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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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.” 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.

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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 between 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.

References


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