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## Serbian Bioethics from an International Perspective. Genetics and Bioethics

**Abstract:** *Global interests in bioethics have increased drastically since the end of 20th century. The reason for this should be ascribed to a broad application of molecular–genetic methods introduced in human bio-medicine. This has, in turn, produced an involvement and development of numerous inter-disciplines, which have started to apply bioethics as a part of their own subject of interest. This article presents more than a decade of experience of teaching bioethics in our country, particularly under the auspices of the National Committee for Bioethics of UNESCO-commission of Serbia.*

**Key words:** *bioethics, genetics, bioet. committee, Serbia, CoE, UNESCO.*

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Speaking about genetics and bioethics in Serbia, we would like to inform this assembly that teaching Genetics has been included in official programs of the Faculty of Medicine in Belgrade since 1923, and that the Institute of Genetics and Development was established in the mid 1930s, as part of the Royal Serbian Academy of Sciences.<sup>1</sup> In the 1950s and 1960s modern genetic courses were organized at the Faculty of Agriculture in Novi Sad and at the Faculty of Science in Belgrade. The Yugoslav Genetic Society was founded in 1968, and the journal ‘Genetika’ appeared the following year, and has been in publication in English for the last 43 years. In the remaining years of the last century, in the field of human genetics alone, more than twelve symposia were organized, as well as courses on genetics at the Faculties of Medicine, and numerous respected genetic laboratories in the main medical centres and hospitals.

Serbia became a member of the European Council in April 2003. Ethics committees did exist in medical and scientific institutions except in the last few decades. However an official “National committee for bioethics” was founded on October 31st, 2003, as a part of UNESCO-commission within the Ministry of foreign affairs of Serbia and Montenegro, part of the coordinated initiative of our Delegation of UNESCO from Paris and the Serbian academy of sciences and arts. Already in May 2005 our Committee became a member of COMETH, i.e. one of 30 bioethical

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committees established among 46 member countries that belonged at that time to the Council of Europe. In UNESCO, our representatives had been observers at regular meetings of IBC and IGBC in Paris, and as participants when texts of Declaration were discussed. On the initiative of UNESCO ROSTE from Venice, Bioethical committees from Serbia, Macedonia, and Slovakia, were involved for two years in a large national project to study physicians' and medical practitioners familiarity with genetics, as well as to educate them and advise them how to master new knowledge in this field. This survey was properly implemented in more than ten places in Serbia and Montenegro. In subsequent meetings held in Italy and Greece, it was concluded that this was a good model of educational work.

In May 2006 Serbia and Montenegro separated, and the Bioethical committee of Serbia was somewhat renewed and staffed with new members. Presently it contains 15 members from Belgrade, Novi Sad, Niš and Kragujevac Universities, from several of the largest scientific and medical centres, with four members from the Serbian Academy of Sciences and Arts, where the National Committee for Bioethics has its headquarters. Three Symposia were organized at the Serbian academy in October 2006, June 2007, and June 2010 (the first under the auspices of UNESCO, and two following in the presence of distinguished specialists from the Council of Europe).

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The National Committee for Bioethics of the Republic of Serbia is an institution independent of the government, other research centres, and institutions. It consults with the Serbian Academy of Sciences and Arts, and UNESCO through the Commission for Cooperation of the Ministry of Foreign Affairs of Serbia. In the process, it upholds the following regulations: Universal Declaration on Bioethics and Human Rights (adopted at the UNESCO conference in Paris in 2005 and 2007); International Declaration on Human Genetic Data (UNESCO 2003); Convention on Human Rights and Biomedicine (adopted in 1997 by the European Council and amended by Protocols 1999–2006); Statute and Rules of Procedure of the Committee for Bioethics of the Republic of Serbia.

The Committee supports all activities focused on enhancing the general level of public awareness, as well as public and private decisions related to bioethics. It cooperates with international organizations in the area of bioethics, as well as national and regional bioethics associations and committees.

The evident increase in bioethics activity that has taken place in the last ten year in Serbia has resulted in the creation of official bioethics committees in a majority of scientific and medical institutions, establishments of postgraduate and doctoral studies in the field at three of our largest Universities and educational programmes for our medical practitioners. One of the ethics committees was founded in an extensive course organized in the Military Medical Academy in the

fall of 2008 (with the help of top specialists from France and Israel), and a few others within the Serbian Medical Society and in corresponding clinics in Belgrade. This year 27 young postgraduates from Serbian universities obtained valuable diplomas at the Ethics Teacher Training Course (ETTC), organised by UNESCO and taking place at the Serbian Academy.

We are very grateful that one of the co-presidents of our Committee, professor Zvonko Magić, is an active member of the steering committee of the Bioethical Division of the Council of Europe. Another co-president and academic Vladislav Stefanović is actively cooperating with UNESCO's IBC and IGBC Committees, and it is valuable that since UNESCO's 37<sup>th</sup> Conference last Fall, the Serbian Bioethical Committee has been appointed to be a new member of IGBC for the next four years.

82 An important phase for the further development and relations of the Serbian Bioethics Committee with European countries occurred after the separation of Serbia and Montenegro. At that time a member of our Committee had become Serbia's representative in the STEERING COMMITTEE ON BIOETHICS (CDBI—The abbreviation "CDBI" comes from the French: Comité Directeur pour la Bioéthique") in the Council of Europe (CoE). CDBI was formed in 1985 as an Ad hoc Committee of Experts on Bioethics (CAHBI), and in 1992 changed its name to CDBI Committee on Bioethics (CDBI) to function as the Steering Committee responsible for the intergovernmental activities of CoE in the field of bioethics.

In accordance with the decision of the Committee of Ministers regarding intergovernmental structures, the terms of reference of the CDBI and its Bureau are formally ending on 31 December 2012. Starting on 1 January 2012, it is the Committee on Bioethics (DH-BIO) which will be entrusted with the activities in the field of bioethics. The most prominent results of its work have led to the adoption of *Recommendations* of the Committee of Ministers and to the preparation of the "Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine", and *Additional Protocols* to the Convention. This convention has been opened for signature (1997) at Oviedo/Spain and is therefore also cited as "Convention of Oviedo". The aims of this international convention are: the protection of human rights and dignity of the human being with regard to the application of biology and medicine, including medical research and routine work of physicians or other healthcare professionals. The basic aim of the convention is the guarantee of respect for the integrity and other rights and fundamental freedoms of the person concerned and the prohibition of any kind of discrimination. Parties to the convention are obliged to introduce into their internal legislation the appropriate measures for safeguarding these principles.

Conventions and additional protocols need to be signed and ratified by Member States in order to be legally binding. Signature and ratification of an additional

protocol require that the underlying convention has already been signed, or else that it be signed and ratified at the same time. So far, of the 47 member states of CoE, 28 have ratified the Oviedo Convention, while 7 signatures have not been followed by ratifications. Serbia ratified this convention in February 2011.

When an idea for a legal instrument is presented by the public or a Non Governmental Organization (NGO), members of the Parliamentary Assembly or the European Parliament, governments of member states, the Committee of Ministers, may propose a regulation for a specific scope. A further step then is involvement of a competent Steering Committee, i.e. CDBI, which, through discussion, debate and a working group on the plenary assembly drafts a version of the document. Finally and at the end of this, the CDBI adopts the text of the convention. An adopted text is given to the Committee of Ministers. At the end of this counselling procedure the Committee of Ministers decides definitively on the legal character of the new instrument and proposes it for signature by the Member States.

Following such a procedure, the Council of Europe presented following documents for the field of bioethics:

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- Convention of Human Rights and Biomedicine (Oviedo, 1997);
- Additional Protocols: on the Prohibition of Cloning Human Beings (1997);
- concerning transplantation of organs and tissues of human origin (2001);
- on Biomedical Research (2004);
- on genetic testing for health purposes (2007), pending Protocol on genetic tests—workplace, insurance, on the protection of human embryo and foetus.

CDBI Recommendations:

- 2001 – on the management of organ transplants;
- 2002 – on the protection of personal data collected for insurance purposes ;
- 2003 – xenotransplantation, organ donor registers, organisation of palliative care
- 2004 – organ trafficking , autologous cord blood banks ;
- 2004 – Recommendation concerning the protection of the human rights and dignity of persons with mental disorder;
- 2006 – Recommendation on research on biological material of human origin.

Some of the topics issued on the CDBI plenary meetings are: Developments in the field of bioethics in member and other states; Developments in the field of bioethics in international organisations; Developments in the field of bioethics in other Council of Europe bodies; Chart of signatures of the Convention on Human Rights and Biomedicine, the Protocol on the Prohibition of cloning human beings, the

Protocol concerning Transplantation of organs and tissues of human origin, the Protocol concerning Biomedical Research and the Protocol concerning Genetic testing for health purposes; Examination of the revised draft Paper on predictability, genetic testing and insurance, with a view to its publication for consultation; Consideration of new issues that could be included in the CDBI's future programme of activities: Neurosciences, in particular brain imaging; Access to medical files; Clinical Ethics Committees.

We assume that cooperation between Serbian National Committee for bioethics and CoE is best presented through two meetings that were organized within the framework of the Cooperation Programme to Strengthen the Rule of Law. These cooperation activities aim to be informative about the principles laid out by the Council of Europe instruments in the field of Bioethics, and to identify the difficulties encountered by national authorities in the implementation of these principles.

- 84 The first meeting was organized in June 2007 in collaboration with the Serbian Academy of Science and Arts and the National Committee for Bioethics of the UNESCO-Commission of Serbia and Bioethics Division. It was a bilateral meeting on ethics in biomedical research. Two members of the Steering Committee on Bioethics (CDBI), Professor Elmar Doppelfeld (Germany) and Professor Jozef Glasa (Slovakia) participated in the meeting as designated European experts. The main objectives of the meeting were: – to present an overview of legal standards in the field of human rights and biomedicine in Europe; – to examine the state of implementation of fundamental ethical principles in Serbian law; – to exchange views with the members of Research Ethics Committees

For the second meeting held in 2010, the topic chosen was genetic testing. The development of new molecular biology technologies made human genetics and genetic testing a very dynamic sector. Although, benefit of these developments for the patients is more and more evident in everyday medical practice it is also a source of very important and complex ethical dilemmas.

Genetic data is considered a particular category of personal data because it relates not only to the individual it derives from but also to his/her family members who share this data. Therefore, access to “biological intimacy” of individuals via genetic testing constitutes risks for private life of the recipients as well as their families. Moreover, the potentially predictive nature of genetic data may also constitute a risk for the right not to know. Possible abusive use by third parties of information resulting from genetic testing is another concern because it would lead to discrimination on the basis of genetic heritage. Last but not least, the issue of quality of the data resulting from genetic testing as well as the difficulty to interpret this data remains a problem. These considerations prompted the Council of

Europe to draw up a legal instrument with a view to protect fundamental rights with regard to the application of genetic testing. On 7 May 2008 the Additional Protocol concerning genetic testing for health purposes was adopted by the Committee of Ministers of the Council of Europe.

As of Oviedo's Convention, its Protocols, and UNESCO's Declarations on human rights and biomedicine, we would like to offer some general comments. It is a fact that a huge variability of types and examples of bioethical behaviours presently exists, which does not cover all cases that are mentioned in our legislature, not even in all the paragraphs of the mentioned Convention and Declarations. e.g., the role of the *family* in contemporary society is not appreciated and emphasized enough. Restrictions and warnings of potential malformations and unwanted events are more clearly emphasized than activities that may prevent non-ethical behaviours. The absolute value of a scientific achievement should be more appreciated than its relative value; etc. Non-defined behaviours are numerous when standards for scientific work are proposed, such as: when one compares quality vs. quantity of someone's achievements, competition vs. cooperation, the size of co-authorships, papers published in one book vs. in many journals, local specificity vs. low citation index, a non-existence of scientific critics, the monopoly and politicization of restricted numbers of instances of scientific recognition, etc.

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The recipients of doctoral degrees have to take an oath (i.e. to swear when receiving their diplomas) that they shall produce all their prospective discoveries for the good of human society, avoiding all harmful effects that could be a consequence of their discoveries. The Serbian Bioethics Committee has submitted such a proposal, signed and with support of the president of the Serbian Academy of Sciences and Arts, to the Senat of Belgrade University ("KONUS"), but has not received an answer to its request that such an oath should be part of the ceremony when candidates are receiving their PhD degrees.

The aim of our present meeting is not only to compare our achievements since the previous meetings held in this institution, at the Faculties of Medicine and Philosophy, in the Serbian Academy, and elsewhere, but also to enhance our efforts for cooperation of regional bioethics committees and societies, especially in our educational programs. It is also important to control the *standards* that must exist among European countries in relation to the numerous new discoveries that are characteristic both in the fields of social and of biomedical ethics. As the hosts of this Conference, we are certain that the organizers will be happy to achieve these goals, and we wish you all good results in this direction.

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Bioetika u Srbiji kao perspektiva u međunarodnim okvirima: genetika i bioetika

Apstrakt

Globalni interes za bioetiku drastično se povećao krajem dvadesetog stoleća, što treba pripisati širokoj primeni molekularno-genetičkih metoda uvedenih u oblasti humane biomedicine. Ovo je dovelo do priključenja i razvitka brojnih interdisciplinarnih oblasti koje su bioetiku prihvatile kao deo svog opsega interesa. U ovom se članku iznosi iskustvo dugo preko deset godina o primeni edukacije bioetike u našoj zemlji, posebno u organizaciji i pod okriljem Nacionalnog komiteta za bioetiku UNESCO-ve komisije R. Srbije.

**Ključne reči** bioetika, genetika, bioet. komitet, Srbija, CoE, UNESCO.