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Jurisprudential Landmarks Regarding the Informed Consent

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Abstract: *A court decision that admitted the patient's right to decide with regard to his body took the American medical world by surprise in 1914. After decades of silence, the decision of a judge who asked the doctor to share the decision with the patient marked the beginning of a change in the communication pattern between them. Today, the culture of human rights, the wide access to medical information, the risks involved by the new technologies impose a permanent re-adjustment of the doctor-patient relationships and of the relationship between medicine and law. The analysis of the jurisprudence of international courts attempted in this paper may provide a few hints in this direction.*

Keywords: *informed consent, doctor-patient relationship, international bioethics, ECHR case-law regarding informed consent.*

Introduction

We are witnessing a continuous readjustment of the doctor-patient and medicine-law relationships. The law leads to a modification of medical traditions and mentalities, thus marking new milestones of medical ethics. It is hard to indicate the extent to which the medical decision may be the subject of control. The answers are divided between those seeing that the medical profession should be allowed to regulate acceptable behaviors (from one case to another, given the diversity of patients) and those who accept the fact that the relationship with the patient goes beyond the medical staff and, therefore, the field of health should be controlled by law, to the advantage of the entire community (1).

Getting the consent is the fundamental deontological norm in the doctor-patient relationship (2). From an ethical point of view, consent results from the principle of the autonomy of the individual (3) based on the respect for human dignity. From a legal perspective, consent is based on the famous *noli me tangere* principle (4). In its entire evolution the dignity concept (*dignitas*), interpreted as status of individuals who owned *dominion* (at Romans), as fundamental basis of science (Thomas Aquinas), as Imago Dei, as man's ability to choose his place in the

Universe (Pico della Mirandola) or as respect for the individual and refusal of the body commercialization (Kant) called on the human nature. Today, dignity stands as the basis of rights a human being has in virtue of this quality.Dignity outlines the types of autonomy: personal (reflected in the possibility to take a decision), moral (permitting deliberation on the consequences of the personal choice) and political (in the sense of right to opinion, as basis of informed consent) (4). With regard to the *noli me tangere* principle, as Hippocratic imperative (*primum non nocere*), in legal practice, it refers to physical damage.

The consent involves informing the patient (on the diagnostic, on the necessity to apply certain procedures, on risks but also on existing alternatives) and the patient's ability to express his free will. The right to information (for the capable patient) is the warranty of the liberty to decide regarding one's own life and body. Information in view of getting consent is a hybrid concept, based both on the doctor's obligation to disclose information and on the patient's will to follow a certain treatment (5). The level of information disclosure is appreciated to vary from one case to another. The history of informed consent started in 1914 with the statement of an American judge, in Schloenorff vs. Society of New York Hospital that "each mentally sane adult is entitled to determine what happens to their body" (6). Seemed to have passed unnoticed, the *dictum* is resumed in 1957, in the Salgo decision (7) and, three years later, developed in Natanson (8). The cases mentioned above raised the issue that the new technologies are promising, but that they expose the patient to great risks. The case of Salgo, where the syntagm "informed consent" was used for the first time (9), was generated by the paralysis of the lower limbs triggered by injecting a contrast substance to detect a blockage on the abdominal aorta and Natanson claimed the damage caused by cobalt irradiation instead of X-rays after a mastectomy. The judge noted that it was necessary for the patient to be informed, in a simple language, regarding the probability of success, the alternatives, or the possible unfortunate risks on his body.

In 1972, in the famous case Canterbury vs. Spence (10), the courts articulated the doctor's duty to inform the patient, considering the consent to be "the informed exercise of a choice, and that entails the opportunity to evaluate knowledgeably the options available and the risks attendant upon each". The medical community was astounded by the idea of sharing the decision with the patient and by the violation of the "rule of silence" that had governed this relationship along the years (11).

A true definition of the informed consent was formulated in *Harnish* (12), as a duty of the doctor "to disclose in a reasonable manner all significant medical information" that he possesses or reasonably should possess.

It is also important to note the Solomonic answer of the judge in Arato vs. Avedon (13), in the sense of avoiding both the "doctor's paternalism" and the patient's "extreme sovereignty" (14). In this case, the family of a cancer patient sued the doctor for having failed to discuss with the patient the stats regarding the type of cancer the patient suffered from (pancreatic) and having given him false hopes regarding chemotherapy (under 5% of the patients survive for at least 2 years) opened the path to new questions pertaining to the relevance of medical statistics and to the high (scientific) level of patient's information.

The judge took into consideration a minimum amount of information that might cover the doctor against the civil liability for non-communication with the patient. Communication means, after all, reaching a common decision by the doctor and the patient. In other words, the courts imposed certain standards of care and the medical practice of the informed consent has evolved in this direction. The care standard was decided by the British judges as a criterion in the assessment of the doctor-patient relationship in the *Chester* file (12) in which the absence of information on the risks of a spine surgery (which caused the patient a *cauda equina* syndrome) was appreciated as a violation on the part of the physician of the patient's right to choose.

The human rights influence on the development of informed consent

The Hippocratic oath does not refer to a patient as having the power of decision. The primary source refers to treating patients "according to the power and judgment" of the doctor (13) while a second variant (proclaimed by the faculties of medicine) insists on the "laws of Honor and Probity in the exercise of Medicine". The version of Maimonides's oath (12th century) invokes the Man: "May I never see in the patient anything but a fellow creature in pain" (14). The human rights have transformed the patient from "being" into "gentleman", as mentioned in the first medical Codes, to an individual with rights (15): the right to be treated with dignity, to consent to or refuse an intervention, to refuse being subject to scientific experiments without consent, to benefit from equality in front of the law and from progress. Furthermore, the human rights led to a change in

the doctor-patient communication pattern. The new doctor-patient models of communication (informative, interpretative, deliberative) (16) have replaced the old paternalistic pattern, of the protective doctor who encourage the patient to accept what he consider to be better for this one.

Given that the scientific development is a global challenge, new and clear answers to bioethical dilemmas are also expected in terms of international regulations, able to establish legal standards and mechanisms for their implementation (17). One of the most important international documents is the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) which mentions the dignity and the respect for human rights in the beginning of the chapter referring to principles (next to the principle of autonomy and the informed consent of the person).

In Europe, with the establishment of the Convention for the human rights and biomedicine (Oviedo, 1997) the states were confronted with the first international document of a mandatory nature that sets down a minimum standard of human rights protection in the biomedical field and underlines the primacy of the individual's interest over science and society, revolving around the concept of informed consent. Moreover, within the European Union, the Charter of Fundamental Rights of the European Union (now, a constitutive part of the Treaty of Lisbon) dedicates its first part to the concept of the dignity of the individual and, with direct reference to the field of medicine and biology, stresses the compliance with the legal procedures related to the informed and freely expressed consent (art. 3).

The document which continues to be most invoked in the matter of human rights – including those concerning the informed consent– is the European Convention (adopted under the umbrella of the Council of Europe). As it is known, the court created for its enforcement is the European Court of Human Rights (ECHR). It is also competent to express advisory opinion on the legal problems related to the interpretation of the dispositions of the Oviedo Convention (as long as it didn't have its own mechanism) (18).

The European Legal Perspective

As mentioned before, in practice, depending on the complexity of a case, of the patient's power of understanding and the modalities of communicating with the doctor, the level of information is very hard to assess. In order to express their consent, the patients need to be aware of the risks they are exposed to

(including death), the consequences (immediate and subsequent) for their integrity. It was argued that the patient also needs to be informed on the useless treatments because, from a psychological point of view, they may produce an improvement of health, be it short-termed (19).

In the cases regarding the informed consent there is a double determination. On the one hand, the patient's autonomy, the patient having the right to decide where his body is concerned, which affects the doctor's competence and his insistence on recommending a certain procedure to a certain degree. On the other hand, the patient affected by the disease and its consequences (disability, anxiety) needs authority and certainty, a situation which in certain cases leads to, a request for the doctor to decide (20). The odyssey continues, in the sense that doctors are trying to articulate a doctrine and a practice of communication that is able to avoid conflicts and the appeal of patients in court. From a legal point of view, the determination of liability implies an assessment of all the elements of informed consent: disclosure of information, the degree of comprehension on the part of the patient, the free consent and authorization (acceptance or refusal) (21).

In practice, the lack of comprehension of the doctor's information was considered by ECHR a violation of art. 8 of the European Convention in the case V.C. vs. Slovakia (22) in which the plaintiff agreed to sterilization but later invoked the fact that he failed to understand the nature and consequences of such procedure. The Court held that the sterilization without the consent of a mentally competent adult patient was incompatible with the respect for human freedom and dignity and constituted a major interference with a person's reproductive health status.

The omission to inform the patient on the risks of a surgical intervention (at the level of the face) following which the patient suffered paralysis and other sequelae was considered a serious breach of right in the case Codarcea vs. Romania (23). In this case the ECHR reaffirms the state's obligation to take measures so that the doctor should inform the patient on the risks and obtain the consent in full knowledge of the facts.

In the case of Csoma vs. Romania (24) the plaintiff, a medical assistant, opted for a pregnancy interruption in week 16 because the fetus had been diagnosed with hydrocephaly. Following certain complications she underwent complete hysterectomy to have her life saved. The doctor

omitted however to discuss the suggested procedure or its possible complications with the patient, and failed to ask for the signature on the consent form (the government, in its defense, argued that the plaintiff, by the nature of her profession, was informed).

Of a more serious nature, the forced admission in the hospital of an aged patient who refused the services of a clinic was considered a violation of the right to liberty and security of an individual. (art. 5 of the European Convention) in the case Zagidulina v. Russia (25) although she suffered from a psychiatric disorder.

A delicate issue is the refusal of a treatment based on an objection of conscience (following the affiliation to a certain religion). Glass vs. the United Kingdom (26) raised the problem of authorization of a treatment for a child and ECHR ruled that the states are bound to have regulations to favor the patient's life. In the situation of the parents' refusal, the doctors should require the decision of the court. The case concerned the administration of diamorphine to a disabled boy in defiance of his mother's objections (conflicting with the proposed medical treatment) was not considered to be inconsistent with the standards laid down in the Council of Europe's Convention on Human Rights and Biomedicine. At stake was the question if the decision to administer the drug should have been referred to the competent court given that the mother had not given her free, expressed and informed consent. The ECHR found that the decision of the national authorities to override the applicant's objection to the proposed treatment had, in the absence of authorization by a court, resulted in a breach of Article 8 of the European Convention (27).

If the informed consent is the patient's „right to know" what happens when a person refuses it? This is an ethical and also a legal dillema, especially when the right „not to know" or to refuse the information is related to the interest of other persons. If in the old case of Arato the family sued the hospital because the doctors had breached their duty to obtain the patient's informed consent by failing to disclose his statistical life expectancy, new conflicts of rights between the family members could appear nowadays in the field of genetics. The refusal to receive such information related to genetic status as a privilege of the patient's autonomy affects the doctor's duty to inform (28) but at the same time, it raises the question of the relative's interests to know about the possible genetic disease and to choose a treatment, in their turn. In such a situation, the doctor's duty to disclose

information must be read in terms of responsibility to protect the rights of family members.

Conclusion

As one can notice, the informed consent raises numerous problems in the medical practice which reflect, in fact, the permanent changes that have occurred in the doctor-patient relationship. The access of the latter to sources of medical information, the (online) solidarity with other people who were confronted with similar problems and, last but not least, the awareness regarding rights, lead to a (sometimes abusive) appeal to these rights. In this context of the culture of human rights, the national and international courts are called upon to analyze medical ethics, thus stepping in the doctor-patient relationship. To a certain extent, through the creation of health care standards, their role is beneficial. But the main idea is not to ask the law to intervene excessively. Nevertheless, if the informed consent implies mainly good communication, it needs to be learnt, for the adoption of common decisions. Probably the organization of training sessions, of courses in the technique of communication, both in hospitals and in the faculties of medicine, as well as at the level of the civil society may provide solutions in this matter. Finally, it is worth mentioning that it was the American courts once again which initiated certain strategies to prevent or settle legal conflicts between doctors and patients by resorting to mediation and the use of apologies.

References

1. Mason JMcCall Smith A. Law and medical ethics. 9th ed. London: Butterworths; 2013:26.
2. Dermengiu D, Curcă C. Aspecte generale ale practicii medicale şi jurisprudenței în obținerea consimțământului la tratament. Available from: https://www.emcb.ro/article.php?story=20021117102058000.
3. Satyanarayana Rao K. Informed consent: An ethical obligation or legal compulsion?. Journal of Cutaneous and Aesthetic Surgery. 2008;1(1):33.
4. Sandu A, Cojocaru D, Oprea L. Autonomia pacientului în contextul îngrijirilor medicale, în Beatrice Ioan, Vasile Astărăstoae, Dileme etice la finalul vieții, Ed. Polirom, 2013, p.128-131.
5. Katz J. Informed Consent-Must It Remain a Fairy Tale?. Journal of Contemporary Health and Policy. 1994;10(69):70.
6. Schloenorff vs. Society of New York Hospital, 105 N.E.92,93 (N.Y.1914).
7. Salgo V (1957) Leland Stanford Jr. Univ. Bd. Trustees. 154 Cal. App. 2d 560, 317 P.2d 170
8. Natanson vs. Kline, 350 P 2d 1093 (Kan.1960).
9. Toader E. Fundamentul etic şi juridic al consimțământului informat în practica clinică şi în cercetare, în E.Toader, V.Astărăstoaie (editori), Malpraxis medical, Editura "Gr.T.Popa", UMF Iaşi, 2016, p.28.

10. Canterbury v. Spence, 464 F.2d772 (D.C.Cir.1972)
11. J. Katz, op. cit., p.72.
12. Harnish v Children's Hospital Medical Center & others Massachusetts Supreme Judicial Court 439 N.E.2d 240 (1982)
13. The Hippocratic Oath: Text, Translation, and Interpretation, by Ludwig Edelstein. Baltimore: Johns Hopkins Press, 1943, Translation from the Greek by Ludwig Edelstein. Available from: http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html
14. Oath_of_Maimonides. Available from: https://en.wikipedia.org/wiki/Oath_of_Maimonides
15. Wolf SM. Doctor and Patient:An Unfinished Revolution. Symposium. 2006;5(3):487.
16. Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. JAMA: The Journal of the American Medical Association. 1992;267(16):2221-2226.
17. Adorno R. Biomedicine and international human rights law: in search of a global consensus. Bulletin of the World Health Association. 2002;80(12):959.
18. Ciucă A. Conceptul de demnitate a ființei umane în bioetică şi biodrept (II). Revista Română de Bioetică. 2010;8(3):25.
19. Wolf SM. The Silent World. Conflict Between Doctor and Patient. HeinOnline, 16 L.Med & Health Care. 1989;:197.
20. Wolf SM. Doctor and Patient:An Unfinished Revolution, Symposium. 2006;5(3):487.
21. Faden R, Beauchamp T. A History and Theory of informed consent. Oxford University Press. 1986:274.
22. ECHR, V.C.v. Slovakia, Appl. no.18968/07, Judgment 8.11.2011
23. ECHR, Codarcea v. Romania, Appl. no.3175/04, decision from June 2nd, 2009)
24. ECHR, Csoma vs. România, Appl. no. 8759/05, decision from January 15th, 2013.
25. ECHR, Zagidulina v. Russia, Appl.no. 11737/06), Judgment May 2nd, 2013.
26. ECHR, Glass vs. the United Kingdom Unit, Appl. no.61827/00, Judgment March 9, 2004.
27. Council of Europe, Health-Related Issues in the Case-Law of the European Court of Human Rights, 2015 Report, p.11
28. Adorno R. The right not to know: an autonomy based approach. Journal of Medical Ethics. 2004;30:435-440. doi: 10.1136/jme2002.001578.