of bioethics is expanding significantly. In addition to the classical subjects of legal regulation, constructively presented in the "person-person" model, we see its extension to the "person-machine" model (Zakharova, 2021a, pp. 22–24).

The social and legal results of the aforementioned Law adoption were the solution of bioethics-related issues at the level of a major piece of legislation. It has become some kind of a barometer reflecting the defining (reference) points and fluctuations of *Lex Bioetica* at the national/state level. The development of the Law provisions represents a functional task of other instruments (*e.g.*, codified instruments).

IV. Russia: At Lex Bioetica Crossroads

In the proceedings of the aforementioned Conference on Bioethics in France, Jean-François Mattéi, former French Minister of Health, was absolutely right in pointing out the following:

"The absence of a law creates difficulties, but adopting laws based on individual situations in order to establish common [general] rules is not the best solution. It is much more preferable to start with defining common [general] rules based on the agreed principles, and only after that consider individual cases" (Mattéi, 2019, p. 10).

The approach to addressing the issues of *Lex Bioetica* chosen by France is absolutely relative to the logic of the deductive vector of legal thinking of the continental European legal tradition.

In the Russian Federation, there have been attempts to supplement the Russian legal system with a similar piece of legislation as well. In 1997, a group of deputies submitted a draft law entitled "On Legal Foundations of Bioethics and its Ensuring Guarantees" to the Russian State Duma. The draft law on bioethics provided for the possibility of legal regulation of the following relations in the sphere of bioethics: establishment of the legal foundations of [legal framework for] bioethics in the field of health protection (healthcare) as a public benefit and the condition for the survival of society (*inter alia*, during the performance of medical activities), including choice of the treatment method, application of scientific knowledge in practice, relations between medical personnel and the patient, ensuring patients' safety and interests, as well as other issues related to interference in the sphere of physical and mental health of a person.[2]

[2] For details, see "Statement on Draft Law Initiators" concerning the draft federal law "On Legal Framework of Bioethics and Safeguards of its Enforcement". Available at: https://base.garant.ru/3101508/ [Accessed 25.01.2022] (In Russ.).

This legislative initiative has not been further developed. Currently, if the Russian Federation revives the idea of hard *Lex Bioetica*, it can follow one of several ways of reforming the Russian legal system, namely: 1) adopt a central major federal law on bioethics based on the model of the French law; 2) establish regulation for individual elements of *Lex Bioetica* at the level of another major law that needs to be adopted in the Russian Federation (*e.g.*, Genetic Information Law); 3) include a bioethical component in the already existing pieces of legislation (*e.g.*, Law "On Science," and/or Law "On Biological Security").

Each of the above-listed ways of evolution of Russian *Lex Bioetica* has both advantages and disadvantages. For instance, following the French experience in the bioethical segment of social relations regulation is of interest to Russia. We are almost two decades behind France in terms of the so-called hard paradigm of legal regulation of bioethics. However, at the same time, we are able to build a national model of bioethical regulation of social relations taking into account, among other things, the French experience (Zakharova, 2021a, pp. 26–27).

The main argument against hard law in the sphere of bioethics is the fact that when a bioethical component is included in the legal field, we go beyond legal regulation as such (Verspieren, 2012, p. 13).

Also, when the national legal system turns to the vector of hard law with regard to bioethics, there is a danger of creating a latex, exorbitantly bloated, subject-matter domain of legal regulation for the issues of bioethics. In our opinion, France managed to avoid this danger. However, in France, the country's constitution contains an article defining the limits of legal regulation for national laws (which is not the case for Russia). Unfortunately, there is no such article in Russia. And we are increasingly faced with the problem of trivialization of Russian laws (Zakharova, 2021a, pp. 26–27).

A fragmentary solution to the problems of hard *Lex Bioetica* — by establishing (codifying) individual elements of *Lex Bioetica* in the existing or planned pieces of legislation — provides a possibility to promptly address some of the individual issues regarding bioethics, but not the entire set of them.

Whichever of the aforementioned ways of resolving the issues of *Lex Bioetica* is chosen by the Russian Federation in the future, in our

opinion, the current moment in the national history of the Russian legal system requires bringing the bioethics-related discourse to the level of hard *Lex Bioetica*. This is determined by the general evolution of social relations in Russia, by the rapid development of science and technology, as well as by the grand challenges of the external environment that the current Time inevitably poses to the Russian society and the Russian state.

As for the experiments with regard to *Lex Bioetica* at the soft law level, recent years have seen a revival of the discussion about the need for the Russian Federation to accede to the Oviedo Convention. One of the supporters of this initiative is the Ministry of Health of the Russian Federation. At the same time, the science and research community has been rather skeptical in this regard. For instance, according to the opinion of Paul Kalinichenko and Sergey Kosilkin:

"Despite the fact that the possibility to sign it has existed for over 20 years, the Oviedo Convention has not been signed by all the member states of the Council of Europe. Even fewer states are parties to the additional protocols to the Oviedo Convention, including the most important of them — the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998). Despite the efforts and appeals of the Parliamentary Assembly of the Council of Europe (PACE), the situation has not changed so far. This demonstrates the lack of both a global and, unfortunately, a pan-European consensus with regard to the rules established by the Convention. Clearly, some member states have taken a more conservative stance in relation to genome research and gene therapy opportunities, while others fear that the Convention could hamper continuation of important research" (Kalinichenko and Kosilkin, 2019, pp. 110).

However, it is not only the level of European integration that can serve as a platform for the generation of soft law norms. The Russian Federation has already had a positive experience of responding to global challenges and discourses related to bioethics at the CIS level. We are referring to the adoption of the Model Law *"On Protection of Human*

Rights and Dignity in Biomedical Research in the CIS Member States" (adopted at the 26th Plenary Session of the Interparliamentary Assembly of the CIS Member States (Resolution dated 18 November 2005)).

The aforementioned Law occupies a limited subject-matter area in the general system of the discourse related to bioethics. However, its adoption as such contributed to the consensus among the CIS member states on certain specific issues of bioethics.

At the moment, the vector of generating responses to the bioethics-related global challenges of the external environment in the Russian Federation can be continued at the local integration level, in particular, at the level of Eurasian integration.

V. Conclusion

The emergence of bioethics in the overall ethics-related space of humanitarian thought should be seen as a natural response of the society and states to the global technological challenges of the external environment. Potter was right in pointing out that that was caused by a crisis in the ethical thought within the general humanitarian domain.

Both at the dawn of its emergence, and at present, bioethics combines the features of a biological (*bios*) and humanitarian (*ethos*) nature. Initially, *Lex Bioetica* as a regulatory framework developed along the vector of the so-called "soft law." However, the peculiarities of soft law — including such elements as graduated relative normativity, or penumbra of law — do not allow governments to resort solely to it when addressing bioethics-related issues at the national level. To varying degrees, modern states use the maxims of the so-called hard *Lex Bioetica*. France demonstrates a unique experience in this regard with the adoption of a dedicated law on bioethics in 1994.

The internal discussions conducted within legal systems with regard to the ratio of hard law elements and soft law elements are determined by both the general structural features of the legal systems themselves and the defining (reference) points in addressing the grand challenges of the external environment.

As pointed out above, the Russian Federation needs to bring the bioethics-related discourse to the level of hard *Lex Bioetica*, which is

determined by the general evolution of social relations in Russia, by the rapid development of science and technology, as well as by the grand challenges of the external environment.

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Medical Law and Rhetorical Modes of its Presentation in an Institutional Discourse: An Issue Statement

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***Abstract*:** As a result of rhetoric studies development in a specific medicine and healthcare field of interaction, scholars determined the grounds based on which rhetoric of law and medicine is singled out as a subfield of rhetoric. While medicine rhetoric is more focused on the rhetoric of science, the rhetoric analysis of substantive areas of medical law and healthcare prove that application of medicine rhetoric methodology to the areas of medical law results in dehumanization of the subjects of medical law; state healthcare policy implementation is perceived by affected communities as marketization of a national healthcare system; changes in medical law doctrines result in ethical shifts. The authors conclude that development of technologies in general and medical technologies in particular, public access to medical investigations' results and inception of bioethics have resulted in the situation when the subjects of medical law are required to develop new approaches to communication with the audiences (or affected communities) based on rhetorical concepts.

Keywords: medical law rhetoric; ethical shift; dehumanization; marketization; *ethos*; rhetor; affected community

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Contents

I. Methodology

The paper relies on discourse and comparative analyses of general and specific rhetorical concepts in the context of medical law. The authors implement the systems theory as applied to the levels of the medical law regulation where rhetoric can be implemented in practice. The authors provide a foundation for further examination in the field of rhetoric and medical law, since the present study is far from being exhaustive.

II. Introduction

Successful implementation of the healthcare policy depends on specific modes of communication. The renaissance of rhetoric in recent decades has reflected itself in the fact that rhetoric (both general and specific) is best studied in different specific communication situations (discourses) in which it occurs as a persuasive element in interactions between rhetors (subjects of the area under consideration) and their audiences (affected communities). Numerous studies devoted to "linguistic (or textual) turn of the 1970s against the ethical turn of the 1990s and 2000s" (Gehrke, 2009; Gage, 2011) contribute to the necessity to develop a comprehensive methodology based on general and specific concepts and principles of rhetoric to take into account strengths, weaknesses, opportunities and threats this ethical turn can pose in the area of the legal regulation in the field of healthcare.

On the other hand, historically approved understanding of the law as a text motivated literary critics and theorists to treat the law as "literature" (Gurnham *et al.*, 2019; White, 1985, pp. 3–7; Harrington, 2008; Nogueira da Silva, 2021). Many scholars regarded law in the same way as they were "treating their own subject: not as an expression of universal moral values but as historically and politically embedded and compromised with power." However, a focus on the textual power of laws

is of "questionable value" since laws in the medical field are addressing the actual suffering undergone by individuals. The ethical dimension "liberated literary studies in the context of high moral purpose that had formed traditional ideological functions of both healthcare and law," and introduced a positive alliance with moral philosophy [as opposed to normative and regulatory prescription] (Adamson *et al.*, 1998).

In John Harrington's opinion, rhetoric has in fact been a favored literary resource for literature that inspired legal scholars such as James Boyd White (White, 1985), who theorized law as a rhetoric that creates forms of community where "the *ethos* of the law ameliorated through training in rhetoric" (Kayman, 2018, p. 110).

Moreover, in a common law system where the precedent is a source of law, judges share a concept of the law and resources of argumentation in the form of precedent and interpretation. They create intertextual judgments "sharing general sources ranging from classical myths, religious stories and philosophical treatises, to novels, dramas and poetry, and political declarations and tracts' that connect them with horizons of national imagining" (Finlayson, 2018, p. 95).

As compared with other branches of law, medical law needs to engage "broader readership" and to be involved in "conceptual critiques." Political and historical dimensions and their examination in the context of medical law play a significant role in developing a trustworthy and persuasive healthcare policy, since thinking critically about medicine and law is an important element enriching comprehensive understandings of law as a social phenomenon. The emphasis on reading the law as discourse enables us to demonstrate how shifts, tensions and disagreements in law also reflect the "stakes and framings" of particular times.

Since the last decades of the 20th century, rhetoric of medical law has been gaining momentum. A number of authoritative studies were carried out and are being carried out investigating what impact classical understanding of persuasiveness and argumentation can have in different arears related to law and medicine.

A very complex nature of the relationships between medical staff (doctors, pharmacists, nurses, *etc.*) and a patient for the most important

benefit, namely, health and life, include interactions between rhetors and audiences in:

1) patient-doctor-patient communication;

2) health literacy, health enlightening and health education;

3) language constructing disease knowledge and disease-related communication;

4) pharmaceutical advertising (both direct-to-consumer & direct-to-physician advertising, including the issues involving rule-making, enforcement and prevention of infringements in pharmaceutical advertising);

5) medical investigations reporting and outcomes publications;

6) communication between patients and medical administrators and regulators;

7) communication between medical staff and rule-makers;

8) communication between patients and decision-makers in dispute-resolution procedures involving healthcare issues.[1]

A number of factors can explain a complicated nature of communication between the rhetor and the audience in the field of medical law. First, the achievements of medicine cannot always be used for the benefit of citizens and the population. Therefore, the issues of protecting citizens from new threats (artificially created diseases, bioterrorism, *etc.*) are quite acute and in need of resolution. Thus, persuasive argumentation in this area needs to be developed as soon as possible.

Second, the effectiveness of solving the tasks assigned to the medical staff depends on the functioning of the healthcare sector as a whole and its individual sectors, as well as other state and public institutions designed to protect the people's health. Therefore, other public relations tend to be involved in the subject area of the branch of law under scrutiny. Medical law is referred to as a system of legal norms regulating public relations arising in the process of protecting the health of citizens, performing medical activities, as well as the functioning and development of the sphere of public health protection (Mokhov, 2013,

[1] However, the list of interactions in this paper cannot be treated as exhaustive since the very nature of the subject matter requires careful and comprehensive investigation if interextions between multiple subjects concerning multiple issues.

p. 129). However, almost uncontrolled access of population to medicine-related information and mass media coverage can provoke tension and controversies among general public. Thus, rhetorical analysis can help identify the most provocative modes of communication and develop specific language facilitating interaction rather than provoking uncertainty and tension.

Third, the spheres of doctors' activity, the range of tasks they solve are constantly increasing. By now, reproductive technologies have entered clinical practice from the field of experiments. Genetic engineering and other technologies are being actively introduced into practice, which invokes the necessity of developing new ethical and normative regulation (Mokhov, 2013, pp. 135–136) the persuasiveness of which will depend on the concept apparatus developed by rhetors.

It is worth mentioning that the law is served by various disciplines: theology, economics, imperial social science, political studies, *etc*. Rhetoric analysis gives a legal scholar a privileged position in analyzing medical law. Rhetoric appears as a master method not for resolving the indeterminacies of legal decision-making, but for making them visible via its mastery over the master discourse of ethics providing framework for the further development of bioethics (Kayman, 2018, p. 15).

III. Rhetorical Analysis of Medical Law in the Context of Professional Ethics

In the age of technological revolution and digitalization, it becomes obvious that medicine has always developed in a way different from the way the technology develops. Since the earliest times, medicine was regulated by strict moral, ethical and legal prescriptions and regulations concerning practitioner's duties and common understanding of the patient's and practitioner's responsibility for adverse treatment outcomes. Nowadays, the mechanisms of practitioner's relationships with patients, colleagues, the state and the public are subject to comprehensive legal regulation. However, ethical issues of medical law originated many centuries ago, and they are based on principles first enshrined in the Hippocratic Oath (460–377 BC). Still, ethical norms are not laws. However, they constitute ideal standards that every

medical worker should strive to fulfill, and violation of which is not only wrongful, but also punishable.

The main instruments providing an ethical framework for the doctor's communication with the society and colleagues in the Russian Federation include:

1. The Hippocratic Oath;

2. The Oath of a Doctor of the Soviet Union (approved by Decree of the Presidium of the Supreme Court of the USSR No 1364-VIII of 26.03.1971);

3. The Oath of the Russian Doctor (approved by the 4th Conference of the Association of Doctors of Russia, Moscow, November 1994, canceled in 1999);

4. The Doctor's Oath (Article 71 of the "Fundamentals of the Legislation of the Russian Federation on Protection of the Health of Citizens" (ed. Federal Law No 323-FL of 21.11.2011);

5. WMA Declaration of Geneva (1948 with additions 1968, 1983, 1994);

6. The International Code of Medical Ethics (1994, with additions of 1968 and 1983);

7. The Ethical Code of the Russian Doctor (approved by the 4th Conference of the Association of Physicians of Russia, Moscow, November 1994);

8. The Code of Medical Ethics of the Russian Federation (approved by the All-Russian Pirogov Congress of Doctors of 7 June 1997);

9. The Ethical Code of the Nursing Sisters of Russia 2017–2018;

10. The Convention on the Rights and Duties of Doctors in the Russian Federation (adopted by Resolution V (XXI) of the All-Russian Pirogov Congress of Doctors, April 15–16, 2004) (Romanovskiy *et al.*, 2015, p. 15).

The Hippocratic Oath became a kind of a model of professional medical oaths all over the world for all times. The Hippocratic Oath contains 9 ethical obligations:[2] the principle of loyalty to the mentor and his family; the principle of *primum non nocere* (the no-harm

[2] A thorough analysis of the text is available in part 2 of the paper (2001). The Hippocratic Oath as Epideictic Rhetoric: Reanimating Medicine's Past for its Future. Journal of Medical Humanities by Keraenen Lisa. 22(1), p. 55.

principle); obligations to provide assistance to the patient (the principle of mercy); the principle of caring for the benefits of the patient and the dominant interests of the patient; the principle of respect for life and a negative attitude to euthanasia; the principle of respect for life and a negative attitude to abortion; the obligation to renounce intimate relationships with patients; commitment to personal improvement; the principle of confidentiality (medical secrecy).

In pre-revolutionary Russia, there was a so-called Faculty Oath, the text of which was solemnly read out, accepted by graduates of medical faculties and attached to the certificate of graduation (Deryagin *et al.*, 2011, p. 13).

The medical technology shift and inception of bioethics altered moral boundaries and cultural conditions transforming the *ethos* of healthcare. At the same time, due to very sensitive subject matter of the health care, professional oaths are still used in one form or another. Being the examples of epideictic (ceremonial) rhetoric, professional oaths have the capacity to persuade its audience to appreciate the value of the medical profession by lending an element of stability to the health care system (Keraenen, 2001, p. 55).

However, it is the epideictic (or ceremonial), character of the Oath's rhetoric and the values it celebrates that prevent them from capturing "communally shared ideas about contemporary medical practice." Here the question arises whether nowadays the Hippocratic Oath can "best serve the interests of both the medical profession and the society" (Keraenen, 2001, p. 58).

Meanwhile, the Hippocratic Oath's provisions constituted the basis of the WMA Declaration of Geneva (1948–1994). Most of its provisions are also enshrined in the Federal Law "On the Foundations of Public Health Protection in the Russian Federation"[3] (2011) that is in force in the Russian Federation — the key legal instrument defining the basic principles of healthcare in the Russian Federation. Article 71 of the Federal Law is devoted to the Doctor's Oath and highlights its

[3] The Federal Law "On the Foundations of Public Health Protection in the Russian Federation" No 323-FL of 21.11.2011. Available at: http://www.consultant.ru/document/cons_doc_LAW_121895/ [Accessed 08.03.2022] (In Russ.).

ceremonial nature. Under the Doctor's Oath, the person with a degree in medicine undertakes the following commitments: to fulfill the duties and obligations of a doctor devoting their knowledge and skills to the prevention and treatment of diseases, preservation and promotion of human health; to provide medical assistance, to follow the principle of confidentiality, to treat the patient with care acting exclusively in the patient's best interests regardless of gender, race, nationality, language, origin, property and official status, place of residence, attitude to religion, beliefs, membership in public associations, *etc.*; to demonstrate the highest respect for human life, never resorting to euthanasia; to keep gratitude and respect for mentors, to be demanding and fair to students, to encourage students' professional growth; to treat colleagues kindly, ask them for help and advice if the interests of the patient require it, and never reject colleagues help and advice; to improve professional skills constantly, to cherish and develop the noble traditions of medicine.

With the time being, the persuasiveness of the Doctor's Oath increased not only due to its ethical nature, but also due to formalized recognition of values celebrated by the Oath in the form of legal acts. Such recognition provides the mechanism of enforcement that inevitably results in changing the scopes of rights and obligations of all participants. Thus, except the rhetoric that is ethical in nature, at present times a rhetorical analysis of rule-making instruments in the field of medical law requires to develop the methodology of rhetoric analysis that combines the rhetoric analysis of ethical norms and rule-making acts.

It is worth mentioning that rhetoric of professional medical oaths is of universe nature. All principles associated with the medicine are applied in the instruments regulating the medical field at different levels. However, the development of the society and the values it cherishes changes the rhetoric of medical professional oaths enshrining principles based on the principles respected by the general public. Changes in key medical law doctrines (informed consent, reproductive rights, clinical negligence, malpractice, *etc.*) inevitably changes ethical foundations of professional medical activities and legal framework for their regulation.

IV. Rhetoric Analysis of National Health Care Services: An Issue Statement

Such a subject matter as rhetoric of medical law is related to the broader political context and multidisciplinary theoretical scholarship. In the early years of medical law, a predominant focus was put on the relationship between a doctor and a patient. Old-style professionals in law and medicine constructed this relationship in terms of fartherly care for an infantilized patient (Harrington, 2018) when the duty of the patient was to unconditionally follow doctors' prescriptive rules. An absolute and irreproachable nature of the *ethos* of medical profession mitigated the consequences of adverse outcomes of medical treatment for doctors. This was the era when ethical norms were the only ways to regulate the profession. With the time being, the need for rule-making and enforcement mechanisms increased, which made it necessary to change the persuasive power of rhetors' (subjects of medical law) messages addressed to affected communities of peers and patients.

For ages, classical rhetoric was "a staple of education for lawyers and doctors," as well as other professionals in Europe until the rise of rationalism in the 17th and 18th centuries. From this period rhetoric fell into decay, being "increasingly treated as a literally supplement to empiricist and rationalist philosophy" (Harrington, 2018). As a result, rhetoric ceased to form the substance of law and persuasive argument in other professional discourses. Rhetoric was rather viewed "as a term of abuse, synonymous with superfluous embellishment or with spin and outright lies" (Herrington *et al.*, 2019, p. 304).

In 20th century, Chaim Perelman and legal scholars (Goodrich, James Boyd White and Allan Hutchinson) assigned to rhetoric a more central role in analyzing the substance and significance of arguments in law generally (and in medical law specifically).

A rhetorical approach returns the scholars and practitioners to the certain context of any given parliamentary (laws), judicial (precedents in common law countries and jurisprudence in civil law countries) or academic (*e.g.*, medical investigations reports in medical journals) speech. The analysis that involves four criteria — who spoke, when, to whom and for what purpose — draws closer attention to the actual

texts of medical law rules and regulatory acts, decisions and opinions, precedent texts of medical investigations' reports and healthcare strategies. It takes "seriously the forms and idioms, as well as the detailed substance of the arguments, deployed by speakers to persuade their hearers or readers." A rhetoric analysis "counters the tendency in law and ethics towards abstraction, whereby the actual words of the judge or parliamentarian are condensed into a kernel of abstract rules and principles." (Harrington, 2018).

Until now, very few studies were devoted to rhetoric analysis of the activities carried out by health care regulators at the state level. The most authoritative study was carried out by John Harrington, professor of School of Law and Politics at Cardiff University. His monograph "Towards a Rhetoric of Medical Law" provides for an original approach to medical law by "combining a rhetorical turn with a broadly systems-theoretical account of the place of law in modern Britain." The rhetorical approach Harrington elaborated is founded on understanding law in its broader social context, understanding interplay between law and ethics. The rhetorical analysis of medical law involves studying the arguments of legislators, judges, advocates, legal scholars and affected communities as "strategic exercises aimed at persuading specific audiences of the truth of certain facts and the disability of certain courses of conduct" (Perelman, 1982, p. 9).

Among shortcoming of the old-style legal analysis and mainstream ethics the scholar names "blindness as to the identity of the speaker and as to the constitution and location of her audience" (Harrington *et al.*, 2019, p. 308), which can be explained by the need to secure fair, unbiased judgment. At this point, the paradox arises. Aiming at securing fair and unbiased judgment by providing messages created by an "anonymous speaker" (*i.e.*, rules initiated, drafted and passed by law-making agencies), public administration acting in the name of the National Health Care Service (Great Britain) or the Ministry of Healthcare (Russia) encourages the process of dehumanization of the subjects of medical law. In addition, it is the rhetoric that can be applied to elaborate persuasive arguments complying with the expectations of affected communities.

John Harrington (Harrington, 2017) highlighted the decline of "welfarist paternalism" and the rise of "neo-liberal marketization" in health, renewed and extended rhetorical analysis of law developed by modern scholars. He justified the rhetorical stance by applying theories of legal indeterminacy, critical legal studies and systems theory and concluded that rhetorical criticism offers a powerful combination of humanistic and socio-legal approaches to law. He insisted that rhetoric of medical law is needed to resist "technocratic and *populist anti-rhetorics* that dominate the contemporary scene in Britain and beyond."

As soon as National Health Service (NHS) was founded in Great Britain after the Second World War, it became the focus of political battels. In fact, the NHS became the metaphor of the nation's historical achievements (*sic.* alongside Shakespeare, industrialization and James Bond) aimed at creating a responsible and responsive health care system. Jeremy Corbyn, the leader of the Labour Party, in his speech at the Trades Union Congress in London referred to the NHS as "Labour's proudest creation," a "force for civilization" and the "greatest achievements, not just as a Labour Party, but as a country" (Finlayson, 2018, p. 95). The NHS is represented not only as a means of providing healthcare "to be judged by its effectiveness." It also symbolizes and serves the community and demonstrates its ethical development. For example, a ministry of healthcare in any jurisdiction can be aggressively attacked by means accessible to the general public and, as a result, refuse its old-fashioned perceptions of "what is good and what is bad for the patient." Now medical law as a doctrine implemented at the national level can explain to citizens what they could expect from the state and what constitutes "acceptable welfare" (Cloatre, 2018, p. 98).

On the other hand, nationalism sentiments, an increasing range of collective interests of identity groups, powerful forces of individualization put under pressure an idea of the unity of the nation regardless of the form of government under scrutiny. Increasing popularity of classical rhetoric and institutional discourses has already resulted in increasing popularity of such issues as public and social scholarship, improvement of the individual impact through effective presentation skills, media usage and collaboration, self-expression and personal branding. Traditional means of communication have

been complicated (and maybe weakened) due to transformations of the means and platforms of public communication that altered both collective debate and its forms complicating creation, implementation and interpretation of common understandings, reference points, data verification and institutional effectiveness.

The rhetoric methodology allows us to examine national healthcare systems from a critical cultural and historical perspective. Thus, Harrington seeks to explain changes in key medical law doctrines and changes in healthcare organization examining core political conflicts and how they influence medical law: patient's and doctor's rights and responsibilities, patient's autonomy and doctor's professional authority, freedom of patient's will and freedom of choice, reproductive rights and human rights, *etc.*

In any jurisdiction, a centralized system of healthcare and medicine stands for more than itself. Except being a means of providing healthcare that is judged by its effectiveness, it also symbolizes (works as a metaphor) the nation and demonstrates its "health," its "bodies" and capacity to care demonstrating "judgments that are moral in nature: who is deserving of care and to what degree" (Harrington, 2018).

To stand a chance of being persuasive our arguments need to conform to what audiences already think, know and understand. Classical rhetoric refers to what is accepted within the audience. Moreover, common-sense assumptions shared between a rhetor and the audience are necessary to begin an argument. In the field of healthcare nothing can be fixed or uniform. What the audience (or the affected community) already think is not sufficient for grasping new circumstances, scientific progress, different interests or the groups that think differently. It preconditions diversity in judgements, persuasiveness and argumentation. Consequently, rhetoric at the current stage of development of medical law refers to the means that can help to develop, interpret, facilitate and encourage communication between different subjects of medical law and affected communities. The initial stage of the development of the rhetoric of medical law can look like "the field of the battle," since rhetoric is based on common sense and "common sense is both a means of rhetorical struggle and a stake" (Harrington, 2019, p. 57). Historical understandings have resulted in contemporary struggles over the role

of the state in healthcare provision, over what may be considered as acceptable levels and forms of medical care, over competing rights or the influence of regulators in shaping access to health.

V. Medical Investigations Reports as an Object of Rhetoric Analysis

Rhetorical analysis of significant medical law related texts reveals dehumanization of subjects in medical reports and, consequently, "dehumanized language" of documents containing the program of action in healthcare (*e.g., Strategy for the Development of Healthcare in the Russian Federation for the period up to 2025*[4]). Reports of medical investigations as texts related to medical law contribute a lot. The study is significant not only for concerned medical communities, but also for better understanding of public health problems and their perceptions by different audiences.

Since medical knowledge enhances due to long-term studies of illness and health, medical examinations reports publicized in specialized editions and professional journals play a very important role. Technology and digitalization, as well as public access facilitation revealed some peculiarities of medical discourse that influences the public opinion.

Martha Solomon in her study devoted to the rhetoric analysis of official reports describing ill-reputed *The Tuskegee syphilis project*[5]

[4] Decree of the President of the Russian Federation No 254 of 06.06.2019 "On the Strategy for the Development of healthcare in the Russian Federation for the period up to 2025." Available at: https://www.garant.ru/products/ipo/prime/doc/72164534/ [Accessed 01.03.2022] (In Russ.).

[5] The Tuskegee syphilis study was conducted by The United States Public Health Services (PHS) "to trace the natural history of untreated syphilis" in the adult male black Americans (They all were referred to as "Negros" in successive reports). 399 men with syphilis and 201 members of a control group free of disease were subjected to periodically conducted blood tests, physical examinations, X-rays and autopsies. The study gained severe condemnation after the reports were publicized and the public became aware of the fact that the men with syphilis were not provided with any treatment. They were even discouraged and prevented from seeking treatment. However, the thirteen "progress reports" published in major medical journals from 1936 to 1973 "did not outrage the medical community." Devastating consequences on

investigates "the role that rhetoric played in the study's continuation." The researcher concludes that "depicting patients as scene and agency dehumanized the victims, emphasized the discontinuities between them and the physicians" and "consequently, obscured fundamental ethical issues" (Solomon, 1985, p. 234). However, rhetorical analyses of the reports were carried out only after the reports were examined by James H. Jones (Jones, 1993) regarding the rationale provided by PHS officials and the individuals involved. Jones' analysis of the reports proved the experiment to be racially prejudiced, demonstrating confused medical thinking and beurocratic dynamics in instigating and continuing a passive observation of the devastating effects of the disease on human subjects. Prof. Solomon in her study determined the ways in which the reports "obscured ethical issues" (Solomon, 1985, p. 240). She concludes that medical reports published in scientific journals complied with the main requirement applied to scientific discourse and they had all the constrains of scientific writing. However, "rhetorically, the generic conventions of scientific writing not only encouraged neglect of ethical questions but also played an important role in the study's continuation" since their rhetorical function was "to diminish and obscure the moral issues involved." Thus, scientific writing conventions within medical law need reconsideration since scientific writing employs rhetorical conventions which "by their very nature tend to obscure or de-emphasize any ethical, 'non-scientific' perspective" (Solomon, 1985, p. 234). The focus of reports' rhetoric investigation was to understand the role of scientific rhetoric in obscuring fundamental ethical issues and it was concluded that investigators (observers) feel the study was justified because it added to scientific knowledge.

On the other hand, medical investigations enshrined in reports and published in medical journals depict the patients suffering from the disease as the instruments or means through which doctors achieve their goals. The patients-as-agency approach is inherent in the nature of many medical projects or examinations. However, regarding human subjects as agencies tends to dehumanize them and almost equates them

the men involved generated no criticism. As a consequence of the silence of the more knowledgeable medical community, as many as 100 men may have died from syphilis-connected diseases.

with “experimental animals.” Patients may be of different educational statuses. If their level is low, examiners claim it is impossible to appeal to them from a purely scientific approach. Moreover, the studies are focused on purpose, rather than on actual human sufferings. Texts of medical reports implicitly value the knowledge regardless of the human costs and reduce the involved patients to scene and agency if their purpose is to observe a disease, to catalog its effects and course.

Judging by the medical examinations reports, we can argue that features inherent in the genre — *e.g.,* scientific writing — reinforce and substantiate latent discriminatory prejudice of the investigators and the audience can face with latent prejudice of investigators. The medicine discourse conventions of detachment and scientific favoritism result in polarization between subjects and investigators. At the same time, the scientific discourse demonstrates no evidence of the authors’ manipulating the genre for their own purposes and it is the specifics of the genre of scientific writing that encourages societal prejudice.

On the other hand, scientific reporting encourages detachment and isolates us from human reactions. Thus, scientific rhetoric makes no distinction among inanimate objects, animals and human beings. Consequently, a report writer can be limited in his rhetorical choice and insensitive to available alternatives contradicting humanistic conventions limiting rhetoric power of the report. Any medical investigation represented in the report provides the audience with only one part of reality. Such “incompleteness” of reality leads to significant distortions making medical projects unethical, which can happen quite unintentionally. Discontinuity between subjects and observers, the identification of observers with a larger medical community, treating the quest for knowledge as an absolute value create a discontinuity between scientific inquiry and certain human concerns (Solomon, 1985, p. 243). Analyzing persuasiveness of the scientific medical text and its significance for the whole field we cannot but admit that “rhetorical conventions can obscure the vision and perceptions of rhetors and their audiences,” they can encourage neglect of crucial human concerns both on the part of the medical community and general public (Solomon, 1985, p. 244). On the contrary, rhetorical conventions can facilitate stereotypical thinking and distorted vision intellectually limiting the

reliability, rhetoric power and persuasiveness of medical reporting as a genre existing in the healthcare discourse.

Thus, rhetoric analysis of medical reporting demonstrates that scientific language is not always neutral, objective and value-free. Scientific detachment and objectivity can significantly distort the reality, where the pursuit of knowledge is far from being the only value. To increase the persuasiveness of medical reports and program document we need the means that will facilitate and encourage perception of a wide spectrum of human concerns. In the contexts of increasing education level and access to scientific and medical databases, the need for changes is obvious.

VI. Conclusion

Humanistic, legal and political arguments surrounding the domain of medical law result in thorough examination of political culture, rhetoric in general, public argumentation in any jurisdiction. General philosophy of medical law still needs careful exploration of medical law precedents, judicial practice, regulatory instruments, core publications that illustrate key institutional shifts and transitions to the current understanding of persuasiveness and argumentation. In the context of medical law, rhetoric is not a means of manipulation or ambiguous argumentation, nor is it a list of literary tropes. Rhetoric is *argument as action* that takes place as and trough healthcare where arguments can have a decisive effect on the outcomes of both individual treatment and healthcare policy implementation. Discrepancies and controversies in the medical law area demand the participants to act rhetorically — working out what to say about a particular case to a particular audience at a particular time in order to persuade the audience to make the most favorable decision. The combination of formal rules and informal conventions, customs and practice precondition what audiences will hear in legitimate speech or argument, whether the voices they recognize are speaking in the correct way and are worth listening to. Thus, medical law can be referred to as rhetorical practice facilitating communication between subjects in their fight for individual and common healthcare.

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Bioethical Aspects of Translational Medicine

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Abstract: The development of modern medicine is associated with the dynamic translation (transfer) of basic medicine data to clinical research and further on to clinical practice. It is pointed out that research and development in the sphere of genetics and biotechnology, which are of particular significance during the COVID-19 pandemic, are of paramount importance in this regard. The concept of "translational distance" is analyzed as a measure of uncertainty, namely, the number and the size of logical leaps in course of transition from animal model trials to the first stages of human subject research. Translational research ethics has become a revolutionary, diverse, and distinct field of biomedical ethics. When studying the issue, special consideration is given to the critical blocks in translation as well as the characteristic features, types, and phases of translational research. It is emphasized that addressing the issue of minimizing irreducible uncertainty so that research participants could participate in research is a key component of ethical research. In view of the fact that the most important condition for the successful implementation of translational medicine is the adherence to the principles of bioethics when overcoming translational distances is analyzed taking into account the benefit-risk balance. As the development of translational medicine is significantly influenced by the legislation and the practice of its application, the national peculiarities of the attitude of different countries to the issues of ethics and the resolution thereof are studied, including the differences between the continental and the Anglo-

Saxon legal families. Along with the formation of a general approach to the choice of a regulatory model in the sphere under consideration, the acceleration of circulation of the information related to science, research and technology, as well as the rapid obsolescence of innovations, should not be overlooked. At the same time, one should pay attention to the existing biological and other risks.

Keywords: translational research; translational distance; translational blocks; bioethics

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Contents

I. Introduction

The rapid development of bioethics is the most impressive sign of a qualitative change in ethical knowledge, science and culture in general. It has now become common to refer to research — especially the research using new biotechnologies and genetic technologies — as "translational." This term helps to illustrate the need for and the value of analyzing all health-related research (Ashikhmin, 2015; Sychev, 2016).

The need to remove barriers (in the sense of acceleration of introduction of the basic [fundamental] science achievements into clinical practice) determined the birth of translational medicine (Seals, 2013) as a research methodology (Ashikhmin, 2015) in the early

1990s. "Translationality" is an approach consisting in the transfer [or translation] of research results (often of a basic nature) into the actual clinical practice for the benefit of patients (Sychev, 2016).

Translational research is broadly described as "knowledge transfer," *i.e.*, the transfer of knowledge from laboratory research to clinical practice, public healthcare, and policy, and vice versa, resulting in enhancement of the methods of diagnosis, treatment, and prevention. One of the challenges facing translational research is the high pace between a discovery and its development and implementation, which has become especially relevant during the COVID-19 pandemic. It is essential to point out that the most important condition for the successful implementation of translational medicine is the adherence to the principles of bioethics. The development of the translational medicine concept is largely associated with consequentialism — a trend in Western philosophy. Consequentialism (derived from consequent [Latin *consequens*, meaning "consequence, conclusion, result"]) is understood as a set of moral theories where the criterion for moral assessment [judgement] is the result (with regard to the topic in question this would be the research result) (Khokhlov *et al.*, 2021). From the standpoint of consequentialists, an action or inaction is morally right when it produces good results or consequences. Consequentialism is usually contrasted with deontological ethics (which has an ancient history) where rules and moral duty are central. According to this system of views (sometimes opposing), the most important thing is an appropriate balance of benefits and risks for research participants and for society as a whole. Upsetting this balance may lead to negative consequences in the future which are not always easily predictable — therefore, a detailed review of bioethical issues with regard to translational research is required.

II. Definition and Chrarcteristic Features of Translational Medicine

One of the key issues of translational medicine is the elimination of critical blocks in translation (transfer and implementation of scientific concepts in a new environment). The main of such blocks are:

— the block between basic science (research) and clinical research;

— the block between clinical research and the implementation of a particular treatment method at the system level.

Noteworthily, in addition to a direct "translation," there is also a reverse one — *e.g.*, the use of data obtained during clinical studies in the search for new targets (Ashikhmin, 2015). Overcoming these conventional blocks or barriers is in many respects connected with the issues of bioethics.

The following areas related to translational medicine should be distinguished: basic research; evidence-based medicine; biomedical ethics; public health; healthcare economics (Ashikhmin, 2015).

The characteristic features of translational research are as follows:

1) operation "at the junction" of several spheres of knowledge with blocks impeding the "translation" between them;

2) the need to formulate a scientific (research) hypothesis before the start of each of the stages of the experiment or analysis with verification of the correctness of the concept after the completion of each stage;

3) assessment of the clinico-economic, financial or medico-social feasibility of development.

Thus, the difference between "scientific methodology" in its pure form and translational medicine lies in the fact that the latter is focused on a specific result with direct consideration of financial and market factors.

It would be incorrect to directly compare translational medicine to "evidence-based medicine" — although the former uses the evidence-based medicine methodology, it is not limited to it.

The translational approach is very actively used in the development of personalized (individualized) treatment — hence they are often mentioned in the same context. At the same time, "evidence-based" individualized treatment (usually based on the achievements of genetics) should be distinguished from individual healthcare which is based primarily on empirical experience and often runs counter to clinical recommendations.

The following types of translational research can be distinguished (Khokhlov *et al.*, 2021):

1) basic research studying the biological effects of drugs used in humans;

2) researching the disease "biology" (pathomorphology, pathobiochemistry, *etc.*) in sick people with the purpose of searching for new methods of treating diseases (*e.g.*, searching for mutations in the genes of tumor cells that can serve as targets for targeted drugs);

3) non-clinical (most often preclinical) research with the purpose of introducing a particular treatment method into clinical practice or determining the principles for therapeutic intervention (*e.g.*, the study of the antimicrobial and antitumor effects of thalidomide on biological models in the 1990s despite the thalidomide tragedy associated with the teratogenic effect of the drug);

4) any clinical research initiated based on the results of the work referred to in points 1–3, including those for evaluation of toxicity and/or efficacy;

5) integrative analysis and research with the purpose of overcoming the block impeding the translation of research into real clinical practice within the framework of the so-called "science-for-business" research.

Along with that, the term "translational research" is used in a narrow sense to refer to a correctly planned way of treatment method development at various stages of clinical research.

The distinctive features of the translational approach are its integrativity (with upfront research in related fields), verification of the concept correctness after the completion of each stage, as well as performance of a new round of research on biological models when the side effects or therapeutic effects are detected at the early stages of clinical research (Ashikhmin, 2015).

It should be pointed out that, at the moment, increasingly more research publications are attributed to the sphere of "translational" research, but in fact do not pertain to this sphere (for instance, due to the fact that the concept of the treatment method studied by clinicians did not come from a basic research laboratory, but was born in course of a previous clinical study and has never been tested on biological models). Likewise, the most part of basic research where a working hypothesis indicating a specific point of application of the research results in disease treatment was not initially formulated cannot be considered translational research (Ashikhmin, 2015).

Translation should not mean assuredness [confidence or certainty] that the research direction will lead to creation of safe and effective medications or treatments. It is important to keep in mind that, at any stage, the results of well-planned and correctly conducted research may lead not forward, but backward, or in a completely different direction, in order to elaborate (add precision to) and expand knowledge at an earlier stage, or to explore and develop the newly discovered opportunities.

III. Phases of Translational Research

Researchers should have the responsibility of thinking about the future directions of research, foreseeing the relationship between the research design and the research ethics, as well as reviewing and — from time to time — revising the way of conducting research which has scientific and social value, regardless of the direction taken along the translation path from one experiment to another.

The issues of bioethics are often not considered before human subject research, however, there are many issues that deserve attention even when conducting basic research. These include: data integrity, responsible reporting and dissemination of results, as well as ensuring that each study is designed and conducted in such a way that it can yield results suitable for deciding on the next stages of research (Joffe and Miller, 2008).

The use of animal models in preclinical trials remains a necessary stage for the success of future clinical studies. Attempts are being made to minimize the use of animals, however, the potential alternatives — such as computer modeling and body-on-a-chip[1] organoid arrays — have significant limitations and require further development (Esch *et al.*, 2011). Therefore, researchers must take into account the three key principles of testing in animal models (the so-called "3Rs" concept): replacement, reduction, and refinement. The choice of animal models, as well as humane treatment and appropriate use thereof, help to ensure that the principle of "modest translational distance" — a term introduced

[1] Body-on-a-chip — integration of several organoids on a chip.

by Jonathan Kimmelman (Kimmelman, 2009) — is respected in course of research transition from animals to humans.

Translational distance is a measure of uncertainty, namely, the number and size of logical [inferential] leaps in course of transition from animal model trials to first-in-human research.

At the early stages of research involving human subjects, the modest translational distance may provide an analytical model for considering the relationship between research design and ethics. In such instances, this role cannot be performed by the concept of clinical equipoise. This concept can only be applied to later-stage research, such as trials comparing experimental interventions to standard treatment. Clinical equipoise justifies asking patient-subjects to take the risk of receiving unproven intervention in clinical trials. Early-stage research cannot offer the potential for direct benefit to patient-subjects that may be available in later-stage research. Instead, modest translational distance justifies asking patient-subjects in early-stage research to risk receiving an unproven intervention only when the "inference gap" is small enough to predict that the clinical trial can yield useful results. Modest translational distance should guarantee the safety of study participants, which is of paramount importance (Baker *et al.*, 2016).

In order to move from preclinical to first-in-human and other early-stage clinical trials, the principle of an appropriate balance between the risk of harm and the potential benefit must be addressed. This approach applies at all stages of clinical research, but is particularly important in the early stages, because what counts as potential direct benefit to patient-subjects in these trials is limited or — at best — unclear.

In early-stage research, this question is more appropriate than the question "Have the risks of harm been minimized?", as it acknowledges that some risks of harm are still unknown and that it is never really possible to eliminate all uncertainty.

Addressing the issue of minimizing irreducible uncertainty so that research participants could participate in research is a key component of ethical research. Like the more familiar Belmont Report requirement that risks of harm and potential benefits "must be balanced and shown

to be in a favorable ratio" (The Belmont report, 1978), this reasoning forms the basis of productive discussions between researchers, their colleagues and regulators, sponsors and ethics committees.

IV. Ethical Issues of Translational Research

The two key considerations that relate the design of clinical trials to research ethics considerations are scientific validity and social value.

Correct research is methodologically rigorous; it is designed and aims to provide useful answers to the questions it asks — including negative answers.

Research value is usually defined as a progressive value, which implies the likelihood of research progression to its next phase (Emanuel *et al.*, 2000).

However, first-in-human and other early-stage research is also likely to have translational value that is not progressive, but may be reciprocal, iterative, or collateral (Kimmelman, 2009).

Reciprocal value highlights the need for new preclinical trials (also due to getting certain results that need to be clarified).

Iterative value helps to enrich the clinical trial itself by providing new data that can be productively used for in-trial modifications as the trial goes forward.

Collateral value helps one or more different trials by producing new information, gaining experience, and developing methods for researchers in related research or related fields. Researchers who recognize the broad applicability of study data and design translational research to take advantage of many different types of value can readily plan both to eliminate what would otherwise simply be regarded as failures of research progress and to enhance the value of successful research.

Selecting patient-subjects from whom scientifically useful data can be collected and who are also able to make well-informed choices regarding their participation in research is especially important in early-stage research. Choosing the population from whom the most knowledge may be gained and who also can most readily be helped to

make autonomous choices about participation may be challenging, as sometimes those are two different groups of potential patient-subjects.

Researchers should take care to provide reliable (accurate) information, not only to potential subjects in the form and process of obtaining informed consent, but also to the mass media and in publications discussing study results.

Objective high-quality information reduces the likelihood that the "therapeutic misconception" will cause potential subjects, their families, regulators, the media and the public, and even fellow researchers, to overestimate the potential benefits of the research or underestimate the risks of harm. The need for long-term follow-up, both to monitor the health and function of patient-subjects after the intervention and to determine the intervention's success or failure, is often overlooked, not only in study planning and budgeting, but also in disclosure to potential research subjects.

Of course, well-designed translational research has value even when ultimately unsuccessful. Failure in a well-designed first-in-human study supports investigating potential reciprocal, iterative, or collateral value. Reciprocal value could be finding out that patient-subjects with a pre-existing disease react differently from other patient-subjects, leading to a preclinical study done in animals with that condition. The procedural nuances necessary for success may have iterative significance in first-in-human trials. For example, surgical techniques may be improved considerably from one patient to the next within a single protocol and many other in-trial procedural modifications (*e.g.*, special postoperative treatment, specific exercise, bed rest protocol, or specialized physical therapy). Finally, the involvement of a large number of medical specialists is by itself an additional value that is of great importance for further practical implementation of the research results.

Thus, research that can identify potential reciprocal, iterative, and collateral value may prove productive — despite some failures — providing hope that the research may be continued through additional clinical trials.

For the researched intervention to become a successful treatment, it has to function better than the standard treatment. Yet what does

that mean in terms of defining success? On the one hand, it could be reasonable to expect that the researched intervention would ultimately prove to be a panacea, but on the other hand, what if the researched intervention transforms a progressively fatal disease into a chronic one? If partial functional correction is an acceptable goal, then the researched intervention might be introduced into the treatment arsenal as another useful "halfway" medical technology that is not a panacea. A researched intervention that meets this goal of partial functional correction could reduce the need for the relevant therapy.

Financial conflicts of interest are a critical ethical issue commonly encountered at the pre-approval stage of translational research. Profound financial interconnection between sponsors and researchers can interfere with work due to issues such as patenting. Such conflicts can lead to non-disclosure of information about risks to participants and negative results in publications.

In the era of translational research, social injustice is one of the most relevant ethical concerns. It is common for resource-rich countries to conduct translational medical research in countries with limited resources, and if the results of the research are not expected to be useful or are expected to be less beneficial to the country with limited resources, the problem of social injustice arises.

The data generated as a result of each phase of translational research, particularly in the early stages, are vulnerable (sensitive) due to possible ethical issues related to data confidentiality protection.

Sharing research data at inappropriate stages of research can lead to the risk of early unauthorized implementation leading to dangerous consequences, such as the untoward adverse effects or even bioterrorism.

The development of translational medicine is significantly influenced by the national legal system, by the legislation and the practice of its application. The attitude of a state to the issues of ethics and to the resolution thereof has national peculiarities. As for the continental legal family (that is based on written law, on the legal norms adopted by the state and maintained by its enforcement mechanisms), ethical as well as bioethical norms has had little impact on the legislation and the practice of its application. They were generally considered as auxiliary (along

with the norms of morality, religion, and some other norms), and their application was of a subsidiary nature.

In the Anglo-Saxon legal family, the role of ethical norms has been higher due to the precedent-based nature of some cases and judicial decisions made. The argumentation and substantiation for the rulings rendered by courts and other jurisdictional bodies were based not only on the norms established by the state [government], but also on other norms developed by professional communities or other groups and precedents as such (previous decisions made with regard to similar cases).

The widespread development of civil, corporate and other kinds of relations in Russia, including self-regulation and self-government, as well as the formation of new spheres of activity (*e.g.*, clinical research of pharmaceuticals, clinical trials of medicinal products), required reception of the best practices of other countries by Russian legislation and practice. The development of practical (applied) bioethics was no exception. Its norms, lying in the borderline area between legal and other regulators, undoubtedly, influence the development of translational medicine.

This influence manifests itself at several key stages: the transition from basic [fundamental] knowledge to applied knowledge; the obtainment of a practical result (innovation) based on the existing new knowledge; the transfer of a technology (a new product or item) to the healthcare sector.

The development of both basic and applied science is the stage least regulated by legislation or by ethical and other norms. On the one hand, the government is eager to support scientists/researchers and research activities in every possible way, as well as to encourage the growth of scientific knowledge. On the other hand, already at this stage, results of a dubious nature in terms of research ethics, bioethics, or the ethics of the professional community, may appear. Moreover, some intellectual activity results may remain without legal protection if they contradict legal norms, or if they are contrary to public interests, or the principles of humanity and morality (paragraph 4, Article 1349 of the Civil Code of the Russian Federation).

In some countries, already at this stage, the potential ethical and ethico-legal issues are resolved by the dedicated local ethics boards (committees) at research organizations, or ethics boards functioning in science and research communities. In Russia, such structures exist, but not everywhere, as they are not mandatory by law.

Article 10 of Federal Law No 127-FL of 23.08.1996 "On Science and State Science and Technology Policy" it is worth noting in this regard. According to it, the procedure for conducting research may be established by the Government of the Russian Federation. Some kinds of research activity may also require a license.

The ethical and ethico-legal regulation for the stage aimed at creation and subsequent implementation of a new technology (product, item) is somewhat better developed. Quite stringent administrative and other requirements have been established for preclinical and clinical research (trials) of pharmaceuticals, medicinal products, and clinical testing. At this stage, sector-specific ethics boards — currently under the Russian Ministry of Healthcare — are an obligatory element of the approval system even in relation to individual technologies (products).

Despite their long-term functioning and extensive working experience, they are still facing certain difficulties due to the insufficient degree of their institutionalization in Russia, as well as due to the uncertainty of their individual rights and obligations. Further institutionalization of such boards within the Russian legal space will require amending the existing federal laws that govern the circulation of pharmaceuticals, medicinal products, *etc.*

The stage of technology (new product or item) transfer to the healthcare sector typically requires legal rather than ethical regulation. The sector should be ready to accept a new technology or product, which requires not only organizational, financial and other resources, but also timely changes in the legislation governing public healthcare, government/municipal procurement, *etc.*

Backward translation is also important for the development of medicine. The data obtained during research (such as side effects, risks, *etc.*) is of great significance for science/research and the development of the sphere as a whole. It allows to avoid mistakes, reproduce someone else's experience, *etc.* This requires data transparency (publicity)

that can be provided only through placing the obligation to disclose information as established by the federal law on the persons/entities conducting relevant research or on the state regulator in this sphere.

Feedback is important for science/research and practice, as well as (in case of the so-called "post-marketing research") for identifying the side effects of new technologies or products. It can also be provided through administrative regulation, control (supervision) over the circulation of certain technologies and products. Ethical norms, including those of professional ethics, can play a supporting role here. The priority of the interests of the patient and society is higher than the interests of business or individual entities.

Currently, Russia is seeking to create an optimal regulatory model based on studying the operational experience of Russian ethics boards, as well as the experience of the countries (primarily, those belonging to the continental legal family) where the activities of ethics boards at various levels are sanctioned by the legislator, and where there are positive results of ethical and ethico-legal support at the critical stages of activities mediating the relations in the sphere of translational medicine.

Along with the formation of a general approach to the choice of a regulatory model in the sphere under consideration, the acceleration of circulation of the information related to science, research and technology, as well as the rapid obsolescence of innovations, should not be overlooked. In addition, the model needs to take into account the existing biological and other risks that did not disappear with the development of humankind, but remain tangible nowadays. In this connection, in our opinion, it is important to create a model not only for the development of translational medicine in the current, common, ordinary conditions, but also for accelerating its development in the most significant areas. An independent problem requiring a prompt solution is, currently, the elaboration of a work model, which is balanced and adequate to the existing threats or risks, for scientists, innovators, business people, officials, and members of ethics boards during natural or technogenic emergencies. The new coronavirus pandemic has revealed the challenges existing in the development, research, and testing of pharmaceuticals (including vaccines), medicinal products and other items used in medicine.

V. Conclusion

Translational research is of great importance for the implementation of basic scientific knowledge in public healthcare. At the same time, the implementation of basic research results in medical practice has been going on for a long time. A new look at this issue and the concept of translational medicine are connected with the fact that the speed with which discoveries made in laboratories are introduced into medical practice and healthcare has now increased significantly. And this poses new tasks for bioethics. Translational research ethics has become a revolutionary, diverse and distinct field of biomedical ethics. Insights in various ethical issues are necessary to identify potential risks and prevent unethical practices while such research process is undertaken. The well-being of research participants and society should be prioritized over advancement of knowledge. At the same time, in the context of the new coronavirus pandemic, new trends are starting to emerge when the risks for the trial subjects are becoming quite high. An example of this approach could be the research at an artificial infection clinic in the UK. This highlights the necessity of discussing various types of ethical issues, which over time become the basis for the preparation of legal documents and professional guidelines needed by scientists when conducting translational research.

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