

## **REVIEW**

By Prof. Darina Zinovieva Ph.D.,

Faculty of Law, Plovdiv University "Paisii Hilendarski"

**on the dissertation thesis "PUBLIC LAW ASPECTS OF PATIENT SAFETY" by EMILIA YORDANOVA ANGELOVA-HOVAGIMYAN,**

for awarding the educational and scientific degree "Doctor" in the field of higher education 3. "Social, economic and legal sciences", Professional field: 3.6 "Law", doctoral program "Administrative Law and Administrative Process", with supervisor Associate Professor Konstantin Pehlivanov Ph.D.

Pursuant to Order № 903 from 11.03.2021. I was appointed as a member of the scientific jury by the Rector of University of Plovdiv. Further, I was tasked to present a thorough review of the doctoral thesis.

### 1. Details of the candidate and the procedure

EMILIA YORDANOVA ANGELOVA-HOVAGIMYAN enrolled a part-time doctoral training in Public Law Department at the Law Faculty of Plovdiv University in February 2019. The thesis was discussed and recommended for public protection by the Public Law Department of the Law Faculty of Plovdiv University "Paisii Hilendarski"- on February 19, 2021 . The doctoral student has three scientific publications on the topic of the dissertation. The presented abstract meets the requirements and presents correctly with details the work and the conclusions in it. There is a signed declaration of originality.

### 2. Analysis of the dissertation and contributions

The structure of the thesis is well developed. It consists of an introduction, three chapters and a conclusion. It is systematically arranged as follows: first, the definitions of the term “patient safety” in historical aspect and in other countries are analysed. The next chapter examines the concept and manifestations in Bulgaria and the third chapter analyses the factors that contribute to the implementation of patient safety. In conclusion are systemised the conclusions reached and proposals for optimisation of the legislation.

In the first chapter, a detailed historical review of the origin of separate parts of the concept of patient safety is made. The author has analysed sources from different eras and presented her vision for the establishment of the concept of patient safety. The PhD student has made an extensive comparative analysis of the legislation governing parts of the concept or the whole concept of PATIENT SAFETY in more than a dozen EU Member States and third countries. A contribution in this part of the dissertation is the definition of PATIENT SAFETY by the author and its justification. It correctly covers all elements of this concept, including the various obligations to the subject with the status of a patient that the entire health system owes him. The author is also substantiated by a normative approach. A positive assessment should be given to the so-called by the PhD student "basic initiatives" to ensure patient safety worldwide. Thus, it considers acts of the WHO, as the largest public health management institution in the world, the World Alliance for Patient Safety, the European Patient Safety Network Project (EUNetPaS) and others.

As a logistical conclusion of the first chapter, it is a good approach to enter the international sources regulating the protection of patient safety. A number of soft law sources are listed, such as Declaration on Human Organ Transplantation (WMA 1987), Declaration on Euthanasia (WMA 1987), Recommendation on the Legal Protection of Persons Suffering from Involuntary Mental Disorders (CoE Committee of Ministers 1983) ,

Declaration on the Human Rights and Personal Freedom of Physicians (WMA 1985), Oslo Declaration - Opinion on Therapeutic Abortion (WMA 1983), Opinion on In vitro Fertilization and Embryo Transplantation (WMA 1987). and others.

In chapter two, the author makes a good study of the overall legislation, institutions, and their competence and acts of authorities and NGOs that in whole support patient safety. Thus, the author points out the role of the National Health Card as a state approach to provide affordable outpatient and inpatient medical care. She comments the role of the National Health Strategy, the National Development Program BULGARIA 2030.

In sequence, she lists the relevant regulations, with a subject that to some extent regulates the patient safety. A good impression makes the selection of bylaws such as Ordinance №49 of 18.10.2010 on the basic requirements to be met by the structure, activity and internal order of the medical establishments for hospital care and the homes for medical and social care, Ordinance for exercising the right of access to medical care (in force by 02.06.2006, last amend. SG. 29 from April 7, 2017), Decree № 8 of 03.11.2016 on prophylactic examinations and dispensary (effective as of 01.01.2017, last amended, SG. 2 of 4 January 2019), etc.

She considers the role of codes of ethics and their contribution as a soft law for patient safety.

Logistically, she distinguishes all central and local government bodies that are related to the patient safety, including those having exclusive competence during a crisis /e.g. district headquarters/.

In a separate part of the dissertation, Emilia Angelova analyzed the protection of patients by ruling on their complaints related to patient safety. Thus, she analyses the legal possibilities regulated by the Health Act, the Health Insurance Act, the possibilities on the grounds of Art. 93 of the Health Act to refer to regional health inspection in disputes related to medical care. She examines the defence before Medical Supervision Agency when patient challenges the quality of provided in a particular hospital care, and in detail she points out: "difficult access; delay in treatment; complications that occurred during the treatment and diagnostic process; misdiagnosis".

In Chapter 3, entitled "Quality and culture as a factor in improving patient safety - the responsibility of the doctor under Bulgarian law," the author makes an interesting analysis of patient safety, focusing on the quality of medical care. In paragraph (1) she analyses the historical term "Medical quality" and positive evaluation deserves the summary on patient safety consisting of several components: type, quantity and quality, and its conclusion that a set and gave them determine the extent of satisfying not the health needs of the patient. A good conclusion is that of the consumer capacity of medical care and the parameters of its measurement - changes in the health status of consumers; degree of satisfaction and efficiency.

This summary of the legal instruments that guarantee the overall safety of the patient deserves a positive assessment.

It deserves good a good score the ideal of the Ph.D. student to present a few doctrinal and institutional definitions of quality in healthcare, such as given by the Medical Institute (IOM) in 1990 in the United States, the Council of Europe and others.

In this part of the thesis Emilian Angelova considers the so-called risk management in patient safety, in order to minimize unwanted or

unexpected medical treatment outcome. The paper also analyses rather social factors such as risk management culture .

In a separate section, the doctoral student discusses eHealth and its relationship to patient safety. It traces the emergence of the idea worldwide.

She rightly concluded her that in general plan, eHealth affected the rights, rules, responsibilities and risks in health Internet, in use of health data and all information systems related to patients database.

Of interest is the part of the dissertation, entitled "Theories of errors." The author discusses the concepts specific to Medical Law, such as "Adverse medical event" and its content. She presents WHO statistics on patient disability. The author defines medical errors as "the failure of a planned action to be completed as intended or the use of the wrong plan to achieve a goal". She indicates the places in the medical establishments where there is the highest percentage of errors with serious consequences - in intensive care, operating rooms and emergency departments.

Well-presented is the analysis of medical error by correctly quoted author Radoynova and the definition in her study. I believe that Emilia Angelova is right to give her opinion that from a legal point of view a medical error is an act that is illegal and violates laws, rules and regulations.

For the purpose of comprehensiveness, she conducts research on the training related to patient safety in our health system - she focuses on both education and postgraduate continuing education by professional organizations. In the Conclusion, the author summarizes the contributions, namely: definition of patient safety, the proposal for the Patient Safety Act, spreading of territorial units of the Medical Supervision Agency, Register of Adverse Medical Events Reports, national register and internal registers of each medical institution, National Fund for Compensation of Patients.

### 3. Critical notes:

On the merits of the study, it is important for the author to make a clearer distinction between medical error and "adverse drug events" ( p. 270). The ambiguity of what the author means about the connection between these cases is good to be clarified.

The style needs to be optimized, as the author largely follows the style of public administration.

In some places the phrase needs finishment, for example "Responsibility of professional organizations – professional" (p . 292).

Despite the critical remarks, the study has contributions that may receive a positive assessment.

### CONCLUSION:

Based on the above, I believe that there are premises for awarding the educational and scientific degree "Doctor" to **EMILIA YORDANOVA ANGELOVA-HOVAGIMYAN**, and I give my positive assessment. I propose the scientific jury to award the educational and scientific degree "Doctor" in the field of higher education: 3. Social, economic and legal sciences Professional field: 3.6. Law, Doctoral Program Administrative Law and Administrative Process.

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/Prof. Darina Zinovieva/

14.5.2021

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