

STATEMENT

From Assoc. Prof. Silviya Filkova, PhD
Medical College at Medical University "Prof. Dr. Paraskev Stoyanov" Varna

of dissertation work for the award of educational and scientific degree "DOCTOR"

Professional field: 7.4. Public Health

Doctoral Programme: "Public Health Management"

Author: Lora Ognyanova Grupcheva

Form of doctoral study: regular form of study

Department: "Social Medicine and Health Care Organization" at the Faculty of Public Health at Medical University - Varna

Subject: Legal aspects of innovative transplantation technologies in ophthalmology in the light of the law in Bulgaria and other European countries

Scientific supervisors. Prof. Maria Valkanova, PhD, Assoc. Prof. Silviya Nikolova, PhD

The opinion was prepared on the basis of the Order No. P-109-429/ 04.12.2024 of the Rector of Medical University "Prof. Dr. Paraskev Stoyanov" Varna for the appointment of the members of the scientific jury for the procedure and Protocol No. 1/ 16.12.2024 from the meeting of the Scientific Jury.

Brief biographical data about the PhD student

Lora Ognyanova Grupcheva was born in Varna in 1994. She holds a Master's degree in Law with a professional qualification of Lawyer from Varna Free University "Chernorizets Hrabar", Varna since 2019, as well as a Master's degree in International Relations with a professional qualification of Master of Law of the European Union from Sofia University "Sv. Kliment Ohridski" with a degree in International Relations - Law of the European Union from 2020.

She has undergone training as a mediator at the Bulgarian Mediation Association, according to Certificate No. 117 / 26.06.2024 of BAM.

By Order No. P-109-298/ 28.05.2021 of the Rector of Medical University "Prof. Dr. Paraskev Stoyanov" Varna she was enrolled as a full-time PhD student in the PhD program "Public Health Management" at the Department of Social Medicine and Health Care Organization at the Faculty of Public Health of Medical University - Varna, with scientific supervisors Prof. Maria Valkanova, PhD and Assoc. Prof. Silviya Nikolova, PhD.

By order № P-109-429/ 04.12.2024 the full-time PhD student Lora Grupcheva was dismissed with the right to defend. The dissertation topic is "Legal aspects of innovative transplantation technologies in ophthalmology in the light of the law in Bulgaria and other European countries".

Her professional career began in 2016 as a clerk and in 2019 as a legal advisor at Notary Petar Petrov, PS - Varna, No. 224 NC.

During her PhD she worked as a legal advisor at the University Specialized Hospital of Eye Diseases for Active Treatment - Varna Ltd.

She is fluent in French, Russian and English, which is of great help to her in using the specialized literature.

General description and characteristics of the dissertation

The submitted dissertation of the PhD student Lora Grupcheva has a total volume of 148 standard pages and is illustrated with 4 tables and 20 figures. The reference list includes 120 references.

Transplantation requires tissues and organs, and appear to be a very difficult procedure related to legal, social, religious and psychological aspects. In ophthalmology, transplantation requires corneal tissue and/or amniotic membrane. There are “legislative” gaps in Bulgarian laws, which are serious regulatory obstacles for the practice. The analysis of the effect of the lack of legal regulations in this area has an impact on the activities of tissue banks and transplantation in Bulgaria, and is of particular importance for improving the entire process in the actions against impaired vision and blindness.

In his work, the author also advocates the benefits of the development of new biological products and medical devices, as well as highlights the legal obstacles and economic difficulties in their implementations. In the process of this research, an algorithm for optimizing donation was developed by the author and proposed to facilitate the work of donation coordinators at medical institutions. The algorithm includes various mediation techniques which can be applied in communication between the coordinators and potential donors and/or their relatives, authorized to make a decision on organ and tissue donation.

This work was developed with the aim of review, analyze and compare the legal framework and rules for organ and tissue donation when performing ocular transplantation in Bulgaria. In the context of the European legislation and practice the author build a hypothesis about the legality and application of innovative technologies such as bioproducts and personal medical devices in Bulgaria.

To achieve the goal, 6 tasks have been set, which are logically connected and facilitate the fundameths of the work.

The study was conducted in the period 2021-2024 and is based on legislative framework, registers of public data on transplantation and exchange of organs and tissues in Bulgaria and Europe, and information obtained from own questionnaires. The medical aspects are based on public information and internal regulations of the Eye Bank Department at Specialised Eye Hopsital-Varna EOOD. The registers of Executive agency “Medical Supervision” (EAMS) and EURO CET were used. The author used a wide range of methods, including documentary, comparative, comparative-legal, logical-graphic and statistical.

For the analysis of the legal framework in a number of European countries, the public registers of 4 countries were used, namely: Italy, France, Spain and the Netherlands.

Based on the collected and analyzed data, the author has prepared a geographical map of the centers that perform eye banking activities (6 centres) and registered as transplantation centres (28 medical entities). Registration for performing certain activities related to transplantation in Bulgaria does not have quantitative criteria. This determines a pronounced unevenness at national level.

The author analyzes the types of activities, their quantitative characteristics and distribution in the country. Very interesting is the information collected and analysed from authors self-developed questionnaire with two parts, dedicated to banking and tissue transplantation. Human tissue is invaluable and unfortunately in constant shortage. This circumstance requires the implementation of a set of measures by the states to reduce the deficit. In addition, to improve the awareness of the population, an "information brochure" has been developed and printed, which is provided free of charge to all interested parties.

Each country applies different rules, requirements and regulations that organise the donation of organs, tissues and cells, which is why the author decided to analyze Bulgaria and leading European countries - France, Italy, Spain and the Netherlands. In some countries, the maintenance of a national register or the possession of a donor card is adopted, in other countries the so-called "explicit disagreement" is applied, according to which in the legal world it is presumed that if during life the person has not explicitly expressed his refusal. The author's approach to use 2 registers - EAMS and EURO CET is interesting. The results are presented in tables and figures and critically analyzed. Both sources provide more information about the processes related to corneal transplantation and have shortcomings in providing information about amniotic membrane. Amniotic membrane is used much more often, but not only as a transplant, but also as a carrier and or medical device. The author pays special attention to the possibility of using bioproducts and correctly points out the gap in the national legislation of the Republic of Bulgaria, where there is no specific law regulating the application and distribution of bioproducts. The author concludes that this hinders the application of developed bioproducts and deprives many needy patients of their therapeutic effect.

Transplantation activities in Europe are registered in the unified EURO CET system. Eye and tissue banks in Bulgaria are institutions established for the purpose of collecting, processing, storing and distributing donor materials for transplantation. They certify the suitability and safety of the material, ensuring the traceability of documentation related to donors, tissues and recipients in accordance with the current legislation and confidentiality conditions. In the spirit of the detailed analysis, the author has examined leading countries such as France, Italy, Spain and the Netherlands in order to note the positive practices applicable in Bulgaria.

Currently, on the territory of the Republic of Bulgaria, according to the register of EAMS, there are 6 entities with the status of tissue banks and 28 medical institutions with a permit to perform eye tissue transplantation in various volumes. The author supplements the collected information through a questionnaire survey targeting a wide range of participants in the procedures of eye banking and transplantation.

Contributions and relevance of the development for science and practice

The author emphasized the importance of the topic in the summary, drawing seven conclusions and outlining 10 contributions.

As a special contribution of the author, I would like to highlight the developed 5-step algorithm for improving the effectiveness of "donation coordinators", in cooperation with medical specialists in potential donor situations. I was also particularly impressed by the information brochure, which, in addition to professionalism, also shows the candidate's public commitment.

Based on her in-depth work, the author concludes that the Bulgarian map of transplantation distribution shows significant unevenness with a concentration in the cities of Sofia and Varna. The specific nature of the specialty of ophthalmology, as well as the peculiarities of transplantation in a social, medical and legal aspect, create conditions for a complicated interpretation of each individual element of transplantation. Regardless of this complex and incomplete regulatory basis, transplantation is an opportunity to ensure vision and quality of life for thousands of patients in Bulgaria and millions in Europe and the world.

5 publications related to the thesis are presented.

Conclusion

The dissertation contains with scientifically applied and scientifically theoretical results of confirmatory nature.

As a specialist in public health, I highly appreciate the work of this young juror, showing analytical perseverance in the search for legitimate opportunities to improve ocular health through transplantation and, prospectively, through the knowledge of biological products. The dissertation work is written in accordance with the Law for the Development of Academic Staff in the Republic of Bulgaria (LADRB), the Regulations for the Implementation of the LADRB and the Regulations of MU - Varna. In view of all the above, I recommend the esteemed jury to vote positively for the award of the PhD degree to Lora Ognyanova Grupcheva in the field of higher education 7. Health and Sport, professional field 7.4. Public Health, scientific specialty Public Health Management.

06.01.2025
Varna

Opinion Originated
(Assoc. Prof. Silviya Filkova, PhD)

Заличено на основание чл. 5, §1, б. „В“ от Регламент (ЕС) 2016/679
--