Problemy Prawa Karnego 2025, T. 9, nr 1
s. 1 z 24
ISSN 2353-9712
https://doi.org/10.31261/PPK.2025.09.01.04

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A legal impact on the development of medical (clinical) trials at the national level in Ukraine

Abstract: The purpose of writing this article is to compare legal and medical sciences by combining them with further systematization and use.

In today's turbulent environment, the implementation of informatisation of the medical community, including their patients, remains a relevant research vector. Practical implementation of the results of civil society development, in the form of effective activities is to raise legal awareness of a specific area of medical activity. The practical level of medical activity, includes the mandatory criterion of meeting the quantitative and qualitative levels of requirements, such as: specialised (branch) of medical education (also, educational specialization that can be equated to medical); high quality of tasks; professional experience, etc.

Keywords: healthcare professional, innovative development, artificial intelligence, clinical trial protocol, globalization, unification, personal data

1. Introduction

Given the turbulent conditions of existence in which the State of Ukraine is living, in connection with the rapid development of events at the political, economic and social levels of human existence, it is important to take into account public opinion, increase legal awareness of medical professionals and the public in the medical field. An essential condition for integration processes is the innovative development of economic components at the national level. In these conditions, medicine contains socially important sectoral features and needs to be developed in the context of building a democratic society. The medical area of clinical trials contains

components of biomedical innovation, and given the restrictions on advertising imposed by medical ethics, to some extent, it needs to be promoted in order to attract foreign investment. Drawing attention to scientific activities is not a simple process and requires a defined information array, composed of logically constructed and conditioned connections.

However, drawing public attention to complex issues of public importance will usually result in both positive and negative factors. Negative factors will require, first of all, their immediate resolution and preventive actions to prevent their re-emergence. Failure to address the negative factors will result in statutory liability. Given the fact that criminal liability is recognized as the most severe type of sanction that may be imposed on for committing a socially dangerous act, the socially significant issue of criminal law characteristics of medical research (primarily with the participation of a foreign investor) is the one that requires the attention of civil society and a more detailed study. It is advisable to take into account the fact that the procedure for presenting legal informative material with a substantial medical component to an unlimited number of persons is very difficult in the absence of legal awareness among civil society organizations and individual representatives. Therefore, the specific combination of two sciences – law and medicine – is a complicated process. However, the practical result of such a combination may be useful for consumers of medical services, medical professionals as providers of necessary services, as well as the state as a controlling apparatus, which, in certain cases, assumes the chain role of the relationship between doctors and their patients.

The area of study of the article is the social and legal norms, and also the relations of the medical industry and their application, which form the legal framework for the medical research industry (with the participation of a foreign investor). The role of an optional subject of study of this article is played by social relations arising in the regulated area of criminal liability in case of violation of the procedure for conducting medical research at the national level.

The subject of this article is the legal support of the medical research industry (with the participation of a foreign investor) in Ukraine, and specifically, medical (clinical) research. **An additional (optional) subject of this article** is the criminal law support of medical research in Ukraine. The relevance of the chosen topic is explained by the fast changes in the current environment, which are occurring due to the rapidity of state-level reforms. An important criterion in the preparation of the material was the rapid development of civil society, the need for innovative developments, and the need to attract investment.

The purpose of the article is to compare legal and medical sciences and to use them further to serve civil society in general and medical pro-

fessionals in terms of conveying the information content of the Law of Ukraine on Criminal Liability in an adaptive format for understanding. Lack of sufficient understanding and familiarity with the legal regulation of the medical sphere may create obstacles to professional medical activity due to the lack of awareness among medical personnel of certain aspects and conditions of liability, including administrative and criminal liability, which is applied for certain types of acts. The element of misunderstanding of seeking treatment at healthcare facilities on the part of existing and potential patients can be an urgent practical problem for healthcare professionals. Lack of patients' awareness of the defined procedure for treatment, lack of understanding of the criteria for the weight of medical documentation, lack of information on the procedure for defending personal interests are also negative factors that impede the positive dynamics of the healthcare sector, slow down the pace of its digitalization, and the performance indicators of bringing the existing results to the established levels of international standards [7, p. 47–54].[1]

Stage two is the stage that follows the consideration of the merits of the appeal (complaint). The stage of analyzing the submitted document, with the circumstances set out, in order to find signs of a possible unlawful act established by the Law of Ukraine on Criminal Liability. It is always important to remember that the final decision regarding the guilt of the accused person in a criminal offence should be made only by a judicial institution by way of a court decision. All other statements, remarks and considerations, including personal statements, do not have any official, and therefore, decisive significance in the matter of imposing a criminal sentence. Thus, the purpose of this article is to provide an explanation of the possibility of dispositive settlement of adverse situations that may arise in professional medical activity. The driving awareness of the legal component of medical professional activity also finds practical support in the newest area of preventive medicine, and contributes to the development of a compatible doctor–patient relationship. The use of the imperative lever of criminal liability, through objective confirmation of the existence of relevant negative factors, the rules and provisions regarding which are specified in the Criminal Code of Ukraine, contain state regulation of negative consequences, in particular in terms of application of the provisions of the Law on Criminal Activity in Medical Practice. Problematic aspects of the application of criminal liability to medical personnel, in case of proving unlawfulness of actions in the performance of professional duties, have

[1] Khrystyna Kalashnikova and Viktoriia Shevchenko, «Ways to improve information and communication mechanisms for the formation of a positive image of public authorities in Ukraine», *International Economic Relations And World Economy*, vol. 41 (2022): 47–54, accessed May 26, 2024, http://dx.doi.org/10.32782/2413-9971/2022-41-9.

been studied by scientists R. Veresha, S. Dutchak, and others [8, c. 4–12].[2] In their works, scholar-publicists clearly demonstrate the patterns of interconnections between the historical emergence of medical science and the emergence of legal regulation of personal acts [9].[3] A comparison of medical and legal aspects in the subfield of medical law, at the national level, was carried out by such authors as: S. Vasyliev (a scientific publication «Legal basis of state management of creation of innovative medicines: European experience») [10][4], D. Bilyi (a scientific publication «Peculiarities of administrative and legal protection of patients' rights») [11][5], and others. Among the scholars of foreign origin and non-residents who have studied the issues of the comparison of medical and legal activities, we can mention John MacMillan [16][6], who researched the problematic issues of a correlation between a practical activity and medical ethics; Mikheil Bichia, Doctor of Law, whose work is focused on the study of aspects of medical law and its links with other sciences [17][7] and others [21].[8] However, it is worth noting that the determinants of the legal development of the healthcare system have not been fully researched at the appropriate level. This list of authors and research papers is not exhaustive and is provided for informational purposes only. Taking into account the criterion of belonging to the desire to improve the quality of healthcare services, there is no common good practice and no legal position on the combination of medical and legal sectors.

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[2] Roman Veresha, *Subiektyvni ta obiektyvni oznaky kryminalnoi vidpovidalnosti medychnykh ta farmatsevtychnykh pratsivnykiv* (Kyiv: Alerta, 2015), 50.

[3] Andrii Savchenko and Roman Veresha, «Kryminalne pravo na latyni (retsenziia na slovnyk-dovidnyk "Kryminalna yustytsiia v latynskykh vyslovakh i terminakh", pidhotovlenyi Mykhailom Shepitkom)», Pravo Ukrainy (2020/02): 305, accessed May 26, 2024, http://jnas.nbuv.gov.ua/article/UJRN-0001108699.

[4] Stanislav Vasyliev, "Legal principles of public administration for the invention of innovative medicines: European experience", *Law and innovative society,* vol. 1, no. 16 (2021): 35–42, accessed May 26, 2024, http://dx.doi.org/10.37772/2309-9275-2021-1(16)-7.

[5] Do Bilyi, «Features of administrative and legal protection of patients' rights», *Law and Society,* no. 5 (2021): 142, accessed May 26, 2024, http://dx.doi.org/10.32842/2078-3736/2021.5.19.

[6] John McMillan, "Being ethical in difficult times", *Journal of Medical Ethics*, vol. 50, no. 1 (2023): 1, accessed May 26, 2024, http://dx.doi.org/10.1136/jme-2023-109777.

[7] Mikheil Bichia, "The concept of medical law and its place in the system of branches of law", *Law and World,* vol. 9, no. 4 (2023): 54, accessed May 26, 2024, http://dx.doi.org/10.36475/9.4.5.

[8] Fernanda Nogueira, Isabel C.P. Marques and Sónia P. Goncalves, "From Human Rights to the Right to Health: A Systematic Literature Review", *International Journal of Social Welfare Promotion and Management,* vol. 9, no. 1 (2022): 1–18, accessed May 26, 2024, http://dx.doi.org/10.21742/ijswpm.2022.9.1.01.

However, the stable link (segmental) hierarchy, which has the features of the obligation to apply specific legal norms in medicine, plays the role of a fundamental and important criterion for the restoration of a legally impartial society with a democratic system. The condition for the existence of orderly segmental interrelationships of various scientific fields is the desire of civil society for a democratic system, which has an essential feature, namely, the desire for the rule of the people regardless of the form of government of the state. A component of the democratic system of the state is the application of the rule of law by society, on a voluntary and equal basis through self-representation, without the constant use of state coercion at the state level. Legal awareness becomes a driving component of the self-realization of personal interests. The ability to independently defend inherent rights and freedoms includes the right to healthcare and proper treatment guaranteed by the state. Personal rights and interests are inalienable from a person who is a member of civil society and enshrined in the Constitution of Ukraine [22].[9] The implementation of the possibilities of applying the information approach in order to convey adapted legal material to a healthcare professional, as well as to his or her patient or potential patient, has significant innovative features. As an auxiliary (optional) object of the stage of development of the methodological framework, it is advisable to determine, in a discussion manner, the prevention of negative consequences of liability, on the grounds of disciplinary, administrative and criminal nature, which will occur in case of non-compliance with the existing procedure for the implementation of medical activities. A prerequisite for the development of the medical economic segment is the delivery of legal information to potential patients in the medical sector [23].[10] The applied use of the imperative lever of the criminal liability branch of legal content includes the criterion of social significance. Therefore, the author also makes a scientific assumption regarding the possibility of significant public benefit for the State and its citizens from the introduction of opportunities for independent dispositive settlement of predictable conflict events which sometimes occur in the field of professional medical activity between participants to multilateral relations, through independent defense of personal rights and freedoms. In this case, the possibility of mastering the doctor-patient relationship, an information resource of a legal medical nature, seems to be useful. As a result, the state apparatus receives a benefit, which is manifested in the release of free time and human

[9] Konstytutsiia Ukrainy: vid 28.06.1996 (no 254k/96-VR: stanom na 1 sich.) (2020), accessed May 26, 2024, https://zakon.rada.gov.ua/laws/show/254k/96-vr#Text.

[10] "Health 2020: a European policy framework supporting action across government and society for health and well-being («short version)»": 1–12, accessed May 26, 2024, https://iris.who.int/handle/10665/131300.

resources for their further use in the development of socially important criteria and industry segments. The medical development in the field of clinical trials requires improvement of legal regulation and search for innovative approaches. The possibility of highlighting problematic aspects of criminal liability in the field of medical (clinical) research and the medical industry as a whole is a significant supporting factor in the development of the medical segment [24].[11] When summarizing the information block and systematizing the thematic area, the method of systematic literature review was chosen. Given that the ongoing development of value guidelines of general social significance, international practical aspects and international legal norms are also taken into account. Taking the consequences of European integration as regularity, the process of adopting foreign medical legal experience continues. As a practical example, it is possible to cite the terms of the court case "Benderskyi v. Ukraine" (Application No. 22750/02) [25][12], about the concepts of The Nuremberg Code (1947) («The Nuremberg Code», 1996) [26].[13]

2. The aim of the study

An obstacle in understanding the ideology of innovative medical activity, with the possibility of applying the components of international medical law, is the quantitative criterion of the presence of a wide range of participants in medical relations, taking into account regulatory and control bodies. Quantitative subjectivity of multilateral relations to some extent complicates the unification process of implementation of foreign results and experience. The criterion of the doctor's conscious awareness of the requirements of the international clinical protocol, and the subsequent practical implementation of the noted into practical activity, with the final obtainment of a practical result, become the fundamental conditions that are put forward to the doctor or his/her assistant – a member of the research team. The following are other requirements for persons who in-

[11] Helsinska deklaratsiia Vsesvitnoi medychnoi asotsiatsii "Etychni pryntsypy medychnykh doslidzhen za uchastiu liudyny u yakosti obiekta doslidzhennia": Deklaratsiia Vsesvit. med. asots. vid 01.06.1964 r.: stanom na 1 zhovt. 2008 r., accessed May 26, 2024, https://zakon.rada.gov.ua/laws/show/990_005#Text.

[12] Sprava "Benderskyi proty Ukrainy" (Zaiava N 22750/02): Rishennia Yevrop. sudu z prav liudyny vid 15.11.2007, accessed May 26, 2024, https://zakon.rada.gov.ua/laws/show/974_313#Text.

[13] The Nuremberg code, (from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S. G.P.O, 1949–1953): 1–2, accessed May 26, 2024, https://research.unc.edu/human-research-ethics/resources/ccm3_019064/.

tend to become part of a medical research team: the presence of a relevant specialized medical education, or one that can be equated to it; professional performance of medical duties; the existence of a qualifying practical criterion. As an explanatory material containing elements of legal content in its constituent elements, the customer and the sponsor of the clinical study, as well as other interested participants, may provide additional accompanying documentation of the content of the explanatory material to the clinical medical protocol of the research drug that is at the testing stage and an introductory component. For a practical case, the mentioned order of circumstances, it is possible to cite the case of providing accompanying instructions with explanatory material regarding a possible procedure for overcoming the patient's problems without necessarily stopping treatment, due to the detection of unfavorable effects of the influence on the state of health, at the time of taking part in a clinical trial (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.) [27].[14] Taking into account the set of comparable factors, the subject of legal discourse may be the process, and the results obtained as a result of the end point of such a process form the comparison of medical ethics with the practical results of the use of artificial intelligence in professional medical activity, in addition to the expediency of recognizing their results and influencing the results of clinical (medical) research [28].[15]

3. Materials and methods

The following methods were used to achieve the stated tasks and the existing goal: methods of scientific knowledge, namely, philosophical method, theoretical method, general scientific empirical method. Also, the method of correlation analysis and the method of dialectical logic of cognition were applied, while processing the existing article materials, a methodological analysis of the available data was used. With the goal of establishing a correlation, through the application of the norms of law in combination with medicine, the normative-legal legislative base of the

[14] "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" (PubMed): 1–5, accessed May 26, 2024, https://pubmed.ncbi.nlm.nih.gov/36945734/.

[15] Vangelis D. Karalis, "The Integration of Artificial Intelligence into Clinical Practice", *Applied Biosciences* 14, vol. 3, no. 1 (2024): 21, accessed May 26, 2024, http://dx.doi.org/10.3390/applbiosci3010002.

national level, as well as foreign legislation and practical judicial claims and lawsuit examples of European legislation were mastered. The scientific and journalistic works of the theoretical and practical levels of activity developed by scientists and scientific journalists were studied. To prepare the article, the dialectical method of the logic of cognition was borrowed. Using the method of dialectical logic, combining it with the theoretical basic methodology of scientific knowledge, the fundamental general informational structured blocks are documented.

In the part of unifying the aspectual regulation of medical and legal doctrines into a single subject of research, a correlational analysis of the historical state of both sciences was used. Given the empirical methodology, statistical observations of the ongoing clinical research process were performed at the practical level. At the same time, indicators of sociological surveys are taken into account. The assumption regarding the insufficient level of legal awareness among the participants in health care relations can be considered through the prism of a general philosophical complex phenomenon of social life. The complicated issue of insufficient awareness in the field of professional and scientific innovative activity can be subject to legal analysis, using empirical and theoretical methods of cognition. Depending on the territorial subordination, legal systems and forms of their convergence may differ significantly. On the example of the European Union, unified legal norms are considered the most acceptable. Paying attention to the legal model of the practical activity of the USA, the adoption of model legislative acts is considered the most effective. At the national practical level of social legal activity, taking into account the globalization processes of development, the order of application of judicial precedent is actively used. Drawing an analogy with the previously mentioned, medical and legal borrowing can give the expected results, in case of comparison of their thorough and methodological comparative components. The essential content component of the medical and legal systems includes the attachment to the integral levers of social existence: philosophical, ideological, religious, political, as well as other factors and driving factors of the rotating functioning of civil society. A holistic view of the world panorama embodies the conditions of application of comparative jurisprudence in the medical direction. External borrowing, as a consequence of the implementation of the adaptive form of the acquired, requires a sequence of application of the existing components of a holistic process, such as: presentation of the material in an adaptive form, initiation of application stages, and their practical implementation in an adaptive form. Implementation of the above stages will encourage the development of medical projects, make such projects competitive and attractive for

foreign investment [29].[16] Achieving a combination of the fundamental principles of defined legal unity, subject to the application of pluralistic legal norms of national level and international importance, will play a decisive role in the development of the field of scientific research in medicine. The above statement is explained by the following reasoning. The driving factor for the development of clinical trials and scientific research in the medical field is the high-quality frequency of the practical implementation of the stipulated research. However, the medical research field can achieve practical implementation only under the condition of the criterion of legitimacy. Even taking into account the fact that medical practice can use various cultural value orientations and traditions of cultural foundations as a basis of activity, practical professional medical research activities will be subject to limitations due to the inconsistency of the current legal systems applied at the state level of legal systems in the presence of the international nature of clinical research. Therefore, the medical practical possibilities of the transnational level of scientific developments may be somewhat limited in the absence of legal unity of their implementation [30].[17] The presence of an imperative legal mechanism of state licensing, with mandatory regulated registration actions on the part of subjects of the medical economic field, serves as an explanation for the slow interaction of the international level of medical research. Associated factors are mandatory certification and accreditation actions inherent in the regulatory activity of the health care industry. An essential condition is mandatory criteria for compliance with established regulations and rules, implementation of medical programs with subsequent reporting on their implementation.

Therefore, only legalized medical practice and activity in general can be successful. Significant inhibition of innovative medical development is caused by the presence of negative legal factors. As such factors, it is possible to cite lack of documented confirmation of qualifications, failure to obtain a license to engage in medical activity, lack of practical experience of proper clinical practice, lack of understanding of the legal aspects of current legislation and the practical possibility of implementing legislative norms, lack of understanding of the procedure for administrative work with medical documentation, failure to meet established requirements for order of practical implementation of medical (clinical) research, as well

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[16] Bohdan Karnaukh "Standards of Proof: A Comparative Overview from the Ukrainian Perspective", *Access to Justice in Eastern Europe,* vol. 4, no. 2 (2021): 25, accessed May 26, 2024, http://dx.doi.org/10.33327/ajee-18-4.2-a000058.

[17] Valeriia Gansetska "Types and system of foreign civil procedure law sources: comparative legal analysis", *Young Scientist,* vol. 5, no. 81 (2020): 4–8, accessed May 26, 2024, http://dx.doi.org/10.32839/2304-5809/2020-5-81-44.

as other negative factors [31, p. 135–151].[18] Citing as an example, the indicators of the proven facts of the occurrence of severe consequences for the physiological and moral state, in case of ignoring the norms of morality and legal aspects in the medical field, with reference to historically established legal facts, a natural and urgent need for a clear regulatory intervention and establishing a practical order for it can be traced implementation. It is emphasized that there are actions that are criminal in nature and, in addition, that are not incompatible with the practical side of medical ethics. And therefore, as a result, they contain the impossibility of the medical practitioner's performance of the duties assigned to him/her in the content of the professional component. Modern medical science is logically dependent on the innovative development of the present. Not only can technological progress and the introduction of artificial intelligence into medical research be considered innovations, but also adaptive changes in legal norms and their procedural application and procedure. With the development of the latest medical fields of activity, medical law will inevitably undergo changes. Therefore, we should be prepared for the need to improve both the subfield of criminal law and criminal procedure. Given the adoption of the European experience of medical practice in the medical arena at the national level, one should be prepared for legal 'gaps' in national criminal and other legislation. Therefore, it should be acknowledged that the development of medical research at the national level and its legal support, as well as the procedure for implementing legal support, are not at a sufficient level and require further development and improvement.

4. The results

Based on the work "Introduction to the Study of Experimental Medicine" by Claude Bernard, who vividly demonstrated the teaching of a priori dogmatism, the possibility of the precise application of experimental methodology to the study of life phenomena, in particular on the human body, arose. The experimental method in medicine began:

1) physiological research;
2) physiological criticism;
3) the combination of research and criticism, and their combined application in experimental medicine;

[18] Viktoria Kononenko and Marina Demura, "Problematic issues of bringing disciplinary and criminal liability of medical workers", *Problems of Legality*, vol. 152 (2021): 135, accessed May 26, 2024, http://dx.doi.org/10.21564/2414-990x.152.226284.

4) the study of philosophical obstacles that experimental medicine faces on the way to its development.

The listed conditions and circumstances laid the foundation for the implementation and further development of the field of modern medical (clinical) research. The condition of combining the clinical experimental field with legal regulation laid the foundation for the development of the very popular trend of "evidence-based medicine" today. Research developed by the experimental method, based on the content of observations, is implemented with the help of a working scientific idea – a hypothesis. In the practical implementation of the proposed hypothesis, it is not allowed to use a formal approach in combination with a biased idea, that is, the one that does not require confirmation, proof and/or refutation. Research developed by the experimental method, based on the content of observations, is implemented with the help of a working scientific idea – a hypothesis. For example, citing the written work of Galen, it is possible to draw attention to the fact that one hundred and thirty-seven years before the birth of Christ, experimental activity with poisons and their antidotes (antidotes) conducted by Attis III (Philometro), who ruled in Pergamum, took place on individuals who were recognized as criminals and sentenced to death. Another example of Celsus describes the conduct of vivisections by Herophilus and Erasistratus on criminals [32].[19] Claude Bernard describes other fatal experimental cases, among which he cites a fatal case that occurred after the experiment, due to the introduction of a double dose of oleates (opium) into the human body of the subject [33, p.p. 100, 151–196].[20] Continuing the discussion topic, it is possible to recall the times of the Second World War and the events recorded in the documentation from the concentration camps of fascist Germany. Documentary descriptions provide stories about the active use of medical experimental research, bypassing any legal regulation, avoiding publicity, in the absence of even signs of public control and public wishes. Medical experiments, in the absence of a legal component, were carried out on people who were deliberately, and disregarding their will, interests and freedoms, forcibly kept in concentration camps. Subjects were deprived of the right to be called people; they were called bioresources, human organism, material, etc. Pursuing the goal of erasing their own crimes, rejecting remorse, research executioners gave prisoners digital numbers instead of names, forbade con-

[19] "Paroksyzm znachennia slova, rid, transliteratsiia, pereklad, kilkist liter" (Slovnyk ukrainskoi movy. Transliteratsiia imeni, prizvyshcha): 1, accessed May 26, 2024, https://slova.com.ua/word/paroksyzm.

[20] Claude Bernard, *An Introduction to the Study of Experimental Medicine* (London and New York: Henry Schuman, INC), 4–6, 36, 78.

versations, etc. [34, c. 16–48, c. 70, c. 78, c. 96].[21] Supervised and controlled clinical trials on a global scale began to be conducted in 1747. The element of gravity inherent in the field of clinical trials is reflected in the above.

The vocation of clinical trials appears in the search for the newest methods of treatment. Approbation of the methods takes place on natural persons – healthy volunteers (patient volunteers), as well as on persons (people) suffering from certain diseases (diagnoses). The purpose of clinical research is to establish or disprove a hypothesis regarding the safety and effectiveness of the tested research product for its use by individuals. Claims-lawsuit activity did not bypass the field of medical (clinical) research, in the variety of its manifestations. Court proceedings involving representatives of medicine to participate in the case have become rare cases. As an example, it is possible to cite a precedent issue that was considered by the European Commission on Human Rights of the European Court of Human Rights in an extended time period from 1961 to 1977. Thus, the issue of the presence or absence of establishing a cause-and-effect relationship between the process of birth defects in babies and the medical actions of medical workers regarding the creation of the newest medicine development – a medical drug – was considered. The cause of the conflict situation was the release into economic circulation of the drug «Thalidomide» before sale and free circulation by the pharmacy network. The medicine embodied a drug that was first developed in Germany. Instead, between 1958 and 1961, the drug in question was manufactured and released to the UK pharmaceutical economy market by Distillers. The purpose of prescribing the mentioned medicinal product was positioned as a sedative (sedative) agent, which is also approved for use by pregnant women. In 1961, a certain number of mothers who were injected with the specified medicine gave birth to children who, according to the results of the examination, were diagnosed with severe physical defects – heart defects, as well as others. At the end of 1961, a company producing low-quality drugs removed "rejected goods" from the economic market. However, as of the mentioned time, judicial institutions have received numerous claims from the parents of the affected children. Also, the court documents contain written evidence of improperly regulated clinical trials; there are allegations of underdeveloped case studies. The review of the mentioned court events continued quantitative indicators from 1972 to 1977. The pharmaceutical company – the manufacturer of a low-quality drug did not manage to win the court case, moreover, the publicity of the process acquired public importance, which in turn provid-

[21] Ruslana Berndl, Matthias Kaltenbrunner and Tetiana Pastushenko, Viazni z Ukrainy v kontstabori Mauthauzen: istoriia ta pamiat [Prisoners from Ukraine in the Mauthausen Concentration Camp: History and Memory]. (Kyiv: Feniks 2019), 367.

ed the driving force for establishing more correct control over the industry medical (clinical) research [35, c. 7, c. 15, c. 146–147].[22]

Therefore, in order to attract foreign investments to a potentially attractive industry, it is appropriate to express considerations regarding the necessity and importance of implementing in practice the development of quality support programs and the development of conditions for medical (clinical) research at the national level. Considering the achievements of the civilized world in the medical field, it should be taken for granted that proper clinical practice cannot function at a decent level without creating rational technical conditions and proper legal support. The predicted significance and possibility of attracting investment activities of economic and medical levels of national importance is reflected in the following. The National Academy of Medical Sciences of Ukraine (NAMS of Ukraine) is the main institution (body) of state significance (national level) engaged in theoretical scientific and scientific applied research, as well as those containing clinical scientific developments. The fact of state allocation of medical research procedures according to specialized programs, and not according to targeted budget (financial) programs of the National Health Service of Ukraine, which also, in turn, do not finance medical (clinical) research at the national level, seems significant in its essence. That is, national-level medical (clinical) research conducted by institutions (research centers, enterprises and organizations) regardless of the form of ownership, does not receive financial support from the state. Therefore, business entities of the medical economic sector of private and public law, as well as other potentially interested participants and sections of the population, should generate capacities for attracting the necessary resources, including searching for potential investment channels, possibly of foreign origin. The state, for its part, takes steps to meet the research procedures, supporting scientific activity, also in the presence of the criterion of a private law component. As a practical example, here you can cite the regulated legal conditions of the Regulation on the implementation of the technical approach "Industry 0.4" [36].[23] Citing as an example the clinical study of the Danish pharmaceutical company – sponsor "Novo Nordisk", the statistical indicators are defined. As of the end of 2023, according to the data of an

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[22] Times Newspapers LTD and others against I United Kingdom, European Commission of Human Rights, May 18, 1977, Application No. 6538/74 (France (Strasbourg)), accessed May 26, 2024, https://www.stradalex.eu/en/se_src_publ_jur_eur_cedh/document/echr_6538-74.

[23] Pro zatverdzhennia ta vprovadzhennia medyko-tekhnolohichnykh dokumentiv zi standartyzatsii medychnoi dopomohy pry tsukrovomu diabeti 2 typu: Zakon Ukrainy vid 21.12.2012, no. 1118, accessed May 26, 2024, https://zakon.rada.gov.ua/rada/show/v1118282-12#Text.

international medical (clinical) study from an international clinical investor – the pharmaceutical company Novo Nordisk, to the clinical development of a study of semaglutide, which is a cardiovascular drug, which is additionally undergoing testing to cause an action to promote weight loss and weight control of a patient with type 2 diabetes, 9,651 participants are listed on an international scale. The relative quantitative indicator is 101.0% (in percentage terms) of the planned number of 9,555 participants [37].[24] Other characteristic indicators of the "SOUL" clinical trial, whose representative on the territory of Ukraine is Novo Nordisk Ukraine Limited Liability Company, include the following. On the territory of Ukraine, the international clinical study "SOUL" is conducted taking into account the data of the unified clinical protocol of primary and secondary (specialized) medical care: "Diabetes type 2". For greater uniformity of the obtained results, the prognostic component of the study EX9924-4473 (SOUL) is in action on a global scale. Research centers in Europe and Asia, South and North America, South Africa are involved in research procedures on a global scale. An important condition for the demonstrable effectiveness of a medical experiment is high-tech equipment and innovative chemical reagents and a rational procedure for their use, which in turn can be subject to patenting, or which in practice happens more often, fall under legal protection and non-disclosure of commercial secrets. Relationships between the research center and the laboratory diagnostic department, if necessary to check corruption ties, etc., can be checked by specially authorized bodies and officials, however, in the context of current legislation, they are not prohibited. An example that is understandable for the norms of business turnover is the possibility of passing the necessary tests and obtaining their results, which takes place within the limits of medical (clinical) research. The sponsor of a clinical study, which is a business entity of the medical industry, taking into account the identity of a non-resident, has the right to interact with medical (diagnostic) laboratories on its own behalf. The specified development of events seems very logical, due to the fact that the quality of equipment of foreign pharmaceutical laboratories is ahead of the quality of national standards in their practical implementation, demonstrating an innovative level of diagnostic indicators, with a view to international standards accepted by the world commu-

[24] "EX9924-4473: Semaglutide cardiovascular outcomes trial in patients with type 2 diabetes (SOUL) / Clinical Research Trial Listing" (Clinical Research and Drug Information / CenterWatch): 1–3, accessed May 26, 2024, https://www.centerwatch.com/clinical-trials/listings/TX240843/ex9924-4473-semaglutide-cardiovascular-outcomes-trial-in-patients-with-type-2-diabetes-soul.

nity [38].[25] Also, as an example of professional research activity, which is not fully investigated, for the purpose of working out the theoretical and practical levels of responsibility, it is possible to mention the ongoing clinical study "Genomics of T1 D in Ukraine", which is conducted in the electronic database "REDCap" (Research electronic data capture). The essential manifestation of the conditioned practical experiment includes the study of the influence of the genetic code and ethnic origin of a natural person (person) on the treatment of type I diabetes [39].[26] It is important to understand that awareness of the rights, interests and freedoms of a medical worker, as a special (professional) subject of specialized activity, is a strong argument and provides a number of counterweights in the painstaking and somewhat individualized activity of protecting personal interests, provided that the state imperative levers of the punitive mechanism are applied. The indicative criterion of preventive self-training and the possibility, if necessary, of a visual demonstration of the appropriate level of legal awareness of a person as a member of civil society, aims to attract specialists, specialists and professionals, as well as other workers in the medical field, to personal participation in the direction of the imperative civility of the medical direction of the state level. A positive result of this provision is the attraction of foreign investments for conducting clinical research [40].[27] Therefore, it seems appropriate to reproduce the procedural mechanism for the protection of the rights of investment interests of the sponsors of medical (clinical) research at the national level. It is possible to note that at the practical level of potential opportunities for protection and search for investment resources, the interests of a private legal nature of the subjects of investment activity, including those protected by the norms of international law, are defended by subjects of economic activity of medical and investment activity independently [41, c. 7–19].[28]

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[25] Pro vnesennia zmin do Poriadku provedennia ekspertyzy reiestratsiinykh materialiv na likarski zasoby, shcho podaiutsia na derzhavnu reiestratsiiu (perereiestratsiiu), a takozh ekspertyzy materialiv pro vnesennia zmin do reiestratsiinykh materialiv protiahom dii reiestratsiinoho posvidchennia ta zatverdzhennia Poriadku perevirky materialiv, dodanykh do zaiavy pro derzhavnu reiestratsiiu okremykh likarskykh zasobiv, shchodo yikh obsiahu: Nakaz MOZ Ukrainy vid 23.07.2015, no. 460: stanom na 30 hrud. 2016 r., accessed May 26, 2024, https://zakon.rada.gov.ua/laws/show/z1210-15#Text.

[26] Pro udoskonalennia medyko-henetychnoi dopomohy v Ukraini: Nakaz vid 31.12.2003 r. no. 641/84, accessed May 26, 2024, https://zakon.rada.gov.ua/rada/show/va641282-03#Text.

[27] Gustavo A. Jimenez, "Corporate Criminal Liability: Toward a Compliance-Orientated Approach", *Indiana Journal of Global Legal Studies,* vol. 26, no. 1 (2019): 353, accessed May 26, 2024, http://dx.doi.org/10.2979/indjglolegstu.26.1.0353.

[28] Olivier J. Wouters and Aaron S. Kesselheim, "Quantifying Research and Development Expenditures in the Drug Industry", JAMA Network Open e2415407, vol. 7, no. 6 (2024):

Insurance medicine appears to be a model of positive development of the medical field at the foreign, particularly European, level. Due to the occurrence of cases of litigation on the consideration of controversial issues of insurance medicine at the foreign level, which may arise due to dissatisfaction of patients with the decisions taken by the administrative resource, it is allowed to establish police supervision of the patient, in case of establishing a case of dishonest attitude to the doctor's prescriptions, provided that the manifestations of negative conditions are recorded in official way, which caused the deterioration of the patient's physical and physiological condition. The representative of the police authority collects the necessary materials as part of police supervision. In the future, the collected data is directed to the judicial institution. The collected data receive the status of the evidence base of a separate court case [42].[29] The cornerstone of possible adverse events in the medical field is the incompleteness and relative formality of the approach to the preparation of written informed consent given by the patient (patient-volunteer, healthy participant, research participant) to participate in clinical (medical) research. The basis for such an arrangement of circumstances is the lack of clear criteria and requirements for the form of the mentioned document. The multiple approach to the substantive component of an experimental nature is reflected in the set of requirements for the substantive form and scope of clinical research. Therefore, it is predictable that the conditions put forward for the meaningful form of written informed consent for participation in medical research may differ.

5. Discussion

Modern conditions of existence require taking into account scientific levels of achievements, in particular European, and, in addition, in general, international economic indicators of the state development of medical and related scientific achievements.

Taking into account the clinical procedural activity, it is considered appropriate to introduce practical proposals in relation to the formation of

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1–3, accessed May 26, 2024, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820566.

[29] "European Commission and the European Union Intellectual Property Office team up to enhance intellectual property rights in Ukraine, Moldova and Georgia" (European Neighbourhood Policy and Enlargement Negotiations (DG NEAR)): 1–2, accessed May 26, 2024, https://neighbourhood-enlargement.ec.europa.eu/news/european-commission-and-european-union-intellectual-property-office-team-enhance-intellectual-2023-12-12_en?prefLang=uk.

registration dossiers for clinical studies (first of all, those that are supported by a foreign investor).

A practical formulary regarding the volumes and possible content of registration dossiers, possible to be developed under the condition of a practical example of the use of the existing order of formation of registration dossiers in the medical field [43, c. 234–279].[30] The innovation of the use of legal norms of imperative civility in the niche of the criminal law segment is combined with the implementation of the procedure for resolving disputed situations, which requires the use and application of civil norms to the Law on Criminal Liability.

Therefore, it is considered possible to legitimize the terms of criminal liability, which will occur on the condition of proving the legal fact of providing notoriously unreliable data, and such data that are not provided in full by a patient at the request of a medical professional before treatment.

It seems expedient to supplement the Criminal Code of Ukraine with a legal norm regarding liability due to unauthorized (illegal) and non-targeted use of foreign investments, in particular in the medical field [44].[31]

6. Conclusions

Taking the path to improving the existing conditions for the implementation of the Law of Ukraine on Criminal Liability, it is possible to make proposals regarding the specification of the conditions and requirements of written informed (informed) consent, as well as the individualization of said consent and adaptation of its conditions to individual non-standard cases. It is also possible to make proposals regarding the implementation of digital information consent. Taking into account the vector nature of the development of the field of experimental medicine at the national level, on the example of the Order of the Ministry of Health of Ukraine dated May 14, 2021, No. 936/3 [45][32], it seems possible to introduce a proposal

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[30] Vira I. Tymoshenko and Larysa O. Akarenko, "The Impact of Globalisation on Legal Conduct", *Scientific Journal of the National Academy of Internatl Affairs*, vol. 27, no. 1 (2022): 20–29, accessed May 26, 2024, https://doi.org/10.56215/0122271.20.

[31] Maria Mendzhul, "Conditions of Legality of Medical Human Subject Research", *Medicne pravo*, vol. 27, no. 1 (2021): 69, accessed May 26, 2024, http://dx.doi.org/10.25040/medicallaw2021.01.069.

[32] Pro zatverdzhennia prymirnoho dohovoru pro medychne obsluhovuvannia naselennia mizh Natsionalnoiu akademiieiu medychnykh nauk Ukrainy ta derzhavnoiu ustanovoiu, yaka vprovadzhuie ta realizuie novyi mekhanizm finansovoho zabezpechennia nadannia spetsializovanoi medychnoi dopomohy v okremykh naukovo-doslidnykh ustanovakh Natsionalnoi akademii medychnykh nauk Ukrainy: Nakaz vid 14.05.2021 r. No 936/35, accessed May 26, 2024, https://zakon.rada.gov.ua/rada/show/v0936282-21#Text.

for the development of a multilateral transaction, which can be used in the procedure for conducting clinical (medical) research. Innovative methods of treatment and research methods in practical medical activity, taking into account the criterion of the absence of investment at the state level, need to find ways to support Grant loans [46].[33] Therefore, the aspect of administrative intervention in the context of the possibility of exceeding the authority of the field of medical (clinical) research can be recognized as an urgent issue. Therefore, it seems appropriate to develop a procedural mechanism for the protection of the doctor from the administrative resource management side, which to a greater extent performs the function of a punitive entity [47].[34] In practical medical activity, the practical level of imperative civility is reflected in the business turnover conditions of the clinical practice of experimental medicine. As an example of imperative civility in the field of health care, it is recognized for the possible application of medical-technological documentation, medical treatment protocols, and clinical guidelines in the professional medical field. Compliance with the methods of applying the norms of imperative civil approaches to the implementation of established procedural prescriptions and rules, followed by the administration of emergency situations arising at certain stages of clinical research, due to the presence of the "human factor" of working with volunteer patients, is called to be applied in order to protect the order of conducting practical activities, particularly in experimental medicine. As a condition that deserves attention, we can mention the tendency to combine the fundamental moment of the fight against legal bureaucracy, but, at the same time, the normalization of the practical order in evidence-based medicine. The formal approach of legal regulation to the field of clinical research makes normal development of the innovative medical field impossible. The unceasing development of economic investment and other socially significant industries inherent in the qualitative criterion for evaluating the geopolitical development of civilized and leading countries serves as a circumstance that explains the above [48][35],

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[33] Colleen E. Lawrence, Virginia (Nickie) M. Bruce, Libby D. Salberg, Terri Edwards, Casi Morales, Marisha Palm and Gordon R. Bernard, "Quantitative Assessment of the Impact of Standard Agreement Templates on Multisite Clinical Trial Start Up Time", *Journal of Clinical and Translational Science*, vol. 1 (2023): 1–8, accessed May 26, 2024, http://dx.doi.org/10.1017/cts.2023.622.

[34] Sara A. Attinger, Ian Kerridge, Cameron Stewart, Isabel Karpin, Siun Gallagher, Robert J. Norman and Wendy Lipworth "Money matters: a critique of 'informed financial consent'", *Medical Law Review*, vol. 32, no. 3 (2024): 1–3, accessed May 26, 2024, http://dx.doi.org/10.1093/medlaw/fwae015.

[35] Polozhennia pro reiestr medyko-tekhnolohichnykh dokumentiv zi standartyzatsii medychnoi dopomohy: Nakaz vid 28.09.2012, no. 751, accessed May 26, 2024, https://zakon.rada.gov.ua/laws/show/z2004-12#Text.

[49].[36] The conclusions drawn by summarizing the results of this article contain further perspectives based on the dogmatic historical teaching of medical science with confirmed facts of the occurrence of adverse cases and undesirable results in medicine in the absence of proper legal regulation. The criterion of developing a good-faith and solid reputation in society is connected with ethical and qualified legal regulation, the proper level and development of which is intended to contribute to the development of medicine and the development of clinical practice. The novelty of a specific categorical concept with the application of legal norms from a component of imperative civility, in combination with criminal-legal segmentary placement, delimits the regularity of legal integrative actions with the application of civil norms and the Law on Criminal Liability. As an example of the application of the norms of imperative civility, taking into account the driving aspect of the introduction of criminal liability of a legal entity to the norms and sanction conditions of the Criminal Code of Ukraine, it is considered appropriate to use the Medicrime Convention at the national level [50].[37] Therefore, foreign investment acquires an actual level of importance, especially under the conditions of a state of war in the territory of the state of Ukraine. Wartime dictates the situational conditions of the relevance of implementation at the level of practical importance to foreign investment. The basis for the mentioned development of events is the search for economic donor infusions, alternative to budget allocation, subsidization, provision of budget-level subsidized flows. Therefore, the investment result of attracting foreign sponsorship helps to relieve the burden on the state level.

7. Prospects for further research

The existing criterion of the newest component, which is reflected in the comparison of medical and legal practical and theoretical materials in processional activity, can be useful under the condition of its further development and adaptation to the fundamental laws when implemented to the level of practical implementation. Applied popularization of segmental practical application of medical legal norms can serve as a fundamental

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[36] Shinichi Egawa, "Experimental Medicine", *The Tohoku Journal of Experimental Medicine*, vol. 262, no. 1 (2023): 150–156, accessed May 26, 2024, http://dx.doi.org/10.1620/tjem.2023.j096.

[37] Konventsiia Rady Yevropy pro pidroblennia medychnoi produktsii ta podibni zlochyny, shcho zahrozhuiut okhoroni zdorovia: Konventsiia Rady Yevropy vid 28.10.2011 r.: stanom na 7 cherv. 2012 r., accessed May 26, 2024, https://zakon.rada.gov.ua/laws/show/994_a91#Text.

basis for raising the level of legal awareness and medical culture by members of civil society. In accordance with the conditions of the above-mentioned circumstances, the negative criterion of lack of awareness of the procedural mechanism for the realization of socially significant personal rights of members and centers of civil society acquires significant importance and requires the search for ways to resolve the destructive situation. The practical component of conducting clinical (medical) research requires establishing a cause-and-effect relationship between professional medical activity and borrowing the norms of imperative civility of legal regulation of the field of experimental (evidential) medicine.

Financing the work. It was not conducted.

Conflict of interest. There is none.

Compliance with ethical standards. The authors declare compliance with ethical standards when writing the article. No humans or animals were involved in the study, and informed consent was not required.

8. Contribution of the authors to the writing of the article

Establishing patterns of effectiveness of the conducted research are reflected in the discovery of connecting components between legal and medical doctrines. At the practical level of using the cause-and-effect relationship between practical medicine and professional legal activity, the conduct of medical research is imprinted in the order of conducting medical research.

The initial criteria for the criminal-legal assessment are:

- the identity of the patient-volunteer (volunteer of the clinical study), which is considered from the position of the direct victim of the criminal offense (victim);
- the identity of a medical worker, also a special subject of a criminal offense, as a member of a professional research team of clinical (medical) findings;
- persons who can be recognized as being equal to the above-mentioned persons, due to the establishment of signs of engaging in practical medical activity, provided they are admitted to medical practice (in particular, the field of evidence-based medicine) in accordance with the conditions of the current legislation at the national level. Analytical results of the substantive component were obtained based on the results of the informational material of the segmental medical direction, additionally with the help of statistical processing.

Standardized statistical information, social indicators, are used in precedent judicial practice of both national and international significance.

The legal point of view, imprinted in the documentation of the European Court of Human Rights, set out in court decisions and other collegial documents. The practical component of the development of innovative ways of adapting media-communicative content of medical and legal content started the practical interest of public organizations and members of civil society. In this case, the legal monitoring carried out by authorized persons at the state level, as well as the results of the publication of scientific material by scientists, public and other layers of the population, played an auxiliary role. The proper driving component of the vector direction of the innovative development of medical professional activity is provided by the introduction of the legal aspect of understanding the professional component. The legal material, in its adapted form, is considered feasible for practical use by the medical industry. An important condition for the use of legal material by the medical field is the adaptation of the proposed thematic material to the best perception of potential audience circles.

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