

STATEMENT

by Prof. Elena Shipkovenska, MD, PhD

on the dissertation on the topic: "Legal aspects of innovative transplantation technologies in ophthalmology in the light of the law in the Republic of Bulgaria and other European countries" for the award of the educational and scientific degree "doctor"

Professional field:	7.4 Public Health
Author:	Lora Ognyanova Grupcheva
Form of doctoral studies:	Full-time
Scientific supervisors:	Prof. Maria Valkanova, Ph.D. and Assoc. Prof. Silvia Nikolova

1. General presentation of the procedure

The procedure for the defense of the dissertation work of Lora Ognyanova Grupcheva on the topic "Legal aspects of innovative transplantation technologies in ophthalmology in the light of the law in the Republic of Bulgaria and other European countries" under the doctoral program "Public Health Management", in professional direction 7.4 "Public Health" is conducted in accordance with the Order of the Rector of MU-Varna R-109-429 of 04.12.24. at the proposal of the head of the Department of "Social Medicine and Organization of Health Care", Faculty of Public Health, MU - Varna.

2. Evaluation of the dissertation work

Structure of the work

The presented dissertation work is built in an adequate, logical structure. After a staged introduction on 148 pages, with 4 tables and 20 figures, in 4 chapters the current state of the problem is examined based on literary data, goal, tasks and methodological approaches, analysis and discussion of the results, conclusions, directions.

The bibliography includes 120 literary sources.

Relevance

Transplantation in ophthalmology is an important element of medical activity, as it ensures quality of life for people in need. Transplantation requires tissues and organs that must be donated by a cadaveric donor, after the consent of relatives. The difficulties in donation in Bulgaria are associated with insufficient awareness among people about the need for organ and tissue donation, accompanied by the lack of specially trained coordinators in medical institutions and the absence of national campaigns through which accessible information about the benefits of donation would be disseminated to the population.

The Republic of Bulgaria has a satisfactory regulatory framework regarding the complete process of performing corneal and AM transplantation, and the application of medical devices, but the Bulgarian legal system lacks both a law that would regulate the transplantation of biological products obtained by multiplying cells on a suitable substrate - matrix, and legal norms that would regulate autotransplantation.

Therefore, the work of Lora Ognyanova Grupcheva is timely and practically oriented, as it is an attempt, based on her own theoretical and empirical research, to build a hypothesis about the legality and application of innovative ophthalmological technologies in the Republic of Bulgaria.

Purpose, tasks and methodological approaches

The purpose of the study is well formulated. The tasks specifying the implementation of the purpose are practically justified and cover the set goal.

The methodological tools used include documentary, comparative, comparative-legal, logical graphic and statistical methods. The survey on good practices in eye banking covers 4 managers and 8 employees of eye banks, 6 managers and 37 doctors from 23 medical institutions in the Republic of Bulgaria.

Evaluation of the results of the study

This dissertation work traces the historical emergence of transplantation eye surgery and contains a legal overview of the legislative framework in the Republic of Bulgaria and other EU countries.

The results provide substantiated data on the lack of legal regulations for biological products used in ophthalmology, which affects the activities of tissue banks and

transplantation in Bulgaria. The lack of legislative framework creates obstacles and an objective legal impossibility for the distribution of such products. The development assesses the country's prospects for the creation of new biological products and medical devices.

The social harm and negative consequences for public health associated with the lack of awareness among people about the need for organ and tissue donation are analyzed. The critical link between donation, transplantation and their financing, which is one of the fundamental problems in Bulgaria, is emphasized.

The study is an important step towards developing an algorithm including 5 steps for improving the effectiveness of "donation coordinators" at medical institutions. The author proves that improving communication between medical specialists 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.

The development analyzes the basic legal framework relating to donation and transplantation in several European countries, which reported the largest share of transplants performed per capita and the highest contribution in the field of donation.

Information from public registers on performed eye tissue transplants in Bulgaria and Europe shows that Bulgaria is the carrier of 4.2% of corneal transplantation in Europe, with a population of 1.4% of the European population, i.e. Bulgaria occupies a worthy place on the European map in this indicator. An analysis of the registers at the "EUROCET" was made and the strengths and weaknesses in collecting and publishing public information were identified.

The conclusions correspond to the results obtained, which shows that the tasks set have been fulfilled and the goal has been achieved.

I agree with the contributions formulated by the dissertation candidate.

The abstract to the dissertation correctly reflects the structure of the dissertation work and contains the most significant results of the study.

4 scientific publications have been published in connection with the dissertation work.

Personal Impressions I have no personal impressions of Lora Grupcheva, nor participation in joint projects and publications.

CONCLUSION

The development of a dissertation has **two aspects**: scientific and educational. Regarding *the first*: Lora Grupcheva's work represents a completed scientific product that meets the requirements set out in the Regulations of MU-Varna for the development of the academic staff. The goal and tasks are well formulated. The results and discussion correspond to the topic. An analysis of the legislative framework concerning transplantation, medical devices and biological products in the Republic of Bulgaria and Europe has been made, with an emphasis on leading countries: France, Italy and Spain. The weaknesses and legislative gaps have been assessed in the context of European directives. A special algorithm has been created for the implementation of a donor situation and processing of corneal tissue.

Regarding *the second aspect*: the author shows good knowledge of the problem, expressed in a rich literature review and assessment of modern scientific information and a specific scientific discussion of the results obtained. She has mastered the scientific methods - documentary and historical, as well as the methods - comparative, logical and sociological analysis.

All this allows me to propose to the members of the Scientific Jury to vote in support of awarding the educational and scientific degree "Doctor" to Lora Ognyanova Grupcheva in the field of higher education 7 "Health and Sports" and the professional direction 7.4 "Public Health".

15.01.2024

Signature:

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

Prof. Elena Shipkovenska, MD