

The incorporation of the *lex artis* in the Law

La incorporación de la *lex artis* en el Derecho

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Abstract:

Health protection acts require special legal regulation, since scientific principles constitute a parameter for assessing whether the biomedical act was carried out correctly. In order to provide legal validity to such principles, their incorporation into the rules of law is required and thus be able to establish their enforceability, considering the experimental nature of medical sciences.

Keywords:

Law, *lex artis*, legal rules, legal provisions

Resumen:

Los actos de protección a la salud, requieren de una regulación jurídica especial, pues los principios científicos constituyen un parámetro para la valoración de si el acto biomédico se ejecutó de forma correcta. A efecto de dotar de validez jurídica a tales principios, se requiere su incorporación a las normas de Derecho y así poder establecer su exigibilidad, considerando la naturaleza experimental que tienen las ciencias médicas.

Palabras Clave:

Derecho, *lex artis*, reglas jurídicas, disposiciones jurídicas

INTRODUCTION

This work aims to analyze and identify the *lex artis*, for the assessment and regulation of the actions of health personnel, incorporating it into law.

The practice of health professions, referring particularly to medical practice, has a special legal regime, since medicine is an inexact and evolving science, so each human body responds differently to the medical act.

As previously mentioned, the purpose of this paper is to identify how ethical, bioethical, and scientific principles are incorporated into the legal system, as well as to propose their need, and usefulness to regulate the content of medical obligations, through means such as the *lex artis*, and to achieve a more objective assessment of the medical act in the light of the General Theory of Law, taking into account the nature of medical science.

LEX ARTIS AND LEX ARTIS AD HOC

The *lex artis* has been defined as a set of general rules, techniques and procedures applied for the assessment and regulation of the medical practice. Nevertheless, this concept refers to universal criteria for action, so a second meaning is necessary for those that can and should be considered correct in a particular situation, which translates into *lex artis ad hoc*.

Martínez-Calcerrada (Fernández, 2004 p. 195), stated as the criterion for assessing the correctness of the specific medical act performed by the medical professional that takes into account the special characteristics of its author, of the profession, of the complexity and vital importance of the act, and if applicable, of the influence of other endogenous factors such as state and intervention of the patient, of his/her relatives, or of the health organization itself, to qualify said act as conforming or not to the required normal technique.

Moreover, the guidelines or "standards" for the performance of healthcare personnel are subject to the constant evolution of the health sciences, so that the content of the *lex artis* is dynamic.

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Referring to the content of the *lex artis* and the *lex artis ad hoc* can only be constructed by Medicine itself. That is why, to establish general and prudential criteria, consensus and repeated practice in the practice of this science are required. As an illustration of the above, clinical guidelines and action protocols, to mention a few, have been developed, resources that provide a great deal of material for the assessment of cases. These principles are constantly updated in response to new needs. Furthermore, beyond these assumptions, the *lex artis* can also be generated from the magisterial literature, the indexed Biblio-hemerography, the criteria of the health authority, and the criteria of competent commissions and committees.

Citing Martínez-Calcerrada, CasaMadrid reproduces some of the methodological elements that he proposes when systematizing the study of the *lex artis ad hoc* and that are necessary for the analysis of cases (CasaMadrid, 2005, p. 7):

1. The reference to rules of conduct measurement, per scales that make up the *ad hoc lex artis*.
2. The necessity of evaluating medical conduct according to the rules of the generality of professional conduct in similar cases.
3. The need to assess the technique and personal art of the author of the medical act.
4. The existence of axiological integration modules:
 - a. Circumstances of the author.
 - b. Object of the care.
 - c. Endogenous factors of the intervention and its consequences.
 - e. Necessity of assessing the concreteness of the *ad hoc* medical act.

As can be seen, the *ad hoc lex artis* allows that, through the general principles established by the *lex artis*, particular cases can be analyzed according to different circumstances such as mode, time, and place that directly or indirectly influence the development of the medical action. So then, once again, the possibility and necessity of analyzing and regulating the acts of healthcare personnel employing the incorporation of ethical and bioethical criteria can be affirmed.

LEX ARTIS AND DEONTOLOGY

The concepts, importance, and usefulness of *lex artis* and *lex artis ad hoc* have been explained, but it is necessary to address, albeit briefly, their relationship with medical deontology.

The latter can be conceived as the discipline in charge of establishing the duties of healthcare professionals, insofar as it is the Ethics applied to the professional practice of Medicine, which orders to act always in the patient's best interest, personalizing care and promoting the best scientific and human quality.

Nonetheless, various currents and opinions seek to influence philosophical and bioethical thought, which generates a series of aporias and for whose solution it is not enough to accept or reject such currents or opinions, even when they represent a majority in bioethical thought in a given country, because,

under these pluralities of contributions, one lives with various integrated morals. A systematization of deontology is therefore necessary.

On one side, health personnel conducts themselves with a scientific and health protection attachment. on the other hand, the patient claims a principle of autonomy which, on many occasions, they seek to impose on the law and public order. This conflict seems difficult to resolve.

In this regard, to present a solution to the antinomies that can be generated, it is essential to quote Casa Madrid Mata in his exposition of useful guidelines for such a purpose. (CasaMadrid, 2005, p. 15).

Part of the enormous contribution of García Morente with the principles to evaluate or qualify progress.

The first group refers to the realization of values and gives the following axioms: progress exists before the discovery or invention of a value. in addition, the institution is destined to a value implying progress. Also, the increase of goods in quantity is progress. On the contrary, the increase of evils will always be a setback. The conversion of an end good, in an average good, does not constitute progress, it would be a setback.

The second group is the estimation of values, from which the following axioms derive: every increase in estimating human capacity is good, every rectification of aberrations entails progress.

The third group is directed towards the judgment of universal progress: the promotion and development of an inferior value, to the detriment of a superior value, constitutes a step backward, the discovery of a problem and change of attitude is progress.

The parallel development of values must be sought; in themselves, they are compatible, only the technique of their realization can put them in conflict.

To conclude, the elements that, in the light of the principles of the medical art, are proposed by this jurist are taken up again, enunciating them in what should be the order of application (CasaMadrid, 2005, p. 15 and 16):

- preserving life;
- alleviate suffering;
- not harm;
- tell the truth;
- respect patient autonomy; and
- treat patients fairly.

As can be appreciated, such principles allow a systematized approach to the solution of aporias and dilemmas, a task that is not easy but that can be achieved with fairer criteria, incorporating elements of medical ethics.

in this section, since it is the subject of extensive work. With this, we intend to present "*lato sensu*" the concept of Law.

LEX ARTIS AS A SET OF INTERPRETATIVE LEGAL RULES OF LAW

Once the legality of bioethical and deontological principles and the content of the *lex artis* have been considered, it is unavoidable to deal with their legal relevance.

Therefore, not only ethical and bioethical principles are necessary for the assessment of the medical act, but also scientific principles must be considered.

To identify how to assess the adherence of the health professional's actions to such principles, CasaMadrid Mata is quoted in his enormous contribution to Health Law (CasaMadrid, 1999, p. 9 and 10).

For the assessment of the scientific principles (in terms of *lex artis*), it must be established whether:

- There was a diagnosis and prognosis.
- The diagnosis and prognosis were correct.
- The technique used was following the indications and contraindications established in the accepted literature.
- Each of the members of the health team fulfilled their duties.
- There was adequate supervision.
- The instructions were precise and well-founded.
- Therapeutic support measures were adopted.
- Elaboration of mandatory reports.
- Consequences on the patient's health, according to the doctrine of *res ipsa loquitur*.

As regards ethical principles (in terms of medical deontology), the following should be identified:

The *animus* of the health personnel when offering their services. For instance, licit or illicit, ethical or unethical.

- Whether there was sufficient information to the patient or his/her legal representative.
- Whether informed consent was obtained. Whether the patient was subjected to unnecessary risks and harm (therapeutic obstinacy).
- Consequence on the patient's health, according to the doctrine *res ipsa loquitur*.

We can appreciate with the implementation of this guide, how some "standards" become interpretative legal rules. It is important to clarify that these rules are a daily support tool in therapeutic decisions and not only parameters to evaluate malpractice because although they are used for the latter case, it is also as a consequence and not as an essential purpose.

THE LEGAL DUTY OF OBSERVANCE OF THE LEX ARTIS; APPLICABLE LEGAL PROVISIONS

As has been explained, the obligatory nature of the observance of the principles of the *lex artis*. For example, scientific, ethical, and bioethical depend on their recognition and incorporation in the legal norms. In this sense, considering them as legal rules of an interpretative nature, it is unavoidable to resort to them for the assessment of the medical act.

While the *lex artis* refers to a set of rules, procedures, and general techniques, the *ad hoc lex artis* is useful for the specific assessment of cases. As for ethical principles, although they

have a tinge of moral norms characterized by interiority, arising from medical deontology, they do pursue external coercion by imposing certain sanctions in case of non-compliance.

As an example, we can observe the different codes of ethics formulated by professional associations, in which, in the event of non-compliance with their duties, they are sanctioned with expulsion from the guild or suspension of certain rights.

However, the legal norm, in various provisions, refers to the observance of such principles, thus giving them a legal relevance that makes it possible to demand them.

It has also been mentioned that the content of the *lex artis*, as "standards", do not have the essential purpose of serving as parameters to evaluate malpractice, but as useful elements to provide adequate and timely medical care, but that function is a consequence of it.

The following are some of the legal precepts, especially those of the health legislation, which mandate the observance of the aforementioned principles.

The Regulations of the General Health Law on the provision of health care services provide:

Article 9°. Medical care must be carried out under the scientific and ethical principles that guide medical practice.

This precept, which has been cited frequently in this work, makes it possible to incorporate the content of the *lex artis* and the duties imposed by medical deontology in the provision of medical care and constitutes one of the legitimizing criteria for the acts of healthcare personnel, since it means that the observance of bioethical principles such as beneficence, non-maleficence, autonomy and justice are not left to internal jurisdiction, but can be enforceable by means of legal standards.

Regarding the General Health Law

Article 51. Users shall have the right to obtain timely health benefits of suitable quality and to receive professional and ethically responsible care, as well as respectful and dignified treatment from professionals, technicians, and auxiliaries.

The users will have the right to choose, freely and voluntarily, the doctor who will attend them from the doctors of the first level of care unit corresponding to their domicile. According to the working hours and the availability of space of the chosen doctor and based on the general rules determined by each institution. In the case of social security institutions, only the

insured may exercise this right in favor of themselves and their beneficiaries.

Article 51 Bis 1. The users shall have the right to receive sufficient, clear, timely, and truthful information, as well as the necessary orientation regarding their health and the risks and alternatives of the procedures, therapeutic and surgical diagnoses, indicated or applied to them.

Article 51 Bis 2.- The users have the right to decide freely on the application of the diagnostic and therapeutic procedures offered. In case of urgency or if the user is in a state of temporary or permanent incapacity, the authorization to proceed shall be granted by the accompanying family member or his/her legal representative. In case the above is not possible, the health service provider shall proceed immediately to preserve the life and health of the user, leaving a record in the clinical file.

The users of public health services, in general, will be provided with facilities to access a second opinion".

As can be seen, the first paragraph of article 51 grants the user of the health care service the right to demand ethically responsible health care services. Consequently, by the bilateral nature of the legal rules, since this right can be demanded by the patient, it is a correlative obligation for the service provider. Regarding the second paragraph and numeral 51 Bis 2, in concordance with what was stated when Bioethics was addressed, it incorporates rules derived from the bioethical principle of patient autonomy.

Regarding 51 Bis 1, it can be stated that they derive from the principles of non-maleficence and autonomy since truthful information does not deceive the patient and allows him/her to be aware of his/her state of health and treatment to make a conscious decision.

Article 75. The internment of persons with mental illnesses in establishments intended for such purpose shall be adjusted to ethical and social principles. Besides the scientific and legal requirements determined by the Ministry of Health and established by the applicable legal provisions.

The obligation to resort to ethical and scientific principles for the internment of these patients is evident.

Article 100. Research on human beings shall be carried out on the following bases:

I. It must be adapted to the scientific and ethical principles that justify medical research, especially concerning its possible contribution to the solution of

health problems and the development of new fields of medical science.

In research on human beings, it is essential to justify the intervention of health personnel in principles of beneficence, non-maleficence, and autonomy, since it is an act with special consequences because the person is subjected to an experimental study. In this regard, Article 103 of the General Health Law allows the use of new therapeutic or diagnostic resources when there is a well-founded possibility of saving a life, restoring health, or reducing the patient's suffering, as long as the patient's consent is obtained and per the law.

Therefore, even in the case of newly discovered means, their application is allowed based on the principle of beneficence. Meanwhile, Title Octavo Bis of the same legal text regulates palliative care for terminally ill patients. It is unthinkable that such provisions do not give legal relevance to the principles in question; by way of example.

Article 166 Bis 3 provides that terminally ill patients have, among other rights, to receive dignified, respectful, and professional treatment in an attempt to preserve their quality of life and to receive clear, timely, and sufficient information on the conditions and effects of their illness.

Article 166 Bis 18 provides that to guarantee the quality of life and respect for the dignity of the patient, treatments considered as therapeutic obstinacy will not be applied. Once again, the principle of non-maleficence is applied.

Likewise, in several Mexican official standards, it is ordered that for their correct interpretation, the scientific and ethical principles that guide medical practice will invariably be taken into account, especially the freedom of prescription in favor of the medical personnel through which the professionals, technicians, and auxiliaries of the health disciplines will render their services to the best of their knowledge and belief, for the benefit of the user, taking into account the circumstances of the manner, time and place in which they render their services.

CONCLUSIONS

As it has also been exposed, the health legislation in the Mexican legal system, through different precepts, recognizes the legal relevance of scientific and ethical principles, establishing, on one hand, the duties of the health professional and on the other hand, granting the subjective right to the patient to be able to demand its compliance, not only to determine malpractice but pursuing to establish general criteria that will invariably raise the quality in the provision of medical care.

Given the foregoing, it is possible to affirm the usefulness and legal importance of ethical, bioethical, and scientific principles for Law, essentially in Health Law, to legitimize the medical act utilizing a fairer and more equitable assessment in agreement with the legal order. Law was well defined in

Roman law as *Ius est ars et Boni et aequi*, Law is the art of the good and equitable.

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