SOME LEGAL ISSUES ON INFORMED CONSENT IN CROATIAN LEGISLATION AND PRACTICE

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The informed consent is one of the basic rights of patients, containing several authorizations.
Accordingly, a patient is entitled to be informed and instructed inline with the informed consent regarding the character and seriousness of the own illness, the risks and seriousness of the proposed treatment or medical intervention, alternative and even experimental methods to fight an individual disease. This practically means, that the patient achieves all other basic rights based on the right on informed consent, like the right on co-deciding and the right to be informed.
In this work, the author will present the current status of Croatian legislation „de lege lata", including the practical problems of the implementation of the right on informed consent in the Republic of Croatia, also giving some propositions „de lege ferenda".
The right of Croatian patients on informed consent has been, until the Law on protection of patients rights came into force in 2004, generally defined within the provisions of the basic regulations in the field of medical laws – the Law on medical protection and the Code of medical Ethics and Deontology.
Despite all this, recent research showed that both the Croatian patients and health workers have been insufficiently informed about the content and the ways to apply this right.
The coming into force of the new Law on protection of patients rights, despite the hope that by the enactment of this law the quality on patients rights protection in Croatia will be significantly improved, unfortunately didn't change much in reality.
Namely, this legal text, in the opinion of the author, defines and treats the right onto informed consent inadequately and imprecise. This will cause, so thinks the author, only a continuing and generally increased lack of orientation of both patients and medical doctors regarding the achievement of this right.

1. INTRODUCTION

Modern systems of health care, including the Croatian one, see the establishment of a partnership relation of physician – patient as something granted.
The patient nowadays becomes a more and more actively involved participant in the treatment process and the doctor is the ally and mentor. Such a standing point is light years distant from the former, over centuries present paternalistic relationship of the physician towards the patient, characterized by the absolute right of the physician regarding decision making, assuming complete passivity and humble obedience by the patient.
The tendency towards a partnership like, equal relationship between the doctor and the patient is a consequence of the growing consciousness regarding the importance of human rights and freedom in medical theory and practice, in particularly in the past decades, a growing social acceptance of the existence and necessity of establishment of patient's rights (within these, the right of the patient onto informed consent, as one of the assumptions for the option of establishment and achievement of all other recognized patient's rights) as a special category within these same human rights. Co-decision making by the patient, in all issues linked to the own health is a very difficult task, impossible to achieve without obtaining previously proper information. The main and most relevant source of all information for the patient is until today, despite the globally accessible printed and electronic media and the internet, the physician in person.
The doctor's role is accordingly, in our current times significantly more complex and demanding, than it was some decades ago. The doctor is both a practician and consultant – it is his duty to properly inform the patient, so the patient is able to play the active role and achieve the basic rights onto being informed and co-deciding about the own health and life.

How much does the Croatian legislation, but even more important for the patients, the practice – comply with the basic medical and ethical postulates that define that health, but nowadays more and more expressed, the **will** of the patient actually represents the basic doctors law ? In this work we will try to answer the above question.

2. THE RIGHT ONTO INFORMED CONSENT AS REFLECTION OF THE BASIC HUMAN RIGHT ONTO PHYSICAL INTEGRITY

The theoretical basis of the patient's right on informed consent is found in the constitutional provisions contained in all supreme legal acts of democratic countries, including the Constitution of the Republic of Croatia, which refers to the rights of every human being on life, the integrity of human freedom and personality, the prohibition of submission, without the persons will, to any kind of medical or scientific tests[1].

In other words, constitutional provisions, but also provisions of the Civil Law[2] guarantee and protect the right of each person onto physical integrity – the right onto own, unobstructed physical – biological being, the right to simply be. The contents of it are mandatory for everybody, a complete private legal power of the person in regard of the own life, body and health, including the authority to exclude everybody else from illegal obstruction and impact onto it.[3]

This right entitles every person onto complete legal power regarding the object of this right- which means life, body and all parts of the body, including the mental and/or physical health, clearly, all under respecting the borders defined by other rights (if by non-treatment the health of other subjects would be endangered) and legal limitations.[4] Any self-willing intervention on the body or the health of another person, of course with exceptions where the illegality is excluded[5] and in situations where the free will of the subject – patient will not be taken into consideration for reasons of the incapability of valid expression of will- or impossibility of expressing a will and such person is without a legal representative or guardian (situations with patients who are under aged or mentally ill). The Constitution of the Republic of Croatia, in its provision from clause 16 offers the option of limitation of rights and freedoms in order to protect the freedom and the rights of other persons and the legal system, public moral and health, while at the same time such limitations must be proportional to the nature of need for such limitation.[5]

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[1] So provision of cl. 21. of the Constitution of Croatia emphasizes the right of every human being on life, while cl. 22 speaks of the inviolability of human freedom and personality. The Croatian Constitution also, in its cl. 3., 14., 18., 57., protects the basic human rights – the right on freedom, equality, dignity and freedom of decision making, it guarantees state protection of the weak, incapable and invalids and the right onto complaint. It is important to stress cl. 23. which says that nobody should be submitted to any kind of abuse or without consent – to any kind of medical and /or scientific tests. Constitution of the Republic of Croatia, National Gazette 56/90, 8/98, 124/00, 41/01.

[2] Cl. 19. Of the Law on obligatory relationship, (herein only ZOO), National Gazette 35/05.

[3] Gavella B., *Osobna prava* , part I, Zagreb, 2000., page 65.

[4] Self-willing interventions in to the human body or health are sanctioned by chapter X, in Criminal acts against the life and the body, cl. 90-105. and chapter XVIII, Criminal actions against the health of humans, cl.238-249. of the Criminal law, National Gazette 110/97.

[5] Such cases would call for immediate intervention, where the failure to intervene would endanger the life and health of the citizens, if the obtaining of consent from next of kin could cause a delay in time that would result in danger to the patients life and the patient at this moment is not able give consent, from cl.21, par.1., item.5. of the Law on health protection, (herein only ZZZ) National Gazette 121/03, or in cases of immedietaly

And exactly in medical and health services, during the treatment of patients and the interaction of the patient with medical staff, especially doctors, the right onto physical integrity is particularly expressed, together with its basic principle – everybody can freely decide to agree to undergo a certain medical treatment or not – this decision is ultimately left to the free will of the patient. Without respecting this free will of the patients, the medical procedure would be illegal, because the freedom of will and the physical integrity are above any reasons of medical nature.[6] Such an opinion can also be found in the national legal theory and judicial practice.[7] But, recently some other points of view seem to be spreading more and more, that claim that the principle of absolute priority of the right on free decision making regarding the own life, body and health should be limited – namely this principle is to back up in face of the dangers that impact human life – which is the ultimate legal good.

Namely, the salutary medical intervention is allowed even against the will of the patient when a patient intends to commit suicide, because in such cases it is considered that the doctor acts in a situation of utmost emergency.[8],[9]

Such view onto this issue make us think about other difficult and complex legal – moral-ethical questions connected to the right on physical integrity, like the right on dignified death – euthanasia, but those questions do exceed the topic of this work.[10]
The right onto informed consent[11], even it has never been closer and in more detailed defined in our laws – we will say more about this later on in this text – theoretically does contain the right of the patient to be informed and instructed regarding the character and seriousness of the own disease, the risks connected with the proposed therapy or treatment and the options regarding existence and application of alternative methods of treatment.[12]

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necessary surgical interventuion, if the person is not capable for reasonable judging or unconcious, cl. 21, par. 1, item. 11. ZZZ.

[6] For instance, a situation where the medical intervention was opposed to religious beliefs (Jechova's Witnesses). An example happened a few years ago in the hospital Split, where a patient died due to severe anemia , because of being a member of Jehova's witnesses, she declined a blood transfusion. More on this type of legal and moral – ethical problems in medicine, see: Bošković Z., *Odbijanje transfuzije krvi zbog vjerskih razloga-pravni aspekti,* Hrvatsko bioetičko društvo, Rijeka, internet : http:/www.hdubl.hr/Predavanja/Boskovic%20Zvonimir .doc.

[7] By Decision of the Supreme court of Croatia in 1975, (1554/74, ZSO, book 1., band 4. page 204..."It is inadmissible and against the principle of inviolability of the physical integrity to perform a surgical intervention on a person against his/her will, even in case when this would be of benefit for this person, except if the reasons are not special and justify such procedure, like endangered life and condition of the sick person, making it impossible for this person to give consent.""", as per Klarić P.,*Odštetno pravo*, Zagreb, 2003., page 403.

[8] Radišić J., *Profesionalna odgovornost medicinskih poslenika*, Beograd, 1986., page176-177.

[9] Greek legal theoreticians think that a medical intervention should be allowed even when it is opposed to the patient's will, caused by the lack of awareness or ignorance of such patient, see: Fotakis, N.S., *Medical responsibility in Western Europe*, Ed. Deutsch-Schreiber, Berlin ,1985., page 325.

[10] More on problems of euthanasia, see: Šegota I.,*Nova medicinska etika i eutanazija*, Društvena istraživanja, 1966, 3-4., Degen S., *Pravo na život i pravo na smrt malformiranog djeteta*, Odvjetnik, 1981, 11-12, Miličić V., *Deontologija profesije liječnik*, Zagreb, 1996, Gavella N., *Osobna prava* I dio, Zagreb, 2000.

[11] It is considered that the term was mentioned for the first time in 1833, when the American physician William Beaumont declared, that a willingly given consent of a patient is necessary, otherwise the medical treatment can not be performed , Grodin Ma.,Historical origins of the Nuremberg Code, as per Annas GJ-Grodin MA.,*The Nazi doctors and the Nuremberg Code*,New York, 1992., page122-144.

[12] The American theory developed the doctrine of the so called " Informed consent" , which contains six basic functions that enable the patient: protection of the individual autonomy, the protection of the patient's status as a human being, avoiding and force and /or cheating by the medical staff, support for the medical doctor to

We think that the right of the patient regarding informed consent represents a **condition „sine qua non“** of the establishment of the conceived status of a patient, who would be an equal partner to the doctor in the course of receiving and performing medical and health services. Namely the right onto informed consent is in its content, at least in our opinion, composed of the right of the patient to be informed and the right of that same patient to accept or decline an individual diagnostic, i.e. treatment procedure. This at the same time means that only through this right onto informed consent, the second basic right of the patient can be achieved – the right on co-decision making. Without the right on informed consent, a patient would be prevented from a complete assessment of the health problem, the reasonable choice between several options.
Only informed patients and a doctor who performed his duty to properly inform the patient on all issues regarding the medical condition, will be able to co-decide in all decisive questions throughout the entire therapy – treatment procedure – from the diagnostics over the medical treatment to the rehabilitation phase and final curing.

Without the patient's consent given for the application of a certain medical treatment, such an intervention into the patient's body would be illegal.[13] The prerogative of the patient's decision over the medical reasons of treatment is today a generally accepted legal standing point, emerging from the right of every human onto self-determination. The freedom of human personality is not to be sacrificed with any, including medical goals.[14] What are these moments on which the patient will be informed by the medical doctor and how is the term of informed consent, as one of the patient's rights, solved and defined in Croatian legislation, will be presented in the next chapter of this thesis.

3. INFORMED CONSENT IN CROATIAN LEGISLATION AND PRACTICE UNTIL THE ENACTMENT OF THE "LAW ON PROTECTION OF PATIENT'S RIGHTS"

Before the independence of the Republic of Croatia, but also after – all the way until the first legal text was enacted, which was dedicated exclusively to the promotion and protection of patient's rights from 204 – The Law on the protection of patient's rights; the right of Croatian patient's regarding informed consent (like the other remaining issues on patient's rights) has been partially and only slightly touched in the provisions of the basic legal texts from the field of health and health care, but nowhere explicitly or in this term mentioned as such, the same as the title of the person that is receiving health care in the health care system – the patient , is not mentioned either.

The legal provisions use the very generalized term "Person". So for instance, the "Law on health care"[15], as well as the Code of Medical Ethics and Deontology[16] mention as one of

consider his decisions properly, support for the patient to bring rational decisions and achievement of the principle of public health care, as per Furrow-Johnson-Jost-Schwartz, *Health Law*, 1991., page 322.

[13] The criminal act of „self-willing therapy „ from cl. 241. of the Criminal law says: " The one who medically treats another person with consent by that person will be punished with a fine of up to onehundredfifty daily wages or six months of prison. Paragraph two of this clause defines, that a medical doctor or dentist who perform a surgery or another medical intervention on the body of another person, without the explicit previous valid and written consent will be fined or can be punished up to one year prison. But, there is no criminal act, so defines par. 3. cl. 241., if the law defines forced therapy or the therapy/treatment , surgical or other medical intervention has been done on a person that was not conscious or was incapable to judge and decide and there was no family member or legal representative near by, while any delay in therapy or intervention would have endangered the life of that patient or caused severe deterioration of health ».

[14] Radišić, mentioned work, page 176.

[15] Cl. 21.,par.1.item. 5., 6. and 11., ZZZ.

the rights belonging to every person, the right on co-decision making – which right is judged based on individual criteria - like urgency of medical intervention that needs to be launched, the state of the patient's consciousness, the ability of judgement and if necessary the need to protect the health of other people[17]. Namely, in these provisions every person is guaranteed a free choice between several possible forms of medical interventions offered by the medical doctor, or the dentist, except in cases of urgent and immediate intervention, which, if not done would endanger the life and health of a person or result in permanent damages. It is considered desirable to obtain the opinion of the legal representative or guardian – if there is one – or somebody next of kin, i.e. in case of a minor person, the legal representative or guardian. In the achievement of medical protection, each person is guaranteed the precise and true information and interpretation and instruction on all health related issues.

Every person is guaranteed the possibility of acceptance or denial of a surgical or other medical intervention into the body, if that patient is conscious and capable to judge. For persons that are unconscious or not capable of reasonable judgment, the legal representative or guardian, marriage partner, parent, adult child, adult brother or sister has to make this decision. An exception of the rule on obtaining consent are situations demanding immediate medical intervention.

The Doctors Code of behaviour during performing their professional duties, under the title "Duties towards the patient" defines within the above listed provisions the way how each doctor must respect the right of a mentally capable and conscious patient, as a previously well informed person, to accept or deny an individual doctor, i.e. the proposed medical help. If a patient is not capable to decide upon the above, the Code defines , as does the Law on health protection, that the legal representative of the patient is the one to make this decision. In case there is no such legal representative present at the moment, the doctor will, if there is no time to wait for a decision, apply the best treatment under best knowledge and experience. The Code also defines the situation of a medical examination and health treatment of minors and children.[18]

As a duty of the doctor towards ill children, the Code defines, that a doctor will in the most adequate way (without defining precisely what an adequate way is !) inform the patient on diagnostic procedures and examinations, the risks and danger involved, their consequences and results and on all other possible treatments and their perspective results; to give the patient adequately necessary information – based on which the patient is able to make the proper decision on the own diagnostic procedure and proposed treatment.[19]

As we could see from the above, Croatia definitely introduced the factual duty of the medical doctors into its health care system a long time ago. This duty consists of information submitted to the patient, even this formally has been defined under usage of – in our opinion – insufficiently precise and concise definitions – thus opening the door to possible abuse or by-passing these legal provisions or even simply the non-recognition of the basic rights and duties of other parties in health care, contained within them. The Law

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[16] Cl. 2., par. 3. and 7. Text of the Code in the internet: http://www.pravnadatoteka.hr

[17] Cl.30. ZZZ speaking of cases of doubt that some person for contagious disease might be dangerous to the health of other persons, in which situation no consent needs to be obtained for medical intervention.

[18] „The examination and health services performed to children and minor aged persons will be done by the doctor sunder consent by the parents or guardians, i.e. the oldest closest adult family members, except in cases of emergency. He will apply the most adequate procedure and deny the requests by laymen that might endanger the life or health of such underage person.", cl. 2.,par. 4. of the Code.

[19] „In case of underage persons or persons that can not make decisions about themselves, the doctor will contact the parents or legal representatives of the patient, i.e. if this is not possible, the responsibility will be shared by consulting other medical doctors", cl. 2. par.7., item 2. of the Code.

on health protection, lets remember, established and defined the duty of informing the patient as the right of any other person, i.e. citizen, on being properly and truthfully informed and instructed on all issues regarding the own health, while the Code of Medical Ethics and Deontology from the year 2002, precisely lists the duty of the medical doctor to instruct (not the patient but the ill person, which in our opinion is not the best choice of term) regarding all questions connected to the health of that person.

After all this, a practical question arises – what kind of information, i.e. instruction is this to be ?[20]

The above quoted legal provision says, that an instruction must be accurate and comprising, but still doesn't define it more precisely. As ethical postulate and legal duty of information and instruction, it must enable the patient to, basically, find out about the type of intervention, the method of performance, the risks and consequences of denying the intervention and alternative methods of medical treatment. Some of the contained details have been elaborated very thoroughly through the individual types of information - information about the diagnosis, type, scope and method of intervention and information on possible risks.[21]

The form of the information is not defined, it can be oral or written. Today written information is prevailing, i.e. the patient is often requested to sign a prepared statement in advance, based on which the patient declares to be fully informed about the medical intervention and risks. Such a practice of course goes in favour of the medical doctors, since it leaves material evidence on given information, without the need to proof any spoken word by any of the parties, as the case would be in giving only oral information.

Only a properly and accurately informed patient is able to give a rational and legally valid consent onto a medical intervention. What is this legally relevant consent by the patient ?

This would be such a consent that was given by a criminally liable patient, a patient that is capable to judge, which means sane. In many of the legal systems exactly such above opinion prevails.[22] The Croatian law adopted this position as well, visible in the provisions of the legal texts from several fields covering Civil Law. The Law on obligatory relationships for instance states, that a criminally liable person is a person of 14 years of age[23], while the Law on health protection in its previously quoted provisions from clause 21 states, that for persons that are incompetent for judgment, legal consent is to be given by their legal representatives, i.e. parents or next of kin. The patient's expression of will that is reflected in the consent onto a medical intervention, must be valid, which means it must be given freely and seriously, as required by the Law on obligatory relationships.[24]

Regarding the form of consent, it can be given in any form[25], even tacitly (submission to the medical doctor without expressing any kind of legally relevant will), but the Law on health protection defines that for certain forms of medical intervention, the person

[20] See more on this issue: Radišić, mentioned work, page 193., Furrow, mentioned work , page 322.

[21] Klarić, mentioned work, page 406.

[22] Overview of legal systems that have taken this standing point, see: Ficher-Lilie, *Arztliche Verantwortung im europaeischen Rechtvergleich*, Koln,1999., page 38.

[23] Cl.1051. ZOO.

[24] Cl. 250., par. 3. ZOO.

[25] So the Helsinki Declaration on ethical principles of bio-medical research done on human subjects from 2000, states „the physician should than obtain the subject freely given informed consent, preferably in writing", *The Declaration of Helsinki 2000. Ethical principles for medical research involving human subjects*, Surrey: Brookwood Medical Publications Ltd.,1996.

expresses the consent by signing a consent, except if such person is incompetent, unable or underage.[26]
Despite the legal provisions, in practice the patient's right onto informed consent is brought down to an incoherent and incomplete oral information of the patient by the medical doctor regarding the basic issues of the health condition, which very often leaves the patient completely confused, since many of the issues are not understandable for him as a medical laymen.
For various „considerations" or unpleasantness, the patient often doesn't dare to ask further questions to clarify the situation he/she is in, all this in order not to create unnecessary problems to his/her medical doctor, who is still the ultimate authority for the patient. The written consent of the patient in today's clinical and hospital practice often means only that medical staff issues written consent forms, together with all other forms the patient must sign when being received into a medical facility, so the patients very often sign this consent form without having obtained any information on the own medical condition and intervention ahead.
Such practice clearly shows up to which degree the legal provisions on informed consent in our country, unfortunately , remained a "dead letter on paper". Medical staff, mainly medical doctors are not sufficiently informed regarding the legal duties, nor do they know about the consequences of compliance and/or non-compliance with these duties for themselves.[27] As for the patients, if they are properly prepared and know about their legal rights (and duties), we at least feel, they often don't dare to significantly insist in achieving those rights, since in their mind, they remained in this, elsewhere in the world a long time ago, already deserted "patriarchal" view onto the relationship doctor – patient, implying the sovereignty of one subject over the other. In the mentioned research, a total of 61,7% operated patients declared not to have given any written consent onto their surgical intervention.[28]
The Croatian patients waited with great expectation during the past few years for the new legal text to be enacted, which for the first time in our country, thus including Croatia into the exclusive circle of European countries that have special legislation on rights of patients, would give in one legal act all acknowledged, listed and protected basic rights of patients, including the one onto informed consent.
Unfortunately after the final enactment of this Law in 2004, these expectations have been failed to a high degree.

4. INFORMED CONSENT BASED ON THE "LAW ON PROTECTION OF PATIENTS RIGHTS"

In the Law on protection of patients rights (herein after only: Law), enacted in 2004[29], Croatia showed its determination on the field of health care, regarding its integration into the European system or rights and values. Becoming a candidate for the membership in the

[26] Cl.21., par.2 and 3., connected to par.1., item7., 8. and 11. ZZZ., consent onto a medical examination or intervention by third persons except the medical doctor – like students, medical staff without expert's certification – and the participation in scientific research and for surgical or other interventions in the body.
[27] Devastating results of the poll done in 204 between medical employees and patients on their duties in the system of health care services, see: Rušinović-Sunara-Lugović-Belicza-Radovančević-Liović J., *Odgovori pacijenata i zdravstvenih radnika u Republici Hrvatskoj na Prijedlog nacrta zakona o pravima, obvezama i odgovornostima pacijenata-pilot istraživanje*, Medix, No.54/55, 2004., page162-166.
[28] See under 26.
[29] Published in National Gazette 169/04.

European Union, Croatia also took over the duty of harmonization of its national legislation with the one in the United Europe, including its health care legislation. The result of this harmonization is the above Law.

With this Law Croatia accepted the duty of protection and promotion of the basic rights of patients. For the first time ever, in the health protection and health care system, in one act all guaranteed rights of patients are listed[30], like the right on co-decision making, the right to be informed, the right to access medical documentation, the right on confidential treatment, the right on maintaining personal contacts, the right to self-willingly leave a medical institution and the right onto indemnification for damages.

As one can see, the legal provisions don't provide the right onto informed consent as a separate patient right. Still, the Croatian patient is granted this right by establishment of its factual content – the right on being informed and right to accept or decline a diagnostic, i.e. therapeutical treatment, which is defined by the Law as right on co-decision making. Pursuant to the existing legal text, Croatian patients are entitled to informed consent only for cases of participation in scientific tests.

In our opinion, this Law incorrectly defines the right on co-decision making as a right of the patient to be informed and the right to accept or decline a diagnostic, i.e. therapeutical treatment. As mentioned earlier in this work, we think that the right on co-deciding represents a separate right of the patient, a right that can be achieved only by guarantee and establishment of the right onto informed consent; this means that viewed by time, the informed consent as a right of the patient supersedes the right of the patient onto co-decision making, because only a timely and fully informed patient is able to give consent, which means that only after this he/she is able to factually achieve the other right that is firmly linked with the informed consent, the right on co-decision making. The patient is entitled to be fully and completely informed on the own health condition, including the medical estimate of the results and outcome of a certain diagnostic, i.e. therapeutical treatment, proposed examinations and/or interventions or the non-performance of such proposed examinations/tests or interventions, the own right onto decision making on proposed tests/examinations or interventions, possible optional solutions of these proposed procedures and the course of these procedures applied during further health care services of this patient, the proposed way of living and all other rights from the health insurance and procedures of achieving these rights.[31]

The Law defines that a highly educated medical employee, directly rendering certain forms of health services, is obliged to give listed information to a patient based on the oral request by the patient,[32] while patients with decreased judgement ability are also entitled to be informed, even in emergency cases.[33]

The consent onto a diagnostic, i.e. therapeutical treatment is given by the patient, except in urgent medical cases, by signing a consent, the form of which is defined by the health Minister. Blind, deaf persons give their consent in form of a notary act or before two witnesses with expressed statement on nomination of a capable and competent person that will accept or decline the consent for individual treatment methods on behalf of such person.[34],[35].

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[30] Cl. 6.-29. Law on protection of patients rights (herein only: ZZPP).

[31] Cl. 8. ZZPP.

[32] Cl. 9. .ZZPP

[33] Cl. 13. i 15. ZZPP.

[34] Cl. 16. ZZPP.

[35] The protection of a patient that is not capable of giving consent for being unconsciousness, having a mental problem or if incompetent or under aged, is done in such a way, that the consent, except in cases of immediate need for medical intervention is signed by the legal representative or guardian., cl. 17., par.1.,2. and 3. ZZPP.

The Law particularly defines situations when patients are required to participate in scientific tests, for which situation it is defined that a patient may participate and submit to scientific research only based on explicit written consent by an informed patient – which practically means the acknowledgement of the right onto informed consent in its legal and full sense.[36]
The intent of the legislator is unclear to us, where unnecessarily and against the full establishment of the patient's rights on informed consent, the giving of information to the patient is limited by oral request of information. We think that this fact is a major fault in the legal text, as is the fact of linking informed consent to the situation of scientific research.
By the enactment of the special legal text that on legislative level is given state support for the promotion of patients rights, a first step has been done towards the establishment of the patients rights in Croatia inline with existing international solutions, but it is still our basic impression that the Law primarily lacks more precise definitions and in general specific determination of terminology, in particular the right on informed consent and the existence of certain material deficiencies that seriously question the possibility of interpretation – and what's more important and serious – the application of this legal text in practice and its efficiency within the goal it was enacted for – the protection of patients rights.[37]

5. INSTEAD OF THE CONCLUSION – SOLUTIONS DE LEGE FERENDA

As presented in this work and despite all expressed reservations towards individual legal solutions, we have strongly greeted the enactment of this separate legislation on patients rights, because this step is not significant only for Croatian patients and its health care system and the legal practice and science – it has a major political – civilization impact onto our brighter future, in which a high degree of proclaimed human rights of all categories of citizens will be established, including the patients.
We realized the practical importance of this patient's right on informed consent and how its poor legal definition can have devastating consequences. These show in the opinion of the author, in further deepening of the overall disorientation of patients and medical doctors regarding achievement of this right, which was the topic of this work.
The author still finds unclear, why the legal text contains such a conditioning of the right on informed consent, since it is clear that the medical staff, giving medical care to a certain patient , is obliged to fully inform a patient only when that patient requests so.
We think that the legal acts were supposed to move exactly towards opposed solutions, whereas medical staff is obliged to give full information in time and also would be obliged to inform the patient about his right to decline such information. This solution would empower the rights of the patient on being informed much more than the existing legal acts, which as such is opposed to the spirit of the Law itself.
It has been missed to define individual situations when patients for special reasons are not able to request orally to be informed, which definitely should be considered to be defined in a separate Regulation, as it was done for some other situations within the Law.
Instead - in our opinion this was wrong – to link the right onto informed consent in cl. 19 of the Law with the situation of scientific research, the right on informed consent should be included as such, exactly under this term, into the general provisions of the Law, where all patients rights are listed up. We also think that through one legal provision, the application

[36] Cl. 19. par.1., 2. and 3. ZZPP
[37] More on critical standpoints on the text of the Law, see: Rušinović-Sunara-Proso M., *Neka pravna pitanja zaštite prava pacijenata*, Zbornik radova Pravnog fakulteta u Splitu, No.3/2005, page 381-389.

of a medical treatment without properly informed consent by the patient should be treated and defined as an illegal act with criminal –legal and civil – legal responsibility. With such corrections, in our opinion, the text of the Law would become more clear and what's more important, more efficient in practice.

This practice is, as this work described, despite the new Law being enacted which should have empowered and promoted the patients rights, characterized by lack of orientation of patients and medical doctors regarding establishment and achieving these rights, especially the right onto informed consent, where this extremely complex and very important right of the patients is too often brought down to simply signing a "blank" form on consent onto medical interventions on which the patient has not been previously informed by the medical doctor. We hope that this work will give at least a small contribution to changes that will include an increasing awareness of patients onto which rights they are entitled to and the need to demand them "loud and clearly", also an increased awareness by the medical staff regarding their duties and obligations towards the patient, that should never be neglected.