

**To  
The members of the scientific jury,  
appointed with order No. R-109-  
429/04.12.2024 of the Rector of  
MU - Varna**

## **REVIEW**

**by Prof. Ivan Rushev Rushev, Ph.D.,  
Full member, Academician of the Bulgarian Academy of Sciences**

**of the dissertation work of Lora Ognyanova Grupcheva on the topic:  
"LEGAL" ASPECTS ON INNOVATIVE TRANSPLANTATION  
TECHNOLOGIES IN OPHTHALMOLOGY IN THE LIGHT OF THE LAW  
REPUBLIC BULGARIA AND OTHER EUROPEAN COUNTRIES"  
for awarding the educational and scientific degree "DOCTOR" in a  
scientific specialty "Public Health Management"**

**Dear members of the scientific jury,**

By Order No. R-109-429/04.12.2024 . of the Rector of the Medical University "Prof. Dr. Paraskev Stoyanov" - Varna , on the basis of Art. 6, para. 11 of the Regulations for the Development of the Academic Staff of the University , I have been appointed as an external member of the jury for the public defense of the dissertation of Ms. Lora Ognyanova Grupcheva - a full-time doctoral student , on the topic " Legal aspects on innovative transplantation technologies in ophthalmology in the light of the law in Republic Bulgaria and other European countries " . On the basis of Art. 9 and Art. 10 of the Law for Development of Academic Staff, Art. 30, para. 2 and Art. 32, para. 1 of the By Laws of the same regulation, by decision of the jury I have been assigned the preparation of a review, which I present to your attention .

### **I. Brief biographical data about the PhD student**

Ms. Lora Ognyanova Grupcheva was born in 1994 in Varna. She graduated from a language school with a major in French and law, and then obtained a master's degree in law at the Faculty of Law of the Varna Free University "Chernorizets Hrabar". She also graduated from a master's degree in international relations at the Faculty of Law of the Sofia University "St. Kliment Ohridski" with the professional qualification "Master of European Union Law". She is currently specializing in economics and tax law (part-time study ) at the Economical University of Varna.

By Order No. R- 109-298/15.07.2021. of the Rector of MU - Varna, Ms. Grupcheva was enrolled as a PhD student ( full-time ) in the doctoral 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, and her scientific supervisors were Prof. Maria Valkanova, D.P. and Assoc. Prof. Silvia Nikolova.

During her doctoral studies, Ms. Grupcheva worked as a legal advisor at Specialised Eye Hospital-Varna. She has completed training as a mediator at the Bulgarian Mediation Association ( certificate No. 117/ 26.06.2024 ) . She is fluent in French. The doctoral student has one publication in a journal with an impact factor and more articles in refereed Bulgarian journals.

By Order of the Rector of MU No. R-109-296/10.09.2024, Ms. Grupcheva was passed with the right to defend. The submitted dissertation was discussed, received a positive assessment and is directed to a public defense at a meeting of the Department Council of the Department of Social Medicine, Faculty of Public Health, MU "Prof. Dr. Paraskev Stoyanov" – Varna on 21.11.2024.

## **II . Content of the dissertation.**

The dissertation submitted for review has a total volume of 148 standard pages of text, illustrated with 4 tables and 20 figures. The bibliography includes 120 literary sources in English; it ends with Appendix 1 a three part questionnaire aimed at managers of medical institutions and specialists performing activities related to transplantation in ophthalmology.

**The topic of the dissertation is complex** - the subject of research is a medical problem, which legal aspects are interpreted.

**The relevance of the topic is undeniable** – it is in depth research, devoted to the problems of innovative transplantation technologies in ophthalmology. There is no comprehensive study on this topic in the Bulgarian scientific literature. The topic of transplantation in ophthalmology in general, is an obvious challenge for modern science, which the student has accepted and has made efforts to deeply analyze some of the scientific aspects.

**The topic is according to the standards for defense**, innovative, it provides an impetus for the development of this still underdeveloped branch of law, with theoretical and practical potential.

**It can be said that the doctoral student has successfully coped with this unconventional issue. The complex nature of the research has inevitably been reflected in the structure of the work, which follows the classical content of a medical research study, but also contains elements of a legal work. Its content includes :**

**Introduction** , in which the PhD student **justifies the choice of topic and its relevance** . The subject, main theses, goals and scientific tasks of the dissertation are outlined, while at the same time the theses are formulated , **which the author works to prove in the subsequent presentation** . According to the "canon" for a dissertation in the field of medical science, **the goals and tasks of the scientific research are reiterated at the end of Chapter One ( p.57 )** , already justified by the precise scientific review.

**The table of contents listed on page 2 of the work**, however, only sets out in detail the points of chapter one, and is content to only indicate the titles of chapters two, three, and four – which makes it difficult to navigate when reading the work.

**The first chapter, follows the classic composition of a dissertation in the field of medical science. It is visibly influenced by the clinical topic under study, but analyzed from the point of view of medical deontology and medical law. The chapter covers several inextricably linked parts, which in an accessible form for the reader, introduce the researched issues:** 1. Historical overview of **transplantation** – emergence and evolution; 2. **Donation** - moral and legal aspects; 3. **Tissues from eye banks** used in ophthalmology ; 4. Donor tissue, biological product, medical device ; 5. Regulations for the collection, processing, storage and distribution of tissues in Bulgaria ; 6. Legal regime of donation in the Republic of Bulgaria; 7. Summary ;

Perhaps from a systematic point of view, it would be more appropriate for item 6 of this chapter "Legal regime of donation" to follow immediately after item 2, dedicated to the moral and legal aspects of donation. The structure of the work, including its conclusion with **the goals and tasks** are unusual for a thesis in law sciences. But as I pointed out above, **this is the typical structure of a scientific study in the field of medicine and medical deontology, which is why it should not be discussed from the point of view of a legal study. The same applies to the content of the chapters and the titles adopted for them, and also include the composition and volumes. In general, chapter one plays the role of a theoretical basis for further research.**

**The second chapter**, entitled - completely in the spirit of medical stylistics " **Materials and Methods** ", includes first of all: (item 1) . **Analysis of the legal framework. However**, the simple enumeration of the regulatory acts governing transplantation in ophthalmology and innovative technologies in it, not fully covers the analysis of the legal framework stated in the title. In item 2. a comparison is made of the legal framework and clinical regulations for the application of tissues in ophthalmology in some European countries ; **Contribution to medical law contains item 3.** in which the legal regime of medical institutions is "identified", i.e. the legal regime of medical institutions is identified - with the status of a "tissue bank", according to the registration of the Medical Supervision Agency. It is examined on the basis of a quantitative analysis of the activities on eye transplantation in authorized medical institutions, through a survey conducted among specialists engaged in these activities; 4. Collection, summary and analysis of information from public registers on eye tissue transplants performed in Bulgaria and in leading European countries countries for the last 10 years; 5. Research into the legal barriers and reasons for the donor activity and formulation of an algorithm for work, facilitating the awareness of the population about the need for donation; 6. A look into the future - legal and ethical aspects of donation and transplantation in Bulgaria.

The study was conducted by the author over a period of 3 years and is based on legislative framework, registers of published data on transplantation and exchange of organs and tissues in Bulgaria and Europe. **The author's contribution** is also emphasized by the fact that the information is collected through own questionnaire surveys. The medical aspects are derived from public information in the available

registers and from the author's own experience as a legal advisor at Specialised Eye Hospital -Varna EOOD.

**Chapter three. Results.** The first part of it is again dedicated to the review of the published literature, and an analytical reading of the legal provisions relating to tissue transplantation in ophthalmology. It should be noted that this point of the dissertation work, although different in content, duplicates the title of item 1 of Chapter One. The two “reviews” have different purposes and content and it would be good to rethink the title of one of them. The chapter also contains a serious legal study, expressed in the comparison of the legal frameworks and clinical regulations for the application of tissues in ophthalmology in some European countries - France, Italy, Spain, the Netherlands. The attempt to analyze national and European specificities through a systematic analysis of legislative norms and to interpret them in the context of tissue banking and transplantation in ophthalmology is a **contribution** of importance.

This chapter again "identifies " the medical institutions with "tissue bank" status and on the other hand users of eye tissues, in accordance with the registration with the Medical Supervision Agency. A quantitative analysis of those authorised legal entities was also performed. While the research reflected in item 2 was conducted on the basis of an online survey , the one in item 3 of this chapter was based on a questionnaire survey among specialists engaged in these activities.

With a pronounced deontological focus are items 4 and 5 of this chapter – (4). Collection, summary and analysis of information from public registers on the performed eye tissue transplantations in Bulgaria and in leading European countries for the last 10 years and (5). Study of legal barriers and reasons for low donor activity and formulation of an algorithm for work, facilitating the awareness of the population about the need for donation. On their basis, the prognostic item 6. entitled “A look into the future – legal and ethical aspects of donation and transplantation in Bulgaria” is built. However, its place systematically would be more in chapter four.

**Chapter Four . Discussion** is also typical of a purely medical study, rather than one of a sociological and legal nature.

**The conclusion** ( p.131 ) is quite short, as the main conclusions are already presented in Chapter IV .

The part called **Conclusions** ( pp. 132-133 ) rather contains proposals de lege ferenda to the existing legal framework.

### **III . WORK EVALUATION**

**The contributions related to the dissertation work** (pp. 134-135) and their division into those of a scientifically applied, scientifically-theoretical and confirmatory nature, but the contributions are also in the preceding exposition of the thesis. A good example is development of new biological products and medical devices. The legal obstacles, as well as the economic difficulties in their application, are highlighted. Special attention is paid to the lack of awareness among society about the need for organ and tissue donation; to the lack of specially trained coordinators in medical institutions through which donation can be promoted; to the absence of national campaigns through

which accessible information can be disseminated to the population, leading to a better understanding of the meaning and public benefit.

In this regard, the algorithm developed by the PhD student for optimizing donation, including the work of donation coordinators at medical institutions, the application of various mediation techniques in order to improve communication between the persons appointed to this position and potential donors (or - their relatives who make a decision on organ and tissue donation in donor situations) should be properly acknowledged.

The Questionnaire for managers in medical institutions and specialists performing transplantation in ophthalmology, prepared by the doctoral student, has a **significant scientific and applied contribution** ( pp. 137-140 ) .

However, serious criticism should be directed at **the bibliographic reference**, the titles in which cannot be traced to what extent they were used in the text, since it completely lacks any citation ( either in the text or in a footnote ) . And this emerges as a significant weakness of the work - leading to the impossibility of verifying the actual use of the cited titles.

The author's basic understanding that " *human tissue is priceless and unfortunately in constant shortage* ", which requires the undertaking of a large complex of medical and legal measures to reduce this deficit is a key point. The measures proposed by the author are derived from the review of good practices in national systems in various European countries in the field of donation and transplantation. At the same time, they are compared with the shortcomings of our national legislation in this area, as well as with the real state of these activities in our country.

The doctoral student used different approaches to the object of research: documentary method (applied to the study of the theoretical basis for national and European legislation); historical method (through which it is traced the historical development of the studied objects); the comparative method (through which they are compared the statistical results of studies, reports and registers in the Republic of Bulgaria and in the studied European countries); legal method (used to compare national and European legislation in the researched area); logical method – (includes analysis, synthesis, comparison, summary of the studied phenomena and facts) ; graphical method (through which method the results of the study ); statistical method (used in processing data from the analyses). The methodology is complemented by activities to improve the awareness of the population. An "information brochure" was developed and printed, provided to a wide range of users. As a significant contribution of the work, **the mediation plan developed by the doctoral student should be acknowledged**, including the most important stages and participants in the complex process from donation to transplantation: coordinators, relatives of the deceased, recipients and society. The developed **algorithm for eye tissue donation** is innovative, with important practical application and demonstrates the author's social commitment.

A certain remark should be made about **the very large volume of the syllabus** – a full 84 pages ( more suitable for a dissertation for the degree of Doctor of Science ) , of which the content of the four chapters – 72 pages. The purpose of the abstract is to orient the reader in the most important conclusions of the dissertation, and not to repeat in detail the individual aspects of the research.

#### IV . OTHER PUBLICATIONS

The doctoral student has attached **4 publications , of which** one: Grupcheva, CN; Grupchev, DI; Usheva, N.; **Grupcheva, LO** Beauty versus Health—How Eyelash Extensions May Affect DryEye Disease? *J. Clin. Med.* 2024, *13* , 3101. <https://doi.org/10.3390/jcm13113101> is in a journal with an impact factor , and two others: **Grupcheva , L. Study** of the legal framework in the European countries in the field of transplantation in ophthalmology, *Varna Medical Forum.* 2024, *13* (online first). - **Grupcheva , L., D. Grupchev.** Legal aspects of transplantation in ophthalmology. GP news. 2024, *6* (289), are **on the topic of the dissertation work . In general, in the field of ophthalmology is the fourth publication:** N. Nikolova, L. Grupcheva, Hr. Grupcheva. Autologous serum drops, a possibility for treating patients with "dry eye". GP news. 2024, *9* (292): 50-5.; 21-5.

#### CONCLUSION:

Despite the critical remarks made on individual points of the thesis - a result of both the novelty of the researched issues and the complex nature of the work - medical and deontological, respectively medical-legal, and the inevitable peculiarities of the structure and the main emphases, such as **successful, the significance of the work and scientific diligence of the doctoral student should be appreciated .** The work contains **a number of scientific-applied and scientific-theoretical contributions, which is why I believe that it fully meets the requirements** of the Law for Development of the Academic Staff in the Republic of Bulgaria and the relevant Bylaws, as well as The Regulations for the Acquisition of Scientific Degrees at the Medical University of Varna, **for obtaining the educational and scientific degree "Doctor" in Public Health.** The indicated weaknesses do not go beyond the limits of what is permissible for a young author, for whom this work is the first significant work.

Based on the above, **I propose to the esteemed scientific jury to award Ms. Lora Ognyanova Grupcheva the educational and scientific degree of "doctor" in the scientific specialty "Public Health Management".**

12.01.2025

Sincerely:

**Prof. IVAN RUSCHEV, DSc**  
**Faculty of Law of Veliko Tarnovo**  
**University "St. Cyril and st.**  
**Methodius", Academician of the**  
**Bulgarian Academy of Sciences**

