Multidisciplinary Study of Medical Errors in the System of Legal Relations Between "Doctor-Patient-Pharmacist-Advocate" During the Circulation of Drugs

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Abstract. Multidisciplinary organizational and legal, forensic and pharmaceutical, clinical and pharmacological, forensic and medical, criminal and legal studies of medical errors in the system of legal relations between "doctor-patient-pharmacist-lawyer" were conducted. The implementation of the rules of the circulation of drugs established by the state to exclude forensic pharmaceutical risks and guarantee the safety of pharmacotherapy of patients was analyzed. Forensic and pharmaceutical analysis of patients' complaints indicates the need for further improvement of pharmaceutical provision and medical care. Normative measures have been developed for the prevention of medical errors during the circulation of drugs of clinical and pharmacological, classification and legal, nomenclature and legal groups.

Keywords: medical errors, crime, multidisciplinary research, drug technology, forensic pharmacy, pharmacology, criminal law, circulation of medicinal products, danger to the health of citizens.

Introduction. In the countries of the world, it is believed that medical errors kill more patients than infections, oncology, addiction, tuberculosis, HIV/AIDS, cardiovascular and endocrine disorders, etc. systems [1-4]:

- 3 million patients die every year worldwide;
- medical errors include incorrect diagnoses, incorrect calculations of drug dosages, delays in treatment;
- 8,220+ preventable deaths in hospitals every day;
- every year more than 5.2 million children under the age of 5 die from preventable causes;
- more than 800 women and adolescent girls die every day due to complications during pregnancy and childbirth.

Forensic-pharmaceutical risks due to fatal cases due to the unprofessionalism of doctors need to be studied in order to join joint efforts to increase the safety of patients in the field of health care in the countries of the world [5-8]. It was COVID-19 that revealed the shortcomings due to medical errors in the countries of the world [9-12].

The 5th Global Ministerial Summit on Patient Safety (February 23-24, 2023 in Montreux, Switzerland) was held to address health care issues. Delegations from more than 80 countries endorsed the Montreux Charter for Patient Safety with recommended actions to eliminate harm [13, 14]. Delegates discussed gaps and key challenges in the implementation of the World Health Assembly resolution (WHA72.6) Global Action on Patient Safety and the Global Patient Safety Roadmap, Global Patient Safety Action Plan 2021–2030: Towards Eliminating the Harms that could be avoided in health care. The Montreux Charter on Patient Safety, approved at the Summit, confirms that:

- harm to patients in the field of healthcare is an urgent public health problem that affects countries with any income level and geographical location;
- patient safety needs to be prioritized, including drug safety, safe surgery, infection prevention and control, and antimicrobial resistance;
- unsafe patient care is one of the leading causes of death and disability in the world. This is particularly acute in resource-constrained settings, with up to 2.6 million citizens dying each

year due to unsafe practices in hospitals in low-income countries. High-income countries are also not immune: almost 15% of hospital costs and activities in EU countries can be attributed to the treatment of security failures;

- it is estimated that more than half of patient harm can be prevented by working together to create a safer healthcare system for all and building a safety culture that emphasizes continuous improvement, learning and innovation.

The COVID-19 pandemic in all countries of the world has caused destruction in the field of health care [15-17]. The pharmaceutical industry became the locomotive on which the burden was placed to protect the life and health of citizens and patients, ensuring their access to vital drugs, vaccines, medical products (sanitary masks, disinfectants, etc.) [18]. The outbreak of the COVID-19 pandemic in the countries of the world had negative consequences [19]:

- completely disrupted the political, industrial, economic, financial, religious, and social systems;
- more than 80 countries of the world and the EU have closed their borders and imposed restrictions on the movement of transport and citizens;
- enterprises and institutions switched to remote/homework, in the worst case – introduced "down time";
- schools were closed for approximately 1.5 billion children;
- a dozen global economies such as the US, China, Japan, Germany, the UK, France, India, Italy, Brazil, and Canada suffered heavy losses. The epidemic caused by the infection had a marked impact on the world's economic, medical, and pharmaceutical development.

Pharmaceutical provision of pharmacotherapy of health disorders against the background of COVID-19 and comorbid health disorders in accordance with ICD-11 actualizes the requirements of proper GxP practices for the production, quality, effectiveness, availability, safety of drugs based on evidence-based pharmacy and medicine [22-30]. The key is multidisciplinary research that combines organizational and legal, forensic and pharmaceutical, clinical and pharmacological, technological, criminal and legal, forensic and medical, etc. [31-34].

Goal. To conduct multidisciplinary organizational-pharmaceutical, forensic-pharmacological, clinical-pharmacological, forensic and medical, criminal and legal studies of medical errors in the system of legal relations "doctor-patient-pharmacist-lawyer" in order to fulfill the rules of the circulation of drugs established by the state to exclude forensic-pharmaceutical risks and guaranteeing the safety of patients' pharmacotherapy.

Materials and methods. The scientific sources of Ireland, the USA, Ukraine, Great Britain, the Netherlands and the countries of the European Union were examined according to the topic of the work. Experimental research base during 1990-2022:

- criminal proceedings (forensic-pharmaceutical, forensic-medical, forensic-narcological, forensic-psychiatric and forensic examinations in criminal cases) in relation to doctors and pharmacists;
- citizens' appeals to the hotline of institutional structures (refusal to provide drugs for privileged categories of patients, inadequate medical care, complaints about the quality of drugs, prescription of drugs with side effects);
- citizens' appeals and court decisions on protection of rights to the "Apotheosis" Bar Association and “Protecta” International Bar Association;
- referral of patients suffering from various health disorders to the Public Organization "Association of Medical and Pharmaceutical Law".

The methods of documentary, normative-legal, retrospective, clinical-pharmacological, classification-legal, nomenclature-legal, forensic-pharmaceutical, comparative, graphic and tabular analysis were used.

The study was carried out under the initiative of the R&D of the State institution "Luhansk State Medical University" "Conceptual interdisciplinary approaches to pharmaceutical supply and availability of medicines taking into account organizational-legal, technological, analytical, pharmacognostic, forensic-pharmaceutical, clinical-pharmacological, pharmacoeconomic, marketing

and socio-economic competences (as of March 03, 2023, state registration number 0123U101632, terms 04/2023-03/2027).

Results and discussion. Interdisciplinary research approaches were carried out taking into account the fact that an important element during the organization and management of pharmaceutical competences in the system of legal relations "doctor-patient-pharmacist-lawyer" is the understanding of the legal aspects of drug circulation, based on the principles of medical and pharmaceutical law [35]. Pharmacists and doctors need to be aware of all the latest legislative and regulatory changes in the field of pharmacy and medicine in order to avoid violations of the rules of drug circulation and prevent administrative and criminal liability.

The second key element in this area is forensic pharmaceutical, forensic narcological, forensic medical, forensic psychiatric and forensic research [7, 14, 26, 28, 29]. Forensic pharmaceutical research allows to identify and analyze unscrupulous producers and sellers of the drug business.

The third element is medical-immunological, clinical and pharmacological, technological and pharmaceutical research, which studies the correct dosage, physical and chemical properties of drugs, the interaction between drugs and the immune system of the patient's body. Such studies are necessary because patients with a background of COVID-19, addiction, and tuberculosis have an increased risk of developing comorbid disorders [20, 21, 30, 36-38].

All these elements, as noted during personal meetings and conversations by leading scientists of Ukraine, Europe and the world, academician of the National Academy of Sciences of Ukraine, prof. Trachtenberg I.M., Academician of the National Academy of Sciences of Ukraine, Academician of the National Academy of Sciences of Ukraine, Doctor of Law, Prof., Hero of Ukraine Tatsii V.Y., Academician of the National Academy of Sciences of Ukraine, Hero of Ukraine Doctor of Law, Prof. Stashys V.V., MD, prof. Sosin I.K., member-cor. National Academy of Sciences of Ukraine, Doctor of Medicine, Prof. Gubsky Y.I., MD, prof. Kutko I.I., MD, prof. Voloshyn P.V., academician of the National Academy of Sciences of Ukraine Stefanov O.V., MD, prof. Shevchenko S.I., academician of the National Academy of Sciences of Ukraine (physics and diagnostics of nanosystems), doctor of physics, prof. Machulin V.F., member of the National Academy of Sciences of Ukraine, Ph.D., prof. Georgievskii V.P. and Ph.D., prof. Tikhonov O.I. should be interconnected and integrated into the multidisciplinary system of organization and management of medical and pharmaceutical competences, laws and regulatory acts of Ukraine within the scope of specialty 15.00.01 – drug technology, pharmaceutical business organization and forensic pharmacy and others. Multidisciplinary research (organizational and legal, clinical and pharmacological, technological, forensic and pharmaceutical, medical and immunological) helps to ensure the availability, safety, quality and effectiveness of drugs during their circulation in the field of pharmacy and medicine. The legal aspects of such studies are no less important, as they allow to create a legislative and regulatory framework for regulating the circulation of drugs, to ensure the interaction of various state authorities during the coordination of the work of health care institutions, pharmacies, lawyers, courts, prosecutors, and law enforcement agencies [39-43].

Organizational and legal, documentary and regulatory analysis recorded numerous appeals from citizens to the contact center of the Ministry of Health of Ukraine (as of 11/25/2020), more than 49,000 appeals were received. Complaints were recorded [44]: 36% about the work of family doctors; 26% for hospital services; 10% of complaints about the work of laboratories; 8% for the work of polyclinics and outpatient clinics. Appeals from citizens relate to: 52% regarding diagnostics; 10% - outpatient treatment; 7% - free and paid testing; 7% - signing declarations; 5% - procedure for self-isolation. Minimum response delays of contact centers: Volyn, Vinnytsia, Rivne, Poltava, Cherkasy, Khmelnytskyi, Ternopil, Odesa, Mykolaiv, Lviv, Zhytomyr and Kherson regions of Ukraine.

Considering the completeness, comprehensiveness, objectivity and multidisciplinary of research by specialists of the Public Organization "Association of Medical and Pharmaceutical Law" in Ukraine shows that the contact center of the Ministry of Health of Ukraine does not consider regional and local appeals of citizens. As a proposal of the Ministry of Health of Ukraine, there is a need to create an electronic system for summarizing all appeals (complaints) of citizens to form an

objective picture of the situation in the field of medicine and pharmacy. Initiate an annual increase of 10 percent of funding in the budget of Ukraine, starting from 2024 [45].

Forensic-pharmaceutical and criminal-legal studies have shown that state policy requires further optimization and reform of Ukrainian drug policy in the system of legal relations "doctor-patient-pharmacist-lawyer". There is excessive regulation of the circulation of drugs of classification and legal groups. The level of availability for patients of all contingents of narcotic analgesics does not meet the needs [46]. According to the UN International Narcotics Control Committee, the rate of prescription of narcotic analgesics in Ukraine is 20 times lower than in EU countries. Punitive ideology should be replaced by more humane and effective approaches based on the principles of pharmaceutical and medical law, human rights [25, 27, 31, 35].

Forensic-medical, documentary, organizational and legal research showed that EU countries lose 125 billion euros every year due to non-compliance with the treatment regimen [47].

- almost half of all adults and approximately 8% of children (aged 5-17) in the world have at least one chronic disease;
- adherence to treatment is only 50% in high-income countries and even lower in low-income countries;
- nonadherence to pharmacotherapy costs between $100 and $290 billion in the US, €125 billion in Europe, and A$7 billion in Australia.

Forensic and pharmaceutical, clinical and pharmacological, classification and legal studies of errors by doctors and pharmacists in Great Britain indicate that almost half of the drugs prescribed by doctors are taken incorrectly by patients. Governments must contribute to the problem of commitment. Measuring adherence at the national level is a key first step, as is investing in person-centered interventions for patients who are at risk and already living with chronic conditions."

The experience of Guernsey B.G et al. about 12-day peer-review audit was performed in the outpatient pharmacy of a large teaching hospital [48]. The audit process was not masked, that is, the pharmacists were aware of the peer-review evaluation. During the 12-day period, 9394 prescription forms and their corresponding pharmaceutical products were examined manually before being delivered to the patient. A total of 1165 (12.4%) dispensing errors were detected, with 141 (1.5%) of these considered potentially serious. Seventy-six prescriptions contained two errors and four prescriptions contained three. There were no statistically significant differences in the dispensing-error rate for the eight pharmacists audited. There was a trend for the number of pharmacist-hours containing at least one potentially serious dispensing error to increase as the prescription-filling rate accelerated. Outpatient pharmacies with high volumes should set a limit to the number of prescriptions filled by their pharmacists and should experiment with quality assurance systems to reduce dispensing errors and subsequent legal liabilities.

Studies of a random sample of prescriptions in pharmacies showed that about half of hospital interventions (49.8%) were aimed at preventing adverse reactions; 29.2% were evaluated as a positive change in the effectiveness of pharmacotherapy; 8.6% affected both efficacy and adverse reactions [49].

The analysis of forensic pharmaceutical practice in Ukraine also records the errors of doctors and pharmacists during the circulation of drugs of nomenclature and legal groups.

Forensic and pharmaceutical example No. 1. Police investigators in the Kharkiv region, under the procedural guidance of the prosecutor's office, are conducting a pre-trial investigation in criminal proceedings based on the fact of violation of the established rules for the circulation of narcotic drugs under Part 1 of Art. 320 of the Criminal Code of Ukraine [50].

Forensic and pharmaceutical example No. 2. Criminal proceedings were opened by police investigators in the Odesa region under the procedural guidance of the prosecutor's office [51]. It was established that the channel for the supply of narcotics was blocked in the city of Dnipropetrovsk. The criminal activities of four medical workers of the anti-tuberculosis dispensary were documented. The head doctor and nurses of the substitute supportive therapy office violated the established rules for the circulation of narcotic drugs "Methadone", "Buprenorphine", "Ednok". Medicines were

illegally issued to persons who are not sick, who were registered in the dispensary and did not have medical indications and grounds for their receipt and use.

Forensic and pharmaceutical example No. 3. Criminal proceedings were opened by police investigators in the Kyiv region under the procedural guidance of the district prosecutor's office [52]. Doctors illegally wrote out prescriptions for obtaining strong and narcotic drugs (methadone, sonnate, etc.) at the pharmacy. Drugs were illegally sold to drug addicts.

Forensic and pharmaceutical example No. 4. Criminal proceedings were opened by police investigators in the Kharkiv region under the procedural guidance of the prosecutor's office [53]. The doctor illegally issued prescriptions for narcotic drugs.

Forensic and pharmaceutical example No. 5. Police investigators in the city of Kyiv and the Kyiv region, under the procedural guidance of the prosecutor's office, opened proceedings on the fact of smuggling precursors and illegal sale of narcotics [54]. A resident of Lviv established a channel for the smuggling of the precursor pseudoephedrine from the Kingdom of Spain to the territory of Ukraine. Through the created account on the Internet, the suspect accepted orders and sold foreign-made drugs containing pseudoephedrine. The circulation of the drug was carried out by delivery to the territory of Ukraine with the help of the international road transport service. To make it impossible to detect the drug by customs authorities when moving across the border, the product was disguised among food products.

Pharmaceutical safety of certain drugs from forensic pharmaceutical practice considering clinical and pharmacological characteristics.

Methadone. It is used for opioid addiction. A synthetic agent with a sedative and analgesic effect like that of morphine. It has a detoxification or maintenance effect in case of opiate addiction. Contraindicated for use in drug-addicted patients

Burrenorphine. They are used for opioid addiction. Causes greater safety in relation to the development of respiratory and heart failure compared to morphine. It has contraindications for alcohol intoxication, concomitant use with drugs for the treatment of alcohol or opioid addiction, alcohol, psychotropic drugs, depressants

The organizational and legal, forensic and pharmaceutical, forensic and medical study of the problems of abuse and illegal circulation of classification-legal groups of drugs [55] highlights modern trends in the early detection of new psychoactive drugs, the system of early notification of the danger of abuse in Europe and the world. The solutions are outlined:

- ✓ proposed options and ways of implementing European experience in Ukraine regarding the use of preventive measures to reduce the level of abuse;
- ✓ the experience of the countries of the European Union, which have laws that criminalize the possession and distribution of drugs, their policies define drug abuse as a public health problem, and not a criminal offense;
- ✓ proposed to check narcotic analgesics for harm reduction considering the dose.

Among the problems of abuse, polydrug addiction and circulation of narcotic analgesics of nomenclature and legal groups, the following are indicated [56-63]:

- improper countermeasures by law enforcement agencies against the development of the drug business, which is not a preventive, but a reactive character;
- individual norms of anti-narcotics legislation are imperfect and do not fully comply with international law;
- violation of the rules for dispensing drugs with narcotic analgesics;
- forensic and pharmaceutical risks and pharmaceutical safety in the development of new drugs;
- the global problem of polydrug addiction.

The organizational and legal study of Ireland's experience shows that 64% of pharmacist respondents indicate insufficient information about the nomenclature and legal characteristics of drugs to be dispensed [63]. A clinical-pharmacological study of prescribing, dosing, and dispensing errors in hospitals and pharmacies in the United States and Europe [64] insists that additional research is needed:

- errors (dosing) and drug dispensing in middle- and low-income countries;

- quality of medicines, internal audit of prescriptions, personalized approach to medical prescriptions, strategy of adequate communication with patients to prevent administrative errors.

In summary, medication errors are an unfortunate part of the health care delivery system [65-66]. Health care provider attitudes must change in the approach to prevention of these errors. Patient education is an important aspect of any program to prevent medication misadventures. The collection of error data and analysis in the health care delivery process will minimize the risk of medication and pharmaceutical errors and improve patient safety. Medication error reduction programs are necessary to achieve improvement in patient care. Those who pay for health care services (government, employers, and individuals) would benefit from a reduction in costs that would result from the reduction in adverse events associated with medication errors.

Thus, conducting multidisciplinary research in the organizational-legal, clinical-pharmacological, medical-pharmaceutical, forensic-pharmaceutical, forensic-medical and criminal-legal spheres to study the mistakes of doctors and pharmacists in the system of legal relations "doctor-patient-pharmacist-lawyer" under the circulation time of drugs helps to increase the level of protection of patients' rights during pharmacotherapy.

Conclusions. Multidisciplinary organizational and legal, forensic and pharmaceutical, clinical and pharmacological, forensic and medical, criminal and legal studies of medical errors in the system of legal relations "doctor-patient-pharmacist-lawyer" were conducted. The implementation of the rules of the circulation of drugs established by the state to exclude forensic pharmaceutical risks and guarantee the safety of pharmacotherapy of patients was analyzed. Forensic-pharmaceutical analysis of patients' complaints indicates the need to improve pharmaceutical provision and medical care. Ways to solve the problem are proposed. Normative measures for the prevention of medical errors have been developed.

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