

## **OPINION**

by **Assoc. Prof. Dr GENA GEORGIEVA PENKOVA, MD, PhD,**

for the dissertation of **LORA OGNYANOVA GRUPCEVA**

for awarding the educational and scientific degree "DOCTOR"

in the scientific specialty "Public Health Management"

on the topic:

**Legal aspects of innovative technologies for transplantation in ophthalmology in the light of the law in the Republic of Bulgaria and other European countries**

By order R-109-429/04.12.2024 of the Rector of the Medical University - Varna Prof. Dr. DIMITAR RAYKOV, MD, DSc, and on the basis of Protocol No. 235/27.11.2024 of the Faculty Council of the Faculty of Public Health, I am appointed as a member of the Scientific Jury in the procedure for acquiring the educational and scientific degree "Doctor" in the doctoral program "Public Health Management", professional field 7.4 Public Health, with a candidate Mrs Lora Ognyanova Grupcheva, PhD student in full-time education at the Department of Social Medicine and Health Care Organization, Faculty of Public Health, Medical University "Prof. Dr. Paraskev Stoyanov" – Varna.

According to Protocol No. 1/23.12.2024 of the first meeting of the Scientific Jury, I have been appointed to prepare an opinion.

### **Brief data on the career development of the PhD student**

Mrs Lora Ognyanova Grupcheva was born on 28.03.1994 in rp. Bapna. In the period 2013-2019 she graduated with a Master's degree in Law with a professional qualification of a "Lawyer" at Varna Free University "Chernorizets Hrabar", after which she continued his studies in the specialty "International Relations" with a professional qualification "Master of European Union Law" at Sofia University "St. Kliment Ohridski" and the International Master's Program "European Union Law" at the University of Lorraine, France (2019-2020).

By Order No. R-109-298 / 28.05.2021 of the Rector of MU-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, Faculty of Public Health of the Medical University "Prof. Dr. Paraskev Stoyanov" Varna.

Since 2019, Mrs Lora Grupcheva has been working as a legal adviser, initially in a notary's office, and since 2020 she has been a legal adviser at the "University Hospital of Eye Diseases' for Active Treatment – Varna". She has also completed training as a mediator at the Bulgarian Mediation Association, according to Certificate No. 117 / 26.06.2024 of the BAM. He speaks English and French.

### **General characteristics of the dissertation and its relevance**

The dissertation has a total volume of 148 standard pages and is structured in four chapters: 1. Literature review; 2. Goals and objectives, materials and methods; 3. Results; 4. Discussion. This is followed by conclusions, contributions, publications, appendix and bibliography. The dissertation includes 4 tables and 20 figures. The bibliographic list has 120 literary sources only in foreign languages. It would be appropriate to include in the list at least the 29 Bulgarian laws and regulations, as well as the EU Directives.

**Relevance of the problem.** The dissertation is dedicated to an extremely topical, difficult and previously undeveloped problem - transplantation in ophthalmology. Impaired vision and blindness are some of the most important components of quality of life. At the same time, it is this type of transplantation that is associated with the most serious legal, social, religious and psychological aspects. The inclusion of tissue banks under the Medical Institutions Act in the classification of health care institutions is an appropriate step, but this does not solve the various problems faced by transplantation in ophthalmology and the activities of this type of health care institutions.

### **Evaluation of the structural parts of the dissertation**

**The literature review** is an extremely in-depth examination of the wide range of problems related to transplantation in ophthalmology. Starting with a brief historical overview of the origin and evolution of transplantation, the PhD student logically traces the moral and legal aspects of donation; focuses on the tissues of the eye banks in ophthalmology; distinguishes between the concepts of "donor tissue", "biological product" and "medical device"; examines the regulations for the collection, processing, storage and distribution of tissues in Bulgaria and the EU, as well as the legal regulation of donation in Bulgaria.



**The purpose of the study** is clearly and precisely stated: to review, analyze and compare the legal framework and the rules for organ and tissue donation and eye transplantation in Bulgaria, in the context of European legislation and practice, to build a hypothesis for the legality and application of innovative technologies, as well as the practical implementation of organic products in the Republic of Bulgaria.

To achieve this goal, **six specific tasks** have been set, in the process of implementation of which appropriate methods have been used.

The study was carried out over the course of 3 years, which allowed the PhD student to cover the problem under study comprehensively and thoroughly.

Comparative data on transplants performed are extracted from the European Register of Organs and Tissues – EURO CET, and for Bulgaria – from the register of the Executive Agency for Medical Supervision. The specific difficulties and problems in eye transplantation are evaluated through the opinion of the managers and specialists working in the tissue banks in Bulgaria, on the basis of an author's questionnaire in 3 parts.

**In Chapter Three "Results"** the implementation of the 6 research tasks is presented sequentially. A detailed analysis of the legal provisions concerning tissue transplantation in ophthalmology is made. In the analysis of the legislative foundations of transplantation in ophthalmology, examples of good European practices in terms of regulatory framework and practical implementation in 4 leading European countries – France, Italy, Spain and the Netherlands - are indicated. The tissue banks in Bulgaria are pointed out according to the register of the Executive Agency "Medical Supervision" and their activities in the field of eye transplantation are analyzed. The difficulties and problems in the field of eye transplantation are presented on the basis of a survey among the specialists working in these tissue banks. A summary and analysis of the information extracted from the public registers of eye transplants performed in Bulgaria and in leading European countries for a 10-year period is made.

The study focuses on the need to improve people's awareness of donation and especially corneal tissue donation. For this purpose, an "information brochure" has been developed and printed, provided as an electronic file to all eye tissue banks in Bulgaria.

Particular attention should be paid to the ideas presented in the **section "Looking to the future"**, which focuses on approaches to increasing donor activity. The Spanish model is examined in details. The connection between donation, transplantation and their financing is emphasized. Improving communication between medical professionals and coordinators working in hospitals, on the one hand, and potential donors and their relatives, on the other hand, is a strategic and necessary step in the process of overcoming the shortage of donor material. To optimize the work of donation coordinators at the medical institutions, a 5-step algorithm using mediation approaches is proposed.

**In Chapter Four "Discussion"**, the PhD student brings out even more systematically the main ideas for the development of donation and transplantation in ophthalmology. The role of the state in improving the legislative framework is emphasized. Policies for reforming national transplant systems must be based on long-term commitments and strategies to achieve sustainable success.

**In the final part of the dissertation**, the PhD student has synthesized **seven main conclusions**. Legislative changes are needed in accordance with the European directives; adoption of the Organic Products Act; the need for collaborative work between institutions, eye banks, medical institutions and eye surgeons in order to increase transplant surgery; improving communication between all structures and staff who carry out various activities related to donation and transplantation; the application of new technologies requires new regulations; The lack of tissues requires liberalization of processing procedures. Translational medicine is the future of processed and artificial tissues and requires legislative changes allowing the application of new technologies beyond the scope of medical devices.

**I fully accept the 10 contributions** formulated by the PhD student with a scientifically applied, scientific-theoretical and confirmatory character. The use of the phrase "For the first time" is quite justified and appropriate.

**My overall assessment of the dissertation is extremely positive.** This is a unique development with a pronounced innovative character, proving the in-depth knowledge of the legal aspects of the transplantation problem in ophthalmology. The dissertation is written in a very high academic style. The abstract fully reflects the content of the dissertation.



## CONCLUSION

The presented dissertation is distinguished by its relevance, originality, methodological innovation, precision and contains well-grounded scientific contributions. The overall organization of the collection of the material, the analysis and discussion of the results prove the excellent capabilities of the PhD student to conduct independent research work.

**The dissertation "Legal Aspects of Innovative Technologies for Transplantation in Ophthalmology in the Light of the Law in the Republic of Bulgaria and Other European Countries"** fully complies with the requirements of the Law on the Development of the Academic Staff in the Republic of Bulgaria and the Regulations for its Application, as well as the Regulations for the Development of the Academic Staff at the Medical University - Varna.

I give a very high assessment of the dissertation and propose to the esteemed members of the Scientific Jury to vote positively for the **award of the educational and scientific degree "Doctor" to Mrs Lora Ognyanova Grupcheva** in the scientific specialty "Public Health Management", field of higher education 7. "Health and Sport", professional field 7.4. Public health.

08.01.2025

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Prepared by:

Assoc. Prof. Dr Gena Penkova, MD, PhD

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