

## **REVIEW**

**by Prof. Dr. Yanka Teneva Tyankova**

professor of civil and family law,

Faculty of Law of the "St.St. Cyril and Methodius University of Technology",

member of the scientific jury, appointed by order No. P-109-429/ 04.12.2024 of the Rector of the  
Medical University "Prof. Dr. Paraskev Stoyanov" – Varna

**Subject:** public defense of a dissertation for the award of the educational and scientific degree "Doctor."

**Field of higher education:** 7. Health, **professional field:** 7.4. Public Health (doctoral program - Public Health Management)

**Doctoral student:** Lora Ognyanova Grupcheva

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

**Scientific supervisors:** Prof. Dr. Maria Valkanova, Assoc. Prof. Dr. Silvia Nikolova

### **I. Dissertation data**

Lora Ognyanova Grupcheva completed her secondary education at the 4th Language School "Frédéric Joliot Curie" – Varna, with studies in French. Subsequently, in 2013, she was admitted to the Faculty of Law of the Varna Free University, where in 2019, she received a Master's degree in "Law" and a professional qualification "Lawyer". The candidate also has a second Master's degree in "International Relations - EU Law", and after graduating, she received the qualification "Master of European Union Law" from Sofia University "St. Kliment Ohridski".

The doctoral student began her professional career in 2019 as a legal consultant with notary Petar Petrov, Varna. Since 2020, she has been a legal consultant at the University Specialized Hospital for Eye Diseases and Active Treatment - Varna. This also determined her interest in eye transplantation, particularly the administrative and legal aspects of donation and transplantation in Bulgaria.

In 2024, Lora Grupcheva underwent training as a mediator at the Bulgarian Mediation Association (BMA), as evidenced by the submitted Certificate No. 117/ 26.06.2024 of BMA.

She is fluent in French and English.

## **II. Data on doctoral studies, abstract and publications**

Lora Grupcheva is enrolled as a full-time doctoral student at the Department of Social Medicine and Health Care Organization, Faculty of Public Health, the doctoral program "Public Health Management" of the Medical University - Varna, with scientific supervisors Prof. Dr Maria Valkanova and Assoc. Prof. Dr. Silviya Nikolova, according to Order No. R-109-298/ 15.07.2021 of the Rector of the Medical University - Varna. During the doctoral studies, she successfully passed the mandatory exams in the specialty and dissertation topic. The dissertation work was discussed and proposed for defense by the Departmental Council of the Department of Social Medicine at the Faculty of Public Health at the Medical University - Varna with a decision of 21.11.2024 (Protocol No. 18/21.11.2024). The student was dismissed for defense with Order No. R-109-296/10.09.2024 of the Rector of MU-Varna. By Order No. R-109-429/04.12.2024 of the Rector of MU-Varna, the scientific jury was appointed. At a meeting of the scientific jury, a chairman and reviewers were elected under the announced procedure. From the arguments presented in this way, supported by the attached documents, it is evident that no violations of the regulatory framework were found during the conduct of the procedure.

From the materials submitted for participation in the public defense of the dissertation for the award of the educational and scientific degree "doctor", it is evident that the doctoral student's scientific interests are in transplantation, particularly eye transplantation.

The dissertation is on the topic of "Legal aspects of innovative transplantation technologies in ophthalmology in the light of the law in the Republic of Bulgaria and other European countries". Until now, there has been no independent study of the legal aspects of transplantations in the field of ophthalmology in the Bulgarian legal literature, either due to the complexity of the legal framework or due to insufficient knowledge of their specific features, which makes the scientific work suitable for defense. This scientific research provides a comprehensive analysis of the legal framework regulating transplantations in ophthalmology through a comprehensive historical and comparative legal analysis. The opinions expressed by the doctoral student on several controversial or unexplored issues related to transplantations in the field of ophthalmology are supplemented and debated. In this regard, the relevant Bulgarian and European legislation provisions have also been analysed.

The doctoral student has prepared and presented an 84-page syllabus that complies with the regulatory requirements. It is recommended that its length be 25-30 pages so as not to repeat the thesis statement but to present only the contributing parts of the scientific work.



The following publications have been attached for participation in the procedure: 1 personal publication by the author — *A study of the legal framework in European countries in the field of transplantation in ophthalmology*. Varna Medical Forum. 2024, 13 (online first) and 3 publications in co-authorship: Grupcheva, CN; Grupchev, DI; Usheva, N.; Grupcheva, LO *Beauty versus Health—How Eyelash Extensions May Affect Dry Eye Disease?* J. Clin. Med. 2024, 13, 3101. <https://doi.org/10.3390/jcm13113101>; N. Nikolova, L. Grupcheva, Hr. Grupcheva. *Autologous serum drops, a possibility for treating patients with "dry eye"*. GP news. 2024,9(292): 50-5; L. Grupcheva, D. Grupchev. *Legal aspects of transplantation in ophthalmology*. GP news. 2024,6(289): 21-5.

The articles submitted for participation in the competition are directly related to the topic of doctoral studies, as they are in the field of transplantation in ophthalmology and have their own contribution. It should be noted that one of the articles has an impact factor.

The articles published by doctoral student Lora Grupcheva collected more points than the required number—80 points (out of the required 30 points). Therefore, the doctoral student fulfils the scientometric requirements for obtaining the degree of "doctor" (dissertation—50 points and published articles—30 points).

### **III. Characteristics of the dissertation work and scientific contributions.**

The dissertation is developed in a volume of 148 standard pages and is illustrated with four tables and 20 figures. The content is distributed as follows: summary, introduction, four chapters, conclusion, outcomes and contributions, and appendix. Finally, a detailed bibliography on the topic is indicated. The literature used includes 120 titles, all in a foreign language. No footnotes are indicated, as they are contained in the presentation itself in brackets, referencing the corresponding number from the bibliographic reference.

The dissertation submitted for defense, dedicated to transplant surgery, in particular eye transplantation, examines its economic manifestations, as well as contains a legal overview of the legislative framework in the Republic of Bulgaria and other EU member states. The best European practices that have helped to increase donor activity in some EU countries are outlined. Both the regulatory obstacles and the economic problems hindering the development of donation and transplantation in Bulgaria are analysed in detail. Considering all these national and European features, the author systematically analyses the relevant legal norms and their interpretation in the context of tissue banking and transplantation in ophthalmology.

**The abstract** states the subject of the author's research, its purpose and the tasks set to achieve this purpose. The research methods used are outlined. **The introduction** is brief and contains arguments in favor of the significance and relevance of scientific research.

**The first chapter** provides a detailed historical analysis of the emergence of transplantation both in the world and in Bulgaria. The historical review is followed by a study of the donation concept, and an analysis of its moral and legal aspects is also made. Tissues from eye banks used in ophthalmology are examined in detail. A distinction is made between the concepts of donor tissue, biological products (bio-products) and medical devices. The legal regime of donation in Bulgaria is carefully studied. This first chapter, consisting of six sections, ends with a summary, which includes a synthesis of the author's conclusions during the presentation.

**Chapter two** is devoted to a study conducted in 2021-2024, which was carried out based on a study of the legislative framework and the registers of published data on the transplantation and exchange of organs and tissues in Bulgaria and Europe. The medical aspects of the scientific research were carried out based on public information and the internal regulations of the Eye Bank Department at the University Eye Hospital - Varna. A comprehensive legal analysis of the legislation in force in the country regulating donation and transplantations and all European acts in this regard was carried out. The medical institutions that have the status of a "tissue bank" and users of eye tissues according to the registration of the Medical Supervision Agency were identified, and a comprehensive quantitative analysis of the activities related to eye transplantation in the authorised medical institutions was performed, based on a questionnaire survey among specialists engaged in these activities. An algorithm is presented to improve the efficiency of the work of coordinators in collaboration with medical specialists in potential donation situations, and recommendations are made for using the knowledge and skills for mediating.

In **the third chapter**, they compared the legal frameworks and clinical regulations for applying tissues in ophthalmology in some European countries based on an online survey. It is explicitly stated that transplantation activities in Europe are registered in the unified EURO CET system. The doctoral student analyses several European countries' main legal frameworks for donation and transplantation. Countries were selected to have the largest share of transplants performed per capita and the highest contribution in the donation field. These are France, Italy, Spain, and the Netherlands. In a separate section, the medical institutions in Bulgaria with the status of "tissue bank" and users of eye tissues are identified, according to the registration in the Medical Supervision Agency. A quantitative analysis of the activities related to eye



transplantation in authorized medical institutions was conducted based on a survey among specialists engaged in these activities. It is concluded that based on statistical data from all 28 member states of the European Union, Bulgaria ranks last in terms of transplanted patients per 1 million population.

**The fourth chapter** is devoted to the scientific discussion on the topic. It begins with a legal analysis of the fundamental law that regulates in detail the process of implementing transplantation in the Republic of Bulgaria — this is the Law on Transplantation of Organs, Tissues and Cells (ZTOTK). It is noted that in the field of postmortem donation, according to the provisions of the same law, the so-called principle of presumed consent is applied in Bulgaria, according to which it is assumed that every person who during their lifetime did not explicitly express his unwillingness to donate, for the purposes of transplantation, organs, tissues or cells from his body, agrees to be a cadaveric donor after his death. It is noted that in Bulgaria, there is an official register at the Executive Agency for Medical Supervision, in which every person during their lifetime has the right to express their disagreement to be a donor of organs, tissues and cells after death. The applicable European legislation is analysed in detail.

The dissertation ends with a summary and conclusions containing scientific proposals. The author takes into account the need for legislative changes that are in line with the goals set out in the analysed European directives and justifies the adoption of a Biological Products Act. The author's main argument is that biological products can accelerate the development of ophthalmic transplantations since they involve the processing of the patient's cells into bioproducts and their subsequent implantation into the patient's eye for the purpose of treatment and regeneration.

#### **IV. Scientific and applied scientific contributions.**

The scientific work submitted for review contains several contributions of a scientific-applied and scientific-theoretical nature, the most important of which are:

1. For the first time in our doctrine, an independent monographic study of the legal aspects of transplantations in ophthalmology is being conducted. This scientific study provides a comprehensive analysis of the legal framework in force in Bulgaria regulating transplantations, particularly those in ophthalmology, and also examines all applicable European directives in this field.
2. The study's undeniable contribution is the first systematic comparative legal analysis of the current regulatory framework and good practices (to meet the needs of transplantation, export and import of tissues) based on those for EU member states that are leaders in eye

transplantation in the EU, such as France, Italy, Spain, and the Netherlands.

3. The dissertation's practical focus should be highly appreciated, both in the field of transplantations and in view of the proposed changes in the current legislation aimed at optimising donation in Bulgaria in the field of ophthalmology.

4. The information brochure on donation in ophthalmology prepared by the doctoral student is of practical and applied importance. It aims to raise public awareness of the importance of donation and increase the number of transplants.

5. The proposal to use the mediator as an intermediary in the complex negotiation process, within the framework of which the potential donor will be transformed into a practically realised donor situation, also deserves admiration.

6. Last but not least, the use and analysis of such a large number of foreign sources (legal acts), scientific literature (120 monographs, articles and reports), the extraction of data from various types of registers at the EAMS and EURO CET, their systematic analysis, followed by proposals for changes not only in the current legislation but also for the creation of a comprehensive algorithm for the implementation of the donor situation and processing of corneal tissue should be positively noted.

7. The questionnaire surveys conducted by the doctoral student, the figures produced, and the attached comparative tables testify to an excellent knowledge of the legal framework and the ability to transform theoretical knowledge into practically applicable models subordinated to the common goal: Bulgaria's worthy place on the European map of corneal transplantation.

Propositions *de lege ferenda* are derived and systematised in the final part of the dissertation.

The contributions correspond to the content of the thesis and objectively reflect what the doctoral student has achieved.

## **V. Main critical notes and recommendations.**

Some recommendations can be made regarding the dissertation, namely:

In terms of structure, the work would benefit if, before publishing, some changes were made to create a better systematic presentation. In Bulgarian and English, the summary should be located at the end of the table of contents since placing it before the introduction would reduce the reader's interest in the overall presentation. The tasks and objectives indicated on page 57 of the dissertation should be contained in the introduction, where, in principle, the subject, goals and objectives of any scientific research are systematized. In the table of contents, in addition to



the individual chapters, all sections and subsections should be indicated (such are contained only for chapter one).

In terms of the literature used, the use of such a large number of foreign literature was considered positive. However, no Bulgarian literature has been mentioned. In a broader aspect, since a general law regulates issues related to transplantation and donation, it would be appropriate to mention Bulgarian scholars who have already conducted a legal analysis of donation and transplantation in Bulgaria, such as: *Zinovieva, D.*, Medical Law, S., 2016 (part two: Organ donation and transplantation. Legal problems of donation...), *Goleva, P.*, The doctor's liability for harm caused to the patient, S., 2004 (chapter nine: Peculiarities of the doctor's civil liability in transplantation), *Goleva, P.*, Some legal problems of transplantation of human organs or tissues from a living donor (article), etc.

In my opinion, the scientific work would benefit if it began by examining, albeit in general terms, an important and controversial issue in civil law: that of organs(respectively tissues and cells) as the object of civil legal relations. Several authors have already discussed this issue in their monographs and articles, such as *Pavlova, M.*, Civil Law; *Stavrou, S.* The Human Body as an Object of Property Rights, etc. At the end of the presentation, the issue of the civil liability of the doctor in transplantation, which is of great practical applicability, should also be touched upon.

The notes made, which also contain recommendations, should be accepted as inevitable not only about any scientific work but also because they aim to convey a more significant scientific value to the work.

## **VI. Conclusion.**

The dissertation work of Lora Grupcheva undoubtedly demonstrates that she has rich theoretical knowledge of transplantation in the field of ophthalmology. The doctoral student undoubtedly can work with a large amount of information from which she can formulate relevant scientific conclusions. The dissertation bears the marks of a work with a great practical and applied focus, which represents a contribution to the scientific literature and complies with the Law for Academic Development in Bulgaria, the Regulations for its implementation and also the Regulations for the development of the academic staff at the Medical University "Prof. Dr Paraskev Stoyanov" - Varna.

In conclusion, referring to the aforementioned considerations, I support and propose to the scientific jury that doctoral student Lora Ognyanova Grupcheva be awarded the educational and

scientific degree "Doctor" in the field of higher education 7. Health, professional field: 7.4. Public Health (doctoral program—Public Health Management).

09/01/2025 Reviewer

prof. Dr. Yanka Tyankova

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