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Philosophical and Legal Foundations of Informed Consent

Antonio SANDU[1]
[1] PhD in Philosophy, PhD Student in Law, Doctoral School of Law, Titu Maiorescu University of Bucharest, Romania, antonio1907@yahoo.com

Abstract: *Ethical deliberation has been an important component of human culture since the dawn of political and legal thought. Ethical theories analyze the moral acceptability of human actions from the perspective of a set of principles that, in turn, are derived from the process of implementing, in social practice, some human values considered fundamental at the level of a given society or culture. Ethical theories, similarly to scientific theories, shape the reality in which we live, and although they do not constitute the real world, but only a perspective on it, they allow us to understand and react to facts that occur in the real world. Even if the world is perceived in the form of a social construction - we rather react to social perceptions of events and phenomena, which are most often subjective, through the consequences that our own perceptions or the social perceptions we adhere to have on us and on those with whom we interact with.*

Keywords: *legal philosophy; informed consent; right to autonomy.*

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1. Introduction

Ethical paradigms have the capacity of reification – that of making a subjective perception or reaction appear to us as objective, due to the consequences they have on us or on others (Manea et al., 2013). Ttheir capacity for reification brings along the need to implement ethical paradigms in social practice through sets of norms that operationalize sociability. As long as a moral norm is only idealized, not having the constraining force of the legal norm, its application represents a pure virtue, which often remains without object in the social world. Christian morality, built around the idea of love for the Other, has the ability to generate behaviors that highlight social solidarity, as a convergence around ttheir value, but it is not mandatory or imposed through legal acts with punitive force, and it remains in the sphere of benevolent attitudes. Ethics - based on justice and equity -, because it has benefited from normative transposition, codified by laws, has punitive force and, as such, represents a behavior adopted and imposed within society; deviation from ttheir may result in penalties.

Although philosophers such as Immanuel Kant believed that ethical norms should be universal, appliable to all individuals - regardless of the culture they belong to and the particular situation they are in -, modern ethical theories speak rather of moral particularism, showing that there is no universally valid ethical theory, rather different models of moral actions, that are valid, particularized according to different societies and situations. Ttheir would lead to the conclusion that moral particularism should correspond to a legal particularism, each society building its own normative system according to the values and needs perceived at the level of that society. However, with globalization - and even before it, in the process of colonial expansion, a series of norms specific to Western society, such as the idea of democracy and human rights, tend to become ideologically universal, even if, in practice, colonialism or great world conflagrations have questioned these generous ideas, as humanity periodically returned to the application of the law by force, instead of adhering to the force of law.

The acceptance of cultural relativism brings with it the acceptance of some practices considered immoral here and now, and therefore ethical particularism aims at acceptability in a socio-cultural context, while normative ethics identifies principles and ways of implementing these principles, with potential for universalization.

In terms of health care, the doctor's obligation to do all that is diligent in favor of the patient - within the limits of their professional

competences and the resources at their disposal - has been known since the first forms of codification of moral norms in the form of laws, in the Code of Hammurabi or in Roman law.

Patient rights can be considered as deriving from natural rights, more precisely from fundamental human rights such as the right to life or the right to dignity. Natural rights, understood as deriving directly from the individual's status as a human being, are codified in the modern period by the legal institution called "human rights" (Barac, 2009). Understood as a set of rules that take into account the particular nature of man - as an intelligent being - and their purpose in the world - the realization of human, social and spiritual potential, according to their aspirations, values and beliefs -, natural law is a set of principles and norms related to the human nature of the person, seen as immutable and universal, which precedes and is superior to positive law (Beck, 1986). For Plato (2005), natural law represents the paradigm of all laws, while for Aristotle, natural law represents the minimum condition necessary for the existence of any public order, since natural law has an immutable character and, as such, is universal (Craiovan, 2010).

Of course, the constructivist perspective on law is that all norms, regardless of their importance and their primacy in the normative hierarchy, are social constructs that codify ways of implementing some human - social or cultural - values. The hierarchy of values, which we can think of as being either constitutive for a given society - those values that make necessary a series of fundamental institutions in that society -, or operational - which regulate the operation of the previously mentioned institutions -, generate a hierarchy of norms that come to regulate the performance of those values (Sandu, 2017).

It is the merit of the Salamanca school (formed by Francisco de Vitoria, Domingo de Soto, Martín de Azpilcueta, Tomás de Mercado, Francisco Suárez) to reformulate the concept of natural law according to that of sovereignty and, respectively, that of human rights, to be able to reconcile the teachings of Thomas Aquinas about the ideal city with the political-economic order of the Renaissance and the beginning of Modernity (Copleston, 2019). Theories on human rights, especially those formulated by Francesco de Vitoria, formed the basis of the social philosophy of Hugo Grotius (1968) and later of the contractarians.

The importance of Francesco de Vitoria resides in the fact that he considered that human beings are bearers of rights - including the right to create laws -, even if they belong to other cultures, such as that of South America, ideas that contrasted with those uttered by to the Spanish or Portuguese in legitimating their rights to occupy South America and

generally to develop colonial empires, according to which natural right is of divine origin and as such applies only to Christians who have received ttheir right by virtue of the adoption of the Christian faith, the only one revealed directly by the Divinity. It is the merit of Hugo Grotius to secularize natural law, in the volume *On the Law of War and Peace*, which was published in 1625, a volume that claims that "man is a rational, social and sociable being" (Grotius, 1968) and, as such, the rules of reason are the basis of human laws, regardless of divine law.

Starting from the rights considered to be natural - such as the right to life, the right to one's own body, to property -, human rights develop as inalienable and universal rights of the human being, seen as being above positive law, but also as a consequence local factors that could intervene, including gender, nationality or ethnicity (Manea et al., 2013).

The legal protection of human rights is based on theories about the human being, its place and role in the world, as well as ways to protect the human individual. A number of characteristics are taken into account when the necessity of protecting these rights is discussed, and the most general characteristic is that of being born a human being. Behind these ideas is a true ontology of what it means to be human, which invokes particularities of the species, such as the existence of consciousness / self-awareness, reason, the capacity for verbal expression etc. Of course, each of these specificities of the human species can be questioned in the case of some or other individuals, in particular the conditions of their existence - and, as such, they cannot be considered axiological foundations of human rights.

On the other hand, the extension of some ontological features of the human beings – such as the ability to be aware of one's own existence - were later extended to other species, and thus the rights of animals became a topic, which, however, in a legal sense, is only related to the predominant human interest in safeguarding the existence of some species. These rights are, rather, of a moral nature, even if, in time, the need for ecoethics will justify the development of the biolaw applicable to non-human entities.

The development of society from the perspective of the protection of human rights knows several stages, from the affirmation of individual freedom, correlated with the right to life and safety, to the affirmation of property, political freedom and then moving forward to second-generation rights, such as the right to work, to education, to unionization and, respectively, to third-generation rights, as the right to peace, the right to health and bioethical rights (Manea et al., 2013).

2. The right to autonomy - axiological foundations of informed consent

Ethically speaking, the concept of autonomy operationalizes the axiological category of freedom, which is valid in the sphere of regulating the behavior of the person capable of action - that is, of the moral agent. By expanding the scope of ttheir concept to the scope of the moral patient / the person who suffers the consequences of an action loaded with ethical value -, we can talk about the establishment of a right, the right to autonomy and the need to protect it, as well as encouraging the expression of ttheir right. In an ontological sense, freedom appears as an inherent capacity, in which case it is the prerogative of Divinity. On a human level, the experience of freedom is configured precisely by identifying the limits between which it can be achieved: individual, social-political or the freedom of conscience. Freedom is correlative with the affirmation of identity, whether we refer to the individual level or to the social-political level. Affirmation of identity is achieved subjectively through the experience of limitation and difference - that is, the individuals, in the face of their own limitations, can opt out for a behavior of self-determination - autonomy - or obedience - heteronomy (Sandu, 2012).

The expression of autonomy, as the ability to manifest the will of the subject, acquires significance for bioethics and biolaw, as it puts the patient in the position of a being who decides. Beyond the pure expression of the patient's subjectivity as a human being, the expression of autonomy through informed consent and, in general, through the manifestation of will, regarding the treatment or its refusal, represents an attitude of overcoming the immediacy in which the subject is passive to suffering, through active control on the decisions they make (Sandu et al., 2013).

G. Dworkin considers autonomy as representing a general characteristic of a person's condition, namely the ability or inability of the individual to live their life according to their own reason, starting from their own motivations, making their own free decisions - ideally not manipulated or distorted by external forces (Dworkin, 1988). This way of understanding autonomy ideally underpins the ability to consent, in general to conclude acts that have legal value.

J. Dryden describes three distinct forms of autonomy: individual, moral and political (Dryden, 2010). Individual / personal autonomy is the ability of the individual to make decisions for themselves in the most proper way, when they set their own path in life. Individual autonomy is the least formalized, representing everyday choices, including whether or not to act in

accordance with the law, with the norms of social coexistence, as well as assuming responsibility for the consequences of one's choice and actions. Moral autonomy is the ability to make decisions about the moral value of an action and to act with or without integrity – consistency with one's own moral values or with the moral values of various groups to which the individual is a member. Conflicts of an ethical nature are generally based on conflicts of values between one's own values and those of the group of origin or the reference group. A choice conforming to deontology – the Kantian-inspired ethical theory that treats moral obligations in their absolute value – can be questionable when viewed from an utilitarian-consequentialist perspective – the utilitarian paradigm originating in the work of J. S. Mill and J. Locke believes that the analysis of a moral action should look at its results and consequences and only after that at the intention with which the action was carried out. Political autonomy refers to the individual's ability to have a political opinion that, once expressed, is recognized.

We believe that the three meanings of the term autonomy refer to the ontological, axiological and pragmatic dimensions of individual freedom. The ontological dimension concerns the concrete existence of the individual and their choices - rational or not, assumed or not - being, as such, rational or deliberative autonomy. The axiological dimension aims at the individual's ability to have a judgment on the value and the meaning of the world and their own life and the ability to make decisions based on the conclusions of their judgment - being, as such, relational autonomy. The pragmatic dimension represents the ability of the individual to express their free decision - thus considering it an expressive autonomy - and to be recognized and accepted as such, together with the expression of their own freedom, where it does not contradict the moral or legal norms of a society.

Ideally, we can talk about autonomy in the form of a synthesis of its three forms, the individual being able to attribute meaning to the world and to their own existence, which contrasts with the autonomy of actions or agent capacity, in the expression of which the awareness of limits intervenes, given the particular situation in which the subject is in, especially by the limits imposed by the respect for the autonomy/freedom of others. These limitations, related to objective or subjective factors, can lead, in concrete terms, to the partial realization or even the non-realization of one's own intentions, one's own choices, which, however, does not excuse the individual from the moral - or legal, where applicable - responsibility related of the action which, although not performed, was desired or even planned.

3. The Kantian origins of the concept of autonomy

Practical reason is, in Immanuel Kant's view, the one that should dictate any moral behavior to the agent. For the philosopher, morality is based on a separate category of reason - entitled practical reason -, which establishes the categorical imperative (Kant, 1972). By virtue of this principle, we must act so that our own moral maxim can have universal value, including by being consistent with decisions made on the basis of practical reason, regardless of their consequences, in such a way as not to harm the freedom and exercise of autonomy of others (Gruyer, 2004). For Kant, autonomy represents the virtue of acting consistently with universal law. This universal law is necessarily rational, so that any immoral act is at the same time an irrational one. Moral conduct, being in accordance with the universal law, is not only rational, but also mandatory, and any deviation from it makes the individual a slave to passion (Johnson, 2012).

Kant states that each individual possesses the capacity for self-determination, being endowed with the necessary reason to be able to base their ethical decisions on it. Respect for the rights of the individual and for the individual himself are established starting from the existence of self-determining reason and the ability to realize what the universal law is and act in accordance with it (Sandu et al., 2013). The source of the individual's moral dignity resides in their capacity as a legislator of their own moral conduct - also called the capacity of a moral agent (Johnson, 2012). But, for Kant, the ability of the individual to be an abstract moral legislator is not enough, the obligation being established - for the individual - to completely respect self-determined moral conduct. Therefore, autonomy expresses, at the same time, the capacity for moral self-determination, but also the need for moral conduct that is in accordance with reason. The moral character of an action is not only rationally determinable in abstracto, but also determined in concreto by reason. From this, we deduce that autonomy is the very source of human dignity. The objection to this principle comes from several directions, the main objection being that not all human individuals have the same rational capacity to understand the meanings of moral behaviors, the same volitional force to comply with their own moral decisions and, above all, the fact that the moral decision does not take into account only universal laws, because the individual is obliged to act, in particular situations, when they must face the consequences of their own actions or inactions.

Kant speaks of the moral conscience, which is guided exclusively by moral law, being that which allows the individual to act exclusively with their

moral will. The self-administration of the universal moral law represents, on the one hand, the basis of moral obligations in general, and on the other hand, the respect that we can claim and that others owe us. Kant, in *The Foundation of the Metaphysics of Morals*, argues that "man is the subject of the moral law, which is holy by virtue of his freedom" (Kant, 1969). For Kant, man's humanity is sacred, showing that man must always be an end in himself and not a means. Kantian rational autonomy is, in fact, the autonomy of the will, which is seen as a faculty of the rational being to determine itself in terms of action or non-action, in accordance with the law self-established by the moral consciousness of the individual, on the basis of a purpose universally and rationally acceptable as moral.

It is precisely morality that makes a rational being count as an end in itself, as a "legislating member of the empire of ends" (Kant, 1969). The dignity of the human being resides in its uniqueness, in its standing above any "price" that could make the individual equivalent to any other individual. Moral uniqueness, i.e. moral consciousness, is the cause of the dignity of the individual, since uniqueness is not seen, in the contemporary manner, as a serial uniqueness of each individual, that differs from all others, but places the individual in the position of the sole depository of moral reason and moral lawgiver in terms of universal law. Humanity is capable of morality and, therefore, Kant attributes dignity to it, since it is the only one that acts by virtue of the law that it alone institutes. For Kant, dignity thus defined requires respect for the person.

Practical reason is generic and not contextual. Kant ignores the concrete moral agent who has preferences, influences, lives in a certain social environment, possibly has preconceived ideas, or is in a situation where the health condition or emotional state prevents them from having moral judgment in accordance with pure reason.

Ethics derived from the Kantian view is considered to be deontological - the term deontology means the theory of obligations of a moral nature. For a follower of deontology, both as a moral philosophy and as applied ethics in the sphere of various professions – including medical or legal ones – an action is considered right if and only it is in accordance with a moral rule considered universal, but which has a subjective nature for the individual. This moral rule - universal but subjective at the same time - is called a maxim. For a rule to be considered maximal, its intrinsic correctness must derive from its rationality and admit no exceptions (Manea et al., 2013). Both Kant and the neo-Kantians, who emphasize deontology, believe that justifying the morality of an action must exclusively consider its rationality -

more precisely the intention that led to the action - and not its consequences, which are beyond the rational control of the individual.

For a deontologist, an action is not in itself good or bad, as this would refer to the consequences of the action – for oneself or for another – and whether it is morally right or wrong, i.e. conforms to pre-established rules. From a legal point of view, deontologists consider that, when we impose a duty on someone, a correlative right with that duty is born for their benefit. Duty generates rights, including human rights in general, rights that are universal and that do not aim at the good of the individual, but at the justice that is done to them, more precisely the ability to benefit from the rights to which they are entitled.

Kant distinguishes between what we do out of duty, what we do according to duty, and what we do from inclination. What is done out of inclination, even if it is a good deed, has no moral value in itself, because it has no moral reason behind it, but is merely the follow-up of our own inclination. If we act correctly by virtue of our professional obligations, this is a duty. If, however, we act right only because that action conforms to our own inclinations, it is not a moral action, even if the result is one that can be considered good. Acting according to duty, although meritorious, does not have the same moral value as acting out of duty, since we can act in accordance with the norm - that is, with the duty -, without reflecting on its meaning. Only voluntary conformity to the norm, which is the result of a deliberative process, has moral value in itself (Kant, 2007). There is, indeed, for each individual the duty to do good, but fulfilling it otherwise than from a rationally instituted obligation does not constitute a moral action and, therefore, the moral evaluation of actions (moral deliberation) is not commendable as such, from a deontological point of view, only when it is aimed at the performance of duties and not to charity.

L. Alexander and M. Moore show that, from a deontological perspective, each individual must respect moral norms, in any situation, and that is why these norms have the vocation to be legislated (Alexander & Moore, 2008). The *de lege ferenda* process regarding human rights, international conventions, but also their transposition into national legislation, tend to refer to principles, while cases – when judged by the ECHR or other courts – refer to the particular situation brought to the court and how the invoked principle is or is not applicable in the given situation.

4. Criticism of the Kantian concept of autonomy

Post-Kantian theories depart from the transcendental foundation of autonomy in the principle of practical reason, focusing on the decision-making process of the moral agent in its entirety, which includes - along with reason - emotions, feelings, values, but also the external conditions in which the decision was taken (Dryden, 2010). The metaphysical dimension of autonomy is abandoned, autonomy being understood as the result of a process of social construction – that is, the result of a negotiation between individuals within a community regarding the meaning attributed to a concept (that of autonomy, in our context) and the concrete situations in which that concept applies.

Also in the post-Kantian tradition, J. Christman refers to moral autonomy as the ability of the individual to impose their moral law, even if it was originally the result of a process of social construction, as constraining (Christman, 2009) and quasi-objective, ignoring the subjective contents that might appear in the process of constructing autonomy.

In practice, when we talk about the individual's competence to make autonomous decisions, we should take into account the individual's level of information, but also the ability to understand the information and make estimates of the consequences of their choices - decisional autonomy being a combination of rational and consequentialist autonomy. Julien Săvulescu believes that, from a legal point of view, the ability to consent to or refuse a treatment is correlated with the level of information and the ability to use the information in the decision process, when the individual reflects on their medical condition or participation to a possible biomedical experiment. The information that the individual should take into account concerns the nature, purpose and effects of the treatment or medical experiment, as well as its consequences on themselves, those close to them or an undetermined group of people - present or future (Săvulescu, 2007). Autonomous and informed choice reflects both normative and axiological deliberation over existing medical opinions. The axiological deliberation, along with the rational one - of a deontological or consequentialist nature - are both important in the process of informed consent, true autonomy being, for J. Săvulescu, a result of the confrontation between the desire to act on rational bases and the rationalized pressure coming from emotional, cultural, social or medical factors that determine behavior.

For her part, Christine Korsgaard bases normativity – both ethically and legally – on the capacity for self-reflection, axiological reflection being an aspect of self-awareness (Korsgaard, 1996). The author points out that, in

reality, the individual does not manifest a practical self-identity, which is the source of auto-normativity, because not all facets of our identity have a moral foundation - based on practical reason, as Kantian philosophy would assume. The idea of practical identity represents that facet of the self that manifests itself rationally and has the capacity to assume obligations. That is why, says the author, we can think of a core of the individual's practical identity that constitutes their moral identity - in the sense of Kantian moral consciousness. As such, the individual can assume obligations relatively independent of contingent factors, and for this reason autonomy is the source of any obligation, but also of any right that the individual may claim from others by virtue of their own autonomy.

The idealization of the capacity for reflection represents another criticism brought to the Kantian concept of autonomy, starting from the fact that individuals have different mental capacities and, implicitly, different moral judgments. The choices that the individual makes freely and autonomously are not based on a causal reflection based on an universal normativity, but on conjunctural situations that the individual faces and that they must manage. The ambiguity of the problematization of the ethical dilemmas that the individual faces places them outside the categorical imperative, but not outside any moral reflection, the individual maintaining their integrity - compliance with their own values and moral norms -, even if we are talking about a particular judgment and not one which is universal (Sandu et al., 2013).

Returning to the views of Christine Korsgaard, the author believes that human action places the individual simultaneously in both active and passive modes (Korsgaard, 1996). The actions of the individual are oriented towards the future, generally following a project that they create regarding their own life, their own health or various particular actions that require a rational construction (Kennett, 2007). The ability to react projectively and not reactively builds the real level of autonomy, as the projected action is a rational one, while reactive action is most often carried out under the impulse of momentary emotions or states and is, most often, conjunctural. Precisely in order to be what we are in the present, we need the construction of identity, which is based on how we re-signify the experience we have and build, starting from this, the project of the future. As such, there is no autonomy outside of subjective experience over time and reflection on one's own personality, or one's own values, aspirations, desires, fears - which are, rather, the result of a social construction, than universal and abstract ideas, which practice can establish (Velleman, 1997).

5. The utilitarian origins of the concept of autonomy

Since the modern period, criticisms of Kantianism have led to the emergence of another major ethical paradigm, the utilitarian one - which replaces the ethics of intention with an ethics of consequences. The results - and not just the intention with which the action was performed - underpin the moral judgment of the action, both individually and collectively. The utilitarian ideal is the achievement of the greatest amount of benefit, for the greatest number of people, under given conditions. "Amount of good" is the ethical measure of action. For John Stuart Mill, the deontology presented by Kant cannot be the only source of moral judgment, but it can certainly be a part of it (Mill, 2001). Following rules and doing moral duty is what makes society work – and as such, following moral or legal norms is generally useful. We can consider that moral judgment based on deontological principles represents a particular case of an extended ethical system, which includes both utility and moral duty, in the Kantian sense, united in the form of responsibility.

J. S. Mill, however, formulates a series of exceptions to the deontological principles related to the situation in which the negative consequences of an action are obvious, and the rule, which would possibly be the basis of that action, must be questioned in terms of its status of universality (Mill, 2001). Although obeying the law is an obligation of every citizen, when the law manifests itself unjustly, disobeying it or challenging it can generate an amount of good for a number of individuals – which can be greater than simply obeying that law. The consequences of each action are calculated based on how the action affects different individuals. In the process of maximizing good, the individuals should neglect themselves in favor of others if, in the course of their action, to do good to as many people as possible would produce a dose of harm to themselves. In this direction, Mill is congruent with Kant, who institutes the individual's duty to others and only secondary - and subordinated to the first one - speaks of the individual's duty to himself.

The individual who acts is called an agent, and in the case of moral action, is called a moral agent. The individual who suffers the results of an action is the person who suffers the results of another person's moral/immoral action, therefore is called a moral patient. The individual, in their capacity as a moral agent, acts in accordance with their own definition of well-being, whether it is rational or, on the contrary, instinctual, impulsive, being apparently unjustified. Mill identifies a correlation between the autonomy of the individual and the originality of their action (Iliescu &

Socaciu, 2009). The originality of the individual's choices constitutes what is called authenticity. That is why the individual involved in controversial choices has a greater degree of autonomy than one who uncritically submits to norms derived from social customs (Săvulescu, 2007).

For Stuart Mill, the restriction of any freedom is illegitimate in any other situation, except to prevent harm done to another person (Iliescu & Socaciu, 2009). The correlation between the view of J. S. Mill and J. Locke constitutes the idea of private life – as a sphere in which the decisions of the individual should be free, as long as it does not oppose the freedom of other people. The public sphere is that in which the decisions of the individual could be opposed by courts, by coercion, acting in the name of the public good.

Starting from J. S. Mill, utilitarians believe that moral judgment should return to the concepts of good and evil or even to the Aristotelian concepts of virtue and vice. To be considered morally good, an action must produce the greatest good for the greatest number of people (Manea et al., 2013). Measuring the amount of good is extremely difficult, since good is rather an ambiguous philosophical concept, which cannot be operationalized in a sociological sense and then measured as such, through instruments of an economic, sociological, political nature. Of course, a partial operationalization of the idea of good can be done in the form of well-being - including the subjective one – through the ideea of the quality of life.

For J. Bentham, the measure of good is pleasure and, as such, maximizing good is equivalent to increasing pleasure and decreasing pain. Of course, this operationalization is also open to criticism, insofar as the maximization of pleasure can be contrary to the idea of the higher good or the public good, by virtue of which the satisfaction/pleasure of some individuals can be diminished (Bentham, 1970).

Moving ahead with the operationalization of the idea of pleasure and pain, this time we talk about the pursuit of interests and the avoidance of fears as motives of individual or collective action (Manea et al., 2013). Replacing the concept of pleasure with that of happiness leads to the reformulation of the principle of utility in a consistent way, which can lead to moral decision, namely: an action is good if it leads to the best possible balance of beneficial consequences and the least number of negative consequences. In Millian's utilitarian vision, any formulation of rights should be subordinated to the maximization of benefits and the minimization of risks or unwanted effects, the idea of beneficence having a greater utility than that of duty, but also compared to that of rights (Mill, 2001). We can, thus, consider that the theory of justice in the Kantian view rather manages

the behavior of individuals in society, while the theory of utility manages the functioning of society and the ways in which it can intervene in limiting the exercise of certain rights by the individual.

Double effect theory, also of utilitarian-consequentialist inspiration (Foot, 1978), argues that an action should be permitted even if a major harm might be involved - if that harm is a secondary and limited effect of a greater good, which represents the intent of the action. Even if an action is not morally justified, the theory of double effect allows such an action in certain situations if a greater harm is prevented or if a greater good could be produced for a greater number of individuals.

6. Formes of autonomy

A first form of autonomy comes from John Locke's theory of negative rights – known as the right not to interfere with the individual's decisions (Locke, 2011). The same right underlies the idea of liberal democracy and the political autonomy of the individual. In the context of political philosophy, this theory is brought into discussion when talking about the limits of the legitimization of authority and the intervention of the state in the private life of the citizen. In bioethics, this approach concerns the limits of medical paternalism and the acceptability of refusal of treatment, which the patient/clinical trial subject can formulate at any time.

In the affirmative form of autonomy, this appears as a struggle for control, which takes place within various social groups. R. P. Wolff believes that, in societies where the autonomy of individuals is limited, the lack of humanism and respect for the dignity of others is manifested (Wolff, 1970).

Starting from J. Locke, Jennings proposes the idea of consensual decision as a way of harmonizing the interests of individuals (Jennings, 2007). Of course, autonomy and self-determination can also be associated with social disorder and a lack of social solidarity. Contemporary society - with reference especially to the American one, but we can consider that the observations are valid for the entire Western culture - is, in the view of R. Hughes, voided of the traditional element of social solidarity, precisely because of the emphasis placed on individualism and the autonomy of the individual (Hughes, 1993). Another criticism of society based on individualism and autonomy is formulated by S. Hauerwas - who believes that, from a moral point of view, individuals become increasingly selfish as long as they are socialized in a culture based on individualism and the exacerbation of autonomy (Huerwas, 1974). C. Lasch even speaks of a culture of narcissism in contemporary society (Lasch, 1978).

L. Kohlberg points out that autonomous decisions require processes of conscious deliberation; and when they - in the Kantian manner - aim at obedience to rules they self-administer, this denotes a stage of full maturity of the individual's moral development (Kohlberg, 1981).

A second form of autonomy is the expressive one - also called expressive individualism (Jennings, 2007) - and the forms of ethical thinking that privilege this form of autonomy are known as the ethics of authenticity (Bellah et al., 1985). Authenticity refers to the individual's consistency with their own values. These, however, can undergo transformations during the evolution of the individual - either due to anticipatory socialization processes, or due to changes in the medical condition of a psychiatric nature. A person can accept a certain treatment at one stage of their evolution and later refuse it - under the effect of some neuroleptics or some conditions that change the mental state of the patient. Both decisions represent an act of autonomy and informed consent, and should be considered valid in both situations, only to the extent that the ability to discern the meanings of one's own decisions is not profoundly altered, to the point where the subject becomes legally unable to decide.

Authenticity is, indeed, a condition of autonomy, because without it one is unable to affirm that the individual's decision derives from their own character or that it is an expression of their moral conscience (Bublitz & Merkel, 2009). However, some authors show that the lack of authenticity of some decisions that individuals make - especially under the pressure of the state of suffering that appears as a result of their own medical condition - should not vitiate informed consent, since the existence of a minimal capacity of the subject to understand the situation in which one finds themselves, as well as the consequences of their own decisions, can be argued. In these conditions, expressive autonomy is, rather, a consequence of a deontological type of ethical thinking. Relational autonomy, on the other hand, which requires that the informed decision take into account all the subjective elements, which are considered by the subject in the decision process, rather represents a transposition of the consequentialist utilitarian perspective into practice.

The deconstruction of the idea of authenticity starts from the fact that, when we discuss major behavioral changes - whether under the influence of socializing factors, such as the environment and education, or under the influence of changes in the health condition -, we should take into account the fact that the old system of values no longer works for the individual, and one's decisions seem inauthentic, if they are related to the old value system.

From a legal point of view, the use of the concept of authenticity in regulating the legal expression of autonomy – namely consent – is limited to the situation when the inauthentic decision is caused by the patient's medical condition, which makes one unable to decide. On the other hand, the concept of autonomy and its connotations of self-determination and respect for the person represent constitutive elements of both bioethics and biolaw. Even if, in law, respect for the person and, respectively, for their capacity to consent, underpins most civil relationships, in the context of this paper, we refer only to a series of characteristics that are specific to medical law and, respectively, biolaw. In this sense, the term is defined, for example, in a series of documents including the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1976), Reports of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1981) or Canadian Law Reform Commission (2007). Of course, the Oviedo Convention (1997) plays an important role in defining the concept of autonomy and, above all, its legal correlative, informed consent.

In the construction of the instrument to protect the autonomy and dignity of patients or participants in research on human subjects - informed consent -, several meanings of the term autonomy are discussed which, although they come from the great ethical theories previously described, are formulated in a way accessible to the public interested in bioethics and biolaw, but also to professionals in the field, and can be codified in the form of legal acts with practical applicability.

1. Autonomy as free action: an action is autonomous if it is voluntary and intentional.

2. Autonomy as authenticity: an action is autonomous if it is consistent with the system of attitudes, values, dispositions and life plan of the individual.

3. Autonomy as effective deliberation: an action is autonomous when the decision that grounds it is taken by a person aware of their health, social, medical, legal condition, out of the alternatives available to the individual in choosing the best ways to react in a given situation, following a process of evaluating the significance of the choices they made. The doctrine of acceptance/informed consent imperatively requires that the patient be aware of the risks and benefits of the treatment/trial to which they are a part, as well as of the alternatives available to them, as effective deliberation is facilitated, based on the transmission of information in a manner and in a language that is fully accessible to them.

4. Autonomy as moral reflection: an action is autonomous if in the process of reflection the entire set of values of the subject was taken into account, including a reflection on alternative values, with adherence to the way of evaluating them and the ways to put them into practice.

The centering of bioethics on the concept of autonomy and its understanding especially as negative freedom is located in the vicinity of scientific, cultural and moral research, legitimizing medical practice as a significant human experience (Sandu, 2012).

7. Situations that justify the limiation of autonomy

In the bioethical literature, a series of situations are formulated in which the limitation of a person's autonomy is allowed, when the public interest must take priority (Săvulescu, 2007). According to Julien Săvulescu, these situations could be the following:

1. distributive justice – when the correct allocation of limited resources is necessary;

2. the harm done to others – when respect for the autonomy of a certain individual endangers the life or health of other people;

3. public interest - when the limitation of the right to autonomy aims to respect the freedom of others, their well-being or public safety.

8. From autonomy to informed consent

From a pragmatic point of view, autonomy represents the ability of the individual to formulate an opinion, which is recognized and respected. The formulation of this opinion is consent. Its most used form in the field of bioethics and medical law is informed consent. Consent represents the effective expression of the patient's will (Sandu, 2012). The deontological theories regarding the patient's rights (Kamm, 2007) do not only aim at the affirmative expressions of these rights, but also at the ways of limiting the interference of the medical personnel in the patient's decisions, formulating as such the duties of the doctor or the researcher in the medical sciences (Alexander, 2004) .

It is ethically incorrect to use the patient as a means, for example, in a clinical trial from which one has no benefit, without recognizing their inalienable right to their own body as well as their mental capacities. The recognition of this right is achieved by obtaining a valid informed consent from the patient, which, however, should not be seen only in the form of a simple form of adherence to medical decisions, but as the result of a process of informing the patient in terms and ways that ensure their understanding

of their situation, the consequences of the therapeutic acts to which they will be subjected, as well as the risks hey entail.

Precisely by virtue of the patients' rights, the right to renounce to individual autonomy is also recognized, and also the right not to be informed - in favor of other values, such as trust in the doctor, in the authority of medical sciences, the importance of family relationships and, why not, of fear of the unexpected. This right, to refuse treatment, is also seen by Turoldo as a form of autonomy - namely relational autonomy, which is the basis of the so-called liberal multiculturalism (Turoldo, 2010).

Bioethics and biolaw have adopted a series of principles, the best known of which are those formulated by Tom Beauchamp and James Childress (Beauchamp & Childress, 2001). These principles can be formulated as follows:

1. respect for autonomy (respect for the person's ability to choose);
2. the duty to do good (the obligation to provide medical benefits, maintaining the balance between advantages and risks);
3. the duty not to do harm (avoidance of causing harm);
4. the principle of justice (the obligation to treat the patient correctly).

Among these principles, in the theory of informed consent, respect for autonomy is transposed, and therefore refers to the protection of the moral and personal values of the individual, to the integrity of the person, seeking to balance the influence that the doctor has over the patient, due to the professional authority the doctor enjoys.

9. Conclusions

Informed consent should counterbalance the influence of the doctor and the medical system as opposed to the patient, diminishing the impact of paternalistic approaches, guaranteeing the opportunity to choose between treatment options of the patient, namely participation or non-participation in research. Informed consent invests the patient's decisions with legal value, constituting a contractual basis for the therapeutic relationship. The philosophical foundation of the idea of informed consent allows us to understand the evolution of the concept, as well as the rational grounds that led to the appearance of this tool for the protection of the rights and dignity of the individual who is, in the present case, in interaction with the health system.

Whether we are talking about the need for a rational decision or the evaluation of the consequences that the patient's decision has on the patient,

but also on those close to them, legal and bioethical pragmatism finds a foundation in the great philosophical programs, in the great moral paradigms of humanity, even if the individual called to decide for their own health or the law scholar called to ensure the respect of the patient's rights do not directly consider the philosophy of Kant or Stuart Mill, but only their echoes in bioethics and biolaw.

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