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Salute e Società

Informed consent in medicine: ethical and juridical aspects

edited by
Carla Faralli

FrancoAngeli

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EDITORIAL

by Stefano Rodotà*

When consent concerns existential situations, it moves away from the schemes and the criteria around which it was framed in legal modernity. We should not forget that the revolution enacted with the *Code Civil*, aptly described by Jean Carbonnier as "France's civil constitution," was not built on the idea of absolute property alone. True, the idea so codified did mark a transfer of power from one class to another, that is, to the historical subject of the French Revolution, the bourgeoisie, and did so in a way that way anything but symbolic. So, too, there is no denying what Cambacérès observed, underscoring that the code regulates all relationships "by reference to property." But then, if property had not been coupled with a tool that could ensure its free circulation, the outcome would have contradicted the very point of its codification, which was to free property from its feudal bonds.

Hence the contract as the power to freely dispose of one's property, an act recognized as having a force equal to that of law, as can still be found stated in Article 1372 of our own Italian Civil Code. Therein lies the root of the "dogma of consent," framed in such a way as to guarantee freedom and security in the circulation of goods. It is precisely this "need to ensure the circulation of goods" that we find invoked in the fine book by Emilio Betti on the legal transaction, when the discussion turns to the "practical problem of private autonomy."[1] And here we also encounter the term *self-determination*, but this in relation to the goal of "furnishing individuals" with goods and services, as is befitting in the given context, where the problem is that of governing the "patrimonial relationship" under the statutory definition of contract (Article 1321 of the Italian Civil Code).

This simple reference alone should suffice to alert one to how inappropriate it is to rely on these frames of reference and these concepts in an attempt to outline the institutional setting within which to locate the right to self-determination, for this

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Translated by Filippo Valente.

[1] E. Betti, *Teoria generale del negozio giuridico* (1950; Turin: UTET, 1952: 40-43).

right pertains to life, in itself irreducible to the logic of the market: it is a right that must accordingly find its abode in the sphere of personality, and ultimately in that of sovereignty. As Paolo Zatti has rightly commented, "dignity, identity, freedom and self-determination, and privacy in its different meanings are rights to be fashioned by specifying the qualifier 'in the body,'"[2] and so in life.

What we are witnessing is indeed a shift in the legal paradigm: a new connection between a person's will and life, a connection recognized in constitutional law. This moves us away from the earlier connection between will and patrimony (a person's estate) by which the civil codes have traditionally been characterized, in a setting where private autonomy is constructed solely by reference to the economic sphere, with an exclusive interest in making for reliable business affairs, while neglecting the need to secure a person's self-government, in a sphere, that of the self, irreducible to that of the market. Individuals, then, are no longer regarded only or mainly as economic actors, but also as free makers of their own personality, in such a way that the object of their action is no longer confined to managing their economic interests but embraces the entire unfolding of their lives.

The legal principle underlying the "constitutionalized" person is thus grounded in a different anthropology than that of the civil codes. Self-determination in governing the body cannot be collapsed into the consent necessary to transact business in the economic sphere. Indeed, if we are to avoid cultural misunderstandings and inappropriate political conclusions, we will have to bear in mind that the notion and rules of autonomy as consent were framed by reference to the market and its dynamics, and it would be a mistake to move that notion or the accompanying rules out of their original context.

The change we are witnessing does not, however, come out of nowhere. A different conception of consent emerged in the wake of WWII, when the Nazi doctors were brought before the Nuremberg Military Tribunal in the so-called "Doctors' Trial" of 1946: the dramatic discovery that medical power had been abusively exercised in the experimentation carried out on human beings (it would later be discovered that the same practices had been undertaken in Japan, too) sparked an immediate reaction which led to the document that would come to be known as the Nuremberg Code, whose very first words, not incidentally, are: "The voluntary consent of the human subject is absolutely essential." Life is thus freed from encroachment by any outside power, for it belongs to the person and to his or her determinations, and the perspective is that of the constitutional principle recognizing everyone's right to freely construct a personality.

This different way of viewing self-determination in relation to life and the body forms the basis of an understanding of consent disentangled from the formalisms owed to an external criterion – namely, the need to guarantee secure economic transactions – in such a way as to bring consent under a different standard, that of the government of life.

[2] Zatti P. (2009), *Maschere del diritto volti della vita* (Milan: Giuffré), p. 86.

We can appreciate in this sense why bio-law, when it comes to the problem of determining a person's will, should have devised methods that mark a clear departure from the criteria in use in other situations and other areas of the law. Precisely this choice to chart a different course has attracted criticisms as harsh as they are blind to the undeniable peculiarity of the subject matter.

These criticisms have been aimed in particular at the opinion rendered in Italy's landmark case, the previously discussed one concerning Eluana Englaro, where instead a good example is offered of the way we ought to proceed in renewing our legal concepts and doctrine by reference to Articles 2, 13, and 32 of the Italian Constitution: arguing on the basis of principle makes it possible to design a framework within which to locate concrete situations. The Italian Court of Cassation has thus found it possible to explicitly invoke lifestyle as a criterion on which to rely in determining what end-of-life choices the person concerned would in fact have made. This is precisely the path followed by the Mental Capacity Act passed in the United Kingdom in 2005 and the German law of 2009 on patients' instructions and provisions. It is worth recalling that under the British law, those entrusted with deciding on behalf of an incapacitated person are asked to look to this person's wishes and feelings, along with the beliefs and values that gave purpose to his or her life, as factors illuminating the meaning of a life through its entire arc, so that when it comes time to make the most dramatic of all personal decisions – the one concerning the end of life – this is done through an understanding of that life's complexity as an existential affair, rather than by stripping that complexity away through a formal act exclusively based on criteria of administrative procedure. No less explicit is the German law: "A patient's presumed will must be ascertained on the basis of concrete elements. It is necessary, in particular, to take into account any oral or written statements the patient made before becoming incapacitated, along with this person's moral or religious beliefs and any other values he or she may have espoused." And that is also the line taken by the Oviedo Convention on Human Rights and Biomedicine, with its broad principled statement that we must take the patient's "previously expressed wishes" into account.

Self-determination is thus identified with the life plan pursued by the person concerned. And here life is to be understood in Montaigne's sense as "an uneven, irregular, and multiform movement,"[3] irreducible to any rigid formal scheme, for it is governed instead by an uninterrupted exercise of sovereignty, enabling that free construction of personality which we find enshrined at the outset of our own constitution as well as in others.

Neither a life plan nor a lived life can be bounded within the logic of the itemized consent proper to the instruments of private autonomy designed to govern patrimonial relations.

[3] De Montaigne M. (1588), *Essais*, livre III, chapitre III, "Des trois commerces." Quoted from *The Complete Essays of Montaigne*, book 3, chap. 3, "Of three kinds of association" (Stanford: Stanford University Press, 1958).

What is needed in either case is an institutional framework making it possible to uniquely appreciate each person through a narrative unfolding over time, through a sequence of behaviours comprising an entire biography, and it is on this basis that a reconstruction of consent can have any legitimacy.

INTRODUCTION

by Carla Faralli*

Informed consent has had an essential role in shaping the therapeutic process, but it raises issues that are not just medical – for they also bear legal, moral, and philosophical import – and they intersect in several ways. That is why the discussion is fundamentally interdisciplinary: as can be appreciated from the vast literature on the topic, the debate draws scholars from different backgrounds, constantly engaged in an effort to grasp the complex and multiplex nature of the issues arising in connection with the practice of informed consent in medicine.

The contributions in this issue are grouped under four headings – Theory, Discussion with Roundtable, Research, and Debate with Comments – and from different angles they develop some of the important issues at the heart of the contemporary bioethical debate. What this gives us is an overall view highlighting, on the one hand, the multilayered reality of informed consent and the new areas of research in clinical practice and, on the other hand, the different approaches and solutions that one cannot fail to take into account in dealing with these issues.

We start out with the Theory section, which includes five essays, the first two of which analyze the philosophical and legal premises of informed consent, while the last two key in on the theoretical and legal implications of informed consent in clinical practice and in specific contexts: genetic screening and the use of genetic data, the different cases involving patients in a vegetative or a minimally conscious state, and finally, from a comparative perspective, the different rules and principles adopted in European and American law. The opening essay is by Patrizia Borsellino, who with a critical eye looks at the "good reasons" offered as to why we should want to approach informed consent with the specific tools of legal

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philosophy, which is called in to help whenever a conflict arises among competing theoretical and legal views, as happens with informed consent – hence the need to bring the different arguments and solutions under close scrutiny. Finally, Borsellino assays the critical literature on informed consent by testing the theory against practical scenarios in end-of-life care and in the use of genetic knowledge in research and clinical practice.

In the next essay, Luigi Balestra and Riccardo Campione closely analyze the good and the bad in the way the principle of the patient's autonomy is bodied forth in the Italian legal system. Their analysis proceeds from an awareness that this principle cannot be equated with any notion of full and unbridled self-determination, given the unconditional limits set forth in that system. The arguments are illustrated by reference to the issue of the patient-physician relationship in two specific cases: when patients refuse life-saving treatment, and when they assert surviving interests, namely, interests which survive a patient's ability to make them known to medical staff directly.

In the third essay, Marco Seri, Claudio Graziano, Daniela Turchetti, and Juri Monducci turn to the different types of genetic testing, taking into account the latest large-scale genetic-sequencing techniques and considering whether these pose a threat of genetic discrimination. They accordingly assess the available practical and legislative tools for protecting the person from such discrimination.

Silvia Zullo, for her part, takes up the volatile issue of whether to prolong or discontinue life-sustaining care for patients in a vegetative or a minimally conscious state: she points out the pressing need to find shared ethico-legal solutions on which basis to make that decision, taking into account some recent diagnostic findings and neurological advances that call into question the established way of doing diagnosis and prognosis for these patients. And, finally, we come to the close of the Theory section with a comparative investigation by Carlo Casonato, looking at two models of informed consent in legal systems across Europe and beyond (in countries like France, Italy, the United Kingdom, and the United States). There is a model tending to *impose* choices, and another one tending to make them more *discretionary*. The analysis brings out the commonalities between these two models – such as their balancing the claim to freedom against the need to impose restrictions – while also highlighting their critical points.

In the Research section we have a contribution by Susi Pelotti, a medico-legal expert, and another one that Amedeo Santosuosso, a judge serving in the Milan Court of Appeals, has written with Valentina Sellaroli,

assistant district attorney for the Juvenile Court of Piedmont and Valle d'Aosta. Pelotti calls the attention of the legal profession to the most problematic aspects of communication between patient and physician and brings the idea of shared decision making to bear on that of informed consent, so as to reduce the asymmetry of power in that relationship. Santosuosso and Sellaroli look at the critical aspects that come up when dealing with personal freedom, the right to self-determination, and the protection of personal data: they do so against the background of Italian and European case law, laying emphasis in particular on the intersections in such law.

Next we have the Discussion and Roundtable, with Laura Palazzani, Enrico Cieri, and Francesca Ingravallo engaging one another on the topic of care and informed consent. The three speakers – by training a legal philosopher, a judge, and a medico-legal expert, respectively – work from these different backgrounds in discussing three specific issues: the principle of informed consent to medical treatment vis-à-vis the right not to know, or how to balance the two, especially in medical genetics; the spread of so-called defensive medicine; and the shaping of a model enabling patients and physicians to communicate in such a way that they can both take part in the decision-making process.

Finally, there is the Debate, consisting of an essay by the British scholar Roger Brownsword with comments by the jurists Alessandro Piccinini and Francesca Faenza. The focus of this section falls on the role of informed consent in the information society. Brownsword criticizes the view that informed consent would hold back the progress of research and should accordingly be replaced by a criterion of so-called broad consent, at least where biobanks are concerned. The conclusion he offers is that informed consent in the information society should retain its key role as a regulative principle, for in any form of society that principle goes "hand in hand" with the recognition of rights.

A special thanks goes to Silvia Zullo, who has been an invaluable help at every stage in the process of producing this special issue, from that of selecting the topics to be treated, to that of working with the authors – to whom I am particularly grateful for their contributions – to the editorial work needed to bring the texts to press.

THEORY

Informed Consent. Some Philosophical-Legal Concerns

by Patrizia Borsellino*

The paper frames the issue from the philosophy of law's viewpoint to determine the current "state of health" of informed consent starting from some critical areas (like the physician-patient relationship, illnesses with poor prognosis and the end-of life medical care, genetics, clinical research and practice) and from its legal sources (like judicial decisions). The author's claim is that informed consent does not need to be weakened in this historical period in order to strenghten solidarity and trust to achieve common goals for all human beings. Instead, she aims at proving that trust and solidarity should be placed in a participatory and cooperative scenario which should be fed by the respect, at the highest levels, of individual self-determination, and therefore of informed consent.
Keywords: informed consent, philosophy of law, legal sources, judicial decisions, end of life care, genetics

1. Why a philosophical-legal analysis?

Since a quarter of a century informed consent has become a central issue in bioethical discussion on research and clinical practice. Today, it is a core element in the legal-doctrinal approach with regard to the medical practice and liability as well as to the sociological inquiry on the health reality. Furthermore, despite some resistance, health care professionals have begun to consider informed consent not only as a mean to proceed with and follow

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up a legal action, but also as a useful tool in the set of relationships centred on health care. This relatively new approach is rooted in the cultural and social developments, which were, in some cases, strictly related to the health care system. These new trends, which highlighted the weakness of the paternalistic model, speeded up the shift from paternalism to an informative physician-patient relationship.

Considering this enduring, widespread, and transverse presence of the topic in the different bioethical areas, which contribute to define bioethics's "multidisciplinary" character, the question is: are there still good reasons for considering once again informed consent from the point of view of the philosophy of law?

I think that the answer to this question goes back to the consideration that the efforts -founded on good ethical, legal, and clinical arguments- to recognize informed consent as a criterion to guide health practice have a strong relation with the opposite recurring attempts to bring it into question.

Critical arguments against informed consent involve different aspects. Between the 1980s and the 1990s, some authors pointed the finger at several, – and according to some- insuperable obstacles that would hinder the actual implementation of informed consent, for instance the patients'conditions, the difficulty, or even the impossibility to adequately inform the patient, the patient's cultural affiliation, and in some areas, the familial barriers. In some cases, the patient's will intended as a requirement to medical treatment has been considered a risk for the implementation of the therapeutically most convenient procedures, as – it was said – it could conflict with the physician's mandatory duties (Borsellino, 1995). In most recent times, the critics of informed consent has focused on its conceptual correctness.

In literature, indeed, informed consent has been increasingly qualified as an "aporetic" (Marzocco, 2010) notion, which is in need of a radical "rethinking" (Manson e O'Neill, 2007), or even to be rejected for many reasons: as it does not permit, in its practical implementation, to safeguard patient's genuine self-determination (Habiba, 2000; Castellano 2010); as it is arranged to satisfy a need -i.e. the involvement in the decision-making process on medical care- which is not considered a primary aim in neuralgic areas of the health care system, such as the mental health service, and especially the terminal patient care, as well as the palliative care at the end of life (Borsellino, 2001); as it is unsuitable to guarantee the necessary balance between the protection of the individual's autonomy and that of other actors' interests, and in general, of the community (Marzocco, 2010) in the new areas of clinical research and practice as emerging from recent

advances, above all in genetics. Finally, if we focus on the Italian context, the criticism can be completed by adding the absence, in doctrine as well as in jurisprudence, of a univocal qualification of informed consent. Indeed, in Italy only civil law, and not criminal law, aknowledges informed consent, without doubts and reluctances, as a source of justification and as a legitimating criterion for clinical research and practice on human beings. (Casonato, 2009; Marini, 2010; Gentilomo, 2011). If we observe informed consent with this background in mind, we must admit it mirrors a very controversial issue. That is the reason why the philosophical-legal analysis on this topic is not only adequate, but even necessary.

Indeed, framing matters from the philosophy of law's viewpoint can be useful for at least three reasons. First, philosophy of law plays a key-role in those cases, like the one of informed consent, in which there are still controversies at the theoretical-doctrinal level as well as uncertainties in jurisprudence. In such cases, philosophy of law can be very helpful to analyse and to evaluate the correctness of the argumentative reasoning which founds the different positions and solutions. Second, a philosophical-legal look at institutions like informed consent is needed when they seem to have lost certainties and clearness in relation to their ethical assumptions, to their practical implications when they are being adopted, and to the model of law they appear to be consistent with. And finally, and perhaps above all, philosophy of law assures the best perspective to evaluate if (and in what sense), a notion like informed consent, though steadily entered in the legal, bioethical, and clinical lexicon, is really in need of being reshaped, or even of being put away in the tool shelf as it has become useless.

Framing this issue from a philosophical-legal perspective contributes, on the one hand, to determine the current "state of health" of informed consent. But, on the other hand, it is also useful to clarify that we are playing for high stakes when we deal with the debate on informed consent, even though the general impression is that both critics and bewildered authors undervalue, or do not get this point.

And as the adopted perspective in this paper will be the one termed in the 1960s with Norberto Bobbio's formula (1965: 37) "the jurists' philosophy of law", i.e. the critical-methodological approach that requires the theoretical analysis being based on what occurs in the legal world, my legal discussion on informed consent will start from its legal sources. In this way, it will be possible to verify, already at the legal level (hard and soft law), if the claim that informed consent is still an ethically shared demand as well as a legally and ethically binding commitment to legitimately practice medicine and human experimentation is true or false.