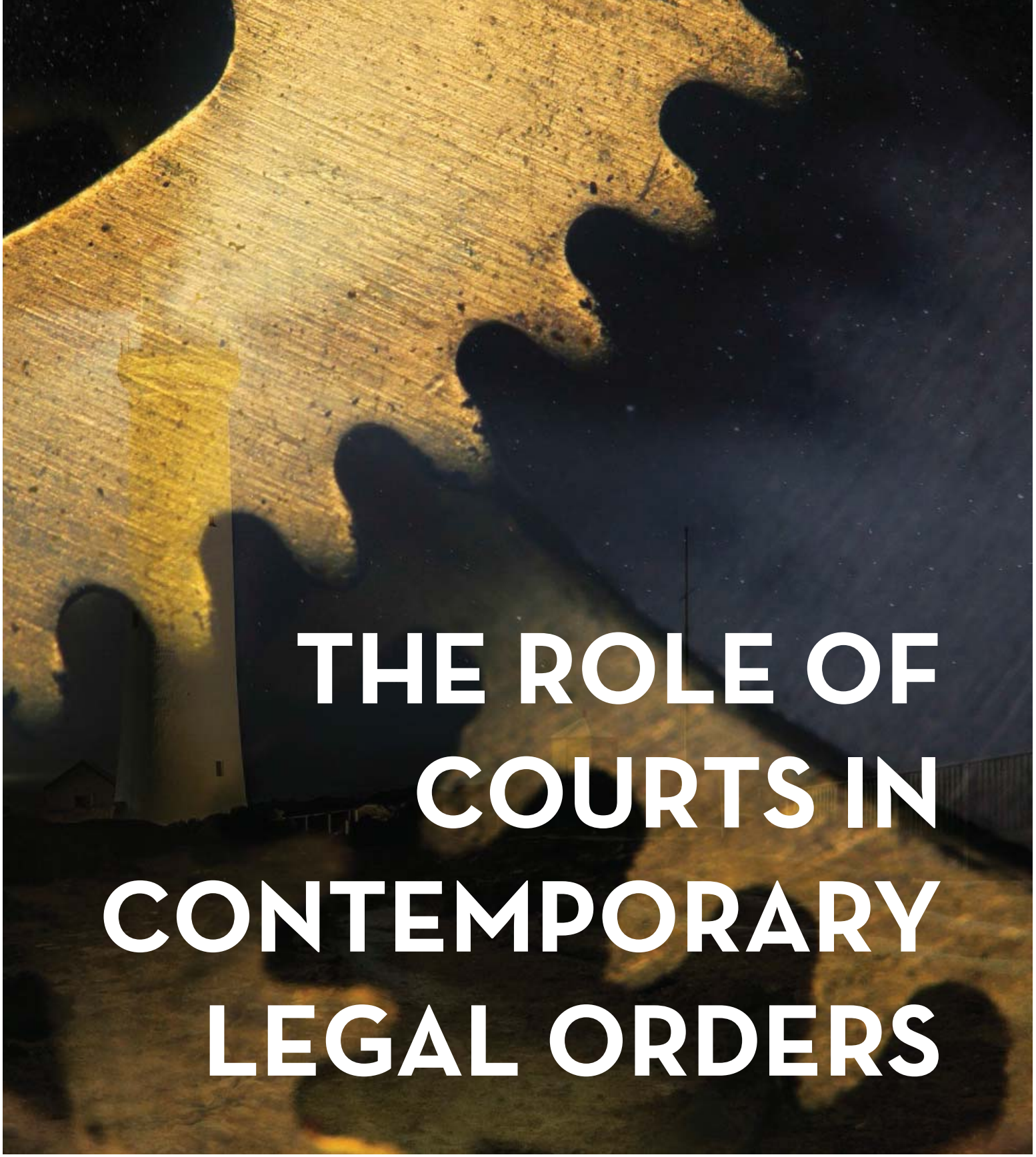

THE ROLE OF COURTS IN CONTEMPORARY LEGAL ORDERS

Martin Belov (Ed.)

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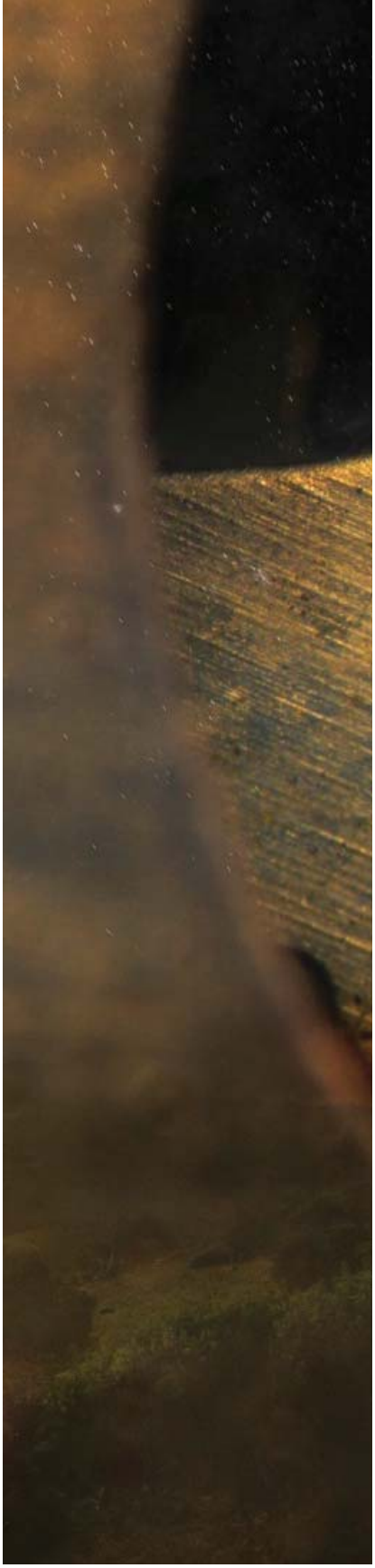

The Role of Courts in Contemporary Legal Orders aims to address the rising importance of courts in contemporary legal orders. It explores the role of courts on national, international, supranational and global level. The book provides for a multi-discursive analysis – theoretical and comparative, exemplified with case-studies.

This book is a timely and topical analysis of pressing issues related to the enhanced role of courts in politics and the increased impact of politics on courts. It explores fundamental issues such as the legitimacy of courts, judicial activism, theory and philosophy of judicial decision-making, and the impact of politics, ethics, logic and technology on legal argumentation. It provides an analysis of the role of courts in supranational and global constitutionalism. Furthermore, the role of constitutional courts, administrative courts and criminal courts as well as the most important international and supranational courts is critically assessed. Special attention is devoted to the role of courts in the context of democratic backsliding, illiberal democracies and populist constitutionalism. Key issues related to the impact of courts on environmental and human rights' protection are also addressed. The book finishes with the provocative chapter on the alternatives to courts.

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Guerino Fares

25.1 The Freedom of Self-Determination: General Framework

The self-determination principle, on a conceptual basis, is the expression of a principle of freedom. Therefore, a person can be self-determined because he or she is free to make a choice regarding a fact or an act, commissive or omissive that becomes important for the scopes of his or her plans and interests, in various ways and situations. The objects or goods with which the private individual can exercise such freedom of choice are of a different nature: the freedom to do or not do anything, to ask for something or renounce something, to authorize or not to authorize others to do something that is intended to have repercussions on one's personal and legal sphere.

Self-determination, being a right of the personality, is endowed with a certain ampleness and expansive capacity; therefore, it has a natural aptitude for manifesting itself from the premises that condition the most delicate areas of human existence: from personal identity and personal data protection to physical integrity, from the protection of health to the actual right to life. In other words, self-determination is a wide concept and covers many important aspects of one's personal life.

Take the case of the patient's right to self-determination: that – in principle, is expressed right beginning with the choice of the treatment center where to receive the service – has its constitutional foundation in Articles 2 and 32 of the Italian Constitution, in conjunction with Article 13. Thus distinguishing itself in assuming the right to freedom of people, the same way as unanimous teachings according to which the right to

personal freedom, given the ontological and primordial nature of the interest that it protects, emerges in the system like a prerequisite for all the other rights of freedom, because preceding them logically and influencing them at an operational level, and makes it possible for them to be fully expressed and then executed.[1]

After all, as J. Locke explains in the Second Treatise on Civil Government, all men and women share the earth in the state of nature: everything is common to everyone except for the body, one's own body to which only he or she has a right to, and no one other than him or her.[2] Likewise, the Supreme Court clarified that self-determination is, like moral freedom and like physical freedom of the person, intended as the right to be respected for one's own physical integrity, one of the profiles of personal freedom proclaimed as inviolable under Article 13 of the Constitution,[3] representing the backbone of the relationship between the patient and the doctor expressed in the so-called therapeutic alliance.[4] Moreover, the Court of Cassation has repeatedly stated that the right, which is also fundamental and inviolable, to self-determination is different from the right to health,[5] showing itself to be, at the same time, both a form of respect for the freedom of the individual and a means of pursuing his or her best interests actualized as the faculty to choose between the various possibilities of a medical treatment, and then refuse or interrupt the therapy.[6]

But self-determination, in addition to legitimizing the choice on whether and how to treat oneself, concerns other important areas of the personal and social dimension. If we consider that the so-called informative self-determination, now a constitutional law,[7] consisting in the power of the individual to decide which personal data, in the form of

1 *See* M.L. Di Bitonto, *A proposito di Eluana*, in *Giust. Civ.*, 2009, II, p. 314.

2 *See* J. Locke, *Second treatise on civil government*, cap. V, § 27, p. 249, it. Tr. Edited by L. Firpo, Torino, Utet, 1982.

3 It. Court of Cassation, civil sec. I, 16 October 2007 no. 21748.

4 It. Court of Cassation, civil sec. I, 20 December 2012 no. 23707, where we find the reference to the fundamental and unavoidable principles of identity and freedom of the human person pursuant to Arts. 2 and 13 of the Constitution.

5 It. Court of Cassation, civil sec. III, 13 July 2010 no. 16394, which highlights how there is a responsibility for the violation of one of the two rights even in case of compliance with the other.

6 It. Court of Cassation, civil sec. III, 9 February 2010 no. 2847, which, recalling the personalistic principle that inspires the Italian Constitution, reminds that informed consent, intended as an expression of an aware adherence to the medical treatment proposed by the doctor, takes the form of a real right for the person. Similarly, Civil Cassation, sec. III, 30 March 2011 no. 7237.

7 *See* F. Modugno, *I 'nuovi' diritti nella giurisprudenza costituzionale*, Torino, 1995, 20; S. Rodotà, *La «privacy» tra individuo e collettività*, in *Pol. Dir.*, 1974, 552. On the contribution to the elaboration of the informative self-determination principle given by the German constitutional jurisprudence, *see* G. Giannone Codiglione, *Risk-based approach e trattamento dei dati personali*, in S. Sica, V. D'Antonio, G.M. Riccio (ed.), *La nuova disciplina europea della privacy*, Padova, 2016, p. 58.

information, can be made known to others, even deciding who should be the recipients and users, for what purposes and with what methods and limits.[8]

In the multilevel system, the right to informative self-determination, in the European context, has established itself "thanks to the need to combine developmental needs in the internal market with the assurance of a high level of protection for fundamental rights on informative self-determination issues".[9] Ultimately, with regard to the health-care system it is possible to identify roughly two different types of self-determination, whose common root is personal freedom: (1) the medical (or curative) self-determination, consisting in the patient's willingness to undergo a treatment; (2) the informative self-determination, consisting in the authorization of the person concerned to the processing of his or her personal data concerning health.

One of the main implementing tools for the self-determination principle, both with regard to the freedom of treatment and control over personal data, is the informed consent.[10] The European Court of Human Rights and the Italian Constitutional Court have developed interesting criteria for interpretation with regard to the right of both treatment and informative self-determination. By circumscribing the scope of this discussion immediately, it is good to clarify that the end-of-life issues are excluded: in respect to which, the European Court has ruled several times, starting from the well-known *Pretty v. United Kingdom*, to exclude that the right to life can be understood in a diametrically opposite meaning like the right to die.

Instead, the expressions of the principle of self-determination that will be unraveled here are precisely those based on that fundamental implementing tool for the same principle that – as stated above – goes under the name of informed consent. Informed, or knowingly provided, consent translates into a kind of 'authorization' or permission that the involved party gives to third parties in order to carry out an activity intended to produce effects that are relevant to himself. As we shall see, it presents itself differently depending on the areas in which it is applied.

The most important examples are three: (i) the consent to undergo medical treatment and health care, (ii) with the addition of taking part in clinical trials within scientific

8 *See* L. Califano, *Il Regolamento UE 2016/679 e la costruzione di un modello uniforme di diritto europeo alla riservatezza e alla protezione dei dati personali*, in L. Califano, C. Colapietro (ed.), *Innovazione tecnologica e valore della persona*, Napoli, 2017, p. 12.

9 *Ibid*., p. 17.

10 On the relationship between informed consent and self-determination of the patient, *see* G. Fares, *Problemi attuali dell'ordinamento sanitario*, Napoli, 2013, p. 9. On the consent as a central institution in the construction of the right to data protection, *see* L. Califano, *Il Regolamento UE 2016/679 e la costruzione di un modello uniforme di diritto europeo alla riservatezza e alla protezione dei dati personali*, in L. Califano, C. Colapietro (ed.), *Innovazione tecnologica e valore della persona*, Napoli, 2017, p. 28; likewise, on the typical function of the consent, as an institution that embodies «the essence of the power of informative self-determination», C. Colapietro, A, Iannuzzi, *I principi generali del trattamento dei dati personali e i diritti dell'interessato*, in L. Califano, C. Colapietro (ed.), *Innovazione tecnologica e valore della persona*, Napoli, 2017, p. 108.

research projects and (iii) consent to the processing of personal data related to the provision of health services. The ultimate scope of this investigation is to verify whether, in the light of a solid attitude by the institutions involved in the cases under investigation, the circular harmonization of the fundamental rights evoked in jurisprudence with particular reference to the relationship between the right to self-determination (curative and informative) and health protection is true.[11]

25.2 The Informed Consent to Health Treatment in Jurisprudence of the European Court of Human Rights and Italian Constitutional Court

The European Court of Human Rights (ECtHR) has established that

> it is important for individuals facing risks to their health to have access to information enabling them to assess those risks. It has considered it reasonable to infer from this that the Contracting States are bound, by virtue of this obligation, to adopt the necessary regulatory measures to ensure that doctors take into consideration the foreseeable consequences of a planned medical procedure on their patients' physical integrity, and to inform patients of these consequences beforehand, in such a way that the latter are able to give their informed consent. In particular, as a corollary to this, if a foreseeable risk of this nature materializes without the patient having been duly informed in advance by doctors, the State Party involved may be directly liable under Article 8 for this lack of information.[12]

In practice: (a) providing information to a patient in advance of treatment is compulsory, after prior notification of the possible risks and complications; (b) for the procedures that entailed risk, the written consent of the patient is required within the medical records; (c) doctors have to discuss the proposed procedure and the possible side effects with the patient and his or her family, and to obtain the signature expressing the written consent to the proposed procedure; (d) the fact that the patient is a health-care professional, that is, a trained nurse, doesn't exonerate the doctor from established procedures and informing him or her of the risks involved in the same procedure; and (e) because the Court

11 The theory of 'strict circularity' tends to show that the rights of the personality, even if situated on different levels, can harmonize with each other. The case we are dealing with is that of health protection as an open and dynamic notion that can be integrated with the protection of personal data, also understood as a social and not just individual value. *See* It. Court of Cassation, civil sec. I, 19 May 2014 no. 10947 and the precedents there mentioned.

12 *See Csoma v. Romania*, 15 April 2013, no. 8759/05, § 42; *Trocellier v. France*, 5 October 2006, no. 75725/01, § 4; *Vo v. France* [GC], 8 July 2004, no. 53924/00, § 89; *Codarcea v. Romania*, 2 June 2009, no. 31675/04, § 105; and *Pretty v. The United Kingdom*, 29 April 2002, no. 2346/02, § 63.

attaches weight to the existence of prior consent in the context of a patient's right to be respected for his or her physical integrity, any disregard by the medical personnel of a patient's right to be duly informed can trigger the State's responsibility in the matter, not having the State complied with its positive obligations set out in Article 8 of the Convention.

Now I would like to deal with the Italian Constitutional Court. But first it is necessary to take into account some fundamental premises. The protection of health as a right to freedom faces a limit in Article 32, Paragraph 2, which legitimizes the imposition by law of mandatory medical treatment. However, there are some limits the legislator must take into account to exercise the faculty mentioned above. The same rule also establishes that the law cannot violate the limits set down for the respect of the person in any situation.

Another condition for the admissibility of the obligatory health treatment is given by the insufficiency of the law as such: it is necessary that this law is inspired by the protection of health as a collective interest[13] and that its content is endorsed by the scientific community based on an adequate and repeated experimentation. And, again, the power conferred to the authority to impose the treatment can affect, sacrificing it, the self-determination of the private individual but not on his or her health; hence, the need to provide a compensation that restores the negative consequences produced by the compulsory treatment on health of person subjected to it.[14] However, the provision of compulsory medical treatment to be established by the law, according to Article 32, Paragraph 2 of the Italian Constitution, has its opposite implication. If there is no law imposing it, the health treatment must always be voluntary, subject to the consent of the person enduring it. As mentioned above, the same conclusion may be reached based on Article 13 of the Constitution: insofar that the medical service assumes an intervention on someone else's body, it is the holder of this, namely the person that has the power to dispose of his or her body (Art. 5 of the Italian civil code) who must authorize it; so, without an authorization, the medical service results in a limitation of personal freedom.

The other general rule to which the provisions of Article 32, Paragraph 2, can refer to is Article 23: the obligation to undergo health treatment, established by law, is nothing but a personal service imposed under Article 23 of the Constitution.

In this regard, the Italian Constitutional Court stated that

13 In other words, the protection of health as a right to freedom finds a limit in Art. 32, para. 2, It. Const, according to which a health treatment can be imposed only by law and only if the individual, refusing to seek treatment, risks jeopardizing the health of other people (the compulsory vaccinations) or the safety of others (internment in a neurological department of the mentally ill person who is demonstrating aggressive behavior). *See* G. Corso, *La salute: variazioni sull'art. 32 Cost.*, in *Scritti in onore di Giuseppe Palma*, Torino, 2012, I, p. 196.

14 In case of a minor or disabled person, those who give assistance to him or her can be infected; therefore, the damage they suffer must be refunded too. *See* It. Const. Court., June 22, 1990 no. 307 and April 28, 1996 no. 118.

> informed consent, as an expression of the conscious acceptance of the treatment proposed by the doctor, is a right based on the principles expressed in Articles 2, 13 and 32 of the Constitution and synthesizes the two fundamental principles, such as the right to self-determination and the right to healthcare.[15]

In another judgment, the same Court specified that informed consent is a fundamental principle for health protection. Therefore, the regional legislator can't regulate the aspects related to the forms and modalities of the release of informed consent and to the subjects entitled to give informed consent. In fact, these aspects do not assume the character of detailed rules but contribute to the conformation of this principle, so that they can be regulated only by the State.[16] That is an implementation of the principle of uniformity: the same rules must be applied to the whole national territory. In turn, the Italian Supreme Court ruled that the informed consent is a fundamental right and helps to make health treatment lawful by attenuating the information imbalance between the patient and the doctor.[17]

25.3 The New Frontiers of European and National Legislation: From Clinical Trials to Medical Devices, from the Off-Label Use of Drugs to Living Wills

Many international regulations require the patient's informed consent within the context of medical treatments. In particular, Article 24 of the Convention on the Rights of the Child, signed in New York on 20 November 1989, ratified and enforced by the Italian Law 27 May 1991 no. 176, considering that the states "acknowledge the minor's right to enjoy the best possible health and to benefit from medical and rehabilitation services", establishes that "all groups in society, in particular parents and minors, must receive information on health and nutrition for the child". Article 5 of the Convention on human rights and on biomedicine, signed in Oviedo on 4 April 1997, ratified in Italy by the Law 28 March 2001 no. 145, provides that "medical treatment can be performed only if the person concerned has given a free and informed consent". Article 3 of the Charter of fundamental rights of the European Union, which was proclaimed in Nice on 7 December 2000, states that "every individual has the right to his or her own physical and mental integrity" and that "the free and informed consent of the person concerned, according to the procedures defined by the law" must be respected especially in the field of medicine and biology, among others.

15 It. Const. Court, December 23, 2008, no. 438.
16 It. Const. Court, July 30, 2009, no. 253.
17 It. Court of Cassation, civil sec. III, 9 February 2010 no. 2847, 30 March 2011 no. 7237 and 20 August 2013 no. 19220.

The need for the patient to be aware of his or her own therapeutic path ahead comes also from different national laws governing specific medical activities: for example, by Article 3 of law 219 dated 21 October 2005 (New regulation for transfusions and the national production of blood products), Article 6 of law 40 dated 19 February 2004 (Rules on medically assisted procreation) as well as by Article 33 of law 833 dated 23 December 1978 (Establishment of the National Health Service), which provides that undergoing treatment is normally voluntary and no one can be obliged to receive medical treatment if not provided for by a law.

Recently, more specific ones have been added to these regulations, with various and multiple objects. According to the EU Regulation no. 2014/536 of 16 April 2014, every clinical trial shall be subject to scientific and ethical review (Art. 4, para. 1). The ethical review must be carried out by an ethical committee, and it is up to the single states to establish the rules of informed consent and of the organization and activity of the ethics committees.

The EU Regulation establishes the main features of the ethics committees, aiming to guarantee in particular the principle of independence from undue external influence. An ethics committee can be defined as an independent body that systematically and continually addresses the ethical dimensions of the health sciences, the life sciences and the innovative health policies. It is an expression of an institutional health or scientific research unit constituted by doctors and non-doctors. An ethics committee is typically composed of a range of experts and is usually multidisciplinary, and its members employ a variety of approaches to work toward the resolution of bioethical issues and problems, especially moral or bioethical dilemmas. The same members mostly develop more awareness, in addition to the right knowledge, and skills required to deal more effectively with the aforementioned questions and to provide the best solutions.

Fundamentally, the task of an ethics committee is to verify that security and the integrity of the rights of the person are safeguarded and to provide opinions and create training opportunities on the ethical elements, on the procedures and research in biomedical sciences, this way providing a public guarantee and referring to the deontological aspects with the connected professional bodies.

Informed consent must be given by the involved party or by his or her legal representative according to the specific rules set up by Article 29 and the following ones of EU Regulation[18] without prejudice to the possibility of a further regulation by the Member States. In turn, EU Regulation no. 2017/745 of 5 April 2017 on medical devices establishes specific rules to give the informed consent, defining it as the

18 M. Ferrari, *The new legislation for an harmonized approach to the regulation of clinical trials in the EU countries*, in *Resp. Civ. Prev.*, 2016, p. 702.

> subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate. (Art. 2, no. 55)

The case of the off-label use of drugs is also interesting. In individual cases the doctor may, under his or her direct responsibility and after first informing the patient and acquiring the patient's consent, use an industrially produced medicine for something other than that for which it was authorized for marketing. It is common practice that consists in a different use of the drug, nevertheless evidence-based, in the event that there is no valid therapeutic alternative for the treatment of a disease.[19] Furthermore, when a patient consents the use of an off-label drug, the doctor will be less responsible for any future consequences (the side effects mainly depend on the producer of the drug), whereas in case of an operation (always with the consent of the patient) the surgeon has more autonomy in performing surgery and for this reason he or she is more responsible.[20]

Therefore, informed consent, validated by the Ethics Committee, is the pillar of the discipline; however, its failure to be acquired, detrimental to the patient's self-determination, assumes, in practice and in the prevailing jurisprudential interpretation, a concrete importance only in the case in which there is damage.[21]

Finally, it is the case to report the regulations of the Living Will of December 2017. In 1985, a law proposal about the end-of-life was discussed for the first time in the Italian Parliament. But a lot of proposals concerning this topic were rejected by the same Parliament, particularly during the first decade of the twenty-first century. For a long time, political positions prevailed on the articles of the Italian Constitution, for which an end-of-life law is necessary. The situation of a sick person and his or her power of decision concerning treatments are forecasted by Article 32, in which it is established that

19 According to Art. 3, para. 2, It. Law 8 April 1994 no. 98, in that case it is allowed to use the drug «for an indication or route of administration or a method of administration or use a different one from the authorised one, that is acknowledged for the scope of the application of Article 1, paragraph 4, of the law-decree 21 October 1996, no. 536, converted by law of 23 December 1996, no. 648, if the doctor deems, on the basis of documentable data, that the patient cannot be usefully treated with medicines for which that therapeutic indication is already approved or that route or method of administration and as long as this use is known and compliant to research appearing in scientific publications accredited in the international field».

20 The prescription of the *off label* drug, in case of confirmation of its therapeutic efficacy, is more difficult to obtain than actual surgery, paradigm of the model and characterized by a marked invasive imprint determined by a personal choice, which falls into the sanctioning consequences typically identified by the jurisprudence.

21 The informational obligation must relate to the peculiarities that characterize the off label treatment, differentiating it from the authorized therapies for which the effectiveness has already been formally verified (Court of Cassation, penal section I, 21 January 2009 no. 2437; Court of Cassation, civil section III, 15 September 2008 no. 23676): the doctor must, in particular, inform the patient on the reasons that induce him or her to undergo the off label treatment instead of the authorized treatment, and on the possible major risks or side effects that are accompanied by possible major expectations on improving the health condition.

"Nobody can be forced to undergo treatment without a law provision". At the same time, Article 13 requires the priority of personal freedom from authority. On the other hand, the Italian Constitutional Court stated that the right to health includes the right of self-determination for treatments. In December 2017, this debate culminated in the approval of Law no. 219, which finally allows the end-of-life treatment, especially in cases where the sick person is unconscious. In practice, the new Law fulfils the real idea of freedom legitimized by the Italian Constitution: the choice of going on living in tragic situations has now the same value of the choice to end one's life. In this perspective, we can respect the sick person only with good information about his or her health situation and the connected possibility for him or her to make a free and conscious choice.

There are several central points of the Law: (a) golden rule is the alliance or agreement between doctors and patients (the patient trusts the doctor and the doctor trusts the patient); (b) equally important is the duty of informing and the rule on which basis the information must be adequate and appropriate with respect to the patient' specific capability to understand, taking into account his or her cultural development (the so-called standard of the average man is not acceptable[22]); (c) no health treatment can be commenced or continued without the free and informed consent of the person concerned, except in cases explicitly provided by the Law; (d) the relationship of care and trust between patient and doctor, based on the informed consent, must be promoted and valued as a kind of 'therapeutic alliance'; (e) every person has the right to be informed in a clear and complete way about the risks and benefits of health treatments offered to him or her by the doctor and/or by the hospital. The patient's consent can be provided or revoked at any time, and it is provided in writing or electronically (when the digital medical records or electronic health records are operating), as more appropriate.

25.4 The Consent to the Processing of Personal Data Concerning Health in the Multilevel Legal System

The evolution of the multilevel system requires a fair balance between the needs for efficiency and transparency of the health systems and the main provisions on the protection of personal data and on informed consent. The right to the protection of personal data, among which the data concerning health play a very important and delicate role, was codified at the European level first by the Directive 95/46/EC and lastly by the EU

22 *See* It. Court of Cassation, civil section III, 4 February 2016 no. 2177.

Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

Sensitive data concerns any information gathered anywhere and anyhow from which it is possible to deduce the knowledge on the health status of a person, and by this, it is bound thematically and objectively to health protection.[23] This is a special category of data[24] to which a high level of protection must be applied and for which processing is prohibited, unless an exception applies.

The main exception is therefore represented by informed consent. It was found that "in comparison to the Data Protection Directive, the GDPR sets out stricter requirements for obtaining valid consent of the data subjects".[25] Pursuant to Article 9 Section 2 lit. (a) GDPR, the prohibition of sensitive personal data processing shall not apply if the data subject has given an explicit consent to the processing of those personal data for one or more specified purposes,[26] except where EU or EU Member States legislation provides that the prohibition may not be lifted by the data subject's consent.[27]

According to the definition given by the aforementioned Regulation, consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes, by which he or she, by a statement or by a clear affirmative action, makes official the agreement to the processing of personal data relating to him or her. At the same time, data concerning health – within the category of sensitive data – are personal data related to the physical or mental health of a natural person, including the provision of health-care services, which reveal information about his or her health status. As noted, processing of such data is unlawful if it is carried out without the consent of the person concerned or the other waivers strictly allowed occur. In case of violation of this

23 Among the atypical sources of knowledge of the data and the many types of sensitive data are the use of visual or auditory prostheses, the consumption of alcohol or smoking, data on allergies communicated to private entities or public bodies, the belonging to support groups or pathologies and so on: in these terms Eur. Court of Justice, 6 November 2003, C-101/01, Lindqvist. On the same topic, *see* T. Kugler, in D. Rücker LL.M., T. Kugler, *New European General Data Protection Regulation, A Practitioner's Guide*, Nomos, 2018, p. 237.

24 «In general, the more sensitive the information involved, the narrower the scope for compatible use would be»: in this way, T. Kugler, in D. Rücker LL.M., T. Kugler, *New European General Data Protection Regulation, A Practitioner's Guide*, Nomos, 2018, p. 63.

25 P. Voigt, A. Con dem Bussche, *The EU General Data Protection Regulation (GDPR). A Practical Guide*, Springer, 2017, 114, 93.

26 The purposes can be: (a) the preventive or occupational medicine, (b) the assessment of the working capacity of employees, (c) the medical diagnosis, (d) the provision of health/social care or treatment and (e) the management of health/social care systems and services: *see* P. Voigt, A. Con dem Bussche, *The EU General Data Protection Regulation (GDPR). A practical Guide*, Springer, 2017, 114.

27 As underlined by P. Voigt, A. Con dem Bussche, *The EU General Data Protection Regulation (GDPR). A Practical Guide*, Springer, 2017, 112, «It is unlikely that such prohibition will be created at EU level as the EU only has limited areas of competence to create legislation. As regards EU Member States, it is in their discretion if and to what extent they will limit the possibility to consent. Nevertheless, as such prohibition touches on the fundamental right to privacy of the data subjects, it will only be legitimate in particular cases».

set of rules, both the Court of Justice of the EU (CJEU) and the ECtHR reinstate the legality playing a very important role.

The CJEU underlined that the processing of personal data revealing data concerning health is prohibited, even if this prohibition does not apply, *inter alia*, where the data subject has given his or her express consent: in a particular case, the Court stated that European Parliament's duty of transparency cannot justify the disclosure of personal data relating to the state of health and the presence of a person with disabilities in the applicant's family.[28]

On the other hand, the concept of 'private life' according to Article 8 of the European Convention on Human Rights is an autonomous and wide-ranging notion, incapable of being exhaustive,[29] which the ECtHR's case law tends to interpret extensively and in accordance with the general aims of the protection pursued by the Convention, which does not guarantee "theoretical and illusory" rights but rather "concrete and effective" rights.[30]

Regarding more specifically the protection of the health rights, the ECtHR constantly held that, although those rights are not explicitly enshrined in the Convention and in its Protocols, the states which are high contracting parties to the treaties are subject, simultaneously, to the positive obligations arising from Article 2 ECHR. Whereas there are many positive obligations as per Article 8 ECHR, on the one hand, the substantial obligation to have legislation that imposes on public and private health-care facilities the adoption of appropriate measures to protect the physical integrity of patients and, on the other hand, a procedural obligation to ensure that victims of medical negligence have access to an internal remedy which enables them to obtain fair compensation for the damage suffered.[31]

On this basis, the ECtHR has detected several violations of the right to the protection of personal data concerning health, sanctioning the processing carried out without the consent of the person concerned. In a first case, the ECtHR judged as unlawful the disclosure at a court hearing of confidential information regarding the mental state and psychiatric treatment of a patient: in fact, obtaining such confidential information from

28 Eur. Court of Justice, December 3, 2015, *CN v. European Parliament*, T-343/13. In that situation the data shouldn't have been published; therefore, it was necessary to provide for a compensation for the related damages.

29 *See ECHR S. And Marper v. United Kingdom [GC]*, 4 December 2008, § 66.

30 *See ECHR Airey v. Ireland*, October 9, 1979, § 24. C. Eur., Mat 4, 2000, ric. N. 45305/99, *Powell c. Regno Unito*; March 21, 2002, ric. N. 65653/01, *Nitecki c. Polonia*; December 16, 2010, ric. N. 25579/05, *A., B. E C. V. Ireland*, §§ 244-249. Without a diligent and timely state intervention to safeguard the law, this is destined to remain «merely theoretical or illusory»: in this sense, A. Saccucci, *Responsabilità medica e tutela della salute nella Convenzione europea dei diritti umani: quando lo Stato risponde per le carenze dei servizi medico-sanitari*, in G. Corso – E. Balboni (ed.), *Le responsabilità in ambito sanitario*, Torino, 2011, p. 177.

31 *See, inter alia, Benderskiy v. Ukraine*, 15.11.2007, §§ 61-62, Codarcea c. Romania, 2.6.2009, §§ 102-103, Yardımcı c. Turkey, 5.1.2010, §§ 55-57, Spyra and Kranczkowski c. Poland, 25.9.2012, §§ 82 and 86-87, Csoma c. Romania, 15.1.2013, §§ 41 and 43, SB c. Romania, September 23, 2014, §§ 65-66.

a psychiatric hospital had constituted an interference with the applicant's right to respect for his private life.[32] In another case, the ECtHR declared that the medical staff from an AIDS hospital center was guilty of disclosing that some patients were HIV positive.[33] In another case again, the ECtHR disapproved the disclosure of some Jehovah's Witnesses medical files to the prosecution authorities following their refusal to have blood transfusions during their stay in public hospitals. It stated that there had been a violation of Article 8 (right to respect for private and family life) of the Convention, noting in particular that the details at issue were incapable of affecting the outcome of the litigation, that the first-instance court's request for information was redundant, as the information was not "important for an inquiry, pre-trial investigation or trial", and was thus unlawful for the scope of the relevant Psychiatric Medical Assistance Act.[34] In brief, the ECtHR noticed numerous data breaches related to data concerning health.

25.5 The Circular Harmonization of Personality Rights: A Comparison between Self-Determination Freedom and Health Protection

While the consent to health treatment adds substance and completion to the right to health as a right to freedom, and therefore tends to encourage a spontaneous harmonization between personal freedom and health, the consent to the processing of personal data does not overlap with the right to health in an obvious way. Instead, there needs to be a careful balancing, the outcome of which depends on the commitment of many and on the positive convergence of various social, legal and cultural factors.

Therefore, there is a need to reconcile values and rights that are not always and not automatically aligned: the right to the processing of personal data and to the protection of health. The relationship established between the protection of health and the right to self-determination intended as the self-management power for personal data is particular. This particularity is already noticeable on the structural side. Traditionally, in fact, the protection of health, as a proclaimed fundamental right by the Constitution, exercises a hegemonic presence in the patient's juridical sphere, as it needs to be reconciled at most with general needs (Art. 32 of the Italian Constitution) and with public interests that may contain an expansion (budget balance and cost reduction).

When, on the other hand, the right to health is confronted with privacy, two rights in the name of the same private individual appear and need to be reconciled: health protection is accompanied by the right to the protection of personal data. In other words, the right to health must face another fundamental right in a relationship that requires har-

32 The ECHR cases law – *Pantlevenko v. Ukraine*, June 29, 2006.
33 The ECHR cases law – *Armonas e Biriuk v. Lithuania*, November 25, 2008.
34 The ECHR cases law – *Avilkina and Others v. Russia*, June 6, 2013.

monization and balance. Hence the question: are these rights divergent and conflicting or are they converging rights and are subject to be placed in a synergistic dimension?

It was observed that a new chapter opens with the recognition of the right to the protection of personal data for the theory and practice of fundamental rights in the Italian experience.[35] And, indeed, the introduction of a new right is an innovation compared to the past when the protection of the rights and fundamental freedoms of persons and other entities fell, rather, in a more restricted sense, between the limits to the lawful circulation of information.

Therefore, the legislation on privacy marks the beginning of a new era for the theory of personality rights: a real turning point to the extent that the right to informative self-determination goes beyond the logic that traditionally marked personal rights with a prevailing individual and defensive moment within. By evolving, the protected interests' framework changes compared to how it had been defined by the system of personality rights until then: it no longer merely and simply aims at preserving the inviolability of the personal sphere and the dignity of the individual, but the area of the scopes pursued by the legislator is significantly enriched.

The issue of the collection and processing of information is freed from the strictly individualistic approach, to take on a collectivist perspective aimed at promoting and encouraging the active participation of the data owner and the opening of his private sphere to an interaction with third parties.

In this evolutionary interpretation of the scopes underlying the new regulatory regime for the protection of personal data, the control over the circulation of information is understood as a constituent element of modern citizenship because it is a precondition for the exercise of other civil, social and political rights.

In other words, privacy does not just involve being alone but how we connect and interact with others. Some authors highlight how important it is to investigate the history of privacy and its philosophical origins.

> The examination of philosophy helps with this in a number of ways. First, important theorizing of being private and public comes from ancient Greece, Plato and Aristotle; second, contemporary understanding of privacy is virtually synonymous with a philosophical school known as liberalism; and third, philosophical ideas and writing on autonomy, consent and rights directly feed into laws on privacy.[36]

35 G. Resta, *Il diritto alla protezione dei dati personali*, in F. Cardarelli, S. Sica, V. Zeno-Zencovich (ed.), *Il codice dei dati personali*, Milano, 2004, 13.

36 A. Mcstay, *Privacy and the media*, Sage, 2017, 5, which underlines that modern tension about security has roots in philosophy and the writing of Thomas Hobbes.

In this regard, we have spoken about the so-called integrated legal strategy as an inspiring logic that permeates the entire control mechanism, anchoring it to the interaction between public and private, of which a special independent authority is the protagonist. It has the task of supervising the correct processing of personal data and also of supporting the involved party by integrating the willful determinations or by setting specific protection measures where sensitive data come into the picture.[37]

However, in principle, the protection of sensitive data is susceptible to tempering or limiting health treatments. These conclusions are reached by taking into account the inversion of the relationship between transparency and advertising that occurs in the health sector. As a rule, the private individual invokes transparency compared to the secrecy of the administration. Instead, in our case, the health administration needs to process personal data for various scopes (the optimization of the curative process, scientific research, spending control), while the data owner has an interest in its secrecy.

Practice shows us a picture that is still anchored mainly to a defensive logic and to the culture of the protection of personal data as a limit to the processing of the actual data rather than as an impulse to the social dimension of this personality right. A number of other factors contribute to this situation: (a) the growing awareness that data-sharing in the health sector is useful and often necessary; (b) the evolution of the actual health concept that reaches the aspiration toward a state of complete psycho-physical well-being; (c) the contribution of the ECtHR through the lever of the so-called positive obligations imposed on the Member States of the ECHR; (d) the precious work of the Guarantor for the Protection of Personal Data, to which we owe a series of interventions aimed at finding a balance between the various instances in the field with the final scope of enhancing the potential of data processing in favor of the most effective and efficient provision of health-care services (it is significant that the first institutional act in Italy by the FSE – the Electronic Health File – was the guidelines issued by the Guarantor Authority).

At the same, time we must also take into account the so-called theory of the paradox of medical confidentiality, developed by some authors. In particular, the so-called paradox of medical privacy underlined by the American scholars emerges[38] because the technological progress, on the one hand, increases the efficiency and quality of the health

37 *See* S. Rodotà, *Tecnologie e diritti*, Bologna, 1995, p. 93.

38 Privacy is considered by some to be harmful in view of the economic analysis of the law to the extent that the power to select information by excluding third parties from an access can encourage the commission of fraudulent conduct and cause information asymmetries that generate market inefficiencies. In this regard, R.A. Posner, *An Economic Theory of Privacy*, Regulations (May/June 1978), p. 19, deplores the tendency of people to manipulate the world around them by the selective disclosure of facts about themselves. However, the US Supreme Court, in principle and subject to the necessary guarantees, recognized as predominant the disclosure of private medical information (judgment *Whalen v. Roe*, February 22, 1977).

system[39] but, on the other hand, it increases the fear of an uncontrollable access to the clinical documentations of private individuals and of possible abuses that damage the latter.[40]

In other words, paradoxically, technological advances that privacy advocates fear will increase access to our medical records are the very same technological advances that society looks to for improving the efficiency and quality of the health-care system.[41] Because of the evolution of the doctor-patient relationship, the gaining of an economic value for health data and the relative deterrence of the deontological rules on the subject of secrecy, the risk of the weakening of information exchanges[42] appeared, with the negative consequence that absolute confidentiality and the acceptance of privacy as the right to exclude others from one's own private sphere may compromise the protection of the community, frustrating the research purposes.

This opens the chapter on security measures and on the adequacy of control (on information flows and on the uses of the data) in the form of the assisted control model thanks to the supervision, support and assistance to the private autonomy of a special guarantee authority. And the chapter opens on the citizens' trust in the institutions and the correct use by the latter of the data concerning them. The centrality of trust in the system is understood by bearing in mind that the obligation to consent to the processing of personal data is increasingly diminishing in the health sector.[43] In order to understand this aspect correctly, it must be understood that the consent is no longer required even for

39 Information sharing can help detect preventable illness, save lives, reduce hospitalization, improve treatment health care and grant better opportunity for frontline practitioner care. Medical treatment may require disclosure of medical information. To provide appropriate care, health-care professionals need to obtain information from other professionals and facilities. For example, doctors need to know about a patient's medical history, allergies, use of prescription drugs and results of lab tests. Moreover, consultation with other doctors could be delayed if the patient must give prior written consent to disclose information if physicians cannot consult with each other about patients without written consent (it isn't a good result): too much privacy could be bad for patient's health. The disclosures of private medical information to doctors, to hospital personnel, to insurance companies and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient.

40 P. Harris, *Sufficient grounds for optimism? The relationship between perceived controllability and optimistic bias*, in *Journal of Social and Clinical Psychology*, 15, 1996 p. 9, observes that the increasing individuals' perceived control over the release and access of private information – even information that allows them to be personally identified – could increase their willingness to disclose sensitive information, so that such an increase in control can, paradoxically, end up leaving them more vulnerable.

41 All this happens in an atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories and fears [*Jaffee v. Redmond*, USA Supreme Court, reported by D.H. Barlow (ed.), *The Oxford Handbook of clinical psychology*, Oxford University Press, 2011, p. 192].

42 G.M. Riccio, *Privacy e dati sanitari*, in F. Cardarelli, S. Sica, V. Zeno-Zencovich (ed.), *Il codice dei dati personali*, Milano, 2004, p. 263.

43 *See* Arts. 2-*sexies*, 2-*septies* and 75, It. Legislative Decree 10 August 2018 no. 101, which adjusted the Italian privacy code to the EU Regulation 2016/679.

the processing of data for the treatment of the person involved,[44] and no longer just for the scopes of scientific research and cost management.[45]

Therefore, the data processing takes place without the consent but in compliance with the guarantees pursuant to Article 2 – septies of the privacy code and subject to being informed. And except, in any case, for the provisions of the sector[46] like for the very important FSE (Electronic Health File) case.[47]

At the conclusion of this chapter, we can affirm that the right of self-determination can be matched with the right to authorize or refuse treatment or with the right to privacy. On the one hand, the consent to health treatment favors the realization of the right of health care by default and, therefore, it tends to help integrate personal freedom and one's health. In this case, the characteristics, the advantages and the side effects of the treatment are the object of the information; therefore, self-determination and right to health are overlapping by having a common denominator. It is a natural and consequential effect, like a sort of direct and bi-univocal connection between the two rights.

On the other hand, the consent to the personal data processing can at times be in conflict with one's health care because the person fears to remain in the dark about the use of his or her personal data (in the absence of security measures he or she doesn't know what happens to the data). For this reason, a careful balance between the social, legal and cultural sphere must be created because it is not automatic. In this case, the conditions of data processing and the forms of control over the use of data are the objects

44 Hunting for the right balance, the Italian law and the Privacy Authority established that doctors can treat patients without having to request their consent to the processing of personal data, but shall provide them a complete information about use of the data. Instead, it's still prohibited to implement Electronic Health Record without the consent of the person concerned who can decide who can access to which documents, when and for what uses.

45 Art. 75 of the Italian code on privacy (Legislative Decree 196/2003 as amended by Legislative Decree 101/2018) refers to the conditions of lawfulness of treatment defined by Art. 9 of the GDPR.

46 It is to be foreseen that the very interesting topic will be developed further by the Guarantor through provisions provided by Art. 2-septies of the code.

47 E-health is a crucial innovation capable of favoring the progress of health care and improving the quality, costs and effectiveness of the services offered, reducing waste and inefficiencies and making access to services more homogeneous in the different areas of the country. The Electronic Health File consists of a structured set of all the information related to the sphere of the health of an individual (medical reports, medical and surgery checks, first-aid accesses, prescriptions, diagnosis, therapeutic treatments, allergies, medical history, lifestyle, laboratory tests and so on), including administrative data and tax information. The Electronic Health File can be arranged only for the following purposes: prevention, diagnosis, treatment and rehabilitation; study and scientific research in the medical, biomedical and epidemiological fields; health planning, verification of the quality of treatments and evaluation of health care. Born as a communication tool for health professionals involved in the treatment process, the Electronic Health File is subject to a joint management with the patients who participate in the control and management of their own health data, becoming the center of gravity of the system for information suitable to reveal their state of health. The structures and operators, indeed, need the sharing of information and the coordination among them for the pursuit of a greater appropriateness of the clinical paths; the patients, at the same time, are placed at the center of the system as the holder of rights and exercise a series of prerogatives: the access to online health services, the contribution to the setting up the file's contents and, above all, the consent to the supply and consultation of the file necessary for the involved party to undergo health treatments for the case.

of the information; therefore, self-determination and right to health are not overlapping because they are located on two different levels, given that treatment is only one of the goals or effects to which data processing may tend.

The relationship between self-determination and privacy is more complicated than the relationship between self-determination and the right to consent treatments, and so need to be deepened, taking into account that the right of data protection can limit the right to health. In fact, the free movement of personal data is always facilitated by new-generation technological tools, and it is useful for many positive purposes as a valuable opportunity. But it is necessary to find a fair balance between the data processing and the aim to increase the citizen's protection and his trust in public authorities since human dignity is a fundamental right.

Health data has an economic value, and if people don't trust the system, the consent to processing personal data is not given, leading to the detriment of treatment quality, which needs data-sharing. On the contrary, the implementation of public authorities' reliability can encourage people to give the consent. The central point is the right to give the informed consent as a fundamental right of human person, and it reflects how much people trust public authorities who treat their data (the state's ethical behavior is also very important): without forgetting that the conditions and the requirements that can justify the processing of confidential data aren't extensible, while the states could add further limitations with regard to the processing of the same data.

Ultimately, it is necessary to guarantee the contextual realization of two values: the efficacy of the therapeutic path and the protection of data; in other words, "the respect for the right to health and the privacy and dignity of patients, essential values for every path aiming at safeguarding human life".[48] As effectively observed,

> the paradigm according to which the involved party is obliged to protect himself exclusively through the traditional scheme of information and free consent has the risk of no longer being suited for new realities.

It is necessary "to find a compass to help us find the thread of rights in the very changing digital society" so as to reach "a new balance between technical feasibility and legal acceptability". It would be important "to incorporate the protection of rights in technologies making the holders responsible, pushing them towards adopting new organizational data management and control methods". Lastly, it is necessary "to check that a compliance with specific safety measures is balanced with the efficiency of the various devices in the sense that their functionality is not compromised".[49]

48 It. Garante per la protezione dei dati personali, *Relazione 2016*, p. 58.

49 *See* A. Soro, *Liberi e connessi*, Soveria Mannelli, 2016, randomly.