The informed consent “problem”: from the rights of the patient to the depersonalization of the physician-patient relationship

El “problema del consentimiento informado de los derechos del enfermo a la despersonalización de la relación médico-paciente”

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Abstract

The “problem” of the informed consent: from the rights of the patient to the depersonalization of his relationship with the physician.

This work deals with the process of the informed consent.

It analyzes the “new” right to health; then, it focuses its attention on the right to be informed before conducting a healthcare procedure. In the end, it considers the issue of the relationship between the physician and the patient and investigates the problem of its depersonalization.

Keywords: health, freedom, paternalism, informed consent, medical liability, self-determination.

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1. The new right to health

The right to health, in light of the interesting hermeneutic itinerary that has made of man, the fulcrum of the judicial system, represents today, a "*new*" right,[1] taken to a more strongly personalist and subjective dimension. Thanks to the process of depatrimonialization[2] and to the ontological and axiological interpretation of the human person, the concept of freedom of treatment constitutes a perfect explanation of the wider principle of law of which the article 13 of the constitution[3] speaks about: health tutoring must be balanced with the individual's personal freedom, with his capability of self-determination, and safeguard his own physical and psychic integrities. In the absence of such balance, the person would not be capable to exert any other fundamental right guaranteed by our judicial system, and would find itself limited in the full explanation of its own personality.

In accordance with the general principle extracted from the combination of the expressive rules from the most wide personalist principle adopted by our Constitution,[4] the person is put as "*the center of the interests and the values around which the system of personal guarantees is focused*".[5] The individual is the central core, an autonomous subject; he decides by himself without external third parties, could undermine such explanation of his autonomy: they remain strangers, in most of the cases, at the time of decision making of the individual; and, only there, where the decisions of the autonomous individual could in abstract harm his other constitutionally warranty rights, then it will be possible to them shift from one passive to an active side.

But in this case, such shift will be justified by the fact that they, taken as a whole, would have assumed the features of subjects carriers of collective values surely aimed to prevail (in the optics of the constitutional balance) over those exalted by the particular individual in the scope of his own decision autonomy.[6]

2. From autonomy to the informed consent

Under this perspective, the importance of such freedom of election is located in the relevance assumed by so called consent in the therapeutic type relationships. Health is particular of men; from it each one can freely dispose of, according to what is expressly foreseen in the constitutional articles 2, 13 and 32:[7] the consent represents the best way to be able to establish this freedom of election, within the context of the health relationships. That clearly impacts on autonomy, independence, right/duty to care and be cared aspects; it is the essential element in order to be able to legitimize the medial-surgical activity.[8]

It is precisely on the basis of the necessary acknowledgement of the patient’s freedom, in the area of the health relationship, that the *“enlightenment of medicine*”[9] appears as a fundamental moment in an activity already dangerous by itself; It becomes a moment particular of this activity, and corresponds perfectly to the personalist principle that inspires our regulation: [10] the patient, in order to be rightfully submitted to any type of medical treatment, must necessarily declare from the beginning his rightfully own will of election. Otherwise, the physician’s activity would end up by unfairly substituting the client’s one[11]. That has to be read as the expression of the conscious adhesion by the patient to the treatment proposed by the physician[12], as a true and particular right of the person that, finding a secure basis in the most objective fundamental principles expressed by our Supreme Source[13], belongs to the inviolable principles[14].Therefore, it cannot be compromised in any way whatsoever and becomes *«a non-reviewable right»*[15] of the individual.[16]

The principle of consent to the intervention of others on the individual person itself, constitutes the natural corollary of the widest principle of personal freedom[15] and *it is materialized in the exclusiveness of the physical and psychic being itself, by virtue of which, the person cannot be submitted to coercion on the body and mind, to the violation of his corporeal freedom sphere, and even only moral; all power or duty of the physician on the* *patient, finds its root in the sole and exclusive source that is the consent of the patient himself, which represents the focal moment of the same legislative authorization as of the medical activity.*[18]

3. Physician and patient: from paternalism to the liberal model. A relationship that changes

A similar acceptance of consent, as an indispensable element of the treatment relationship, is the reflex of a change in vision that, in the field of the physician-patient relationship, has led to a configuration of a new so called personalistic model, instead of the so called paternalistic model.[19.] The way to understand the kind of interaction between the treating physician and the sick patient, has changed in a substantial manner, only recently. Before, some time ago, in light of a restricted interpretation of Article 32 from the Constitution, it was recognized, without any doubt whatsoever, the superiority and supremacy substantial position of the physician, with respect to his patient. It was considered and believed, that the patient, an ignorant regarding the subject matter at hand, would have been deprived of the technical-scientific knowledge particular to the surgical activity; and that, therefore, should have been necessarily subjected to the specialist will.[20.] The patient's inclusion in the decision phase of the decision making process, evidently was, a minimal insertion; he only was considered as a mere object, in a treatment moment of a process. The patient had to accept without any critics or complaint, the physician's decisions and thus, he used to suffer the therapeutic decisions, and the negative consequences that derived from them. It is enlightening regarding this issue, the definition by Parodi and Nizza,[21] which see the patient in this model, as a passive subject in a forced relationship, an objectively inferior subject,[22] an individual that expects care and health as presents of a generous and miraculous benefit, *"a faithful subject that does whatever is ordered by the physician*".[23] Medicine was considered both an

Art and a Science: that, as such, represented the highest expression of intellectual freedom, before even, than a profession: its practice and results could have hardly been put under discussion. The physician, as a homage to the heaviest Hippocratic principle,[24] used to represent the body’s priest, he presented himself as the wizard of cure, regarding the patient, and represented and performed a paternal role.

Currently, on the other hand, we are assisting to a truly and particular emancipation of the patient[25] and a greater autonomy is acknowledged to the sick individual, who’s free decisions are legitimized in the area of a peer and fair therapeutic relationship: the physician’s figure and character, become fundamental for treatment purposes, but not for the decision purposes that are assumed.[26] On the other hand, *“there is no fingerprint of a paternalistic conception in the constitutional rules, nor it is ever found in the current interpretation of them; it has never been set a limitation to the autonomy of the subjects, except in cases of disability, as a function of the accomplishment of the interests of the subjects themselves*”.[27] Why then, it should be verified in this context such limitation, if never before as in other fields, in the medical one precisely, the individual’s interest in having himself cared for becomes predominant, and not corruptible nor conditional?

In this line of thinking, the physician must include the patient in all the decisions that refer to the treatment of his physical and psychic status, not being able absolutely, to overlook his will of dec-ision. Today, in the “*relationship patient-physician, two centers of assessment and decision of the medical interventions to be performed in sickness management are confronted”*:[28] the patient is aware of his own rights; for him it is fully recognized, his dignity as a capable subject for self-determination, and to decide regarding the diagnostic and therapeutic medical interventions on himself, proposed by the physicians;[29] he, definitely, entrusting himself to a physician, will constitute him as guarantor of his own health, but certainly not as an absolute lord of it. The ultimate responsibility of choosing if to submit himself to a specific medical intervention, necessarily will be a burden, in this sense, over the interested party.[30]

This has to do with the model rated as *"liberal*", focused on the principle of autonomy, to which it is submitted the understanding that the adult and capable individual's will could not be oppressed or nulled not even when the purpose that is being proposed is to do good;[31] that that puts aside definitely the general presumption of the patient's disability, dependent from the paternalistic model, declaring that, the patients will, could not in general be substituted by the will of other subjects.[32]

The patient's role «*tends to become more active each time, in the communication dynamics with the therapist, because it only corresponds to the patient, to specify those concrete indications (of economic, family and in general more existential character) that, integrating them with those strictly scientific made by the physician, allow to arrive to, starting from an abstract range of options (all of them in principle plausible and legitimate), to a concrete decision of treatment*».[33]

4. Information as a fundamental requirement of a valid consent

In order to be able to speak about valid consent, which would provide legitimacy to a medical treatment, it is necessary for it to be accompanied and preceded by a precise information.[34] The physician must provide his patient «*in a comprehensive and complete way, all the information scientifically possible regarding the therapies that are pretended to be applied, or the surgical intervention that is being intended to perform, with their own modalities*»,[35] as well as inform about the scope of the intervention, about the unavoidable difficulties, about the achievable effects, and about the eventual risks, in a way to put it under the conditions of being able to decide in a conscientious or aware manner about the pertinence of the proceedings.[36]

This information does not have the purpose to bridge the cognitive techno-scientific differences between the physician and the patient, for what, rather, the one of tutoring the self-determination right of whom submits himself to a treatment or to a surgical intervention, achieving that such subject could consciously choose if to legitimate it or not.[37] In this way, the need for the consent to be informed, reinforces the vision of a really participative process by the patient, in the decisions that involve his body and his health; and the idea of a sterile formalization of a relationship in which the adherence of the patient for a treatment be disregarded to a mere condition of removal of the illegality of the fact be degraded.[38]

The obligation for information,[39] which must be clearly proper, in terms of the explanation to the capability to understand by the assisted, must be particularly detailed[40] and, while it surely does not include the so called unforeseen risks, or either the abnormal results, could be called truly and directly fulfilled, only in the case of the physician would provide all the possible scientific information about the healing intervention, about the possible normal consequences, even if being so infrequent as to seem extraordinary, in the balance between risks and advantages of the intervention. In other words, also in light of jurisprudence, it can be declared that its only legal the omission of unpredictable risks, those that correspond to abnormal cases, in so far as they are set outside the physician’s control sphere, and they are not relevant whatsoever according to *id quod plerumque accidit (what has mainly happened)*.[41]

It is necessary to point out that, in light of a surgical intervention, or of another specialized therapy or diagnostic invasive verification, the information does not only cover the objective and technical risks related to the subjective situation and to the science situation, but that it covers also the concrete, maybe lacking of, nosocomial situation, related to the provisions and the equipment, and to its regular functioning, in a way that the patient could not only decide if submitting himself or not to the intervention, but also if doing it in that hospital, or else to ask to be transferred to anotherone.[42]

For this, when the information should be inadequate and would not update the patient to the risks and benefit that the intervention implies, the consent eventually granted by the patient, will be invalid, due to the fact that it would be flawed and would be incapable to discriminate the medical-surgical activity, that, as such, would be arbitrary, illegal and the source of accountability (clearly, out of the cases in which the health treatment will be enforced by law or else incur in a state of necessity).

And you also fall into such illegality, even though the intervention would have been well performed and according to the patient's interest. The harm to self-determination right, demands a compensation for damages, regardless of the outcome of the intervention, arbitrarily performed, would have made a biological damage (as it was thought until recently).[43] This damage then, could be determined over a *QUANTUM* plane, which is reparable in a sense that would be valid in order to concretize the persistence of a damage (biological consequence) added to other eventual damages, both patrimonial and/or not patrimonial, suffered due to the harm of his right to self-determination. But the physician's accountability due to the harm to the right of self-determination of the patient, could also be determined in face of a fortunate result, by provoking an expected non patrimonial damage.[44] Obviously it must be considered that, for the purpose of legitimately configure the birth of such right to a compensation, even in absence of a biological damage, the patient must prove have suffered an effective damage, as a consequence of such violation: for instance the case of a subject that after being intervened he regrets the presence of some scars. Here, the patient will have to prove that, if he would have been aware of their presence, he would have not accepted to be operated on, and being able to ask for a compensation due to the patrimonial damages (expenses spent to eliminate by means of a plastic-esthetic surgery of the unaesthetic details *de* *quibus* (*the ones related to*), and eventual gains lost derived from this new esthetic condition; imagine a situation of a nude person, who could be affected, in a working level, by a situation of this type), besides the other ones which are neither patrimonial nor biological (proving, in this case, having endured a harm to her dignity that has marked her existence in crucial moments of suffering, both physical and psychic)·.[45] In an opposite case, the damage derived from the harm to *DE QUO right (the one related to)* that would be configured as a mere damage-event (and thus would be compensable by the sole fact that the physician, with a negligent conduct, has violated the dispositions for the guardianship of the patient). Surely, it will not be simple, for the patient, to be able to prove the subsistence of the non-patrimonial damage mentioned; nor it will be simple, for the judge, to be able to quantify it for settlement purposes. Several problems remain open at this level; the same ones that frequently make courts to decide, then, in a contradictory manner among them.[46]

The Gelli-Bianco law, which has recently participated in the issue, has not specifically treated the question: certain aspects were foreseen in the initial law project, but later, certain points appeared where it is avoided that, being supported in their subsistence (taking into account the fact that such problems cover ethical questions, before the judicial ones), in the political field, there could exist behaviors in order to block the definite approval of the law itself.

Nevertheless, the law impacts in some way, if indirectly, also in some aspects related to such discipline: until now, it was considered that the nature of the physician’s accountability, either in a case of invalid or absent consent would be of a pre-contractual type (chargeable, according to the majoritarian jurisprudence, to the contractual in accordance with article 1218 of the civil code). Today, except the cases in which the accountability of the institution is valid, or else there would subsist a clear and explicit contract with the physician called upon in a trial, the responsibility shall be stated as extra-contractual, without existing there any longer, the possibility to find any other kind of "social contract" between the physician and the patient.

Besides, this normativity, referring expressly to the accountability, as it is foreseen in the Balduzzi law, foresees that, in quantifying the biological damage claimed and proven by the patient, the judge should apply articles 138 and 139 of the private insurance code, instead of the more generous Milan charts.

Currently, the approval of a low project of the parliaments initiative that is hoped will provide clarity on the issue is being processed, controlling all the aspects that today, notwithstanding the clarification word of the jurisprudence, are not very clear.

5. Some critical remarks

Therefore, a communication process between the healthcare professional (who provides news, as he is the specialist expert in the subject matter), and the person to be cared for (who requests explanations, and wants to be informed about the expected results and of possible complications). It has to be clearly stated, in a way such, as to stimulate or motivate the one who receives the information, to have a critical involvement; moreover, the discussion must not be exhausted in a single colloquium, but it has necessarily, to be unfolded and developed along the whole caring process.

Nevertheless, this does not happen: what happens frequently is, that the interchange is exhausted in a single initial colloquium between the physician and the patient; and worse, it does not help at all, for stimulating the patient to participate in any way in the process. Nowadays, people are confronted with an excessive standardization of the information procedures, which most of the time are receded to a mere burocratic formality:[47] therefore, the informed consent loses relevance, and the reason for which it was born is emptied of its moral significance; it becomes a mere duty, a mere behaviorally obligation that, once performed, liberates the physician of the commitment from an eventual future complication; it is set as a formulary form that protects the physician of possible judicial problems, through the optics of defensive medicine,[48] and it is useless for making a truly conscious decision by the patient which is being cared for.[49]

Moreover, the information provided to patients (the main object of the consent), it is well understood, in the majority of the cases, by the people being assisted,[50] but they are still too far away of being in line, with the centrality of the patient. Thus, frequently, many misunderstandings between the physician and the patient arise, of which consequently many compensation petitions for suffered damages are derived and, in the optics of who requires it, non-consensual.

Then, the physician-patient relationship, suffers a strong depersonalization: the obligatory link is marked by strictly contractual models[51] and a communication impoverishing of the healing or sanitary process. An act that should have meant to be an action for the rapprochement of the relationship poles, in reality, it separates them.[52] In this manner, what should have been the encounter between physician-patient becomes a crash; and (the absent) communication becomes *«dialogue of the deaf, which translates into a distant, cold, and full of suspicion relationship; the information translated into the informed consent practice, becomes a mere caricature of itself»*.[53]

Conversely, notwithstanding his own broad decision autonomy, the assisted person needs a physician to stand by him, along the whole healing itinerary process, and must necessarily create together with him, a trustworthy relationship, based on which to be able to choose and to be advised.[54] The foregone is true, due to the fact that the sick person, in use of his autonomous decision, loses in reality, his capability to properly assess in a rational way, his own pathological condition, due to the emotional *status* that is affecting him: to leave him completely alone at the moment of decision making, thus, it means yes, to take the chance of transmitting information, *but «violating the subject, and run over his emotions, instead of establishing with him a communication process».*[55.] Furthermore, the risk is that, in light of it, there would be a trend to diminish the substantial importance of the physician, who would be reduced to a mere service provider, a kind of a highly qualified craftsman, who must limit himself to inform, but cannot give any advise whatsoever.[56.]

If it is true that information procedures represent in this way, a key central moment in the structuring process of a clean, full and well informed conscience, of the therapeutic treatment to which the patient will be subjected to, then, it is appropriate that those procedures be respected. To impact positively in such issues, it would mean not only to recover a communication moment between the two poles of the relationship, but also to avoid, that the misunderstandings of which we have talked about already, would lead to damage compensation petitions (a contingency that impacts negatively on the calmness of the treating physician, and on his professionalism, because he is always afraid of the possibility of an aggression coming from somebody who does not trust him any longer).

There is really a need to recover the so called "therapeutic alliance" in order to achieve that physician and patient concur together in choosing the process and itinerary which better respond to the life vision and the particular person's health who is subjected to the treatment: the patient's human factor and the one of the medical personnel, must be considered as the basis from which to start to establish a new approach between physician and patient. Having abandoned the legacy of a Hippocratic-paternalistic type, it is necessary to foster a new concept for "sick person", seen as a sound subject, aware and capable of looking for options, and of making decisions; of actively involve himself in any and every moment of the process. But it must be recognized at the same time, that the patient cannot be left alone at the moment he is facing the duty of choosing conscientiously.

Also, all the above stated issues, are for the purpose of avoiding that the (relevant) autonomy acknowledged to the patient, could even make a more negative impact on the physician-patient relationship, when the patient, strengthened by his centrality in the health relationship, should pretend, from the physician, a healing and/or, worse, the performing of certain treatments for the sole purpose of satisfying his own desires. Therefore, it is true that *«[. . .] the patient's autonomy and the informed consent, are not provided only as antidotes for arrogant physicians, but also necessary, because nobody else can speak for the patient, but the patient himself»*.[57] But it is also truth that, whenever this election's autonomy is too wide, and the communication contact is cancelled, medicine loses its own historical connotation of medical art, to assume instead, that more depersonalized and lacking responsibility of the medical technique. Medicine should, today, among other things, confront the external compelling requirement of a satisfied public that pretends to obtain a specific result, and does not accept the eventuality of failure due to force majeure causes.[58] Through this optic, the physician must also answer frequently to petitions that not always correspond to the true and proper human needs, or in the best case to mere dreams of the patient, pretentions which are in the limit of what is bizarre, that, in the perspective of who request them, are legitimate as for wanted and chosen as opportune for them and their own health.[59]

Bibliography references

[1] About this issue, the words of F. Modugno are always current, which defines the right to health, as a new right due to its different location in the economic-social sector [1].

[2] About the depatrimonialization process, see what Anna Lasso has written in a recent document on the issue of the centrality of the person in the judicial regulation [2].

[3] The Constitutional Court, in the ruling n. 471/1990 has specifically recognized, that the liberty referred to in art.13 of the Constitution, includes also the freedom of every one to dispose of his own body. The ruling has created a close connec-

tion between the right to health and the liberty of self-determination: constitutional article 13, produces a guardianship that is centrally important in the constitutional project, having as an objective an inviolable right which is included among the supreme values, an unfailing essential core of the individual, in the same way than the adjacent and closely related right to life and to physical integrity, alongside which jointly concurs to constitute the first womb of all other rights constitutionally protected by the person. *On the contrary, against, as it is widely known,* Castronovo thinks that the right to health, and self-determination, must stay separated [3].

[4] The importance of the already mentioned personalistic principle, linked to Article 32 of the Constitution, also has been set as relevant in the hermeneutical activity area of Civil Law. For example, regarding the issue of property guardianship, Article 873 of the Civil Code, is interpreted making an explicit reference to the concept referred to, in the first section of Article 32 of the Constitution. The discussion, after all, cannot exclude the reference to Article 844 of The Civil Code, which acknowledges to the owner of a piece of land, the right to prevent the entry of fumes or heat, the exhalations, the noise, external shock and similar propagations originated at a neighbor’s land, which exceed the normal tolerance levels: consequently, the corresponding inhibition actions can be performed by the affected party in order to achieve the *“end or cease of harmful or toxic activities, which are detrimental to people’s health*” (cf. Civil Appeal, SS.UU, court ruling number 10186/1998). Cf. Also Civil Appeal, Section III, Court ruling number 8420/2006.

[5] The Civil Appeal, Section IV, Court Ruling number 36519/2001 has been expressed in this way or, in the spirit of this writing. Cf. concerning the perspectives outlined by A. Fiori, G. La Monaca, G. Albertacci [4].

[6] In order to weaken such right, the apparent limitations foreseen in our Regulations in Art V of the Civil Law, are valid (they prohibit acts of disposal of a person’s own body that «*could cause a permanent diminishing of their physical integrity, or else be contrary to the law, be a disruption to public order or contrary to good manners»*). It is also valid what is stated in the Second Section of Article 32 of the Constitution (the one which regulates, instead, the relationships between an individual and the community, in light of, and through the optics of the so called obligatory sanitary treatments). As for the first alleged limit, it does not represent an absolute principle. In order to achieve a psycho-physical wellbeing, the patient has the right to submit himself to the sanitary care he needs, which are considered the most efficient for his safeguard; and if as a consequence, the direct interested party may use his right to a psycho-physical integrity within the limits in which, it will work for him for therapeutic purposes, it is normal that, *the* interpretative/applicative *RATIO* of Article V, should be limited to the actions which are not aimed to the guardianship of the personal health. The debate which has been held regarding the relationship between the two standards, has frequently been accommodated, according to Donatella Morana [5, p. 143], to a vague reading of the code’s standard: they have mistakenly started based on it, in order to interpret the constitutional expert opinion; conversely, it should have been started based on the Constitution, in order to examine the validity and the scope of the ordinary legislation. Cf.

also, in reference to this proposal, whatever has been declared by Barbara Pezzini [6, pp. 50 and subsequent]. As the Constitutional Court has declared, Court Ruling number 161/1985, *«By a constant jurisprudence, the acts of disposal of our personal body, when they are aimed toward a personal guardianship, even a psychic one, should be considered legal»*, even if they are specifically going to undermine the physical integrity of an ill person until leaving him/her disabled compared with how he/she was before the disposal. Think about the case of a surgery such as a diabetic foot amputation, without which, the patient would be in death jeopardy: «*the therapeutic nature that science assigns to a surgical intervention, and that the law recognizes […], prevents it from illegality»* (cf. Constitutional Court, ruling number 161/1985; in this theory, M. Bilancetti [7, p. 232]). The statement of article 5 of the civil code, it definitely does not limit freedom of self-determination, but on the contrary, it protects it, for it prohibits abuse, even though the disposal act of the personal body (Cf. P. Barile [8, p. 388]). It is necessary to point out that, the analyzed prohibition is limited only to the positive behaviors, like it is diffusely recognized by the theory (cf. V. Crisafulli [9, 561]: *«therefore, it does not extend to, the mere inertia behaviors that, not withstanding, have as a consequence the diminishing of the integrity. Moreover, that does not find any application, not even in the case in which a diminishing is being discussed, thus called temporary, as it happens, for example, in the case of blood donation, or of a breeding contract»).* Regarding the second limit, Constitutional Court, ruling n. 307/1990 it has been declared that a TSO can be imposed only in prevision that *«does not impact negatively in the health status of who is subjected to him, except for those consequences that, due to its timeliness and scarce entity, would apparently seem normal of all medical intervention, and therefore tolerable».* After all, as it is pinpointed by the Constitutional Court, ruling n. 307/1990: *«the law which imposes a heath treatment, is not incompatible with Article 32 of the Constitution, if the treatment and care is aimed not only to improve or to preserve the health status of who is subjected to it, but also to preserve the health status of the others, for it is precisely such ulterior purpose, concerning to the health as an interest of the community, what justifies the understanding of that self-determination of man, which is inherent to the right of each one to health as a fundamental right».* (Cf. regarding this point the statements of A. Barbera [10, p. 90]). The legislator (law n. 180/1978, art. 1) points out that the cohesive character of a treatment, shall never suppress or prejudge the exercise *"of the civil and political rights guaranteed by the Constitution*". This means that an obligatory medical treatment, cannot negatively impact on the capability of private rights, nor over the capability of the public right of the patient. The determination of this ulterior guarantee is not casual, nor either, a useless repetition. Cf. Constitutional Court, ruling n. 118/1996: «*the health constitutional discipline includes two sides, the individual and the subjective one, the first one (health as "fundamental right of the individual*"*), social and objective the second one (the health as "an interest of the community"). Sometimes the first one can be in conflict with the second one, according to an eventuality present in the relationships between the whole and the parts».* Therefore, to the dynamic individual, are requested some benefits in obedience to those non-derogable duties of political, economic and social solidarity established in Article 2 of the Constitution, and that help to provide clear proof of a clear reconsideration of no low importance of the concept of person. The interest of the community in this sense, represents an external limit of the individual right, a «*barrier that limits its amplitude without conditioning its usufruct» (*Cf. the writing of Donatella Morana [5, p. 163]): The guardianship of the individual's right identifies this way the general rule; the collective interest, conversely, constitutes, from the beginning, its justified eventual exception (Cfr. the perspective highlighted by L. Carlassare [11, pp. 110 y ss.]).

[7] In order to go deeper into the issues of health, autonomy, freedom of availability and the inherent problems of the therapeutic autonomy, be allowed to refer to whatever I have written in the past [12].

[8] There are many international standards that foresee the need for an informed consent by the patient, in the area of medical treatments: see Article 24 of the Convention on the Children's Rights, signed in New York on November 20, 1989, ratified and issued with the Law of May 27, 1991, n. 176; Article 5 of the Convention on the Human Rights and on Biomedicine, signed in Oviedo on April 4, 1997, ratified by Italy with the Law of March 28, 2001, n. 145; Article 3 of the Chart of the Fundamental Rights of the European Union, issued in Nice, on December 7, 2000.

[9] The definition is taken form S. Spinsanti [13].

[10] About the informed consent issue, see, if it pleases you, *Ex Pluribu (in most of the cases)* one of my recent works and the bibliography there referred [14].

[11] A behavior like that would be detrimental *"on the personal sphere of the subject and the moral freedom of the person"*. Cfr. F. Bricola, G. Zagrelbesky, *Systematic Jurisprudence of Criminal Law* [15, p. 424].

[12] Cf. Court of Milan, V civil section, ruling n. 3520/2005: «*The consent must be the outcome of a real relationship, and not only apparent between the physician and the patient, in which the physician is obliged to gather an effective and participative adhesion, not only on paper for the intervention. Therefore this is not a purely formal or bureaucratic act, but the essential condition for transforming a normally illegal act, the violation of the psycho-physical integrity, in a legal act, which is precisely the source of responsibility*».

[13] The consent (properly informed) guarantees «*the free and aware election by the patient and, therefore, his own personal liberty, according to Article 32, second section of the Constitution*». Cf. Constitutional Court ruling n. 438/2008.

[14] Again the Milan Court, declares this way, in the already mentioned ruling n.3520/2005. It is the Nuremberg Code of 1949, the first one in defining as essential the "voluntary consent" of the human subject. Nevertheless, such complete judicial formula has had its origin in the United States, where the debate, developing first in a limited fashion according to the need for the patient's consent in the previous stage to that closely surgical, has come later to consider the information as a fundamental characteristic for its configuration (the so called *INFORMED CONSENT* of the XX Century). The historical background records cited by the American

Courts, which have marked the birth of a consent as a fundamental act, and have followed its evolution until turning it into an informed one, are the *Slater* case (1767) the *Carpenter* case (1871), the *Mohr* case (1905), the *Schloendorff* case (1914) and the *Salgo* case (1957). Finally, the *Cooper* case (1971), that shows evidently how the main objective of the informed consent be in the end, the one of making the patient aware of all the concrete aspects of the therapy, based on which he could later on, conscientiously choose what thing to do / or not to do. In Italy the informed consent has had full recognition only in recent times, notwithstanding that it is still lacking of a unitarian organic discipline. The legislator has often dealt with the informed consent in the health sector, especially with law 107/1990 regarding transfusions (later on cancelled by the law 219/2005), with the law 135/1990 (program of emergency interventions for the prevention and fight against Aids) and the law decree 23/1998 in the issue of clinical experimentation. Nevertheless, it is pointed out that, the law 40/2004 in the issue of assisted reproduction, which dedicates to informed consent a specific availability (Article 6), and the law project 211/2003, related to the application of good clinical practices, in the execution of experiments of medication for clinical use. The frame of the discipline is completed by the deontological standards which confirm the sensitive demand of adjusting the ethical rules to the intervened metamorphosis of the physician-patient relationship. The deontological code in its standard constitution, takes into account social sensitivity and its corresponding mayor conscience that the person already possesses, and sets those mentioned demands to the new goals taken from the advancement of the biomedical and pharmacology sciences, and of the ethical problems collaterally generated and deepened by the bioethics committees. Cf. also, Constitutional Court ruling n. 253/2009.

[15] The definition is extrapolated by the Civil Appeal, section III, ruling n. 16543/2011, which establishes that: «*the right to informed consent, as a non reconsiderable right of the person, has always to be, and in any way respected by the physician, unless emergency cases arise, discovered, as a consequence of an agreed and programmed intervention, and for which had been required, and has been obtained the consent; cases that put in total jeopardy the life of a person, which is a good he receives and which is related to the primary guardianship in the scale of legal values, as a basis of the judicial order and of the civil life; or either it has to do with an obligatory medical treatment*».

[16] Regarding the subject matter, *ex pluribus (in the majority of the cases)*, you will be redirected to the works of G., Cocco [16, p. 485], M., Graziadei [17], G. Marini [18], L. Nivarra [19], P., Zatti [20], C., Casonato [21, 22].

[17] Cf. the work of F., MANTOVANI [23].

[18] Also in his monograph, F., Mantovani [24].

[19] «*The informed consent wants to put at the physician’s center of attention not only, the sickness, but also the person needing treatment; in such a way that to the duty of information by the physician corresponds today the figure of the participant ill person, which can consider the information as his irrevocable right, and not any more as a gentle concession*». Cf. F. Giunta [25].

[20] Cf. regarding this argument, whatever has been exposed by the National Committee for Bioethics [26, p. 39]: «*the so called paternalistic stage has lasted thousands of years, during which the link between physician and patient has been essentially dyadic, and few strangers, except relatives, could penetrate into this personal magic kingdom of the care treatment. It was a model of medicine based on, more than how much it would be today, on the trust in the technical capability of the physician, and on his moral structure, supported in the attribution of magical powers to the physician, and it was featured by the patient's dependence and by the control exerted by the physician».*

[21] Cf. C., PARODI, V., NIZZA [27, p. 417].

[22] Cf. whatever is referred by Paola Helzel [28, p. 615]

[23] R., PODROMO [29, p. 89].

[24] «*I will choose the proper treatment regimen for the patient's good according to my judgement and strength, and I will refrain myself of causing any harm or damage»* (This is the way it is written and read, in the classical Hippocratic Oath).

[25] Cf. P., HELZEL [28, p. 615].

[26] All this, writes C., CORATELLA [30, p. 4], it is the outcome of *«the spreaded out raise of the communities instruction level, and of the renovated cultural environment, that has characterized the eighties and has determined, on one hand, an each time greater capability of understanding of the therapeutic instructions provided by the physician; and on the other hand, the people's awareness of their own rights*».

[27] Cf. the expression *Life* (*right to*) of G., GEMMA [31].

[28] Cf. the monography P., BORSELLINO [32].

[29] Cf. again, the words of P., HELZEL [28, p. 617].

[30] Cf. the thesis of F., VIGANÒ [33, pp. 524-525].

[31] Are exceptions the cases in which it is not possible to refer to the patients will, because he is either naturally incapable, or because he has waived to be an autonomous decision center.

[32] Regarding this issue, in general, it is redirected to the writings of I., ANDORLINI y A., MARCONE [34, pp. 145 y ss.], plus the ones of D., GOUREVITCH [35], P., MAZZARELLO [36, pp. 3 y ss.], G. MONTANARI VERGALLO [37] y M., TRABUCCHI [38].

[33] Cf. the pages of F., D'AGOSTINO and L., PALAZZANI [39, p. 15].

[34] The information *contributes* to validate the consent, because it is necessary, but not enough by itself. Besides such requirement, it is recognized as fundamental, other characteristics that consent must possess in order to be considered evidently valid: it must be free, personal, evident, current, acknowledged (in order to deepen into the above mentioned specifications, cf. Iadecola [40], E., IANNELLI [41, pp. 39-49]). As for the form, nonspecific prescription considers that consent should necessarily be in writing. Only Article 30 of the deontology code makes reference to an eventual documentation only in the case that the intervention would be particularly difficult. The consent must be real and effective, and not only *alleged*; current (not anticipated), must therefore persist, at the time of the intervention's beginning, and it is always revocable. The prevailing jurisprudence denies, in fact, that the so called assumed consent should undertake prominence, or else as ab-

sent, but that it is considered that it was already granted, if the patient could have been able to do it (cf. Civil Appeal, section III, ruling n. 290984/2012; *versus,* Civil Appeal section IV ruling n. 5976/2003, in which it is declared that «for what it is referred to, finally, to the patient’s consent *[…] the consent must be real, informed, peaceful or, if the conditions are given, alleged… under the hypothesis of material impossibility of consent declaration, and of an urgent therapeutic need*).

[35] Cf. Civil Appeal, section III, ruling n. 15698/2010.

[36] The information must be particularized and specific, in such a way to imply *«the total acknowledgement of the medical and/or surgical intervention’s nature, and of its scope and extension, its risks, of the expected results and of the possible negative consequences*» (cf. Civil Appeal, section III, ruling n. 7027/2001). It has been spoken about “informed consent” at the end of the 50’s, when the California Supreme Court had declared it as a principle against Leland Stanford in 1957. In the ruling, the Court has declared the physician’s duty to inform the patient about all the facts which would be necessary to form the basis of a conscientious consent to the proposed treatment care: for the first time, in inquiry about the legality of the medical intervention it is not limited to the subsistence or not of an explicit consent, but concentrates the attention in the presence of a consent previously informed. In Europe, such approach to the issue, had been developed only some years later. In the “Principles of European medical ethics”, the letter signed by 12 countries of the European Community at the conference about the professional medical orders of 1987 (but also see the version of 1982), in which are inspired substantially all the current deontological codes, there it emphasizes the need to provide to the patient a proper information about the effects and the foreseen consequences from the therapy, before requesting their consent.

[37] Cf. Civil Appeal, Section III, ruling n. 18334/2013, according to which, the physician has the obligation to provide all the possible information to the patient regarding the medical treatment care or the surgical intervention to be performed, that is why the patient is submitted, in order for him to sign a non-generic module from which it would be possible to deduct with certainty the acquisition in an comprehensive way by the patient of such information: from it, it is derived that the surgeon does not comply with the obligation granted to him, when he does not provide the patient, in a complete and comprehensive way, all the information scientifically possible about the surgical intervention he tries to perform, and above all the risks/benefits balance of the intervention.

[38] Cf. regarding this point, A., VALLINI [42]. The step from the consent principle to the informed consent is also fundamental, from the cultural point of view, from the moment that indicates the acquisition of the awareness of the patient’s centrality in the treatment path. In Italy, a total judicial acknowledgement of the need for a proper previous information, as a requirement of validity of the consent, it has been had only since the beginning of the 90’s, thanks to the important jurisprudence action in this way, and to the rise of standard specific previsions such as the one in the Law 107 of 1990 regarding transfusion activities, or of the project from Law 230 of 1995, with respect to ionizing radiation.

[39] It is demonstrated that Civil Appeal, Section III, ruling n. 364, had established criteria of general extent by declaring that*: «the validity of a consent is subjected to the information provided by the professional from whom it is required, about the benefits, the various modalities in general, about the several operation modalities, and about the foreseeable risks (even the so small ones, that they can make a serious impact on the physical conditions, or on life which is the supreme good itself) of the therapeutic intervention –information that must be effective and correct– and, in the case that the patient himself is the one who requested a surgery, by its nature, complex and performed by a team, the assumption or presumption of a consent to all the preparatory and successive interventions, jointly with the intervention itself, does not absolve the medical personnel responsible, who has to inform also, about these operational phases (in specific concrete cases such as the related to the various anesthetic methods that could be used, their execution modalities and to their degree of risk), in such a way that the physician's technical decision should happen after a proper information is provided, and with specific consent of the interested party».* In the grounds of the ruling, The Supreme Court had made a pause on the content of the duty of information, where the purpose is, to allow the patient to make a conscious decision through a balance between advantages and risks of the chosen treatment, and certainly not to provide a detailed scientific explanation of the benefits: *«In particular, in the area of the surgical interventions, the duty of information includes the scope of the intervention, the unavoidable difficulties, the expected effects, and the eventual risks, in a way they would be able to put the patient in a condition to decide about the appropriateness to proceed with the intervention, or to cancel it, by means of a balance between advantages and risks. The obligation applies to the foreseeable risks, and not so to the abnormal results, in the limit of the fortuitous facts, or as it is said, the acts of God, that are not assumed relevant, according to ID QUOD PLERUMQUE ACCIDIT (what it had mainly or in its majority happened), having to recognize that, the physician must balance the demand for information with the need to avoid that the patient, by any very remote chance, should decide to cancel to submit himself also, to a trivial intervention. The importance of the interests and goods which are at stake, for the present purpose, assumes relevance, none the less not being allowed, by a mere statistical calculation, that the patient would not be aware of the risks, even if they are small or so reduced, that would impact on his physical condition, or even, about the supreme good of life. Moreover, the obligation for providing information extends to, the specific risks related to certain alternative decisions, in a way that the patient, with the technical-scientific help of the physician, could bend for one or another of the possible decisions, by means of a conscious assessment of the corresponding risks, and the related advantages. From another point of view, it is well known that, in relatively complex interventions, especially the ones involving team work, it is currently normal that, they would present in their various phases, clear and specific risks. In a way, those phases assume their own management autonomy, and in turn they themselves give room to diversified operative decisions, even though, each one of them pre-*

sents diverse risks. The obligation for information thus enhances, and it extends also to such phases and their corresponding risks as well as to the foreseen risks, but not to abnormal results, in the limit of what it is fortuity, […], without ignoring that the physician must balance the demand for information, with the need to avoid that the patient, in a very remote case, would also avoid to submit himself to a trivial intervention». Also the Medical Deontology Code addresses the information problematic, stating I Article 33, the physician’s obligation duty, to provide the patient with the best, essential, and thorough information that must correspond to the cultural level, the patient’s moodiness, and to the intellectual capabilities of the patient, without any unnecessary specification regarding the scientific data involved: the information must cover the diagnosis, the prognosis, the therapeutic perspectives, and of the true consequences of the therapy and of the non-therapy. The eventual will of the assisted person of not being informed must be documented. As a guaranty of the physicians duty to respect also such patient’s desire, without incurring in any responsibility whatsoever.

[40] Cf. Civil Appeal, Section III, ruling n. 2847/2010.

[41] Cf. Civil Appeal, SectionIII, ruling n. 27751/2013.

[42] Cf. Civil Appeal, Section III, ruling n. 4540/2016, among others. Risk management, understood both as a set of reduction modalities of the probability to verify clinical mistakes, as well as the necessary modalities for its management, in the unfortunate case that they should appear, must completely become an integral part of the process of organizational improvement of health, as it also is prescribed by the Medical Deontology Code of 2014 (Article 14), for which the physician *“*…for the purpose of guaranteeing the most ideal safety conditions of the patient …” it is called to contribute to the clinical risk management paying *“*…attention to the information process and to the consent achievement, as well as the communication of an unwanted event, and of its causes…”, and finally contributing to the *“*…revelation, signalization and the assessment of sentinel events, mistakes, quasi-mistakes and adverse events…”.

[43] Cf. Civil Appeal, Section III, ruling n.19229/2013, according to which in a personal relationship with the patient on the verge of diagnostic-therapeutic procedures, this one has the right to be provided with information about the benefits and risks or any alternative there off, of the proposed procedure in a language that must take into account the cultural degree of the assisted person (a clear language that foresees the particular subjective state, and the degree of specific knowledge). It does not have any influence on the illicit fact of the violation of informed consent, in that the treatment would have been performed in a correct way or not. In such perspective, what is emphasized is that the patient, due to the deficit of information, would have not been put into a condition to agree to the health treatment with a conscious will of its implications, performing in him, an injury of his dignity that marks his existence in the crucial moments of physical and psychic suffering. Also, Cf. Civil Appeal, Section III, ruling n. 16543/2011, and Civil Appeal Section II, ruling n. 20984/2012. Under these terms, Civil Appeal, Section III, ruling n. 5444/2006 stated: «*The entirety or not of the treatment, does not assume any promi-*

nence, regarding the subsistence of the illicit for the violation of informed consent, which subsists for the simple reason that the patient, due to the deficit of information, hasn't been set in a condition to agree to the health treatment, with a conscious will of its implications».

[44] Cf. Civil Appeal, Section III, ruling n.2847/2010, in which the Supreme Court has set the detriment of health, dependent on the treatment of health (reckless or not) and the violation of the patient's right to be informed regarding the suggested treatment. For initial comments see A., RICCIO [43] y M., GORGONI [44].

[45] It is necessary that he who considers to be damaged in his right to self-determination, demonstrates the relevant circumstances that justify the compensation for the harm according to Articles 1223 and 2059 of the Civil Code, in accordance with «*it is always necessary as a proof of the entity of the damage, that is to say the demonstration that the harm has produced an analogous type of loss as the one indicated by Article 1223 of the Civil Code, constituted by the diminishing or deprivation of a personal value (non-patrimonial) regarding which the compensation must be measured*» (Cf. Milan Court, Section V civil, March 29, 2005, n. 3520). The issue of the non-patrimonial damage proof, and of the difficulties which imply, have escaped the judge's attention, which have improved the distinction between the inherent damage in the violation (damage *RE IPSA (the thing itself))*, and the proof of damage *RE IPSA (the thing itself):* then they, have tried not to make coincident the damage with the violation of the interest, but to exonerate in any possible way, the damaged party, from the burden of demonstrating the existence of the prejudice (Cf. Civil Appeal, SS.UU. ruling n. 1338/2004).

[46] See, to go further into the issue, whatever has been written in an essay published in magazine "Federalismos" [14].

[47] This information is verifiable in the study performed by Costa G., MAIALE N., PASCOLO PRISCILLA, PEZZINO SERENELLA [45]: here, the authors provide information about a research whose objective has been constituted by a total sample of 207 patient, distributed in three hospitals in the center of Italy, and conformed by 117 men (equal to 56.52%) and 90 women (equal to 43.47%), all of them adults and from which 1.93% are in the age range of 18-30 years old (4 patients), 18.84% in the age range of 31-45 years old (39 patients), 32.85% in the age range of 46.65 years old (68 patients) and 46.37% represented by people older than 65 years of age (96 patients); recently operated (maximum 1-2 days) and all subjected to elective surgical interventions, that is to say performed in conditions of non- emergency (however 11 patients of the total of the sample equal to 5.31% claim to have been operated in an emergency procedure and 3 patients- equal to 1.44%- even in an emergency procedure)

[48] From an AGENAS inquiry, has arisen that 11.8 percent of the total health expense, is precisely caused by the defensive medicine (amount variable between 10 and 13 thousand million euros). «The Defensive Medicine is … a worrying outcome of the increasing judicial controversy that burdens the medical class. From it is derived an ulterior disturbance of the professional practice… The Defensive Medicine takes place when the physicians prescribe tests, treatments or visits, or avoid

patients or high risk treatments, mainly… for the purpose of reducing their own exposure to risk of accusations of *“mala praxis*”,… The Defensive Medicine… produces social damage due to the undue increase in health costs, already very high» (Fiori A., *La medicina legale difensiva. Editoriale* [46]).

[49] Under this perspective, the physician-patient relationship, looks like an ordinary commercial relationship regulated by the law according to precise standards of professional integrity (expertise, truth, faithfulness to facts) and the patient becomes an ordinary client, a common consumer, whereas the physician, as a rightful counterpart, limits himself to put him under conditions to be able to choose (without even worrying for the fact that he would be effectively able to perform it right); the so called *defensive medicine,* is the one that *«is verified when the physicians prescribe test, diagnostic procedures or visits, or else, avoiding patients or high risk treatments, mainly (even not exclusively) to reduce their exposure to a liability trial for malpractice».* The definition was elaborated in 1994 by the OTA, Office of Technology Assessment, USA Congress. About the issue, it is interesting to read a monography by F., LIPAROTI [47].

[50] Always taking into account all what has emerged in the mentioned research [44], 56% of the interviewed has declared that the used language, in the information phase was «very understandable» while 33% said «fairly understandable».

[51] According to E., SGRECCIA [48, p.1], it is not «*desirable to go on a purely contractual line: the impossibility to immediately translate the health relationship in terms of the agreement between the specialist and the patient derived from the existential significance of the sickness, and its ethical and anthropological meaning*».

[52] As a proof of it, see whatever it happens, nowadays, in the telemedicine case.

[53] Cf. S., SPINSANTI [13, p. 92].

[54] The rise and discovery of a sickness, that is not known how to diagnose and face it, writes S. Orefice [49, p. 3] «*it already disables the mind […]. Desperation can be already reduced knowing that there will be a physician capable of helping».*

[55] This way writes E., SGRECCIA [48, p. 22].

[56] We ask ourselves if, in face of a so evidently “passive” attitude by the physician, he himself should be, could still be considered as an active part of the obligatory relationship, or else, reviewed the characteristics, already, of mere material executor of somebody else’s will.

[57] Cf. a miscellaneous work cured by G., PASINELLI [50, p. 55].

[58] All this impacts in the considerations of the body, which transforms into an object to be modified and at the service of his own desires. About this issue declare: A., SANTOSUOSSO [51], P., VERONESSI [52], S., RODOTÀ [53], R., ROMBOLI [54].

[59] «*Contemporaty culture has frequently denounced the limits of the medical paternalism in the name of the patient’s autonomy. To answer to the possible abuses of the medical paternalism appealing only to the principal of autonomy, does not help to rebalance the relationship physician-patient, but it also even seems to condemn it to a legal unrest […]* ». This way writes E. Sgreccia [48, p. 1]. He is clearly referring to, in this case, to the esthetic surgery operations, among others, relative to

which it is allowed to refer to whatever has been written in other occasions in this magazine [55].

Bibliography

[1] Modugno, F. I nuovi diritti nella giurisprudenza costituzionale. Torino: Giappichelli; 1995.
[2] Lasso, A. Centralità della questione etica e rilevanza dell'interesse non patrimoniale nella regolamentazione del mercato. En: Martinez Sicluna, Y., Sepulveda, C (curador). L'etica del mercato. Milano: Cedam; 2011: 115-142.
[3] Castronovo, C. Autodeterminazione e diritto privato. Europa e diritto 2010; 4: 1037-1071.
[4] Fiori, A., La Monaca, G., Albertacci, G. In tema di trattamenti medico chirurgici effettuati per autonoma decisione del medico senza previo consenso del paziente: un passo avanti nella giurisprudenza della Cassazione penale? Riv. It. Med. Leg. 2002; xxiv: 880-896.
[5] Morana, D. La salute nella costituzione italiana, profili sistematici. Milano: Giuffrè; 2000.
[6] Pezzini, B. Il diritto alla salute: profili costituzionali. Dir. e soc. 1983; I: 21-57.
[7] Bilancetti, M. La responsabilità penale e civile del medico. Padova: Cedam; 2010.
[8] Barile, P. Diritti dell'uomo e libertà fondamentali. Bologna: Il Mulino; 1984.
[9] Crisafulli, V. In tema di trasfusioni obbligatorie. Dir. Soc. 1982; iii: 557-568.
10 Barbera, A. I principi costituzionali della libertà personale. Milano: Giuffrè; 1967.
[11] Carlassare, L. L'art. 32 della Costituzione e il suo significato. En: Alessi R (curador). L'ordinamento sanitario. Milano: Giuffrè; 1967.
[12] Posteraro, N. Il diritto alla salute e l'autodeterminazione del paziente tra guarigione effettiva e pericoloso sviluppo della tecnologia. *Medicina e Morale* 2015; 3: 391-416.
[13] Spinsanti, S. Chi decide in medicina. Roma: Zadig; 2002.
[14] Posteraro, N. Liceità del trattamento medico arbitrario: osservazioni critiche sui profili di responsabilità civile e penale del sanitario alla luce dell'evoluzione giurisprudenziale. Federalismi 2015; osservatorio di diritto sanitario: 1-41.
[15] Bricola, F., Zagrelbesky, V. Giurisprudenza sistematica di diritto penale. Torino: Giappichelli; 1996.
[16] Cocco, G. Un punto sul diritto di libertà di rifiutare terapie mediche anche urgenti. Resp. Civ. prev. 2009; 74: 485-506.
[17] Graziadei, M. Il consenso informato e i suoi limiti. En: Lenti, L., Fabris, E., Zatti, P. (curador) I diritti in medicina. En: Rodotà, S., Zatti, P. Trattato di Biodiritto. Milano: Giuffrè; 2010.

[18] Marini, G. Il consenso. En: Rodotà, S., Tallacchini, M. (curador). Ambito e fonti del Biodiritto. En: Rodotà, S., Zatti, P. (dirigido por). Trattato di Biodiritto. Milano: Giuffrè; 2010.

[19] Nivarra, L. Autonomia (bio) giuridica e tutela della persona. Eur. Dir. Priv. 2009; 35: 719-754;

[20] Zatti, P. Il diritto a scegliere la propria salute (in margine al caso S. Raffaele). Nuova giur. Civ. comm. 2000; II: 1-36.

[21] Casonato, C. Il consenso informato. Profili di diritto comparato. Diritto pubblico comparato ed europeo 2009; III: 1052-1073.

[22] Casonato, C. Consenso e rifiuto delle cure in una recente sentenza della Cassazione. Quad. cost. 2008; 3: 545-576.

[23] Mantovani, F. Problemi giuridici dell’eutanasia. Medicina sociale 2007; 20: 249-276.

[24] Mantovani, F. I trapianti e la sperimentazione umana nel diritto italiano e straniero. Padova: CEDAM; 1974.

[25] Giunta, F. Il consenso informato all’atto medico tra principi costituzionali e implicazioni penalistiche. Ridpp 200; 2: 377-410.

[26] Comitato Nazionale per la Bioetica. Scopi, limiti e rischi della medicina. Presidenza del Consiglio dei Ministri 2001.

[27] Parodi, C., Nizza, V. La responsabilità penale del personale medico e paramedico. Torino: Giappichelli; 1996.

[28] Helzel, P. Il rapporto medico-paziente tra principi etici e norme giuridiche. Le Corti Calabresi 2007; 3: 615-637.

[29] Prodomo, R. Lineamenti di una bioetica liberale, Bologna: Alberto Perdisa Editore; 2003.

[30] Coratella, C. La responsabilità penale del medico. Diritto e Giustizia 2006; 3: 42-77.

[31] Gemma, G. Vita (diritto alla). Digesto delle discipline pubblicistiche, vol. XV; Torino: Giappichelli; 1999.

[32] Borsellino, P. Bioetica tra autonomia e diritto. Milano: Giuffrè; 1999.

[33] Viganò, F. Stato di necessità e conflitti di doveri. Milano: Giuffrè; 2000.

[34] Andorlini, I., Marconi, A., Medicina, medico e società nel mondo antico. Firenze: Mondadori; 2004.

[35] Gourevitch, D. Le triangle hippocratique dans le monde gréco-roman. Roma: École Française De Rome Palais Farnèse; 1984.

[36] Mazzarello, P. Rapporto terapeutico in occidente: profili storici, en Lenti, L., Fabris, E., Zatti, P. (curador). I diritti in medicina. En: Rodotà, S., Zatti, P. (dirigido por). Trattato di Biodiritto. Milano: Giuffrè; 2010.

[37] MONTANARI VERGALLO, G. Il rapporto medico paziente. Consenso informato tra libertà e responsabilità. Milano: Giuffrè; 2008.

[38] TRABUCCHI, M. L’ammalato e il suo medico. Successi e limiti di una relazione. Bologna: Il Mulino; 2009.

[39] D’Agostino, F., Palazzani, L. Bioetica. Nozioni fondamentali. Brescia: La Scuola; 2007.

[40] IADECOLA, G. Consenso del paziente e facoltà di curare. En: Ammirati D (curador). La responsabilità del medico. Padova: CEDAM; 2004.
[41] IANNELLI, E. Responsabilità del medico e consenso del paziente. En AMMIRATI, D. (curador). La responsabilità penale del medico. Padova: CEDAM; 2004.
[42] VALLINI, A. Paternalismo medico, rigorismi penali, medicina difensiva: una sintesi problematica e un azzardo de iure condendo. Riv. it. Med. Leg. 2013; 1: 2-16.
[43] RICCIO, A. La violazione dell'autodeterminazione è, dunque, autonomamente risarcibile. Contratto e impresa 2010; 2: 313-322.
[44] GORGONI, M. Ancora dubbi sul danno risarcibile a seguito di violazione dell'obbligo di informazione gravante sul sanitario. Resp. Civ. e prev. 2010; : 1014-1027.
[45] COSTA, G., MAIALE, N., PASCOLO PRISCILLA, PEZZINO SERENELLA. Il rischio di modello nel percorso d'acquisizione del consenso informato. Mondo Saitario 2016; 3:1-11.
[46] FIORI, A. Medicina legale della responsabilità medica. Milano: Giuffrè; 1999.
[47] LIPAROTI, F. Medicina difensiva e colpa professionale medica in diritto penale tra teoria e prassi giurisprudenziale, Milano: Giuffrè; 2012.
[48] SGRECCIA, E. Manuale di Bioetica. Fondamenti ed etica biomedica. Milano: Vita e Pensiero; 1999.
[49] OREFICE, S. La sfiducia e la diffidenza. Milano: Giuffrè; 2002.
[50] PASINELLI, G. (curador). Il consenso informato. Una svolta nell'etica medica. Milano: Franco Angeli; 2004.
[51] SANTOSUOSSO, A. Corpo e libertà. Una storia tra diritto e scienza. Milano: Giuffrè; 2001.
[52] VERONESI, P. Il corpo e la Costituzione. Concretezza dei casi e astrattezza della norma. Milano: Giuffrè; 2007.
[53] RODOTÀ, S. La persona costituzionalizzata e la sua autodeterminazione. En: RODOTÀ, S., TALLACCHINI, M. (curador). Ambito e fonti del Biodiritto. En: RODOTÀ, S., ZATTI, P. (dirigido por). Trattato di Biodiritto. Milano: Giuffrè; 2010.
[54] ROMBOLI, R. (curador). Atti di disposizione del proprio corpo. Pisa: Edizioni Plus; 2007.
[55] Posteraro, N. Vanità, moda e diritto alla salute: problemi di legittimazione giuridica della chirurgia estetica. *Medicina e Morale* 2014; 2: 275-302.