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Important Issues of Providing Genetic Services in Serbia from the Perspective of Medical law

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Abstract Medico-legal issues that arise from the work of genetic health services became in recent time very current, especially regarding the Serbian law issues and dilema how to treat rare deseases patients among other voulnerable groups, whish often were not recognized in society. The legal system shall be an important mechanism, which could help by giving some solutions concerning the relations, rights and obligations of all parties in providing genetic services (informing, counseling, testing, keeping privacy). The law is invited to establish a delicate balance between legal qualification and more practical issues. In many countries there are medical guidelines for health professionals and biologists who work in the area of human genetics, according to which is done the essential rules for medical proceedings, with also significant parameters for legal decisions. Sometimes the legal situation is more complex when it includes malpractice cases due to violation of rights or breach of professional duties and contractual obligations in genetics. All issues should be consider from the aspect of Serbian legislator efforts to make a new codification in the area of genetic dignostics, which is adopted in January 2015.

KEYWORDS: medical genetic • legislation • human rights • case of Serbia

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1 Introduction

Nowadays the procedures of medical genetics requires more oriented examinations, which shall be made through the human rights aspects that are present as well. Some of them are connected to the issues of discrimination, insurance, employment, the rules of evidence, data-sharing, and especially the possible impact of the new human genetics on health policy and legislation. The highest states' officials often speak about the use and collection of genetic material in the clinical trials (Penn State Law, 2015). The discussion is focused on the question how new genetic technologies affect the right to privacy, particularly in the system of forensics and criminal justice. This includes the collection, storage and analysis, the development of new technologies that create new needs for legal protection, in order to improve safety and prevent negative implications to privacy and the prohibition of racial, genetic and every other discrimination. These issues are the key for a broader dialogue on the safe introduction of genetics in society. The benefits of consideration from the standpoint of medical law are: 1) better regulation of authorities and obligations of providers; 2) cooperation between health services, autonomy and responsibility, codes of ethics as a law of medical profession; 3) the development of the patient's rights as basic human rights of every individual (inviolability of the body, human dignity, autonomy and self-determination), as well as responsible attitude towards the treatment of the patient; 4) achievement of standards of patients' rights and protection.

Every person, as a human been has its own identity from the standpoint of individual rights and this identity can be expressed through genetic identity as well. If it is put into the context of the health care system and some medical treatment, then it becomes the question of patient's rights and position. It starts from the general approach to the particular approach that gives the possibilities of genetics. What happens with the rights of individual person? It comes up to some kind of inversion because the relationship between physician and patient becomes less medically complex, but more legally expressed. The treatment is simplified, schematic without usually demanding procedures and it is reduced to the laboratory result, analyzed by performed genetic test. This a little different situation asks from for the physician to act according to specific procedure in providing genetic services, genetic counseling, and genetic information with whole seriousness and ambiguity, which certainly does not exist in other areas of medical practice. From this point, medical genetics should be developed in a manner to help practice in other medical branches as well, in every situation of serious problem or kinds of failure in medical treatment, e.g. therapy in concrete patients' health conditions (Klajn-Tatić, 2006).

Convention on Human Rights and Biomedicine of the Council of Europe has provoked in many member states of the European Union an intensified activity in the field of genetics. The Convention contains two dispositions that are of particular interest for the domain of genetics: articles 11 (prohibition of any form

of discrimination on the ground of genetic heritage) and 12 (predictive genetic testing only for health purposes and subject to appropriate genetic counselling). However, a clear understanding of these dispositions requires that they are placed within the general framework of the Convention and the protection of human rights in health care in general (Nys et all., 2002).

2 State of law and practice in Serbia

Human rights in the area of health are present in legislative form in different segments, and also well considered and commented regarding to medical law theory and practice. Serbian Constitution guarantees that every citizen provides protection of individual rights, autonomy and bodily integrity and, among others, the right to health care as a subjective right (Radisic, 2008).

Human dignity has a meaning one of the essential constitutional provisions protecting through other basic rights of the individual wich are directly connected with (Simonović, 2012). The dignity and the free development of the personality of each individual part of the constitutional guarantee of the Republic of Serbia, which states that human dignity is inviolable and that you all are obliged to respect and protect it (Art. 68, Constitution).[1]

Everyone has the right to the free development of his personality if this does not violate the rights of others (Art. 23, Constitution RS). Thus, protecting the right to life provision that human life is inviolable, no death penalty and banned the cloning of human beings (Art. 24, Constitution). It protects the inviolability of the physical and psychological integrity because no one can be subjected to torture, inhuman or degrading treatment or punishment, or to medical or scientific experiments without free consent (Art. 25, Constitution). There is a prohibition of slavery, servitude and forced labor, which states that no one shall be held in slavery or servitude, and that any form of trafficking in human beings is prohibited (Art. 26, Constitution). In relation to the right to liberty and security, treatment of persons deprived of liberty shall be treated humanely and with respect for the dignity of his person, and forbidding any violence against persons deprived of liberty, as well as extortion of confession (Art. 27-28, Constitution). The protection of human dignity is the subject of the criminal law sanctioned by imprisonment for anyone who abuses, or tortures, or treated another in a manner that offends human dignity (Art. 252, Criminal Code).[2]

The dignity of the person in a position of the patient (consumer of health care) is fully protected by observing the provisions of the health law, especially in the part that regulates the patient's rights (Kandic Popovic, 1999). Although the termology of the law does not use the word dignity, it is clear that the prohibition of discrimination on any grounds or human relationship with the patient is required in the provision of health services means requirement of human dignity (Art. 3 and

9, Act on Patients' rights).[3] General order that the physician has to respect the dignity and rights of every patient and to behave in accordance with the fundamental principles of medical ethics, which is especially true for physician who work in closed institutions and other institutions in which the patient is placed by force of law, which are required to protect patients' personal rights, particurlary the physical/psyhological integrity and human dignity (Art. 31 and 47 Professional Code) .[4]

Protection of the patient's dignity is certainly one of the key principles in the area of health care and health insurance law in general and it is important concerning private and genetic sfere.[5] There are also special health law' s provisions related to a different part of health practice. For example, the principle of protecting human dignity is implemented through the process of infertility treatment and artificial insemination by applying BMPO methods with preservation of human dignity, the right to privacy, preservation of health, welfare and rights of future child (Art.10 BMPO Act).[6] There is also the protection of subjects in the clinical trials of medicinal products that shall ensure the rights, safety and interests of the examined person, who has a priority over the interests of science and society as a whole (Art.60 Medicines Act).[7] The exposing of the patient in the scientific and teaching purposes is possible only with his consent. It should be ensured respect for his personal dignity and privacy (Art. 21 Professional Code).[8]

When it comes to the law on medical genetics, Serbia was lacking in terms of the regulatory framework for a long time, even the fact that genetic services were developed with standardized practice. The exception in this regard was the pre-implantation genetic diagnosis in biomedical assisted fertilization, which is allowed in emergency of transmitting hereditary disease or if it is necessary for the procedure of fertilization (Art.54 BMPO Act). Permission for such a diagnosis gives Directorate of Biomedicine at the Ministry of Health. In terms of autonomous rules of the medical profession, there are not specific guidelines and protocols related to genetic testing and counseling. The exception is the provision contained in the Code of Professional Ethics of Serbian Medical Chamber, which includes tests that predict hereditary diseases, whether they are presumed to identify carriers of the gene responsible for hereditary predisposition or susceptibility to disease. Test can be performed only in medical context or when it is a part of the clinical research for medical purposes and no comercial genetic counseling (Art.35 Professional Code). The current situation in terms of financing services for genetic testing and counseling are mainly sources from funding: the National Health Insurance fund, the budget of the Republic of Serbia (in the case of special concern for the health of that RS provides for particularly vulnerable categories of the population), personal budgets or some other form of financing. Great importance has recently established budgetary Fund for treatment of diseases, conditions and injuries that can not be treated in the Republic of Serbia, which will have a special role in the genetic diagnosis, for example, diagnosis of some rare disease (BF Decision, 2014).[9]

The legal assessment of genetic practice is significant work because of the fact that in 2010 Serbia ratified the European Biomedical Convention (Oviedo, 1997) and mostly incorporated regulation of the European Charter of Patients' Rights (Roma, 2002). The Convention has four Additional protocols dedicated to prohibition of cloning, transplantation, biomedical research, and genetic testing. Protocol on genetic testing for medical purposes regulates different genetic issues and represent for the Member States commonly accepted harmonized law (Protocol No 4, 2008). Good example of legislative activity in respect to Protocol gives Germany by adopting the Act on genetic diagnostics in humans.[10] German law was inspirativ model for the recent work of Serbian legislator, especially in terms of the general part of the law, principles and used terms. In addition to the German law in drafting the legal text were used and other laws of comparative law, such as: Public health Act (French prenatal diagnosis amendments),[11] Act on the organization of prenatal diagnostic tests and prevention of abuse,[12] Act of improving prevention, diagnosis and treatment of rare and neglected diseases,[13] Act on rare diseases,[14] Judgement of European Court of Human rights Pavan v. Italy,[15] Act to help people with rare diseases,[16] Act on congenital defects and civil liability.[17] The entire work has resulted in January 2015 when The Serbian Parliament pass The Act on prevention and diagnostics of Genetic diseases, Genetically caused anomalies and Rare diseases (ZPiD, Off. Gazette RS, 8/2015).[18]

One of the reasons that genetic issues were not been regulated in Serbia until now is that some physicians were against any legal attempt in this field being of the opinion that professional guidelines of good medical practice provide enough protection for an individual. They perceived work of health institutions and human genetics' departments as a regularly part of the health care practice and professional guidelines (Stojanov LJ et all, 2006). However, new law was made under the pressure of the patients' organizations and thanks to theorists in the field of medical law. The text itself had been written for months and it involved a group of physicians of different specialties (geneticists, pediatricians, gynecologists, etc). Initially, the work started with an example of rare disease, but for the reason of a wider approach and the need of more rational codification it has covered the whole field of genetics and general principles of a diagnostic procedure with special regard to genetic. Legal regulation of genetic health in Serbia clearly distinguishes the service providers and potential users in the public and private health sector.

Enacting new legislation in the field of genetics makes more rich list of specific health laws, different then general law in this frame. It creates conditions on a higher level for respect of human rights related to genetic and reproductive health, and for regulation of certain procedures for health professionals with transparently established their actions and responsibilities. Legal text, which entered into force

is fully in line with other health laws and regulations, primarily with the regulations governing patients' rights, the scope of health services, as well as diagnosis and medical treatment abroad. The final text of the law contains forty two provisions arranged in ten chapters: 1) The basic provisions; 2) The provisions concerning the prevention; 3) The rights and obligations of participants in the diagnosis; 4) Predictive diagnostics; 5) Prenatal diagnosis; 6) Postnatal diagnosis; 7) Targeted diagnostics in children and adults; 8) Responsibility for damage suffered by the patient; 9) penalty provisions; 10) Transitional and final provisions. The content of the law to the extent differs from the previous drafts' version, which had sixty provisions and included issuess of prenatal ultrasound diagnosis, the tripartite composition of the Commission for a diagnosis in terms of sub-specialty of physicians and biologists in complex cases, as well as provisions on criminal responsibility, finaly missed from the adopted text.

3 Genetic services

Law and health practice in developed European countries pay great attention to the entire field of genetic services. This perspective is followed by Serbia as well. Considering genetic services they are defined as one type of health services in particurlar area of medical practice. They are highly developed, very demand and take place at the tertiary level of health institutions. Regarding the services essentiall elements are genetic information in terms of informing and communicating results, genetic counseling, and genetic privacy. Those elements are something what distinguishes this area of medical practice from others. This is the reason that qualifies the medical genetics to be the subject metter of a special legislation. Regarding the existing legal relations in the cases of these services follows determining the concepts of services, diagnosis and counseling that deserve special attention.

The genetic testing is form of providing health services which is designated for the analysis of human genetic characteristics in the diagnosis of hereditary diseases or conditions (Sjeničić, 2011). General provisions of the Health Care Act are applied in this sense and for this services according to prescribed nomenclature of health services. Setting the diagnosis through genetic testing includes all important elements of such testing for medical purposes. It is necessary to accomplish certain qualifications and education from the side of those who take the test, and appropriate conditions for the information and counseling the patient or another person who is subject to testing. Ethical and legal aspects are mixed, taken as complementary, and in the process of law enforcement and concretization that will be explained in terms of adequacy and improving the quality of services.

Genetic service could be health service of preventive medicine, but also a service of current diagnostics and after that treatment, when it includes genetic examination, genetic counseling and genetic informing. Genetic service is given by authorised provider in order to support an individual, couples, groups or

families in solving a health problem and to reach a finding in relation to occurrence or risk of occurrence or re-occurrence of a genetic disease, genetically caused anomalies or a rare disease. Authorized person is defined as a person who makes an indication or / and undertakes genetic examination in medicine (Art. 3, ZPiD). From the viewpoint of users of genetic services the terminology is not of the most essential importance, but the scope of the rights available to them. The terminology is the question of the consensus between all professions which provide services, e.g. professions from medical, legal and other working sectors (person, consumer, client, etc.). The term *patient* is not in dispute, if it is interpreted in a broader sense, as any person (ill or healthy) seeking for some genetic service. In this context it makes a small distinction between terms of *informing* as a process, and *information* as a given data. Law has a mechanisms that offer schematic and simplified terms that will be the minimum, regardless of the medical terminology that is sometimes huge and non-operative. Genetic informing means an action in which a patient or family members that are under a greater risk of genetically caused disease are introduced to the consequences of the disease, probability of transmitting and ways of prevention and treatments. Key constituents of genetic information are: 1) information of detected risk or illness, recurrence risk for monogenic disorders, chromosomal aberrations, multifactor diseases; 2) information for genetic susceptibility and pharmacogenomics; 4) information about whole genome sequencing possibilities. Genetic informing and genetic information needs to be seen like a process and its outcome, pointing that genetic information by itself is ambiguous, and different from other types of health information.

One of the central topic of bioethics and law in medicine, including in the field of genetic testing, is to empower the patient in the process of decision-making. The law established the legal principle of informed consent of the patient (*informed consent*) which is an expression of an autonomous decision-making. This goes beyond the previously dominant paternalistic model of decision-making by a professional who is a representative of the interests of the patient. In addition to the legal basis of decision making process is now widely promote an ethical approach to a common share or exchange the doctor and the patient (*shared decision-making*). Ethical model is an extension of the legal principle of informed consent (Widdershoven & Verheggen, 1999). These models are somewhat differently, but each of them is based on the recognition of asymmetry in the amount of information and understanding that are exchanged between patients and physicians. The patient should not be seen as a clinical problem, but as a person who carries your personality, experience and knowledge. These are the elements to talk about the possibilities of treatment, reducing risk and unwanted damage. All this shows that the standard contained in the legal principle of informed consent of the patient evaluated in a sense, but in legal categories still remains dominant.

4 Genetic diagnosis

Genetic diagnostic procedure is a genetic testing for health purposes, that are the purpose of prediction or detection of genetic diseases, caused genetic anomaly, or rare disease when the patient is expressly agreed in writing, or a pregnant woman as a patient is agreed in terms of diagnosis of embryos or fetus (Art. 7, ZPiD). In the course of genetic testing welbeeing of the patient takes priority over other non-medical and scientific interests exclusively. Concerning the health prevention the provider is obliged to: 1) perform in the context of preventive programs prenatal and neonatal screening as organized forms of implementation of diagnosis of hereditary diseases; 2) performed testing on certain genetic diseases within the allowed measures of health care.

Generally, every patient has the right to a diagnosis, always when it is possible and available to the state of development of biomedical and technological knowledge (Art. 14, ZPiD). Diagnosis precedes treatment and it is an integral part of the owed notification to the patient, to be self-determined in relation to the proposed treatment and to give consent with full awareness. For serious difficulties or unclear situations regarding to diagnosis, or when there is no diagnosis, it will be set consultative, hypothetical or working diagnosis as a form of temporary diagnosis. The physician is obliged to set diagnosis on the basis of patients' medical history and physical examination performed in accordance with the professional rules and with due care. He is obliged to act in accordance with the applicable standard of medical diagnostics. The physician has a freedom of choice to diagnostic procedure taking into account the personality of the patient and to appropriate his condition applying all possible and available the original scientific medical knowledge in this area. If the initial diagnosis is not sure the doctor is obliged to check it and to exhaust all other possibilities for testing. The over-diagnosis and the diagnosis in the form of unnecessary and excessive procedures are not allowed. When invasive diagnostic procedures increased the risk, the physician is obliged to make the distance between these procedures so as not to hurt the patient. Early diagnosis is a priority and obligation of the physician to timely diagnose.

The physician who performs health activity from the service provider is obliged to adopt new and improved diagnostic, therapeutic and preventive methods that are scientifically based, which is the provider received the approval of the relevant committee of the Ministry. The application of new experimental diagnostic methods requires physician's duty to assess the balance of benefits and risks to the patient in relation to its undertaking or failure. The new method can not be carried out for purposes other than prevention and treatment of health conditions and diseases.

Special attention is given on the proposed diagnostic measure. Prior to obtaining the patient's consent to genetic testing, the responsible physician is obliged to

inform the patient about the nature, meaning and scope of the test, leaving the patient enough time to decide about the consent. The duty of notification includes: 1) an explanation in terms of the purpose, type, scope and significance of genetic tests, as well as basic information about the limitations of the method applied; 2) an explanation of certain health risks for those who are being investigated in relation to the knowledge of the results of genetic tests or taking genetic samples needed for this, including the cases of pregnant women and explanations of risk to the embryo or fetus related to conducting tests and taking the necessary genetic samples; 3) an explanation of patients' rights to withdraw their consent at any time; 4) an explanation in terms of patients' rights to refuse the disclosure of results, without limitation, in part or in its entirety, including the right not to raise the test result, and that result is destroyed; 5) explanation that when examined in the case of mass genetic screening on the results of the evaluation program. Physician or other responsible staff who are acting in examination make en evidence of all medical records, contents of these explanations in time before performing tests. Savings diagnosis of established disease, genetically determined anomalies or rare diseases is communicated only b y physician who undertakes a diagnostic measure. Diagnostic measures of the patient are carried out only with his consent, except when reasons of urgency do not permit. Generaly the patient can give consent to the proposed diagnostic measure in explicit statement or actions that means the agreeableness, but genetic diagnostics in form of a test, analysis and sampling can be performed only after the patients' written consent (Art. 17, ZPiD) .

In the process of predictive diagnostics is necessary to carry out genetic counseling and testing. Prenatal diagnosis is undertaken for the purpose of bringing up healthy and desired offspring in any order determining or exclude the existence of certain genetic diseases, genetically determined anomalies or rare diseases in the embryo or fetus. Measures of mandatory newborn screening are regulated by a specific professional - methodological guideline of medical profession only for a few diagnosis. Law includes also targeted diagnosis with children and adults when it is based on unclear clinical symptoms or when there is suspicion of some rare disease or rare condition of the patient. Diagnosis has always carried out in the form of measurement and interpretation of results obtained from an authorized laboratory.

Concerning the different diagnostic procedures, special act of Ministy of health defines which health institutions at the tertiary level of health care can perform the tasks of human genetics. Currently in the issues of rare diseases there are in Serbia five clinical Centers for rare diseases and each of them is authorised to establish Multidisciplinary council for issues of diagnostics. The council is obliged to submit a report on performed diagnostic procedure and the opinion weather is possible to ensure diagnostic procedure in the Republic of Serbia. When taken genetic analysis has no clear outcome, why the patient remains without a

confirmed diagnosis, or the possibility of further diagnostic procedures for more than six months, and the patient's condition is seriously deteriorating, the Council is obliged to immediately submit a proposal for additional procedures in the foreign health institution. The proposal contains an opinion about the necessity of sending biological material or referring the patient to the choosen foreign institution (Art.31, ZPiD). The decision on the necessity of diagnostic procedures is finaly issued and covered by the Health Insurance Fund, or by the decision to allocate sourses from this propose established Budget's Fund for treatment of diseases, conditions and injuries that can not be treated in the Republic of Serbia.

5 Genetic counseling

From the stanpoint of available ethical and medical standards any use of genetic tests without adequate counseling and support to the person should be avoided. The communication and the interpretation of a test result, as well as the counseling regarding the potential implications, should be considered integral parts of a genetic test. It is necessary that the informed consent makes a dialogue in which the patient receives from the geneticist complete and accurate information about all potential implications of a test result. From the practical work the process of genetic counseling can be understood as an individual or consultative joined and institutionalized work. Counseling is usualy done from specially trained team, or from individual counsel of the specialist geneticist or gynecologist within its medical practice alone, or in consultation with the laboratory issuing and interpreting results.

Current law in Serbia regulates genetic counseling only in the form of general provision which indicates the essential qualifications of the process that needs to be understood in the absence of influence on patients' personality and freedom to decide whether or not to accept the proposed testing (Art.5 and 24, ZPiD). The regional clinical centers have a divided departments specialised to work on human genetics and provide an appropriate counseling. There is no answer to all issues in their capacity, but it is clarify that the counseling process sall be also the subject of more detailed by-law or guiding rules regulation. Genetic counseling is provided as a mandatory procedure in predicative examination or testing for purposes of predicting monogenetic diseases, determining genetic predispositions or sensitivity for a disease, and identification of persons that may be a healthy carrier of genes responsible for causing a disease. The means and reach of genetic counseling should be in compliance with the anticipated testing results and their meaning for the examined patient, particularly when the patient is a woman, to her partner or a family member. Genetic advice about insemination or labor of a child is communicated in a manner that respects the freedom of a woman in regard to her reproductive conduct (Art.24, ZPiD). The gynecologist determines indications for referral of pregnant women in the genetic counseling that is tailored to a state that is being investigated in a manner to allow: 1) assessment of the risk to the unborn child that suffers from particularly severe disease, with regard to family

history and medical reports tests during pregnancy; 2) informing pregnant women about the characteristics of the disease, how it is detected, therapy options, the performance results that may be obtained from the analysis, as well as about their possible consequences; 3) informing pregnant women about the hidden risks of samples and their limitations; 4) informing pregnant women about the fact that the child will be born with physical or mental disability is a legal indication for termination of pregnancy in the proceedings at the request of pregnant women, and after the approval by the council of doctors, and the Ethics Committee of the health institution. Physician should make sure that the pregnant woman understood the given information (Art.27, ZPiD).

The main dilema in connection with the applicable law is about the role of coucelor and the obstacles in practice. They may consist in the social acceptability of the test or characteristics groups of persons who are being tested. This gives a special sensitivity and importance of the result obtained from such tests. Compared to all the uncertainty of the process of genetic counseling it is necessary to bring closer the by-laws and rules of medical profession. Problems are related to insufficient equipment and personnel in providing genetic services. Concerning the medical education in Serbia after a basic specialisation there is a sub-specialisation in clinical genetics for physicians, which is organised at the Faculty of Medicine. There are specialist academic studies in genetics for biologist at the Faculty of Biology. Health practice in this area makes a difference between rutine testing and complex cases where a team approach should be applied, services covered by health inssurance fund and direct testing based on the Internet . Among the the stakeholders and their relations it should make a difference between scientists, physicias and patients in one side. There are as well specialists, research units and sample banks relations. Additionaly, genetic services' providers are connected with health insurances funds and in many countries it includes also forensic institutions, state agencies, genetic counseling firms and policy makers.

With regard to achieved professional standards, necessary recommendations on genetic counseling could refer that genetic counselors vs. their clients have to: 1) serve those who seek services regardless of personal or external interests or biases; 2) clarify and define their professional role and relationships with clients, and provide an accurate description of their services; 3) respect their clients' beliefs, inclinations, circumstances, feelings, family relationships and cultural traditions: 4) enable their clients to make informed decisions, free of coercion, by providing or illuminating the necessary facts, and clarifying the alternatives and anticipated consequences; 5) refer clients to other qualified professionals when they are unable to support the clients; 6) maintain information received from clients as confidential, unless released by the client or disclosure is required by law; 7) avoid the exploitation of their clients for personal advantage, profit, or interest (Stojanov LJ et all, 2006). Also accepted practices are that genetic counselors vs. colleagues have to: 1) share their knowledge and provide mentorship and guidance for the

professional development of other genetic counselors, students and colleagues; 2) respect and value the knowledge, perspectives, contributions, and areas of competence of colleagues and students, and collaborate with them in providing the highest quality of service; 3) encourage ethical behavior of colleagues; 4) assure that individuals under their supervision undertake responsibilities that are commensurate with their knowledge, experience and training; 5) maintain appropriate limits to avoid the potential for exploitation in their relationships with students and colleagues.

6 Conclusion

The medical genetics increasingly finds its application in many fields of diagnosis, counseling, and other procedures, which common are characterized by very strong confidentiality and sensitivity of results and consequences for the persons and families. Procedure of reading genes can be targeted by emerging frauds, which therefore requires greater legal protection as well. Issues of responsible and conscientious work in health care sector should emphasize equally the work of all health services, including those that provide services with the aim of prevention and medical care of genetic and reproductive health. There is no excuse. Good medical practice in health care should eliminate controversy of procedures and brought a clear solution of duties and rights. They help to achieve better treatment in every day practices and reduce potential errors and disputes, as well as the unjustified and unnecessary prosecutions in the court practice.

Serbian law opens up new perspectives and offers new possibilities of treatment for patients. But enforcement of the law encounters certain problems and do not take place within the time limits. By-laws are not adopted within the legally prescribed deadlines. The practice of applying the law goes with difficulties. Currently it suffers from a lack of enforcement that has stalled due to the reluctance of health services and lack of organization of Health Authorities. Despite everything outlined as difficulties in common is the view that no aspect of medicine nor law does not stand in the way of improving genetic services and achieving the highest standards of work and respect for human rights in the field of medical practice. Medical law provisions wants to improve the work of health institutions in genetic area, to improve procedures, to support acts of public health policy, as well as providing services of genetic and reproductive health, which in the same time should take into account the needs and possibilities for the patients suffering from hereditary diseases. The application of legal norms and legal protection shall be carried out on the model of mainstream comparative law and the most important European treaty and directives in the field of genetic health.

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