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Maria Karpushyna*
Kyiv, Ukraine

Roman Veresha**
Kyiv, Ukraine

Unification of Medical Legal Norms and Criminal Liability in the Context of Globalization of Clinical Research

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Abstract: The relevance of the article is attributed to the swift evolution of the social and state system. With the advancement of the political, economic, and social dimensions of existence, there is a growing need to consider public opinion and enhance public legal awareness in the medical domain.

The purpose of the study is to apply correlation analysis in comparing legal sciences and medical sciences, combining them, and subsequently utilizing applied legal dialectics within the realm of medical law knowledge.

To achieve this goal, dialectical and logical methods, as well as general scientific methods such as observation and generalization, were employed.

Globalization processes are supranational in nature, and under conditions of driving factors are subject to constant development. The medical field is not an exception and is influenced by other sciences, including legal doctrine, informatics, and economics.

Clinical research in the medical field is subject to international influence and development, unification and legal regulation. Internationalization processes are making innovative adjustments to the development of medical science, introducing advancements such as artificial intelligence, personalized medicine, predictive medicine, preventive medicine, participatory medicine, and precision medicine. Consequently, personalized patient data is designated as sensitive and necessitates additional legal regulation. Additional attention is paid to the issue of criminal liability of medical workers as special subjects of professional activity.

The results of research are reflected in the established search routes of the possibility of improving legal awareness of medical personnel in the context of practical professional activity. Such practical ways can serve as: the creation of informative material of legal content, adapted to the

* Maria Karpushyna – Postgraduate Student, Academy of Advocacy of Ukraine; ORCID ID: https://orcid.org/0000-20003-4125-4202; e-mail: karpushyna@meta.ua.

Roman Veresha – Doctor of Law, Academy of Advocacy of Ukraine; ORCID ID: https://orcid.org/0000-0003-4996-0283; e-mail: rveresha@gmail.com.

understanding of persons who are not specialists in the field of law, instead, they are professionals of high intellectual level of medical services.

The practical importance of the results of creating information and legal content of the medical industry can be reflected in the results of advanced training by medical personnel, in addition, in the elements of self-education of doctors – researchers, private doctors – specialists, etc. Analytical study of the statistical informative material of the medical industry is reflected in legislative and normative legal acts, taken into account in the case law of the national level, taking into account the decisions of the European Court of Human Rights.

Keywords: medical worker, innovative development, criminal liability, clinical trial protocol, globalization, unification, personal data

Introduction

In the context of the global development of the modern information society, with the rapid passage of time and a significant amount of changes in the digital industry and digitalization of the global economic market, civil society always needs high-quality medical services and legal awareness in their provision and receipt. In order to develop the pharmaceutical and medical industries of the global drug market, leading pharmaceutical and medical companies and corporations occupy a separate economic niche in relation to the development of new medicines. For the legitimacy of the implementation of the procedure for the development of medicines in the international arena, uniform unification norms are formed regarding the procedure for conducting medical research in Europe, Asia, America (Siddaramanna et al., 2016).

Madadin et al. (2021, p. 521-526) outline the requirements for the international clinical protocol of the latest study drug. The study discusses criminal liability for committing criminal acts in the medical field and the medical case. As part of the development of globalization processes, authors propose a unified intercontinental approach to the use of medical-legal case (MLC).

The article's relevance is attributed to the globalization of the medical and pharmaceutical sectors of the economy, marking a qualitatively new stage of internationalization. The global processes of the human community are associated with the expansion of human activity beyond the national framework, with the subsequent transformation of such activity into transnational forms. Consequently, the conditions of coexistence of the individual, national and supranational are constantly changing. Global phenomena determine the independent existence of national state institutions and doctrines (Lauber & Brooks, 2023).

Globalization processes are covered by geopolitics, and political measurement, containing structured elements of various models and forms of world order. Formation of a single social, political, economic (Mialon, 2020), cultural space, determines the formation of a single legal space. Implementing globalization seeks to establish uniform legal processes in the medical sector, aiming to enhance legal awareness and understanding within civil society. Reporting to interested persons of socially significant information material should take into account the specifics of medical activity (Ma et al., 2023).

The functioning of the global social system is impossible without appropriate legal regulation. Legal regulation is an effective way to prevent conflicts of interest, creates an established order of existence (Godziewski, 2020).

Globalization processes serve to create legal socialization, which is manifested in the expansion and improvement of social activities of the state. In supranational machines there is an expansion and strengthening of the sphere of procedural regulation, there is an improvement of the procedural form. By legal analogy, with reference to Article 8 of the Civil Code of Ukraine, imitating the content of the proposal of S.V. Hrynchak (Hrynchak, 2019, p. 15–25), it is a rational proposal to combine Articles 139 and 140 of the Criminal Code of Ukraine into one article with division into parts – with the provision in the first part of such article for liability for criminal misconduct, namely for failure or improper performance by a medical professional of his professional duties, and the second part of establishing responsibility for a crime – the same act that entailed grave consequences for the patient (Streltsov & Kuzmin, 2019).

Relations in the field of national jurisdiction of states, interstate relations, private legal relations between persons of different states constitute a global socio-legal system. The above components form legal supranational relations – transnational law, which is an international contractual autonomous system of

private legal regulation. Qualitative unity between these legal phenomena, as defined by Professor R.V. Veresha, is termed an integrated legal system. (Karpuntsov & Veresha, 2023, p. 101–104).

Methodology

In the study of the fundamental documentary base, the following methods were used: the method of correlation analysis, the method of dialectical logic of knowledge, the methods of scientific knowledge – the general scientific empirical method and the theoretical method, the philosophical method.

During the writing of the article, the following methods were used: a general empirical method of observation, a theoretical method of the general form of the movement of scientific cognition, the law of reflection of reality in thinking and a complex elementary theoretical method. The problem of ignorance in professional and scientific and innovative activities is subject to analysis using empirical and theoretical methods of cognition. By matching and comparing objects, the basis for convergence of legal systems is formed, the methodology of comparative law is formed. Forms of such rapprochement can differ significantly in some cases: for example, within the framework of integration processes in the European Union, the unification of legal norms is considered optimal. Otherwise, the adoption of model legislation is more effective. This type of harmonization of legislation as a form of rapprochement is successfully used in US legal practice. Under modern conditions of development of globalization processes, a practical form of application of judicial precedent is actively used. Legal borrowing gives the expected result if it is based on the methodology of comparative law. Conducting comparative and legal studies establishes the possibilities and limits of convergence of legal systems. The essence and content of legal systems is linked to the inherent factors of social existence: political, religious, ideological, philosophical and other factors of functioning of civil society. If comparative law is applied, it is possible to formulate a holistic view of the world legal panorama. A positive consequence of legal comparison and legal borrowing is the effective formulation of a respectful attitude to a foreign legal culture. Legal borrowing as a national requires the use of an adapted form and revision of the sequence of presentation of material that reveals the formation, evolution and functioning of various legal systems (Legal comparativistics (Topic 1), d.b.), (Zharovska, 2015, p. 191–195).

In combination with the possibility of pluralistic application of legal norms of national level and international importance, the outlined legal unity, if applied, will play a decisive role in the development of scientific research in the field of medicine. The statement given is explained as follows. The development of innovative medicine is impossible without clinical trials and scientific research in the medical field. However, the development of this industry can receive only if it is legitimate. Medical practice can be based on different cultural foundations and traditions, use several methods regardless of state boundaries, provided that doctors recognize a specific approach by specialists and their patients. However, subject to the various legal systems that apply in the legal systems of different states, the medical capabilities of the transnational level may be somewhat limited (Gansetska, 2020).

The basis for this is the imperative state lever for licensing and carrying out mandatory registration actions of the subject of medical activity, the presence of certification and accreditation in the medical field, the obligation to comply with certain norms and rules, the development of special medical programs with the indication of a certain procedure for actions, and reporting on their further compliance. That is, given the desire for innovative medical development, only legitimate and legalized medical activity can be successful. Significant inhibition of the development of the medical industry plays negative legal factors. They may be recognized as non-confirmation of qualification, lack of a medical license, improper clinical practice, lack of understanding of the current legislation, lack of awareness of the administrative procedure for working with medical documentation, non-compliance with the established procedure for conducting a clinical study, etc. (Kononenko & Demura, 2021, p. 135–151).

Significance of national-level clinical studies involving a foreign investor

The modern world cannot exist in conditions of seclusion of legal cultures. There are processes of in-

teraction between legal systems and legal cultures at the level of legislation, judicial practice, legal science, legal education. The globalisation jurisdictional system certainly accommodates legal borrowing. Legal borrowings are characteristic features of the evolution of law. The reason for this development is the lack of monopoly in the legal system on legal discoveries. On the other hand, a sign of the implementation of legal borrowings is their criticism. Criticism and negative attitude to such innovations arise due to the relative risk of deterioration of the existing legal situation due to the consequences of the introduction of the latest legal (legal) models.

The following authors were involved in the study of the field of medical errors in the context of globalization aspects: Lauber, K., & Brooks, E. (2023), Madadin, M., Alqarzaie, A. A., Alzahrani, R. S., Alzahrani, F. F., Alqarzea, S. M., Alhajri, K. M., & Al Jumaan, M. A. (2021), Mialon, M. (2020), Godziewski, C. (2020), Karpuntsov, V., & Veresha, R. (2023), Zharovskaya, I. (2015), Gansetska, V. (2020).

Certainly, we can acknowledge the social significance of the author's scientific journalistic works. However, given the continuous development of the information society, the provided information materials may not fully reflect the current state of events. And then the topic needs improvement.

The following authors paid attention to the issue of increasing the legal consciousness of medical professionals in their works: Ma, T., Li, C., & Liu, Y. (2023), Ost, S. (2020), Chekhun, V., & Rossilnaya, O. (2023), Săraru, I. (2018), Siddaramanna, T.C., Kumar, D.R., & Yogesh, C. (2016).

Exploring this direction appears suitable in the context of dogmatic development and popularization. Due to the novelty criterion of this topic, potential procedural procedures and ways of development require further refinement.

The authors paid attention to the journalistic development of the problematic issue of criminal liability of medical professionals: Raposo, V.L. (2019), Hutorova, N.O., & Pashkov, V.M. (2019), Grynchak, S. (2019), Kononenko, V., & Demura, M. (2021), Streltsov, Y., & Kuzmin, E. (2019).

It is very appropriate to follow the procedure for finding imperative civil ways to overcome contradictory conditions and understudied points that serve as the material basis of the legal norms of the law on criminal liability.

This article offers a definition of the legal application of the international clinical protocol for drug studies conducted with the participation of a patient-volunteer, commissioned by the study from a foreign investor, a commercial pharmaceutical company. The International Clinical Protocol contains symbiosis of legal norms and medical prescriptions, and therefore falls under complex specific regulation in the combination of two doctrines ("Awareness of Medico-Legal Issues among Medical College Health Professionals", 2020).

A wide range of participants in relations together with regulatory and regulatory authorities, to some extent complicate the unification of the process of a sound understanding of international medical law and innovative medical activities.

Awareness and implementation of the conditions of the international clinical protocol by the doctor is the main condition imposed among other requirements, such as the presence of an appropriate specialized medical education, the performance of the duties of a doctor in the specialty, and appropriate qualifications for participation in clinical studies by medical personnel. As a rule, other related explanatory and informative documentation is provided to the main protocol of the drug subject to testing. For example, during the main study, an accompanying instruction was provided with tips for overcoming the patient's problems and avoiding discontinuation of treatment (Effects of oral semaglutide on cardiovascular outcomes in individuals with type 2 diabetes and established atherosclerotic cardiovascular disease and/or chronic kidney disease: Design and baseline characteristics of SOUL, a randomized trial – PubMed, d.b.).

A relatively new subject of legal discourse can be the process and results of the process of comparing medical ethics in medical activities, taking into account the introduction of artificial intelligence in professional activities, and their impact on the results of pre-education (Parker, d.b.).

Leading countries, such as North America, Canada, artificial intelligence introduced into use with the regulation of legal regulation of the latest development. The goal of using artificial intelligence is to simplify the procedural order of medical clinical research by using innovative technologies. In medi-

cal science at the practical level, artificial intelligence is used in software interfaces, including voice recognition, in order to simplify the process of filling out clinical and administrative documentation for computer detection of deviations in medical images (Jassar et al., 2022).

Therefore, subject to the perception of medical ethics of the use of medical practice of artificial intelligence in professional activities, the development and implementation of the latest educational programs, with the subsequent application of the obtained results in professional activities, becomes logical (Tackett et al., 2021). The scientists O. Chekhun and O. Rossylna have examined the problematic issues related to the contemporary search for ways to introduce an integrated legal model of human-indicative medicine. The transformation of the health system aimed at addressing the challenges of the present in relation to the definition of criteria and the clear legislative delineation of certain medical categories. The factors contributing to the development of innovative medical tasks include: 1. Personalized (personalized) medicine. 2. Predictive (predictive) medicine. 3. Preventive (preventive) medicine. 4.Participatory (participatory – motivative in the context of patient participation) medicine. 5. Precision (precision) medicine. The listed factors represent a fundamentally new ideology of medicine. The transformation of the medical industry, especially its preventive components, is a lengthy process that necessitates in-depth analysis and reforms in related sectors of the economy. Innovative medical development of medicine determines the introduction of specialties and qualifications of a new format, such as: – manager for human capital development; – specialist in artificial intelligence in the field of medical technologies; – manager for health management, doctor-designer of health programs, organizer of health space, etc. (Chekhun & Rossilnaya, 2023, p. 142–159).

Patient Rights Protection Issues

In the field of medical research activities, safeguarding the rights of patients who voluntarily participate in medical research is a crucial concern at the national level. With the development of information technologies in the medical field, namely, the introduction of information and telecommunication technologies in combination with an increase in the volume and direction of the use of information, its transmission by the latest means of communication has significantly expanded the possibilities for collecting, storing and processing information in health care institutions. Activity in the formation of automated databases, processing and dissemination of information about persons without their knowledge, consent, led to the problem of information security of both medical workers, patients and third parties regarding the protection of personal data. That is, the problem of protecting the interests of a person in the medical field is also the problem of protecting personal data regarding the activities of a person in health care institutions. The lack of a well-defined mechanism for the comprehensive regulation of the collection, utilization, and disposal of personalized information in the medical domain poses a potential risk, as indicated by scholars, for the infringement of the right to privacy concerning such information. (Kotaleychuk, 2006, p. 45–46).

From the moment the Ombudsman (the Commissioner for Human Rights) is entrusted with the powers in the field of personal data protection, after a full open discussion and proposals made, by order of the Commissioner for Human Rights, the documents regulating such activities have been approved. We are talking about: Typical procedure for processing personal data; Procedure for implementation by the Commissioner of the Verkhovna Rada of Ukraine for Human Rights of control over compliance with the legislation on the protection of personal data and appendices thereto; The procedure for notifying the Commissioner of the Verkhovna Rada of Ukraine on the processing of personal data, which poses a special risk to the rights and freedoms of personal data subjects, about the structural subdivision or responsible person organizing the work related to the protection of personal data during their processing, as well as the publication of the specified information and appendices thereto (On Approval of Personal Data Protection Documents, 2014).

Civil, disciplinary, criminal and administrative liability shall be applied for violation of the legislation on the protection of personal data in accordance with the procedure stipulated by the current legislation (Muliar, 2020, p. 45–49).

Criminal liability in the field of medical research

On the grounds that criminal liability is recognized as the strictest type of punishment, the issue of research and development of aspects of criminal liability remains relevant (Hutorova & Pashkov, 2019, p. 9–25). Following an analytical review of the current versions of articles 141 and 142 of the Criminal Code of Ukraine, there are proposed refinements. These refinements emphasize the author's revision, giving special attention to the conduct of clinical trials of medicines without informed consent. Additionally, it is suggested to include the term "written consent" in the content of Article 141. The concept of "informed" or "personalized informed electronic or written consent" would be further clarified through a detailed explanation in the article's notes. The reason for this is the public importance of protecting personal data at the national level (Mohd Salim et al., 2023). It seems possible to make a proposal in terms of the layout of hypotheses, dispositions and sanctions of Articles 142, 321-2 of the Criminal Code of Ukraine in one article, with the concretization of qualifying circumstances by the substantive form of Article 321-2 of the Criminal Code of Ukraine and the addition of the hypothesis and dispositions of Article 142 of the Criminal Code of Ukraine by Article 321-2 of the Criminal Code of Ukraine. By analogy (taking as a prototype) of the criminal legislation of France, it is possible to provide proposals for the introduction into the Criminal Code of Ukraine of sanctions codified norms of criminal liability as a subject of a legal entity (Menchinsky, 2017).

Codified US criminal liability legislation does not contain certain criminal liability of a legal entity. However, according to the formation of a judicial precedent, on the example of applying sanctions to corporations, the introduction of liability to legal entities, in the form of property fines and confiscation of property, is practiced in criminal proceedings. A notable innovative aspect involves the potential option of incorporating, within the sanction component of the Criminal Procedure Code of Ukraine, a mandatory provision stipulating the obligatory dissolution of a legal entity. This question remains debatable (Panchenko, 2017, p. 193). The proposal of Hovpun O.S., stated in the scientific dissertation "Administrative and legal support of pharmacy in Ukraine" regarding the development of the adoption and implementation of the Pharmaceutical Code at the national level, seems very acceptable. It appears prudent to broaden the scope of regulation in the proposed legislative act. Therefore, it is suggested to consider the adoption of the Medical Code of Ukraine. This code would encompass administrative, economic, and civil aspects of the medical process, featuring both imperative and discretionary norms to regulate the field of medical law. (Herring, 2020, p. 149–172). In addition, with the adoption of the Medical Code at the national level, the question of supplementing the Criminal Code of Ukraine with certain acts directly or indirectly regulated by the legislation proposed above (Ost, 2020) is appropriate. Preventive measures for the commission of misdemeanors and crimes described in the articles, which can be supplemented by the current Criminal Code of Ukraine, could be implemented in much easier and simpler ways, since all of them would be subject to assembly in one legislative act – the Medical Code of Ukraine, and therefore became easier to perceive, both by medical personnel and patients, other interested persons who are not specialists in the field of law, therefore, they face significant difficulties in the process of understanding and implementing relevant specific legal norms (Khovpun, 2020, p. 158). In addition, in medical practice there are cases when the question of the legality of the act seems to be a very ambiguous and debatable issue. Sometimes, acting conscientiously and professionally, a specialist in the medical field can border on the "junction" of the legitimate and illegal (Săraru, 2018, p. 93–95).

Conclusions

The description above implies that, according to the law of Ukraine on criminal liability, an individual who acts as a volunteer, patient, or someone seeking medical care can be considered a victim. This suggests that they may come under the existing provisions of criminal offenses (misconduct), even if such individuals have no complaints against a medical specialist and may even support them in a contentious situation. The primary focus for a criminal legal assessment is the patient (a volunteer in a clinical study) as the direct victim of a crime and a special subject of criminal violation of patient rights. Additionally, medical work-

ers (members of the research team) and individuals considered equal to them and authorized to practice medicine according to the current legislation of Ukraine are also relevant in this context. However, in order to obtain the status of a victim in a number of criminal offenses in criminal proceedings, it is not always necessary for an individual to acquire the status of a patient as a participant in legal relations with medical institutions, institutions, etc. The form of guilt in the violation of patient rights can be characterized by direct intent or be mixed. The medical professional's attitude towards the violation of the patient's rights can be both intentional and negligent, with the consequences being careless. However, it is possible to formulate proposals to improve the system of legislative regulation of legal relations regarding the protection of patient rights in the understanding of legal support for the field of medical research with the participation of a foreign investor. In the process of forming proposals to improve criminal legal policy in the field of combating violations of patient rights and the procedure for conducting clinical studies (with the participation of a foreign investor), with the aim of increasing the level of social trust in the state, developing the medical field internationally, and further preventing crimes in this sphere, it is also suggested to emphasize the effectiveness of applying sanctions to individuals who have violated the procedure for conducting clinical trials. Such violations may lead to infringements on patient rights and result in serious consequences for the patients involved, justifying the deprivation of the right to hold positions or engage in professional activities for those responsible. A proposal could be made to legislatively outline, within the provisions of Part 1 of Article 55 of the Criminal Code of Ukraine, the possibility of imposing punishment in the form of deprivation of the right to engage in professional activities for the specific individuals involved in the crime, taking into account their positions and professional activities. In respect of persons who have not previously had and do not have a professional status in the medical field, it is advisable to create a specific register with the introduction of personal data in order to create a (potential) ban for a certain period (term) to receive the right to engage in professional medical activities and other medical activities, other types of medical activities. Guilt as a criminal legal category and an integral component of the grounds for the occurrence of criminal liability of a special subject of a criminal offense in the medical field should not be identified with some other related legal concepts. Taking into account the general separate highlighted provisions of a significant mass of information flow of specific medical documentation and special legal norms of the medical industry, it is a rational proposal to supplement the existing legal norms with the adoption of the Medical Code of Ukraine. According to the results, the state of development of medical law of Ukraine is investigated. 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 of the medical industry, medical personnel and civil society have an insufficient level of legal awareness of the medical industry. The novelty of this work is reflected in the combination of certain aspects of the two sciences in the legal subgroup, with the possibility of applying its provisions at the practical level. A significant need to popularize the socially significant segment of medical legal norms is the ignorance of participants with a procedural procedure for exercising their rights and obligations at a sufficient level. The results of the study are reflected in the establishment of a legal relationship between the two doctrines – legal and medical, and in the tracing of the causal relationship between the application of legal science in the medical segment and the procedure for conducting medical research.

Primary for criminal-legal assessment defined:

- patient (volunteer clinical study), as a direct victim of the crime, defined a special subject of criminal violation of the rights of the patient;
- medical worker (member of the team of researchers);
- as well as persons, equated to them and admitted to medical practice in accordance with the current legislation of Ukraine.

The form of guilt in the violation of patient rights can be characterized by direct intent or be mixed. The medical professional's attitude towards the violation of the patient's rights can be both intentional and negligent, with the consequences being careless. In the Criminal Code of Ukraine there are articles that contain a disposition, hypothesis and sanction regarding actions for which criminal liability in the medical industry is possible in the execution and/or

improper execution by a medical industry employee of the obligations assigned to him.

Certain articles of the Criminal Code of Ukraine directly establish the responsibility of a medical professional in relation to the actions clearly indicated by the Criminal Code of Ukraine. The certain act is characterized by the signs of several articles of the Criminal Code of Ukraine. Sometimes, it is not possible to trace the components of the crime immediately. An example of this is criminal legal qualification in relation to articles 140, 142, and 321-2 of the Criminal Code of Ukraine. It is important to remember that the subject of proof of all four components of a criminal act can change during the process of proof. Important can be every circumstance and their totality, which can affect the qualification of the act. It may be noted that due to the busy work schedule, constant changes and reforms, and the factor of performing complex and responsible intellectual work with the use of practical skills, medical workers may have difficulty finding, mastering and mastering legal information (Raposo, 2019, p. 240–254). The analytical study of statistical information in the medical industry is reflected in legislative and regulatory legal acts, taking into account national case law, decisions of the European Court of Human Rights, and international practices (Hodson, 2019, p. 183–203). Legal monitoring of authorized officials at the state level, the practical interest of public organizations and certain segments of the population began the innovative development of media-communicative content, designed in an adapted form to convey the necessary materials of the legal component in the medical field (Tsimpri, 2018). This example can serve as the final media products of the thematic direction. The resources developed by the Academy of the National Health Service of Ukraine are useful, supplemented by an electronic periodical. The peculiarity and significance of the state course of development of the medical industry in the legal sense is reflected in the specially worked material and the procedure for its presentation, taking into account the lack of awareness in the potential audience of legal education.

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