

ppi 201502ZU4645

Esta publicación científica en formato digital es continuidad de la revista impresa  
ISSN-Versión Impresa 0798-1406 / ISSN-Versión on line 2542-3185 Depósito legal pp  
197402ZU34

# CUESTIONES POLÍTICAS

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de la Facultad de Ciencias Jurídicas y Políticas de la Universidad del Zulia  
Maracaibo, Venezuela



Vol.41

Nº 79

Octubre

Diciembre

2023

# Institution of Patient's Advance Directives in the Context of Ukraine's Aspirations for European Integration

DOI: <https://doi.org/10.46398/cuestpol.4179.15>

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## Abstract

The development of legal science in Ukraine is connected with the processes of reform of society oriented to European values and standards of human rights. The most important among them are life and human health, which are related to the realization of patients' rights in the health sector. In this context, the purpose of the article was to analyze the status and prospects of the legal regulation of the institution of patient advance directives, in terms of the methods of medical intervention for the future. The research methods used were: systems analysis, comparative and legal analysis, formal and logical method, prognosis. In the conclusions, the authors have offered civil means, which should create new opportunities for the exercise of subjective rights of patients during the provision of medical care. Finally, suggestions have been made for draft normative acts on improvement of legal regulation of the health care sector of Ukraine in accordance with European legal norms.

**Keywords:** European legal norms; health care; patients' rights; advance directives; provision of health sector organization.

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## Institución de instrucciones anticipadas del paciente en el contexto de las aspiraciones de Ucrania para la integración europea

### Resumen

El desarrollo de la ciencia jurídica en Ucrania está relacionado con los procesos de reforma de la sociedad orientada a los valores y estándares europeos de derechos humanos. Los más importantes entre ellos son la vida y la salud humana, que están relacionados con la realización de los derechos de los pacientes en el sector de la salud. En este contexto, el propósito del artículo fue analizar el estado y las perspectivas de la regulación legal de la institución de las voluntades anticipadas del paciente, en cuanto a los métodos de intervención médica para el futuro. Los métodos de la investigación usados fueron: el análisis de sistemas, análisis comparativo y legal, método formal y lógico, pronóstico. En las conclusiones, los autores han ofrecido medios civiles, que deberían crear nuevas oportunidades para el ejercicio de los derechos subjetivos de los pacientes durante la prestación de la atención médica. Finalmente, se han formulado sugerencias para proyectos de actos normativos sobre la mejora de la regulación jurídica del sector sanitario de Ucrania, de conformidad con las normas jurídicas europeas.

**Palabras clave:** normas jurídicas europeas; asistencia sanitaria; derechos de los pacientes; voluntades anticipadas; prestación de la organización del sector sanitario.

### Introduction

Ukraine has actually decided the direction of further movement after signing the Association Agreement in 2014 between Ukraine, on the one hand, and the European Union, the European Atomic Energy Community and their Member States, on the other hand, by choosing the European integration vector of development. It means the need for gradual integration to European standards. We mean both the legal and the medical direction of European integration. The availability of an effective model of medical care for the population depends on their successful implementation. The significance of the legal component is to ensure the development and implementation of regulatory acts aimed at building a patient-oriented healthcare system.

Therefore, the legal direction of the European integration of Ukraine's development primarily involves the implementation of international legal standards in the field of ensuring the rights of patients, including by

bringing domestic legislation in line with the provisions of international treaties with the participation of Ukraine and joining the European legal agreements on these issues.

The issue of ratification of the Convention on the protection of human rights and dignity regarding the application of biology and medicine (hereinafter referred to as the Oviedo Convention), signed by Ukraine in 2002, has been on the agenda for many years (Oviedo Convention, ETS No. 164, 1997). The relevance of this event is confirmed by the Resolution of the Verkhovna Rada of Ukraine (Resolution No. 1338-VIII, 2016), where the Cabinet of Ministers of Ukraine was given a recommendation to prepare suggestions for the ratification of the specified European agreement. The Resolution of the Verkhovna Rada of Ukraine (Resolution No. 689-IX, 2020) provides the adoption of the draft Law of Ukraine "On the ratification of the Convention on the Protection of Human Rights and Dignity in the Use of Biology and Medicine (Oviedo Convention, ETS No. 164, 1997)" in order for Ukraine to fulfill its international obligations. Taking into account the above, the relevant direction of scientific research is the analysis of the normative content of the text of the Oviedo Convention, the European experience of its provisions' application, carrying out doctrinal and normative correlations with the domestic legislation and law-enforcement experience.

## **1. Methodology of the study**

The research was conducted on the basis of the analysis of the provisions of the Oviedo Convention, the legal positions of the European Court of Human Rights, the domestic regulatory legal framework, literary sources, description and generalization of the range of existing achievements and problems. The method of ascent from the general to the specific has been applied. Due to this method the basic principle of the autonomy and dignity of the patient has been highlighted in the special aspect of taking into account the previous orders.

The comparative and legal method made it possible to analyze the norms of the Oviedo Convention, the legal positions of the European Court of Human Rights and the norms of Ukrainian legislation. Due to the formal and logical method, the definition of the main concepts of the institution of advance directives adequate for the application in domestic acts of legislation, has been offered. The forecasting method assisted to prove that the offered civil means should create new opportunities for exercising the subjective rights of patients during the provision of medical care.

## 2. Analysis of recent research

The problem of introducing the institution of the patient's advance directives has not received due attention among Ukrainian scholars. Legal research in the field of patients' rights is conducted in tangential directions: ensuring the right to medical care (Teremetskyi *et al.*, 2019); specific features of the protection of human rights in the healthcare sector by national courts (Teremetskyi and Muliar, 2019); informed voluntary consent (Teremetskyi and Avramova, 2018); deprivation of life at the request (euthanasia) (Bolidzhar, 2020).

Some scholars in their publications offer to eliminate the gaps in Ukrainian legislation by ratifying the Oviedo Convention and establishing in Ukraine the institution of previously expressed wishes (Puchkova and Bogutska, 2021) or patient advance directives (Shchyrba, 2021). At the same time, reasonable suggestions are expressed in regard to the regulation of the institution of advance directives in Ukraine (Myronova, 2020).

We note that the problem of advance directives in the healthcare sector is widely and thoroughly discussed in the European scientific community in various aspects: regarding the implementation of patient's autonomy (Johnson *et al.*, 2018); specifics of observing the ethics of autonomy in caring for the dying (Gómez-Virseda *et al.*, 2019); the significance of autonomy as the ability to make independent rational choices for patients who receive palliative care (Houska and Loučka, 2019); special regime of previous psychiatric directives (Tinland *et al.*, 2019).

## 3. Results and Discussion

### 3.1. European legal standards regarding the regulation of patient's advance directives.

The institution of the patient's advance directives is part of the European concept of human rights and dignity as a participant in the relationship for the medical care provision. The main constituent rules of consent as conditions for the legality of any intervention in the field of human health in the European legal tradition are enshrined in the norms of the Oviedo Convention. Chapter II "Consent" consists of 5 Articles that form the doctrinal framework and normative basis for implementation into national legal systems.

The Article 5 contains a general rule, according to which any intervention in the field of health can be carried out only after the voluntary and informed consent of the person concerned. The Articles 6 and 7 enshrine principles for the protection of persons who are incapable of consenting to medical

intervention. In particular, special rules for granting consent are applied in the provision of medical assistance to minor persons, adult incapacitated individuals, including in the provision of psychiatric care. The Article 8 regulates the granting of consent in emergency situations.

The Article 9 (the Art. 9 "Previously expressed wishes") enshrines a special rule of regulation of the legal institution of the patient's previously expressed wishes for the first time at the level of an international agreement: "The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account". In this way, the patient's advance directives are a component of the rule of consent to medical intervention in the European legal tradition.

The absolute values recognized by the European community (dignity, autonomy, integrity, inviolability) have gradually acquired their concretization due to legal opportunities for a person to independently use and dispose of own body, individual organs, allow or limit access to them. The provisions of the Art. 9 of the Oviedo Convention seek to create a binding legal framework for the legitimacy of advance health care documents, whereby a person will have the opportunity to record own choice of treatment and care methods for the future in advance in a legally binding document. Due to special transactions, the fundamental principle of human autonomy extends to situations where the patient is unable to give or express own consent.

Progressive processes in medicine and biomedical sciences became the catalyst for the initiation of a special norm regarding the implementation of a patient's advance directives. Such new transactions of patients have become relevant due to the spread of the latest medical technologies aimed at prolonging or artificially maintaining life processes, which did not always have favorable clinical results of resuscitation measures.

Those measures immediately showed unexpected effectiveness, when closed cardiopulmonary resuscitation was first used to save patients with cardiac arrest in the middle of the XX century. Thus, 118 cardiopulmonary resuscitation procedures were successfully performed in 1961 just at Johns Hopkins Hospital for patients with circulatory arrest (Berger *et al.*, 2016). According to their data, cardiac activity was restored in 79% of cases, but only 60% of the patients who were saved returned to the state of activity of the central nervous system and the heart, which was before the circulatory arrest.

The routine application of cardiopulmonary resuscitation to all hospital patients who needed it led to new problems in the following years until 1963. Prolonged suffering and a prolonged dying process have in many cases resulted from successful cardiac resuscitation, especially in terminally ill patients. However, there was no legal document until 1976 that would regulate the patient's right to request refusal of resuscitation.

In the light of modern ethical requirements of respect for the patient's autonomy, dignity and individuality, advance directives made in case of their inability to make their own decisions or to report them, have acquired the legal status and are one of the legal means of clinical decision-making.

The Article 9 of the Oviedo Convention is applicable to at least 3 types of different legal situations: a) emergency cases, when a patient does not have the ability to express own opinion; b) situations, when a person in a state of progressive illness or dementia refuses in advance certain methods of artificial life support; c) situations, when a person consciously (for religious or ethical reasons) refuses certain defined methods of medical intervention and certifies own wishes for the future, when he / she may become unable to express own will.

The position of the drafters of the Oviedo Convention that doctors cannot act completely arbitrarily in case of a patient's incapacity to express his / her will has become apparent increasingly over time. That is, they must have good reasons to disregard a patient's legitimate wishes expressed in advance directives.

Although the text of the Art. 9 of the Oviedo Convention refers only to unilateral transactions – advance directives regarding methods of medical intervention for the future, the practice of applying this norm in certain countries shows that advance directives are made in two legal forms: unilateral directives and instructions to another person, which is based on the contract.

Unilateral directives are made in the form of a personal statement-order of a patient regarding treatment, care, life-saving procedures or prolongation of life in case it is impossible to notice his / her choice. A mandate is a form of procuracy based on a contract that appoints a person empowered to make medical decisions instead of a patient. A mandate provides benefits in providing clarification of a patient's preferences, if they have been expressed in vague, ambiguous terms in personal directives and for providing medical care in unexpected situations that have not been specifically addressed by a patient.

Special principles regarding the status and legal mechanisms of the institution for advance planning of treatment and care are laid down in a number of legal acts of the Council of the European Union, which have the nature of recommendations. In particular, the Recommendation of the Committee of Ministers to member states on principles concerning continuing powers of attorney and advance directives for incapacity (Recommendation CM/Rec, 2009: 11) states that states should promote early self-determination of capable adults (in the event of their incapacity in the future) by means of appropriate orders and preliminary orders.

The issue of the priority of those methods over others must be considered in the context of the principles of patient self-determination and the subsidiarity of protection measures. Recommendation CM/Rec (2009: 11) provides model definitions of key terms. A “continuing power of attorney” is a mandate given by a capable adult with the purpose that it shall remain in force, or enter into force, in the event of the grantor’s incapacity. The “granter” is the person giving the continuing power of attorney. The person mandated to act on behalf of the granter is referred to as the “attorney”. “Advance directives” are instructions given or wishes made by a capable adult concerning issues that may arise in the event of his or her incapacity. The “granter” is the person giving the continuing power of attorney.

The Committee of Ministers of the Council of Europe recommends that states should: develop provisions and mechanisms that may be necessary to ensure the authenticity of documents; regulate the procedure for the validity of the power of attorney; standardize the procedures and criteria for determining the legal capacity of patients; decide the extent of advance directives are to be binding; consider the circumstances when a durable power of attorney becomes invalid and what protective measures are to be taken in such circumstances; regulate issues about situations that arise in the event of a significant change in circumstances. Advance directives, which are not binding, should be considered statements of wishes that must be given due respect.

A movement to implement mechanisms for taking into account documents from patients’ advance directives into national legal systems has been also started since 2009 in the Parliamentary Assembly of the Council of Europe (PACE). Hearings on the topic “Living wills and the protection of health and human rights” were held in the period from May to December 2011, the result of which was the adoption of important documents – Resolution 1859 (2012) and Recommendation 1993 (2012) under the joint title “Protecting human rights and dignity by taking into account previously expressed wishes of patients”.

In particular, Resolution 1859 (2012) of the Parliamentary Assembly of the Council of Europe recommended that member States: sign, ratify and fully implement the Oviedo Convention, if they have not already done so (clause 6.1); apply Committee of Ministers Recommendation CM/Rec (2009: 11) (clause 6.2); review, if need be, their relevant legislation with a view to possibly improving it (clause 6.3); for countries with no specific legislation on the matter – by putting into place a “road map” towards such legislation promoting advance directives, living wills and/or continuing powers of attorney, on the basis of the Oviedo Convention and Recommendation CM/Rec (2009: 11), involving consultation of all stakeholders before the adoption of legislation in parliament, and foreseeing an information and awareness-raising campaign for the general public, as well as for the medical and legal professionals after its adoption (clause 6.3.1); to encourage

self-determination of capable adults in the event of their future incapacity, by means of advance directives, living wills and/or continuing powers of attorney, should be promoted and given priority over other measures of protection (clause 7.1); advance directives, living wills and/or continuing powers of attorney should be accessible to all; complicated forms or expensive formalities should thus be avoided (clause 7.5) (Resolution PACE 1859, 2012).

The fact that these norms were included into the Principles, Definitions and Model Rules of European Private Law Draft Common Frame of Reference (DCFR, 2009) testifies to the importance of the legal mechanism of advance directives regarding future treatment. Chapter 8 “Medical services” stipulates the requirement of mandatory consideration of prior orders regarding medical intervention. Thus, the Article IV.C.-8:108 “Obligation not to treat without consent” contains the following rules: in so far as the patient is incapable of giving consent, the treatment provider must not carry out treatment without considering, so far as possible, the opinion of the incapable patient with regard to the treatment and any such opinion expressed by the patient before becoming incapable.

### **3.2. Legal positions of the European Court of Human Rights regarding patient’s advance directives**

The norms of the Oviedo Convention are not directly subject matter to interpretation by the European Court of Human Rights (hereinafter – ECHR). However, there is a fundamental affinity between the Oviedo Convention and the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter – CPHRFF) (ECHR, 1950), which guarantee the protection of human rights both at the conceptual and normative levels.

Both agreements are based on the same approach, the same ethical principles and legal concepts that are developed and specified in the Oviedo Convention for the purpose of protecting human dignity in the field of biology and medicine. That is the reason why the legal positions of the ECHR in medical cases are of particular interest, which provide guidelines on how the ECHR considers and qualifies violations of human rights in the field of medical care. Due to this analysis we have the opportunity to foresee the necessary regulatory safeguards for human rights violations in the formation of national legislation in this area.

It is still unusual for most European countries to make clinical decisions on the basis of a patient’s advance wishes, however, some generalizations can be currently made about the ECHR’s legal position in regard to advance directives. Considering comprehensive moral and legal aspects of taking into account a patient’s advance directives, the ECHR Lambert against France decision (Application No. 46043/14, 2015) formulated the

basic principles that must be taken into account while forming national legislation. First of all, the ECHR noted the conceptual legal difference between euthanasia (assisted suicide), on the one hand, and withholding life-sustaining treatment, on the other. This statement made an important substantive distinction between the institutions of euthanasia and advance declaration of will regarding future treatment.

Secondly, the ECHR reaffirmed its position regarding the mechanism of medical decision-making in a new context, if a patient cannot (or can no longer) participate in this procedure. In this case, the decision is made by a third party in accordance with the procedures set out in national law. However, a patient still should be involved in the decision-making process through any previously expressed wishes.

The wishes of a patient in the medical decision-making process are of paramount importance, regardless of how they are expressed. Thirdly, the ECHR noted that medical factors (in particular, a patient's current condition, changes in that condition, degree of suffering, clinical prognosis) and non-medical factors, including a patient's wishes should be taken into account while assessing whether treatment meets the criteria of unreasonable obstinacy, no matter how they were expressed, how a physician should have paid special importance, as well as the views of a trusted person, family or relatives.

Thus, there is a principled position of the ECHR regarding the paramount importance of a patient's wishes in the decision-making process, regardless of how the wishes are expressed. When two Conventional rights are pitted against each other: the right to life with the corresponding duty of the state to protect life under the Art. 2, on the one hand, and the right to personal autonomy, which falls within the protection of the Art. 8. "Respect for human dignity and human freedom" may prevail in such a contest. If there are no prior orders, the dignity of a person is interpreted in terms of the predominance of the value of life.

Another legal position was formulated by the ECHR in the case *Berke* against the United Kingdom (Decision as to Admissibility Application No 19807/06, 2006). The decision concerned the right of a competent patient to request the treatment defined in the earlier orders. The applicant was concerned that the current professional medical guidelines in the United Kingdom in his opinion would allow treatment to be withdrawn in circumstances that would result in his suffering, death, starvation and dehydration. The applicant wished to be fed and adequately hydrated until he would naturally die.

Applying for protection to the ECHR, the applicant complained under the Art. 8 of the European Convention that he was deprived of the protection of an important aspect of his personal autonomy within

the national jurisdiction because he could not make advance directives regarding the treatment he wished to receive at a time when he was not able to communicate. He considered the presumption of priority of his wishes in favor of life-prolonging treatment insufficient.

The ECHR in its decision expressed the legal position that an applicant cannot predetermine the application of a particular treatment in future unknown circumstances. Neither a competent nor an incompetent patient can demand treatment from a physician that the doctor considers to be clinically unjustified.

Therefore, in the context of the Art. 8 of the Convention for the Protection of Human Rights and the Art. 9 of the Oviedo Convention, as well as in the light of the legal evaluations of the ECHR, the principle of a patient's personal autonomy extends to the situation of the loss of part of his competence and even the loss of consciousness. Physicians in such clinical settings have an obligation to retrospectively consider a patient's expression of will and personal preferences regarding the methods of medical intervention. This approach legally obliges the governments of countries that have joined these agreements to introduce new institutions into legislation, and this has already been done in some countries of Western Europe.

Different jurisdictions choose different ways to introduce legal means that ensure a patient's autonomy in choosing future medical interventions. Some have adopted special legislation regulating patient rights, others have incorporated special norms into general civil legislation. For example, separate norms related to a patient's autonomy and advance directives are included into the Mental Capacity Act in the jurisdiction of England and Wales (Mental Capacity Act, 2005).

The law regulates the spectrum of legal relations arising in connection with a person's loss of competence, which relate to financial issues, personal well-being and the provision of medical assistance. Issues regarding a patient's autonomy and advance directives are regulated in Austria by a separate special Federal law "Bundesgesetz über Patientenverfügungen" (Bundesgesetz über Patientenverfügungen, 2006).

### **3.3. Patient's advance directives in Ukrainian law**

With the beginning of the reform of the health care system in Ukraine in 2017, certain elements of the institution of advance directives were fragmented and legitimized at the level of orders of the Ministry of Health of Ukraine. Thus, the Order of the Ministry of Health of Ukraine "On the approval and implementation of medical and technological documents on the standardization of emergency medical care (Order MoH No 1269, 2019) approved a new clinical protocol "Emergency medical care: pre-hospital stage", which is a translation of the corresponding protocol acting in the

USA and regulating patient's advance directives among other things, in particular, transactions "Do Not Resuscitate".

Advance directives are defined in the protocol as "a document describing the procedures allowed for the specified medical conditions, including all or only in part from the following: actions in case of cardiac arrest, whether artificial nutrition is allowed, whether or not to be a donor, dialysis and other parameters". Paragraph 4.4 of this protocol requires emergency medical providers to recognize and support the various ways, when patients can express their wishes regarding cardiopulmonary resuscitation or end-of-life decisions.

This medical and technological document is somewhat inconsistent with the legislation regulating relations in the field of medical care in Ukraine. In particular, the Order of the Ministry of Health of Ukraine No 1269 contradicts the Art. 52 of the Law of Ukraine "Fundamentals of Ukrainian legislation on health care" (Law of Ukraine No. 2801-XII, 1992), which provides: "medical employees are obliged to provide full medical care to a patient who is in an emergency condition. Active measures to support a patient's life are stopped, if a person's condition is determined to be irreversible". Other orders of the Ministry of Health of Ukraine also partially regulate the institution of "a patient's proxy for notification in case of a patient's emergency" (Order MoH No. 503, 2018; Order MoH No. 2755, 2020). However, there is still no special regulation of the specified relations in the legislation.

The norms of the Art. 6 of the Civil Code of Ukraine (Law of Ukraine No. 435-IV, 2003) provide the possibility of recognizing a contract and unilateral transaction as a source of civil law in cases of gaps in the law regarding relationships not regulated by civil legislation acts. That is, individuals (persons) in Ukraine can theoretically make advance directives.

However, such documents in practice are not considered legally binding. Since there is no special legislation on advance directives, there are no defined legal grounds regarding the degree of obligation, scope and validity of such documents. Given the peculiarities of the domestic legal culture and mentality, the practical meaning of authorizing a proxy in matters of health care is almost lost, because if a patient becomes incompetent, decisions about treatment and care are made by physicians or relatives, guardians, even if they do not agree with patient's personal preferences.

Taking into account the above, and the European integration direction for the development declared by Ukraine, the observance of a patient's recognized rights and the development of adequate ways of implementing the institution of advance directives, taking into account the peculiarities of the legal system and the legal culture of the population, become of urgent importance. The introduction of special norms into the legislation of

Ukraine, which regulate relations of contractual representation of a patient and advance directive, will contribute to the promotion of a patient's autonomy in Ukraine.

We supplement the Art. 3 of the Law of Ukraine “Fundamentals of Ukrainian legislation on health care” (Law of Ukraine No. 2801-XII, 1992) with the following terms and definitions: “Patient’s advance directives” – a legal document drawn up in accordance with the requirements of the law by an individual with full civil legal capacity, which records his / her will regarding the methods of medical intervention for the future.

“Power of attorney for decision-making in the field of health care” is a legal document drawn up in accordance with the requirements of the law by an individual with full civil capacity for the purpose that it remains in force or enters into force in case of the grantor’s incapacity. “Patient’s proxy” is an individual authorized to make decisions regarding medical intervention and to obtain medical information by a person with full civil legal capacity on the basis of a power of attorney agreement.

Paragraph 1 of the Art. 52 of the Law of Ukraine “Fundamentals of Ukrainian legislation on health care” (Law of Ukraine No. 2801-XII, 1992) we offer to be worded as follows:

Medical employees are obliged to provide medical care to a patient who is in an emergency, on the grounds and to the extent determined by legislation, on the basis of clinical protocols and standards for the provision of urgent and emergency medical care, which are approved by the central body of executive power, which ensures the formation and implementation of state policy in the healthcare sector, and taking into account of a patient’s advance directives. Active measures to support a patient’s life, authorized by the patient, his representative, are terminated in case if the person’s condition is determined to be irreversible death.

Besides, the legal mechanism of advance directives must be enshrined in the special Law “On Patient’s Advance Directives”.

### **Conclusions**

The patient’s advance directives are a component of the rule of consent to medical intervention in the European legal traditions. Due to special transactions, the fundamental principle of human autonomy extends to those situations, when a patient is unable to give or express his consent. According to the ECHR’s legal position, a patient’s wishes in the decision-making process, including advance directives, are of paramount importance.

There is no special regulation of relations on the contractual representation of a patient and a patient’s advance directives in Ukrainian legislation. Therefore, the relevant amendments to the legislation, taking

into account the norms of the Art. 9 of the Oviedo Convention in the context of the renewal of civil legislation, which is ongoing in Ukraine, have been offered. New civil legal means will create new opportunities for individuals in exercising their subjective rights by extending the principle of consent to those situations, where a patient's will be not taken into account for various reasons.

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# CUESTIONES POLÍTICAS

Vol.41 N° 79

*Esta revista fue editada en formato digital y publicada en octubre de 2023, por el **Fondo Editorial Serbiluz**, Universidad del Zulia. Maracaibo-Venezuela*

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