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## Aspects of legal regulation of national-level medical research

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■ **Abstract.** The relevance of the study is conditioned by the rapid development of the social and state system. Considering the development of political, economic, and social levels of life, and the issues of considering public opinion and raising the level of legal awareness of the public in the medical industry arise. The purpose of the study was to apply a correlation comparison of legal and medical sciences, and their combination with the subsequent use of applied legal dialectics in the sub-branch of medical law knowledge. To achieve this goal, the following methods were used: dialectical, logical and general scientific (observation and generalisation). The analytical processing of statistical information material from the medical sector is reflected in law-making and rule-making processes and acts, and is considered in the case law of the national level based on the decision of the European Court of Human Rights. Legal monitoring of officials authorised at the state level, practical interest of public organisations and certain segments of the population stimulated the innovative development of media-communicative content, which aims to convey the necessary materials of the legal component in the medical sphere in an adapted form. Such an example is the final products of thematic media content. The Academy of the National Health Service of Ukraine has developed useful resources supplemented by an electronic periodical. The specific feature and significance of the state course for the development of the medical industry in the legal sense are reflected in the specially developed material and the procedure for its submission, given the insufficient level of legal education in the potential audience. An innovation of development is the presentation of specific and significant legal and medical materials in a form adapted for perception and understanding and in a simplified form. The results of mastering the information resource of the medical legal field are of practical importance if it is used by consumers of medical services, medical personnel and the state – the body that monitors the relationship between doctors and patients

■ **Keywords:** medical worker; volunteer patient; medical industry; informatisation; society; information

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## ■ Introduction

In the context of European integration, foreign experience is borrowed at the state level. Due to rapid changes in legislation, civil society and medical professionals are experiencing a problematic issue of lack of awareness of the legal and regulatory framework in the medical industry. Ignorance of the legal regulation of the medical industry can become a real practical problem due to the lack of understanding by medical personnel of certain aspects of the onset of liability, including criminal and administrative liability for certain types of actions. The lack of understanding on the part of society in the person of potential patients of a certain procedure for applying to medical institutions, the lack of understanding of the importance of medical documentation, and the lack of data on the procedure for defending personal interests serve as obstacles in reflecting the positive dynamics of the development of the medical industry, its digitalisation and bringing it to the level of international standards (Demchenko, 2009).

The relevance of the study lies in the investigation of the issue of liability of medical workers. The issue has been considered by such Ukrainian researchers as R.V. Veresha (2014) and S.R. Dutchak (2018). In their papers, researchers covered problematic issues of increased criteria and requirements for the subjective composition and subjective side of the crime. There were proposals for codification and creation of a set of laws and regulations in the medical industry. National-level researchers investigate the positive aspects of the impact of legal regulation of the medical industry.

The European judicial system considers socially significant disputes at the practical level, the subject of which is the protection of a doctor's business reputation based on the results of spreading negative information (Bogomazova, 2020). However, an essential fundamental and weighty criterion for building a legal and impartial democratic society, with its further development and improvement, is the presence of stable stages, with a sign of a certain hierarchy in terms of applying certain legal norms. Foreign researchers have expressed their thoughts on the historical relationship between medical and legal sciences. Even the primitive aspects of medicine in the Far East required legal regulation (Yang & Zhou, 2023). The achieved levels of development of Far Eastern medical science are protected by law due to their social significance (Fu *et al.*, 2023). The European Health Data Space (EHDS), an ecosystem consisting of rules, common standards and practices, infrastructure and management structure, is subject to medical legal regulation. In modern Europe, the Data Governance Act (DGA) is legally defined in terms of protecting the personal data of clinical trial participants (Lalova-Spinks *et al.*, 2023).

Modern medical science uses the biomedical level with the borrowing of bio-jurisprudence, studies the impact on the development of bioethics principles, and uses the results obtained in judicial practice (Tarasevich, 2023). These results are of great importance in practice, but the methods of communicating with medical personnel and potential patients do not reach a significant level. Access to information materials in sufficient volume is provided to a limited number of subjects of disposal of such information. The legal procedure for using the medical legal mechanism is not fully established.

The need to develop medical legal norms is conditioned by the desire for a social democratic system, which is characterised by rule of law in terms of its application by society on a voluntary and equal basis, without the constant application of imperative coercion by the state. Legal awareness is a significant lever in the social "mechanism" for the implementation of personal interests. The right to health care and proper treatment is guaranteed to individuals at the state level, is an inalienable right, and is consolidated in the Basic Law of Ukraine<sup>1</sup>.

The search for an information approach to medical professionals and their patients remains relevant. Communicating reliable content of legal significance in terms of preventing the possibility of undesirable types of disciplinary, administrative, and criminal liability due to non-compliance with the established procedure for performing the duties assigned to a medical worker is of great importance.

The purpose of the study is to compare legal and medical sciences, to combine them with further application, systematisation, and use of the information component of scientific theoretical and practical provisions, including legislative provisions of legal norms. In accordance with the above, an assumption (hypothesis) is made regarding the onset of significant benefits for civil society and the state from the dispositive settlement of potential conflict situations in the medical field by independently mastering the necessary medical information and legal resources by the parties to the doctor-patient relationship. The use of a mandatory punitive method and the search for those responsible by the state in the event of adverse cases loses its effectiveness. Thus, the state can use the released time and human resources for the development of socially significant criteria and industries.

## ■ Materials and Methods

In the course of the study, the data analysis method was used to process the materials of the paper. Correlation analysis was applied to the combination of two separate doctrines – medicine and law – into

<sup>1</sup>Constitution of Ukraine. (1996, June). Retrieved from <https://zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80#Text>.

a specific sub-branch of medical law. In order to identify the correlation between the application of a combination of legal norms and medical science, the national regulatory framework has been developed, in particular: the Law of Ukraine No. 1629-IV of November 04, 2018 “On the National Programme for Adaptation of the Legislation of Ukraine to the Legislation of the European Union”<sup>1</sup>; Order of the Ministry of Health of Ukraine No. 95 of February 16, 2009 “On Approval of Documents on Quality Assurance of Medicines”, namely: guidelines of ST-N of the Ministry of Health 42-4.0:2008 “Medicines. Good Manufacturing Practice”, guidelines of ST-N of the Ministry of Health 42-7.0:2008 “Medicines. Good Clinical Practice”, guidelines of ST-N of the Ministry of Health 42-5.0:2008 “Medicines. Good Distribution Practice”<sup>2</sup>; Council Directive 75/318EEC of 20 May 1975. “On the Approximation of the Laws of Member States Relating to Analytical, Pharmaco-Toxicological and Clinical Standards and Protocols in Respect of the Testing of Proprietary Medicinal Products”<sup>3</sup>; EU directive 2004/9/EU of 9 June 1988 “On Inspection and Verification of Good Laboratory Practice”<sup>4</sup>.

An important information basis of the research was the results of the analysed studies, namely by: Z.I.Y. Gharaibeh (2022), V. Kononenko & M. Demura (2021). Moreover, a fundamental information base consisted of the results of researchers in the practical field of activity. P.H. Davydov & K.D. Yurchenko (2020), N. Antoniuk (2020).

To achieve this goal, the study used: dialectical and logical methods of scientific cognition. Using dialectical and logical methods in combination with the theoretical method of scientific cognition, the main structured information blocks were considered. Correlation analysis was applied in terms of combining legal and medical doctrines in the subject of research. Using the observation method, practical statistical observations of the current clinical study were carried out. The method of dialectical logic of cognition was applied at the theoretical level of the material processing. The methodological basis for the application of the dialectical method with subsequent assimilation and processing of information resources by identifying significant aspects of the legal field with subsequent application of legal norms through comparison – an empirical general scientific method of research,

in the medical field were legal acts, information resources of foreign origin, and research papers.

## ■ Results and Discussion

The study considered the state of development of medical law in Ukraine. Positive changes have been established in the context of reducing the manipulation of personal rights on both sides. Due to the lack of legal information in the medical sector, medical personnel and civil society have an insufficient level of legal awareness of the medical industry.

### Foreign experience in the context of applying national-level medical law

As a natural consequence of European integration, foreign medical legal experience is being adopted. Based on the study of the case No. 22750/02 “Bendersky V. Ukraine”<sup>5</sup> and the trials of war crimes before the Nuernberg Military Tribunals under Control Council law (1949), it was established that there are clear regulatory rules and procedures for their implementation. The law defines acts that are criminalised and incompatible with medical ethics, and as a result, make it impossible for a person to perform medical duties in the professional field.

Indicators of empirical observations, in particular in the framework of the EX9924-4473 Soul study by the Danish pharmaceutical company Novo Nordisk as of November 14, 2022, may indicate a relatively high level of consciousness of medical personnel and citizens of foreign countries. As of November 14, 2022, within the framework of the international clinical study of the Danish pharmaceutical company Novo Nordisk, 9 651 participants were registered in the clinical study of semaglutide (a cardiovascular drug that in some cases contributes to the reduction and control of body weight of a patient with type 2 diabetes mellitus) and other components within the framework of the Soul clinical study, which is represented in Ukraine by the LLC “Novo-Nordisk Ukraine” on a global scale. This number is 101.0% of the planned number of 9 555 participants. According to official data: the number of withdrawn participants is “0” persons (0%); the number of persons participating in the study is 7 344 persons (participants), the number of cases that failed is 1 499 participants, the named statistics are given on the date of November 14, 2022 (Articles of association, n.d.; EX9924-4473:

<sup>1</sup>Law of Ukraine No. 1629-IV “On the National Programme for the Adaptation of the Legislation of Ukraine to the Legislation of the European Union”. (2018, November). Retrieved from <https://zakon.rada.gov.ua/laws/show/1629-15#Text>.

<sup>2</sup>Order of the Ministry of Health Protection of Ukraine No. 95 “On the Approval of Documents on Quality Assurance of Medicinal Products”. (2009, February). Retrieved from <https://zakon.rada.gov.ua/rada/show/v0095282-09#Text>.

<sup>3</sup>Council Directive No. 75/318/EEC “On the Approximation of the Laws of Member States Relating to Analytical, Pharmaco-Toxicological and Clinical Standards and Protocols in Respect of the Testing of Proprietary Medicinal Products”. (1975, May). Retrieved from <https://op.europa.eu/en/publication-detail/-/publication/845d1ac1-0b12-4d7f-8cbc-821ae51a6b2d/language-en>.

<sup>4</sup>Directive No. 2004/9/EC “On Inspection and Verification of Good Laboratory Practice (GLP) (Codified version)”. (2004, September). Retrieved from [https://www.eumonitor.eu/9353000/1/j4nkv6yhcbpeywk\\_j9vvik7m1c3gyxp/vj3ecgdi4vz1](https://www.eumonitor.eu/9353000/1/j4nkv6yhcbpeywk_j9vvik7m1c3gyxp/vj3ecgdi4vz1).

<sup>5</sup>Case No. 22750/02 “Bendersky v. Ukraine”. (2007, November). Retrieved from [https://zakon.rada.gov.ua/laws/show/974\\_313#Text](https://zakon.rada.gov.ua/laws/show/974_313#Text).

Semaglutide..., 2020; Soul: Semaglutide cardiovascular..., 2022).

The EX9924-4473 Soul study is conducted on a global scale: in South and North America, South Africa, Europe, and Asia. It is clear that a sponsor, a medical (pharmaceutical) company, interacts with medical laboratories to submit and receive test results within a clinical trial. This approach is quite logical and understandable, because foreign pharmaceutical laboratories are equipped at a high innovative level in accordance with international standards adopted by the international community (EX9924-4473: Semaglutide..., 2020).

At the national level, this clinical trial is conducted in compliance with the norms and conditions of the clinical protocol for the treatment of diabetes mellitus (type II) (Unified clinical protocol for primary and secondary (specialised) medical care. Type 2 diabetes mellitus)<sup>1</sup>. The above indicates that it is advisable for medical personnel to master the legal norms of the medical field of clinical trials in order to prevent the possibility of adverse consequences in terms of disciplinary, administrative, and criminal offences or crimes.

### **Positivist aspects and media communication channels of legal regulation of the medical industry**

The absence of mandatory training of medical personnel participating in clinical (medical) research at the national level in legal norms and standards in clinical activity reduces the level of development of clinical trials in contrast to the mentioned one. Medical personnel involved in clinical trials receive comprehensive training on the medical aspects of the study with elements of legal regulation. Such classes are conducted by the sponsor of the medical study. The community's attitude to medical innovation plays an important role in formulating a conscious public attitude to the legal development of the medical industry. The correct communication to the civil society of the importance of medical research and the need for its existence for the innovative development of the state, without distortion of information material, serves as a significant contribution to the development of the medical legal field at the national level. At the national level of medical legal science, there is a lack of informative material regarding innovative legal regulation of the medical industry.

Considering the reforms at the national level, medicine as a branch of science is keeping up with modern innovations. Section 2 of the Law of Ukraine "On the Basic Principles of Information Society Development in Ukraine for 2007-2015"<sup>2</sup> states that the main task of developing the information society is to help everyone, based on the widespread use of modern information and communication technologies, to be able to create information and knowledge, use and exchange them, produce goods and provide services, fully realising their potential, improving the quality of their life and contributing to the sustainable development of the country based on the goals and principles proclaimed by the United Nations in the Declaration of Principles<sup>3</sup>. In accordance with the plan of action developed at the World Summit on the Information Society (2003), Resolutions of the Verkhovna Rada of Ukraine dated December 1, 2005 "On Recommendations of Parliamentary Hearings on Development of the Information Society in Ukraine"<sup>4</sup>, building an information society is a global challenge for the new millennium.

The search for opportunities to convey informative legal material to healthcare professionals and their potential patients remains relevant. Ultimately, criminal law and criminal procedure are special branches of legislation and are not necessarily studied by society. To create digitalisation and informatisation of civil society, adhering to the main directions of the state policy aimed at accelerated development and implementation of information and telecommunications technologies, to increase the availability of medical care, and patient safety means proving efficiency and optimising the work of all components of the industry. To create the conditions for a modern information and communication infrastructure for the introduction of insurance medicine and to implement the digitalisation of the healthcare industry, the government developed and implemented an electronic system for the registration and exchange of medical information between healthcare institutions, facilities, and organisations.

For the first time in Ukraine, in 2009-2013, a system of medical data exchange between medical institutions using information and telemedicine technologies was implemented and put into operation. The following innovations were introduced: electronic patient cards and standard statistical forms on electronic information carriers were put into operation;

<sup>1</sup>Law of Ukraine No. 1118 "On the Approval and Implementation of Medical and Technological Documents on the Standardisation of Medical Care for Type 2 Diabetes". (2012, December). Retrieved from <https://zakon.rada.gov.ua/rada/show/v1118282-12#Text>.

<sup>2</sup>Law of Ukraine No. 537-V "On the Basic Principles of Information Society Development in Ukraine for 2007-2015". (2007, January). Retrieved from <https://zakon.rada.gov.ua/laws/show/537-16#Text>.

<sup>3</sup>Declaration "On Principles of International Law Concerning Friendly Relations and Cooperation Among States in Accordance with the Charter of the United Nations". (1971). Retrieved from <https://digitallibrary.un.org/record/202170>.

<sup>4</sup>Law of Ukraine No. 3175-IV "On Recommendations of Parliamentary Hearings on Development of the Information Society in Ukraine". (2005, December). Retrieved from <https://zakon.rada.gov.ua/laws/show/3175-15#Text>.

medical and preventive healthcare institutions were provided with internet access; regional training seminars were introduced for system administrators, responsible managers of medical and preventive institutions on the organisation and operation of local electronic systems for registration and exchange of medical information. The system of medical data exchange between medical institutions using information and telemedicine technologies significantly simplified the work with documents and facilitated the processing of medical data, created for the rational collection, storage, and accumulation of data in the medical industry<sup>1</sup>.

### **Innovations in the medical segment of the economic market**

In order to fulfil the basic principles of the development of the information society in Ukraine for 2007-2015, for the purpose of the functioning of the electronic system of registration and exchange of medical information between institutions and organisations of the healthcare system, the electronic patient register was launched at the state level on June 6, 2012<sup>2</sup>. In accordance with paragraphs 5 and 7 of the resolution “On Approval of the Regulation on the Electronic Register of Patients”, the electronic patient register is an information resource of the Ministry of Health, which is maintained using Information technologies, electronic document management and electronic digital signature. On May 25, 2018, the resolution on the electronic patient register became invalid due to the adoption of a resolution of the Cabinet of Ministers of Ukraine dated April 25, 2018 No. 411 “On Some Issues of the Electronic Health Care System”, which approved the procedure for the functioning of the electronic healthcare system<sup>3</sup>.

Within the meaning of the law of Ukraine on criminal liability, a person of a patient – a volunteer, patient, or other person who has applied for medical care under the Criminal Code of Ukraine can qualify as a victim, an injured person, and therefore, fall under the existing elements of criminal offences (Veresha, 2006). The patient (clinical trial volunteer) as a direct victim of the crime was identified as the primary subject for criminal legal assessment, and a special subject of criminal violation of patient rights was identified – a medical professional (member of the research team), as well as persons equated to them and admitted to medical practice in accordance

with the current legislation of Ukraine. The form of culpability in case of violation of the patient’s rights is mixed: the attitude of a medical professional to the violation of the patient’s rights itself can be either intentional or negligent.

The Criminal Code of Ukraine includes articles that contain a disposition, hypothesis, and sanction for actions for which criminal liability in the medical industry may occur in the performance and/or improper performance of obligations imposed on employees by a medical industry. Certain articles of the Criminal Code of Ukraine directly establish the responsibility of a medical worker in relation to actions clearly defined by the Criminal Code of Ukraine. A certain action is characterised by the features of several articles of the Criminal Code of Ukraine. Sometimes, it is not immediately possible to trace the components of a crime. An example of this is the criminal law qualification in relation to Articles 140, 142, and 321-2 of the Criminal Code of Ukraine<sup>4</sup>. It is important to remember that the subject matter of proof of all four constituent elements of a criminal act may change during the process of proof. Each circumstance and their totality can be important, which can affect the qualification of the action. Due to the busy work schedule, constant changes and reforms, and the factor of performing complex and responsible work of an intellectual level with the use of practical skills, medical industry workers may have difficulties in finding, mastering, and assimilating legal information. The main theoretical provisions serve as a fundamental basis for hypothesising the expediency of applying correlation analysis to a combination of two sciences – medical and legal. The application of the general scientific empirical method was reflected in the practical processing of the medical database of the ongoing clinical study with the participation of international-level volunteer patients with the involvement of persons who meet the selection criteria at the national level in an official manner.

In the process of providing recommendations for improving the criminal law policy in the field of countering violations of patient rights, in order to develop the medical sphere at the international level, a hypothesis was put forward about the effectiveness of applying to persons who have violated the established procedure for conducting medical activities with the onset of serious consequences, deprivation of the right to hold positions or engage in professional

<sup>1</sup>Law of Ukraine No. 675 “On Approval of the Branch Programme “Electronic System of Registration and Exchange of Medical Information Between Institutions, Institutions and Organisations of the Health Care System”. (2008, November). Retrieved from <https://zakon.rada.gov.ua/rada/show/v0675282-08#Text>.

<sup>2</sup>Resolution of the Cabinet of Ministers of Ukraine No. 546 “On Approval of the Regulation on the Electronic Register of Patients”. (2012, June). Retrieved from <https://zakon.rada.gov.ua/laws/show/546-2012-n#Text>.

<sup>3</sup>Resolution of the Cabinet of Ministers of Ukraine No. 411 “On Some Issues of the Electronic Health Care System”. (2018, April). Retrieved from <https://zakon.rada.gov.ua/laws/show/411-2018-n#Text>.

<sup>4</sup>Criminal Code of Ukraine. (2001, April). Retrieved from <https://zakon.rada.gov.ua/laws/show/2341-14#Text>.

activities. It is proposed to provide at the level of the provisions of Part 1 of Article 55 of the Criminal Code of Ukraine the possibility of applying a penalty in the form of deprivation of the right to engage in professional activity by a special subject of a crime in the sense of holding a certain position and engaging in professional activity.

### **Prevention of criminal and administrative offences in the medical industry**

Aspects of medical law in the context of levelling the criminal liability of medical workers by applying methods of preventive legal nature of the medical industry have become the subject of discourse of scientists. A. Mykolayenko & O. Lemeshko (2016) considered legal issues of violation of the right to free medical care. V. Galay (2007) analysed the protection of patients' rights in the human rights mechanism in Ukraine. Yu. Shopina (2020) examined the criminal liability of a medical or pharmaceutical worker for committing a crime related to the performance of professional duties. S.V. Vasyliiev (2021) investigated the possibility of introducing a legal framework for the implementation of European legislation regulating the creation of innovative medicines at the national level. L.O. Hala (2022) conducted a historical analysis of the development and development of good clinical practice. D. Bogomaz & O. Nikiforova (2022) considered the legal aspects of emergency medical care and pre-medical care.

Among the foreign authors who devoted attention and time to the issue of research in this area is A.M.J. ten Have Henk (2009). The issue medical errors were considered by D.L. Weatherspoon & T.H. Wyatt (2012) and Y. Brazier (2017). Human rights through the prism of the components of comprehensive health care were studied by A. Stefano & M. Thérèse (2023). The legal determinants of the proper development of the health care system have not been fully explored, as noted by M. Thomson (2022).

The authors of this study agree with A. Mykolayenko & O. Lemeshko (2016) in terms of the expediency of covering theoretical legal problems of the medical industry. Of rational importance is the establishment by L.O. Hala (2022) of the legal connection between the historical aspects of the development of medical science and the legal conditions for the existence of medical science as such. The scientific developments of Yu. Shopina (2020) appear to be somewhat incomplete due to insufficient disclosure of special provisions of the criminal liability act. In terms of the focus of S.V. Vasyliiev's (2021) research, it is necessary to apply transitional provisions and stages of implementation of the latest procedures. V. Galay (2007) mainly focuses on the interpretation of regulatory aspects of patient protection. In an indirect sense, from this perspective, the

person of a medical professional seems to be always responsible in unfavourable conditions and conflict situations. After comparing this approach, the author of this study suggests that rational truth should be sought with impartiality.

The author shares the opinion of D. Bogomaz & O. Nikiforova (2022) on the positivist approaches of absolute assumption of freedom of speech in the medical field. It seems logical to refer to the judicial practice of the European Court of Human Rights in terms of considering the issue of spreading negative information about a doctor and making value judgments about their practical activities. The question raised by A.M.J. ten Have Henk (2009) in publicist scientific references to normative achievements of biomedical ethics is relevant. Borrowing ethical rules is appropriate because of their uniformity and recognition in the civilised world.

Applying the theoretical aspects of the study by D.L. Weatherspoon & T.H. Wyatt (2012), it seems important to make a proposal for the development of a simulation of theoretical and practical level with the plots of criminal cases and situational tasks for health care professionals. Such theoretical and legal resources and their practical solution in educational languages in a potential sense form the starting point for modelling the legal consciousness of medical professionals. The fundamental thoughts of Y. Brazier (2017) in dogmatic approaches and the search for specifics through the interpretation of concepts embedded in criminal law are relevant.

The author agrees with A. Stefano & M. Thérèse (2023) and M. Thomson (2022) in terms of the significance of social determinants of health, given that it is necessary to pay attention to the lack of research of the institute of legal determinants at the national level. Borrowing the complex components of fundamental historical and ethical aspects in combination with the fundamental legal values of the modern global level, in contrast to the activities of the mentioned researchers, it is necessary to make proposals regarding the consideration of existing legal mechanisms and medical elements from the standpoint of deepening into the criminal legal component. Even considering the existence of a single desire to improve the quality of medical services and the delivery of information data in relation to medicine from the point of view of legal sciences, as of 2023, there is no unified legal position and established practice regarding the combination of legal sciences and the medical industry. Thus, it can be assumed that such ambiguity in the interpretation of medical and legal positions is conditioned by a significant amount of informative data that is the basis for the development of both sciences – law and medicine.

In the study by O. Baranov (2023), in the field of problematic aspects of public law, the latest ways of

using artificial intelligence are considered. Issues related to the introduction of artificial intelligence relate to the medical industry through the introduction of computerised databases. Improper use of databases by a healthcare professional may result in administrative, disciplinary, criminal, and other types of liability. The informative material provided in the aforementioned paper, if adapted by specifying it in terms of medical activities with the provision of specific criminal law provisions, can be used to inform healthcare professionals.

The authors, providing informative materials, mostly prefer to present the material in a professional medical language with a publicist emphasis on the specifics of the medical industry in combination with legal norms without considering the criminal legal discourse. This approach reflects the legal context of the material in an indirect meaning in relation to the norms of criminal law, without summing up the results by providing recommendations in terms of summing up significant components to a rational conclusion of their application in a procedural criminal format. Legal professionals, such as: I.Y. Senyuta (2018) and O.V. Ustymchuk (2018), outlining aspects of medical legal norms, largely focus on normative information of general importance without providing specifics to a specific area of medical activity by improving the relationship between legal and medical sciences. The above means that informative material presented in scientific journals to a certain extent divides the target audience into separate segments. Some of the scientific and publicistic material will be useful for medical personnel, while the other part will be understandable to legal specialists.

Communicating legal norms that are relevant for medical science, given the specifics of the medical industry, is a fundamental lever for the development of medical activities and updating the sub-branch of medical law. Non-application and/or non-compliance with the norms and regulations of law in medicine lead to the connection of the administrative resource of the medical industry management body. As a last resort, the norms and provisions of the Criminal Code of Ukraine and the Criminal Procedure Code of Ukraine are used with subsequent negative consequences.

Therefore, the popularisation and dissemination of an adapted format of information material of a specific legal category in the medical field will serve as a preventive component for averting offences and misdemeanours in medical activities. By participating in clinical trials, the researcher will be able to get acquainted not only with the clinical criteria for rational conduct of medical research, but also receive practical material adapted for a person without legal education of the legal component of the thematic area. Detailed information will save medical

professionals from having to independently identify, systematise, and predict the legal consequences of their professional activities.

## ■ Conclusions

The use of digitalisation of the medical industry occurs with its reform in order to increase the legal awareness of medical workers and the public community. In order to develop civil society, strengthen public security, and improve public services, it is advisable to combine the capabilities of the media communication space with the beginning of the functioning of public media. Special attention should be paid to the development of a procedure for conducting preventive measures in terms of informing about the possibility of criminal liability in the medical industry.

A scientific fact is the phenomenon of the actual application of a combination of legal and medical aspects not only at the scientific level, but also in the daily activities of lawyers and medical workers. The combination of purely legal branches of knowledge with other types of sciences occurs through the reform of the social structure at the state level and through the interest of the masses, for example, in the case of commercialisation of certain types of work, and the provision of services in those areas that may require additional development due to social significance and economic interest.

Trends in the application of material norms in practice directly depend on the chosen dynamic method of their application. Due to the importance of the medical segment and the existence of a rational search for the proper application of the implementation procedure and legal mechanism in order to meet the needs of stakeholders and population groups of the modern state, there is a tendency for further development of medical law. In order to develop and promote practical application, the combination of legal and medical norms is of fundamental importance for the element of theoretical awareness of this segment. In other words, it is essential to inform civil society through media communication channels. As a result, there is a statement about the authenticity of the existence of medical legal norms, the lack of their proper consideration and attachment of true importance to them due to the low level of awareness of the group of interested and potentially interested persons concerned with the procedure for exercising the right to provide and receive medical care. The presence of media pluralism at the national level has been established. Due to the multiplicity of communicative possibilities of social significance, the delivery of the necessary information seems possible and appropriate. The theoretical significance of recognising the existence of medical legal norms and consolidating them in specific forms of medical law is a fundamental block of knowledge that can serve for the benefit of the rule of

law state and civil society, and provide development to the medical segment. The scientific value of the paper is reflected in the originality of the fundamental criterion for presenting information materials of the legal nature of the medical segment with their adaptation for civil society and doctors, healthcare workers, and medical personnel. The fundamental task is to formulate an information theoretical resource and its further application by practical skills.

The originality of this study consists in combining separate aspects of the two sciences into a legal sub-branch, with the possibility of applying its provisions at the practical level. A significant need to popularise a socially significant segment of medical legal norms is the lack of awareness of participants with the legal procedure for exercising their rights and obligations at a sufficient level.

The study results are reflected in the establishment of the regularity of the legal relationship between two doctrines – legal and medical, and in tracing the causal relationship between the application of legal science in the medical segment and the procedure for conducting

medical research. The findings of the study are an important criterion for the legal regulation of the medical industry, as they specify and clarify the materials that are important in the performance of professional duties by a medical professional. The results can be used in the development of a plan to increase the legal consciousness of the subject of application of the developed applied provisions.

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#### ■ Conflict of Interest

None.

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## Аспекти правового регулювання медичних досліджень національного рівня

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■ **Анотація.** Актуальність статті зумовлена стрімким розвитком суспільного й державного ладу. З огляду на розвиток політичного, економічного й суспільного рівнів буття, постає питання врахування суспільної думки та підвищення рівня правової обізнаності громадськості в медичній галузі. Мета дослідження полягала в застосуванні кореляційного зіставлення правових і медичних наук, їх поєднання з подальшим використанням прикладної правової діалектики підгалузі знань медичного права. Для досягнення поставленої мети використано: діалектичний, логічний та загальнонаукові (спостереження та узагальнення) методи. Аналітичне опрацювання статистичного інформативного матеріалу медичної галузі відображається в законотворчих і нормотворчих процесах та актах, ураховується в прецедентній судовій практиці національного рівня з огляду на рішення Європейського суду з прав людини. Правовий моніторинг уповноважених на державному рівні службових осіб, практична зацікавленість громадських організацій та певних верств населення стимулювали інноваційний розвиток медіакомунікативного контенту, що має на меті в адаптованій формі доносити необхідні матеріали правової складової в медичній сфері. Таким прикладом можуть слугувати кінцеві продукти медійного контенту тематичного напрямку. Академія Національної служби здоров'я України розробила корисні ресурси, доповнені електронним періодичним виданням. Особливість і значущість державного курсу розвитку медичної галузі в правовому значенні відображаються в спеціально відпрацьованому матеріалі та порядку його подання, з огляду на недостатній рівень правової освіти в потенційній аудиторії. Новацією розвитку постає подання специфічного та значущого за змістом правового й медичного матеріалів в адаптованій для сприйняття та розуміння формі та спрощеному вигляді. Результати опанування інформаційного ресурсу медичної правової галузі мають практичне значення в разі його використання споживачами медичних послуг, медичним персоналом і державою – апаратом, що здійснює контроль взаємозв'язків між лікарями й пацієнтами

■ **Ключові слова:** медичний працівник; пацієнт-волонтер; медична галузь; інформатизація; суспільство; інформація