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41

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Advance Care Decision Making in Germany and Italy

A Comparative, European and International Law Perspective

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Foreword

This book presents the results of a 2-year interdisciplinary research project on the subject "Legal and ethical questions raised by advance care decision making in Germany and Italy: a comparative, European and international law perspective", which was approved and financed by the German Academic Exchange Service (DAAD) and the Italian Ministry for Education, University and Research (MIUR) in the framework of the Vigoni Program 2010. This joint endeavour was an initiative of Prof. Dr. Stefania Negri, director of the Observatory on Human Rights: Bioethics, Health, Environment of the University of Salerno. Prof. Dr. Jochen Taupitz, managing director of the Institute for German, European and International Medical Law, Public Health Law and Bioethics (IMGB) of the Universities of Heidelberg and Mannheim, gladly accepted her invitation to join the project.

The project brought together German and Italian academics from different fields and backgrounds and was conceived in a period when the debate on end-of-life care and advance directives regulation was particularly lively across Europe and exceptionally topical both in Germany and in Italy. In fact, acceptability and regulation of end-of-life decisions and permissibility of different forms of euthanasia have recently experienced an increasing attention from the scientific community in many European countries. An animated discussion on these topics has thus taken shape in ethical and legal literature, as well as in medical practice. This has also triggered a very emotional reflection on the patients' right to refuse or discontinue life-sustaining or life-prolonging efforts as part of their right to informed consent and self-determination (including the highly controversial right to die with dignity). In this context, several countries have passed legislation aimed at regulating individual choices by way of health care advance directives.

Germany was the last European country that enacted a law on living wills strengthening the principle of patient autonomy. During the 1990s and early 2000s, a Criminal Panel of the German Federal Court of Justice (Bundesgerichtshof) and the German Constitutional Court (Bundesverfassungsgericht) established a general hierarchy of decision-guiding criteria for cases concerning patients who are unable to give or refuse consent to medical treatment, acknowledging the legal validity of advance directives and the primacy of patient autonomy.

However, in a controversial decision of 2003, a Civil Panel of the BGH considerably differed from these judgments, holding a contradictory position on the power to refuse life-sustaining treatment when the patient is not suffering from a terminal disease that is "irreversibly leading to death", thus considerably restricting the right of self-determination. This decision triggered an intense debate that diminished in 2009, when the German Parliament passed the "3rd Act Changing the Custodianship Law" (3. Gesetz zur Änderung des Betreuungsrechts), entered into force on 1 September 2009, by which the German legislator broadened the scope of applicability of advance directives.

In the same year, Italy was confronted with the well-known Englaro case, which lit the spotlight on Italy's lack of an organic legislation on advance directives. This case heated the social and political debate on end-of-life choices and divided the public opinion, as well as the major institutional organs of the State, including the judiciary. It hence prompted the submission to the Italian Parliament of several bills aimed to intervene in this field with an endeavour to regulate the patient–physician relationship, informed consent, and advance directives. As a result of the acceleration impressed on the parliamentary debate, the Senate of the Republic approved on 26 March 2009 Draft Bill 10, also known as Calabrò Bill, which was transmitted to the Chamber of Deputies and discussed in Commission XII as Draft Bill 2350 (Disposizioni in materia di alleanza terapeutica, di consenso informato e di dichiarazioni anticipate di trattamento). The Bill was approved with amendments on 12 July 2011 and sent back to the Senate for final approval of the amended text, but the legislative process was interrupted by the dissolution of the Italian Parliament in December 2012, and so the Bill was never enacted as law. In its substance, the Italian Bill mainly went into a substantially different direction as compared to German law, stating that advance directives are not binding and even strictly prohibiting refusal of artificially provided nutrition and hydration. For its paternalistic approach to patient autonomy, it was the object of harsh criticism both in the political and the academic arenas.

Against this background, this book explores the most controversial ethico-legal questions concerning advance care planning and end-of-life issues, taking the German and Italian experiences as pilot examples to foster a broader reflection on the desirability and efficacy of a regulation by legislation of such a sensitive and complex field of individual decision-making. To this end, the various contributions portray and compare the current legal situation in both jurisdictions, using an interdisciplinary approach that takes into consideration the major legal and bioethical issues at stake, as well as the relevant economic aspects that are usually neglected in current researches on this topic. All topical issues are examined in the light of the responses provided by national legislators and courts, with reference both to domestic positive law (constitutional, private, and criminal) and to the relevant case law, which provides authoritative guidance on how critical problems are dealt with and solved in everyday practice.

Moreover, through contextualisation of the debate in the broader European and international legal frameworks, the book also aims to appeal to a transnational

scientific and political community, in the hope that the lessons drawn from the experiences of Germany and Italy may offer useful insights for other countries facing similar problems.

Salerno, Italy — Stefania Negri
Mannheim, Germany — Jochen Taupitz
June 2013

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Universal Human Rights and End-of-Life Care

Stefania Negri

Abstract Universal human rights like dignity, physical integrity, health, and freedom from torture or inhuman treatment have special relevance to the end-of-life debate and form the basis on which is built the emergence of new biorights. Over the last decades, such rights as the right to informed consent, the right to die with dignity, and the right not to suffer have gained increasing importance in the international legal order. These rights have also contributed to the setting of generally accepted human rights standards that offer authoritative guidance to both domestic legislators and judges. This is particularly important in light of the fact that the regulation of legal questions surrounding the end of life is quite different in domestic jurisdictions, even in a rather homogeneous and integrated region like Europe, where the relevant legal frameworks still differ according to cultural, ideological, and religious diversities and the more or less liberal attitude adopted by individual States, as it is the case with Germany and Italy. Moving from the above considerations, this chapter will discuss some critical aspects of end-of-life decision-making and care within the international human rights framework, with a view to disclosing the relevant legal standards and obligations that may serve as general reference and starting points for a comparison between national jurisdictions. This investigation could also open up the door to a more specific debate on the consistency of domestic legislation on end-of-life issues with international (biomedical and human rights) law.

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1 The Relevance of International Human Rights Law to the Legal Regulation of Ethical Issues Surrounding the End of Life

End-of-life care and advance care planning require a range of extremely sensitive decisions that deeply affect the patients' autonomy and their personal conception of life, death, and dignity.[1] Such decisions touch upon highly debated ethical dilemmas and raise topical medico-legal questions, including the definition of the boundaries of informed consent, the ethics and efficacy of aggressive or futile medical treatments, the withholding or withdrawing of life-sustaining measures, access to palliative care, and the permissibility of euthanasia or assisted suicide.

Legal questions related to these and other key issues concerning end-of-life decision-making and care are regulated quite differently in domestic law, if not regulated at all. This is mainly due to cultural, ideological, and religious diversities and the ensuing pluralistic approach adopted by States to moral, social, and legal values. At the international level—despite a quest for universal bioethical standards

[1] Advance care planning is a voluntary process of discussion about future care between an individual and their care providers, which might include the individual's concerns and wishes, their important values or personal goals for care; their understanding about their illness and prognosis; their preferences and wishes for types of care or treatment that may be beneficial in the future and the availability of these.

that may overcome the diversities inherent in human societies[2]—bioethically-sensitive issues related to the end of life are not specifically regulated. This is one of the evident limits of the emerging international law of bioethics, which has not so far succeeded in expressing those commonly shared values and globally accepted standards necessary for a possible harmonisation of domestic legislations in this field. In fact, although a certain degree of rapprochement between States was achieved in certain areas of biomedical practice and research, considerable differences still exist in their approach to ethico-legal questions concerning, for example, the patients' will to terminate their life, the problematic qualification and efficacy of certain life-sustaining measures (such as artificial nutrition and hydration), physician conscientious objection, and so on. Such a lack of generalised consensus resulted in a noticeable lacuna in both the Universal Declaration on Bioethics and Human Rights[3] and the Oviedo Convention on Human Rights and Biomedicine,[4] both lacking any relevant disposition in this respect.

Furthermore, it is remarkable that some legal questions concerning the end of life are regulated quite differently even in a rather homogeneous and integrated region like Europe, where the relevant legal frameworks still differ substantially according to the more or less liberal attitude adopted by States and their inclination to adopt restrictive or permissive legislations. In Germany and Italy, for example, it is evident that the relevant domestic norms testify to a very diverse approach to the legal regulation of end-of-life issues from both the civil and the criminal law perspectives, as this book will show.

Moving from these considerations, this chapter will discuss some critical issues concerning end-of-life care and decision-making within the international human rights framework, with a view to disclosing those legal standards and State obligations stemming from human rights law that may serve as general reference and starting points for a comparison between domestic legal orders. In short, it aims to assess whether in the three core domains where the comparative analysis between German and Italian law is developed in the chapters that follow (patient autonomy and advance care planning, euthanasia, and palliative care) it is possible to affirm that some relevant international human rights standards exist, whether new rights have emerged at the general level and to what extent they pose international

[2] On the issue whether "universal bioethical standards" can be translated into legal norms, see Ida (2004), pp. 376–377. According to this Author, "Although bioethics legislation exists at the national level … and at the regional level …, there are no international or universal legal rules. The diversity of values within each community is the main reason for this absence of universal legal instruments" (pp. 377–378).

[3] Unesco, Universal Declaration on Bioethics and Human Rights, 19 October 2005.

[4] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, ETS No. 164, entered into force on 1 December 1999 (hereinafter 'Oviedo Convention'). The problems left unsolved by the Convention include the definition of the boundaries of patient autonomy, the refusal of treatments, and euthanasia: see Taupitz (2002b), p. 5.

obligations on States, and whether the relevant international remedies offer a better protection than the one that is available under domestic law. This investigation could also open up the door to a more specific debate on the compatibility of domestic legislation on end-of-life issues with international (biomedical and human rights) law.

The reflections that follow will build on two basic assumptions.

The first is the idea that international human rights law at the universal level can be considered quite "neutral", in the sense that it does not suffer—at least not to a considerable extent—from the influence that ideological, political, and religious factors exert on domestic legislations. Based on the recognition of universal values, generally agreed standards, and internationally acknowledged rights, it can offer a reliable and objective term of reference for domestic legislation, thus guiding legislators in the passing of statutes that do not privilege any dominant ethics (be it laic, Catholic, or others). Moreover, general principles and minimum standards set at the international level can also lend help to national judges when they interpret domestic provisions extensively and evolutively, with a view to making the law "live" and have margins of manoeuvre in its application to the new bioethical dilemmas.[5] Therefore, even if unable to achieve real harmonisation, the human rights standards affirmed and accepted at the universal level can nonetheless realise a certain degree of rapprochement between State legislations around commonly shared values and principles.

The second basic assumption refers to the asserted derivation of biomedical law from human rights law: the most influential literature on the subject insists on the concept that international instruments of biolaw are the "natural extension" of human rights instruments to life sciences and biomedicine.[6] Moreover, according to a commonly shared scholarly view, it is most opportune that biolaw be conveyed within the framework of human rights law, so that human rights and fundamental freedoms may find appropriate tools of legal protection from the challenges of medical technological progress.[7] In this respect, it is often pointed out that all major human rights treaties contain some guarantees related to the protection of fundamental rights in patient care[8] and that, despite the fact that only some of these conventions have been almost universally ratified, they all set minimum standards

[5] In this sense, see Maljean-Dubois (2000), p. 92; Tancredi (2004) pp. 408–409; Campiglio (2012), p. 112.

[6] See Byk (1999); Maljean-Dubois (2000), p. 93; Boschiero (2006), p. 13, 15; Mathieu (2006), p. 85; Andorno (2011), p. 75.

[7] Loreti Beghè and Marini (2001), p. 44; Andorno (2002), p. 960; Boschiero (2006), p. 14.

[8] See Andorno (2005b), p. 133. The Author states that the essence of some principles enunciated by the Oviedo Convention were already framed in more general terms in previous human rights treaties.

that can be considered at least morally binding also on non-Party States.[9] Moreover, the link between international human rights law and biomedical law is ever more apparent in the wording of the majority of biolaw instruments, which regularly refer to the key human rights instruments and endorse them as foundational framework for "supplements" of protection urged by the "potential implications of scientific actions" and the need to shield the individual from any threat resulting from the developments in biology and medicine.[10]

Following this line of thought, this chapter will especially focus on universal human rights—such as life, health, human dignity, physical integrity, freedom from torture—in order to attest to the relevance of international human rights law, and the prominence of universally accepted human rights standards, to the legal regulation of ethical dilemmas surrounding the end of life.

2 Advance Care Planning, Patient Autonomy, and the Right to Informed Consent

Patient autonomy encompasses the right to participate in advance care planning and to make decisions for the future. Therefore, respect for self-determination implies respect for the patients' right to express in advance their preferences as to the treatment options to be performed in case they lose temporarily or permanently their capacity to take part in medical decision-making. It falls within the purview of patient autonomy—provided that we refer to adults who understand the consequences of their choices—to refuse certain medical treatments and interventions, including those that may be administered at the end of life, and to choose that death come naturally.

Advance directives are the legal instruments designed to enable patients to retain decisional authority even in cases of incompetence; they provide a viable alternative to contemporaneous decisions and serve the scope of protecting precedent

[9] For example, the scope of the Oviedo Convention has thoroughly been debated in legal literature also with a view to assessing whether it can offer a pattern for global regulation of bioethical issues: see especially Taupitz (2002b). On the one hand, it is contended that the Convention seeks to promote the universal dimension of the biorights it enunciates and it is also remarked that the participation of Canada, the USA, Japan, Australia, the European Union, and the Holy See to its negotiation undoubtedly confers an added value to the alleged "universality" of its rules (see e.g. Millns (2007), p. 78; Gadd (2005); Boschiero (2006), p. 51). On the other hand, it is denied any "universal aspiration", both because it is substantially a regional treaty with a very low rate of ratification and because its restrictive provisions make it unlikely that it will ever be ratified by third States (on this latter point, see Riedel (2002), pp. 37–38).

[10] The Preambles to the Oviedo Convention and to the Unesco Universal Declarations both "solemnly recall [. . .] the attachment to the universal principles of human rights". See also the Explanatory Report to the Oviedo Convention, paragraphs 11–13.

autonomy.[11] Except for a specific and limited reference to the patient's "previously expressed wishes" to be found in Article 9 of the Oviedo Convention,[12] advance directives in general are not regulated in international law and the legal effects they have in domestic law vary from one jurisdiction to another.[13] In order to assess whether a generally accepted standard has emerged so far, it is necessary to focus on the principle of informed consent, which is considered the very foundation of the "new ethos of patient autonomy".[14]

2.1 The Doctrine of Informed Consent

Informed consent is both a core principle of medical ethics and a well-established fundamental rule of biomedical law. It has gained such remarkable relevance in the international legal framework that virtually all international agreements and declarations on ethical and legal standards in medicine and biomedical research endorse it as a basic rule.[15]

After the famous and most cited opinion delivered by Justice Benjamin Cardozo in the landmark Schloendorff case, according to which "every human being of adult years and sound mind has a right to determine what shall be done with his own body",[16] and the first significant enunciation in the Nuremberg Code,[17] informed

[11] Advance decision-making can take the form of either instructional directives, also known as living wills (providing specific instructions or setting out general principles to be followed for health care to be delivered when decision-making capacity has been lost), or proxy directives, also known as durable powers of attorney for health care (naming surrogate decision-makers such as proxies).

[12] Article 9 of the Oviedo Convention reads "The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account". On this provision, see the legal analysis carried out in this book in the chapter authored by Di Stasi and Palladino (2013).

[13] See Negri (2011a), especially Part II: Advance directives, end-of-life decision-making, and euthanasia in comparative legal perspective.

[14] The quote is from Wear (1992), Chapter two. The body of literature on informed consent is really vast. See, ex plurimis, Faden et al. (1986); Van Oosten (1991); Switankowsky (1998); Berg et al. (2001); Manson and O'Neill (2007); Casonato (2009); Maclean (2009). For deeper insights on the status of informed consent under international law, see Negri (2011c); Negri (2012).

[15] Kollek (2009), p. 124.

[16] Opinion of Justice Benjamin Cardozo, Schloendorff v. The Society of New York Hospitals (105 N.E. 92), Court of Appeals of New York, 14 April 1914.

[17] The Nuremberg Code (1947) was printed in Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Washington, 1949, vol. 2, pp. 181–182. The first and best known provision of the Nuremberg Code stated: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension

consent has enjoyed growing widespread consensus in both 'hard' and 'soft' law and has gained over time broader scope.[18]

In 1949, the World Medical Association recognised the 'right' of competent patients to accept or refuse treatment in its International Code of Medical Ethics[19] and later upheld the rule of informed consent both in the Helsinki Declaration on Ethical Principles for Medical Research (mentioning both the right to refuse to participate in research and the right to withdraw a previously expressed consent)[20] and in the Lisbon Declaration on the Rights of the Patient (where informed consent is subsumed under the right to self-determination).[21]

Turning to the legal instruments adopted by the most relevant international organisations, it is necessary to recall, first and foremost, the WHO Declaration on the Promotion of Patients' Rights in Europe of 1994,[22] the Council of Europe's Convention on Human Rights and Biomedicine of 1997 and its Additional Protocols,[23] as well as the Unesco Universal Declarations on the Human Genome and Human Rights of 1997 and on Bioethics and Human Rights of 2005.[24] To these documents it is also worth adding the WHO Guidelines for Good Clinical

of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. . . ." Among the several relevant contributions, see Weindling (2004).

[18] A collection of the relevant texts is reported in den Exter (2011).

[19] WMA, International Code of Medical Ethics, adopted by the 3rd General Assembly of the World Medical Association, London, October 1949, as amended in 1968, 1983 and 2006.

[20] WMA, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Assembly, Helsinki, June 1964, as subsequently amended and revised up to October 2008.

[21] WMA, Declaration on the Rights of the Patient, adopted by the 34th World Medical Assembly, Lisbon, September/October 1981, and amended by the 47th WMA General Assembly Bali, Indonesia, September 1995.

[22] WHO/EURO, European Consultation on the Rights of Patients, Amsterdam 28–30 March 1994, A Declaration on the Promotion of Patients' Rights in Europe, ICP/HLE 121, 28 June 1994 (hereinafter Amsterdam Declaration).

[23] See Chapter II of the Oviedo Convention; see also Articles 13, 14 and 17 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 January 2002, ETS No. 186, entered into force on 1 May 2006; Chapters IV and V of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, 25 January 2005, ETS No. 195, entered into force on 1 September 2007; Articles 9 to 15 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes, Strasbourg, 27 November 2008, ETS No. 203, not yet in force.

[24] See Article 5 of the Universal Declaration on the Human Genome and Human Rights, 11 November 1997, and Articles 6 and 7 of the Universal Declaration on Bioethics and Human Rights, 19 October 2005. As far as the collection, use and storage of biological samples are concerned, see the Unesco International Declaration on Human Genetic Data, 16 October 2003, in particular Articles 8, 9 and 16.

Practice,[25] the International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the WHO in collaboration with the Council for International Organizations of Medical Sciences,[26] and at regional level, the European Union Clinical Trials Directive of 2001.[27]

In light of the above-mentioned instruments, it is indisputable that the doctrine of informed consent is today widely acknowledged as the expression of one of the basic principles of international biolaw, serving as the cornerstone for the protection of the fundamental rights to physical integrity and self-determination in every field of medical intervention. In fact, according to its generally recognised scope, informed consent provides that any preventive, diagnostic, and therapeutic medical intervention, as well as any scientific research involving human subjects, may only be performed after the person concerned has given prior, free, and informed consent based on adequate information. This implies that the patient's autonomous decision to accept or refuse to undergo a medical treatment, or to take part in scientific research, has to meet some specific requirements: the person must have legal capacity to give consent and must also be conscious and fully competent; consent must result from a decision-making process devoid of any element of force, fraud, deceit, duress, threat, or any other form of constraint or coercion. Moreover, consent must be based on the appropriate disclosure to the patient, by the responsible healthcare professional, of adequate and understandable information concerning the diagnostic assessment, purpose, method, likely duration, expected benefit, and chances of success of the proposed treatment; alternative modes of treatment, including those less intrusive; possible pain or discomfort, risks and side effects of the proposed treatment; chances and risks associated with lack of treatment. In this sense, what is called "genuine consent"[28] represents the very foundation of legitimacy for any medical treatment, so much so that interventions and care provided without prior consent, even if administered in the patient's best interest, may be qualified as illegal 'bodily assaults' and may trigger both civil and criminal liability of health care providers.[29]

[25] WHO, Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (Geneva, 1995). See also the UN Special Rapporteur's recommendations as formulated in his Report containing the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (U.N. Doc. A/63/263, 11 August 2008, paragraphs 21–22).

[26] CIOMS-WHO, International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva, 2002), Guideline 4, p. 32.

[27] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, Official Journal of the European Communities, L 121/34, 1 May 2001.

[28] On the concepts of 'genuine consent' or 'understood consent', see Bhutta (2004), pp. 773–774.

[29] See Justice Cardozo in Schloendorff v. Society of New York Hospital, supra note 16: "a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages".

Only a few derogations to the above-mentioned rules are allowed for compelling reasons or in particular situations and in respect of vulnerable patients,[30] that is to say in case of medical emergency,[31] de facto incapacity (e.g. patients who have become incompetent in consequence of an accident or patients in a state of coma), reduced capacity of understanding (e.g. adults with mental disorders[32]), or limited legal capacity (minors and incapacitated adults). In such circumstances, informed consent is provided by a legal representative (guardian or proxy) with the association to the decision-making process of the person concerned and his active participation to the fullest extent that his capacity allows.[33] However, when a legal representative is appointed as substitute decision-maker, an intervention in case of urgent need can be performed whenever there is no possibility to obtain the representative's consent,[34] and if the legal representative refuses consent to an intervention that the physician deems appropriate and useful in the best interest of the patient, it is necessary to resort to a court or some form of arbitration of an independent body for super partes decision.[35] Moreover, according to well-established standards, whenever the patient is unable to give consent and there is no legal representative or proxy, appropriate measures should be taken to provide for a substitute decision-making process (for example, an independent body provided for by law), taking into account what is known and, to the greatest possible extent, what may be presumed about the wishes of the patient.[36]

In respect to derogations from the basic rule of informed consent, it is remarkable that according to international (hard and soft) biolaw such exceptions are admitted solely when provided by law, in accordance with ethical and legal standards adopted by States, strictly for "compelling reasons within the bounds of public international

[30] See Selinger (2009). It should be noted that, consistently with the exceptions stated in Articles 6 to 8, the Oviedo Convention does not include Article 5 among those non-derogable dispositions mentioned in Article 26, paragraph 2, while it only provides that no restrictions be placed on its protective provisions contained in Article 17, concerning persons not able to consent to research.

[31] See Article 8 of the Oviedo Convention and paragraphs 56–58 of the Explanatory report; see also Amsterdam Declaration, paragraphs 3.4, 3.6, 3.7.

[32] See Article 7 of the Oviedo Convention; Principle 11 of the United Nations Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care, General Assembly Resolution 46/119 of 17 December 1991; Progress of efforts to ensure the full recognition and enjoyment of the human rights of persons with disabilities, Report of the Secretary-General, U.N. Doc. A/58/181, 24 July 2003; Report of Paul Hunt, Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, U.N. Doc. E/CN.4/2005/51, 11 February 2005 (hereinafter 'Report 2005').

[33] See Article 6 of the Oviedo Convention and the Amsterdam Declaration, paragraph 3.5.

[34] Amsterdam Declaration, paragraph 3.4.

[35] Amsterdam Declaration, paragraph 3.6.

[36] Amsterdam Declaration, paragraph 3.7; see also Explanatory report to the Oviedo Convention, paragraph 57.

law" and subject to compliance with international human rights law.[37] These important caveats, included in the Oviedo Convention,[38] in the Unesco Declarations, as well as in the resolutions of the United Nations Commission on Human Rights and of the Committee of Ministers of the Council of Europe,[39] recall very closely the pattern of lawful limitations adopted within conventional human rights regimes[40] and lend support to the argument that informed consent is a rule grounded in international law, especially human rights law, just as much as it is in bioethics and medical law.

2.2 Informed Consent and Universal Human Rights

2.2.1 Informed Consent and the Right to Physical Integrity

Although it is expressly enunciated only in a few human rights conventions, the right to bodily integrity is a well-established fundamental right protecting the universal values of the dignity and inviolability of the human being. It is considered as an element of the rights to the security of the person and to privacy and, above all, of the right to be free from torture and from cruel, inhuman, and degrading treatment. In this sense, its main legal sources at the universal level are Article 5 of the Universal Declaration of Human Rights and Article 7 of the International Covenant on Civil and Political Rights (ICCPR). This latter provision, which is aimed at protecting both the dignity and the psychophysical integrity of the individual,[41] specifies that no medical

[37] See Article 9 of the Universal Declaration on the Human Genome and Article 6 of the Universal Declaration on Bioethics and Human Rights. According to Article 27 of the latter, such compelling reasons may include the need to protect public safety and public health, a situation that finds application in Article 23, paragraph 3, and Article 31, paragraph 2, of the International Health Regulations (2005), legitimising States to apply health measures to travellers, including compulsory examination and vaccination, when there is evidence of an imminent public health risk. However, it is interesting to note that the protection afforded by the International Covenant on Civil and Political Rights under Article 7 is even stricter than the one guaranteed by the norms of international biolaw, since that provision allows no derogations or limitation, not even in times of emergency (Article 4, paragraph 2).

[38] See Article 26 of the Oviedo Convention, which however does not allow restrictions on the rules governing protection of persons not able to consent to research or to organ removal. These are considered 'unconditional norms' (see Andorno (2005b), p. 136).

[39] Commission on Human Rights, Resolution 2003/69, Human rights and bioethics, adopted by consensus on 25 April 2003; Committee of Ministers, Recommendation R(99)4 to Member States on Principles Governing the Legal Protection of Incapable Adults, 23 February 1999, principle 28.

[40] Compare the proviso in Articles 8 to 11 of the European Convention on Human Rights; Articles 12, 18–19, 21–22 of the International Covenant on Civil and Political Rights; Articles 12–13, 15–16 and 22 of the American Convention on Human Rights; Articles 11–12 of the African Charter on Human and Peoples' Rights. The conditions of legitimacy of the restrictions placed on human rights are by now considered the object of a customary rule: see Fidler (2000), pp. 293–294.

[41] International Covenant on Civil and Political Rights, adopted and opened for signature, ratification and accession by General Assembly Resolution 2200A (XXI), 16 December 1966, entered into force on 23 March 1976; CCPR, General Comment No. 20: Replaces general comment 7 concerning prohibition of torture and cruel treatment or punishment (Art. 7), 10 March 1992.

and scientific experimentation is allowed without the 'free consent' of the person concerned.[42] The importance of this provision is twofold: on the one hand, it confirms the link between physical integrity and informed consent; on the other hand, it clearly shows that the right to physical integrity extends well beyond the prohibition of torture or cruel, inhuman, or degrading treatment, to which it is generally associated.[43]

The same proviso contained in Article 7 ICCPR is reproduced in Article 15 of the Convention on the Rights of Persons with Disabilities. This Convention clearly spells out the right to integrity of the person in Article 17 and makes express reference to informed consent in Article 25, para. d, in the context of the right to non-discriminatory enjoyment of the right to health.[44]

Other relevant provisions in regional human rights conventions include Article 5, para. 1, of the American Convention on Human Rights, which protects the right to physical, mental, and moral integrity,[45] as well as Article 4 of the African Charter on Human and Peoples' Rights, which affirms the inviolability of human beings and their entitlement to respect for their life and integrity of the person.[46] It is also worth mentioning the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa,[47] which states at Article 4, para. 1, that every woman is entitled to respect for life and integrity of her person, while at para. 2.h it mandates States Parties to take appropriate and effective measures to "prohibit all medical or scientific experiments on women without their informed consent".[48]

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[42] According to the Committee's interpretation, Article 7 allows no limitations or derogations and implies that the Parties to the Covenant have a legal duty to guarantee protection through legislative and other measures against the acts prohibited by this provision, "whether inflicted by people acting in their official capacity, outside their official capacity or in a private capacity". Moreover, as for the specific prohibition of non-consensual experimentations, the Committee argues that special protection is necessary with regard to persons not capable of giving valid consent, and in fact it recommends that "When there is doubt as to the ability of a person or a category of persons to give such consent, e.g. prisoners, the only experimental treatment compatible with article 7 would be treatment chosen as the most appropriate to meet the medical needs of the individual". See General Comment No. 20, paragraphs 2 and 7; Consideration of Reports Submitted by States Parties under Article 40 of the Covenant: Concluding Observations of the Human Rights Committee: United States of America, U.N. Doc. CCPR/C/USA/CO/3, 15 September 2006, paragraph 31.

[43] Unfortunately, there is no significant case law by the Human Rights Committee concerning violations of Article 7 for imposition of compulsory medication or experiments.

[44] Convention on the Rights of Persons with Disabilities, New York, 13 December 2006, entered into force on 3 May 2008.

[45] American Convention on Human Rights, San José, 22 November 1969, entered into force on 18 July 1978.

[46] African (Banjul) Charter on Human and Peoples' Rights, Nairobi, 27 June 1981, entered into force on 21 October 1986.

[47] Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, Maputo, 11 July 2003, entered into force on 25 November 2005.

[48] It should be added that this protection had been earlier invoked by the Committee on the Elimination of Discrimination against Women in its General Recommendation No. 24 of 1999 concerning action by the States parties to the Convention on the Elimination of All Forms of Discrimination against Women, where the Committee stated that States Parties had to "Require all

As it will be explained in detail further in this book,[49] the most salient expression of the intertwining between the right to physical integrity and informed consent is provided at the European level by Article 3 of the Charter of Fundamental Rights of the European Union, where informed consent is listed on top of the core principles of biomedical law, including the prohibitions of selective eugenic practices, of making the human body a source of financial gain, and of reproductive cloning of the human being. Moreover, Articles 3 and 8 of the European Convention on Human Rights have been consistently interpreted by the Strasbourg Court as encompassing a right to be free from non-consensual medical treatments, testing, and experimentations.[50]

2.2.2 Informed Consent and the Right to Health

Informed consent is also considered an integral and crucial part of the right to health,[51] as protected at the universal level by Article 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR).[52]

According to the UN Committee's General Comment No. 14 on Article 12, the right to health

> contains both freedoms and entitlements. The freedoms include the right to control one's health and body . . . and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation.[53]

Building on the Committee's interpretation of Article 12, the former UN Special Rapporteur on the right to health, Paul Hunt, observed in his Report of 2005 that although the issue of informed consent

> is often considered in relation to the right to liberty and security of the person, as well as the prohibition against inhuman and degrading treatment, it is less frequently considered in the context of the right to health. However, consent to treatment is intimately connected with a vital element of the right to health: the freedom to control one's health and body.[54]

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health services to be consistent with the human rights of women, including the rights to autonomy, privacy, confidentiality, informed consent and choice" (paragraph 31, al. e).

[49] See Di Stasi and Palladino (2013).

[50] On the relevant Strasbourg case-law, see Negri (2011c), pp. 46–49.

[51] Dupuy (1979); Leary (1994); Hendriks (1998); Toebes (1999); Negri (2008, 2010); Riedel (2008); Robinson and Clapham (2009); Tobin (2012).

[52] International Covenant on Economic, Social and Cultural Rights, adopted by General Assembly Resolution 2200A (XXI) of 16 December 1966, entered into force on 3 January 1976.

[53] CESCR, General Comment No. 14 (2000) on the right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights), U.N. Doc. E/C.12/2000/4, 11 August 2000, paragraph 8. Another important element is access to health-related information for health decision-making (paragraphs 21–23) since information accessibility is a specific aspect of one of the four cornerstone elements of the right to health, namely availability, accessibility, acceptability, quality (paragraph 12).

[54] Report 2005, paragraph 87.

Since Professor Hunt called for an "urgent reconsideration [of this issue] with a view to better protecting, at the international and national levels, the right to informed consent" and for strict respect for "procedural safeguards protecting the right to informed consent",[55] his successor, Anand Grover, carried out an in-depth analysis of the evolution and the main components of informed consent in a report specifically dedicated to the topic, which was issued in 2009.[56] Grover's Report is particularly interesting because it represents an important systematic analysis of informed consent from an international viewpoint. The Special Rapporteur embraced the view that informed consent to treatment is a cornerstone of the right to health, stating that

> [g]uaranteeing informed consent is *fundamental to achieving the enjoyment of the right to health* through practices, policies and research that are respectful of autonomy, self-determination and human dignity. An enabling environment that prioritizes informed consent links counselling, testing and treatment, creating an effective voluntary health-care continuum. Safeguarding informed consent along the health-care continuum *is an obligation placed on States and third parties* engaged in respecting, promoting and fulfilling the right to health.[57]

It is to be noted, however, that throughout the whole Report the Special Rapporteur mainly focused on the obligatory aspects linked to informed consent, addressing the relevant duties incumbent on States in the perspective of fulfilling the obligations to respect, protect, and fulfil the right to health as interpreted and precised by the Committee.[58] This view is corroborated by the Rapporteur's conclusions recommending that national and international bodies "emphasize the importance of informed consent as a fundamental aspect of the right to health in relevant policy and practice" and "that States consider whether they are meeting their obligations to safeguard informed consent as a critical element of the right to health", since "guaranteeing informed consent is a fundamental dimension of the right to health" and "safeguarding informed consent along the health-care

[55] Report 2005, paragraph 90.

[56] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, U.N. Doc. A/64/272, 10 August 2009 (hereinafter 'Report 2009'), paragraph 9.

[57] Report 2009, summary, p. 2 (emphasis added).

[58] Report 2009, paragraphs 5, 18. This approach is consistent with the existence of indirect references to the rule of informed consent in the definition of State obligations stemming from Article 12 of the Covenant according to the traditional tripartite typology (to respect, protect, fulfil) employed in the language of the Committee, as well as in the relevant scholarship. In this respect see the indirect references to informed consent in General Comment No. 14, at paragraphs 34, 35, and 37: "obligations to respect include a State's obligation to refrain … from applying coercive medical treatments, unless on an exceptional basis for the treatment of mental illness or the prevention and control of communicable diseases. Such exceptional cases should be subject to specific and restrictive conditions, respecting best practices and applicable international standards … In addition, States should refrain from … censoring, withholding or intentionally misrepresenting health-related information … as well as from preventing people's participation in health-related matters. … The obligation to fulfil (promote) the right to health requires States to undertake actions that create, maintain and restore the health of the population. Such obligations include: … (iv) supporting people in making informed choices about their health."

continuum is an obligation placed on States and third parties engaged in respecting, promoting and fulfilling the right to health".[59] The Rapporteur's conclusions were further upheld by the Human Rights Council in a resolution of 2010, where all States were for the first time invited to "safeguard informed consent . . . as a critical element of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[60]

2.3 *The Emergence of the "Right to Informed Consent" as an International Human Right and its Relevance to Advance Directives Regulation*

Just as much as it is well-established in both domestic law and jurisprudence, the "right to informed consent" has gained prominence also at the international level and it can be argued that it has emerged as an international human right.[61]

Such an argument is not very common in the legal literature devoted to international biolaw and biorights.[62] In fact, scholars tend to use more vaguely worded expressions, stating that informed consent is a 'requirement' that protects the patients' fundamental rights to integrity and self-determination—of which it is also defined as a 'corollary'[63]—and that such 'requirement' is based on the principles of 'respect for persons' and 'respect for human dignity'.[64] Informed consent is also very often defined as a general and basic principle of biomedical law,[65] while sometimes it is referred to as a principle and a right at a time.[66] But it

[59] Report 2009, paragraphs 7, 93–94.

[60] Human Rights Council, Resolution 15/22, 30 September 2010, paragraph 4 (o) (adopted by consensus).

[61] See Negri (2011c).

[62] See, however, Boschiero (2006), p. 53, who states that the 'right to express an informed consent' is codified in the Universal Declaration on Bioethics and Human Rights.

[63] Boschiero (2006), p. 14.

[64] Kollek (2009), p. 126. Similarly, see Millns (2007), p. 79, who argues that "fundamental bio-rights and freedoms are to be respected *through the provisions governing the requirement to obtain an individual's free and informed consent* to medical interventions", and again she speaks of "the general consent requirements imposed by articles 5 and 6" (pp. 79–80); however, when dealing with the Charter of Fundamental Rights of the European Union, she recognises free and informed consent as one of the four basic principles provided by Article 3, adding that the "remit of these is striking in its overlap with that of the principles enshrined in the Biomedicine Convention" (pp. 80–81).

[65] See, for instance, Maljean-Dubois (2000), pp. 94–95; Boschiero (2006), p. 51. Andorno stresses the fact that in the Oviedo Convention, informed consent is "required for the first time as *a general principle* for any biomedical intervention", Andorno (2005b), p. 136, 138.

[66] Compare Tancredi (2004), p. 397, who observes that the 'principle' is considered the basis of the doctor–patient relationship, while, illustrating the relevant European case law, he refers to it as the 'right in question'.

also happens that only its negative element, that is to say refusal of treatment, is qualified as a right.[67]

This lack of unequivocal consensus as to the legal qualification of informed consent mirrors the lack of consistency that also characterises the international instruments of biomedical law. The Oviedo Convention, the first binding instrument to address the issue of consent in a detailed fashion, does not provide any specific legal qualification of informed consent within its text, while its Explanatory Report refers to it as a 'general principle' or a 'general rule' and qualifies as individual rights 'the patient's right to information' and 'the right to withdraw consent'.[68] The Unesco Declarations on Bioethics regulate consent under the rubric of both 'rights of the persons concerned' and 'principles'.[69] Moving to other relevant soft law acts, it is worthy of note that the WMA Lisbon Declaration on the Rights of the Patient articulates, within the right to self-determination, "the right to give or withhold consent to any diagnostic procedure or therapy",[70] while the WMA Declaration of Helsinki on Medical Research Involving Human Subjects, though expanding on consent in medical research, only provides that "the potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate".[71] On the contrary, the European Charter on Patients' Rights, inspired by the EU Charter of Fundamental Rights, proclaims a 'right to consent'.[72]

Although not perfectly coincidental, the views of the UN Special Rapporteurs on the right to health add some further useful hints. In fact, while in his report of 2005 Paul Hunt explicitly referred to a 'right to informed consent' and called for measures aimed at a better protection of that right,[73] Anand Grover's Report seemed to embrace a less clear-cut position, setting as its objective the analysis of "the fundamental role that informed consent plays in respecting, protecting and fulfilling the right to health".[74] Nonetheless, the Rapporteur explicitly mentioned a "right to consent" when referring to legal capacity, which confers on adults "the right to consent to, refuse or choose an alternative medical intervention"; in respect

[67] See e.g. Bompiani, Loreti Beghé, Marini, who define informed consent (as well as dissent), as the "expression" of the principles of autonomy and self-determination, while refusal of futile therapies is instead construed as a "right" (2001, p. 13).

[68] See the Explanatory Report to the Oviedo Convention, especially paragraphs 34, 40, 48, 101, and 136.

[69] See, respectively, Article 5 of the Declaration on the Human Genome and Human Rights and Article 6 of the Declaration on Bioethics and Human Rights. However, Article 9 of the former defined consent as a principle.

[70] WMA, Declaration on the Rights of the Patient, paragraph 3b.

[71] WMA, Declaration of Helsinki, paragraph 24.

[72] Active Citizenship Network, Europe Charter on Patients' Rights, Rome, November 2002, Article 4.

[73] Report 2005, paragraph 90.

[74] Report 2009, paragraph 5.

to "the need for special protections guaranteeing a woman's right to informed consent", especially in the field of sexual and reproductive health; concerning the fact that "the right to consent to treatment also includes the right to refuse treatment"; and with reference to those regional instruments that he considers to be the legal sources of such a right (i.e. the Oviedo Convention and its Additional Protocol on Biomedical Research, the EU Charter, and the EU Directive on Clinical Trials).[75]

In the light of the considerations above, it is possible to posit that an internationally protected human right to informed consent has emerged from the convergence of international human rights law and international biolaw over the same key objective: the protection of the integrity and inviolability of the human being. Moreover, despite its robust rooting in other basic human rights, the right to informed consent has come to live its own life and can be considered sufficiently independent of them. In fact, the scope of informed consent is broader and is not exclusively linked either to the right to health (not only is there a right to assent to or refuse medical treatment but also a right to consent to organs and tissue removal and donation or to participation in non-therapeutic experimentations, both being independent of any healing activity of direct benefit to the person concerned) nor to the right to bodily integrity (since not all interventions impinge on mental and physical integrity).

It could also be added that the non-derogable nature of the international human right to informed consent in respect of adult competent patients should be given paramount consideration in determining the legal value of advance directives.

From the standpoint of international law, advance directives lack any specific regulation and even in international instruments of soft biolaw express reference to them is really scant.[76] Notwithstanding its ambiguities and shortcomings, the pattern provided by Article 9 of the Oviedo Convention, as integrated by the Council of Europe's relevant resolutions,[77] is considered an important reference point to enhance the status of advance directive both at the global[78] and regional level. In fact, although the Convention has not yet been ratified by many of the European Union Member States, it is noteworthy that in a recent resolution on the situation of

[75] Report 2009, paragraphs 10, 20, 28, and 57.

[76] For example, the Amsterdam Declaration took into account "a previous declared expression of will" to the effect of preventing, even in situations of urgent need, the performance of a medical intervention based on a presumed informed consent when, according to such previous will, it is clear that the patient would have refused consent (paragraph 3.3).

[77] Committee of Ministers, Recommendation (2009)11 on principles concerning continuing powers of attorney and advance directives for incapacity, 9 December 2009; Parliamentary Assembly, Resolution 1859 (2012) on protecting human rights and dignity by taking into account previously expressed wishes of patients, 25 January 2012. See Andorno (2010), pp. 119–124, (2011); Di Stasi and Palladino (2013).

[78] See, for example, Beširević (2010), p. 107: "the standards concerning the role of precedent autonomy in treating incompetent patients, guaranteed in Article 9 of the Oviedo Convention could, at least potentially, be implemented on a territory much wider than the territory of the Council of Europe Member States".

fundamental rights in the Union, the European Parliament invited all Member States lacking a specific legislation on living wills to adopt such laws as necessary

> to ensure that, according to Article 9 of the Oviedo Convention on Human Rights and Biomedicine, 'the previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account' and *to ensure the right to dignity at the end of life*.[79]

Such a recommendation is remarkable because it associates respect for advance directives to a 'right to dignity at the end of life'. This element is particularly telling since it lends support to the argument that advance directives favour death with dignity inasmuch as they translate into medical instructions the patient's personal views, values, and beliefs as to their idea of a dignified death. This also means that through advance directives the patient has the opportunity to exercise two fundamental and non-derogable rights: the right to dignity and the right to informed consent.[80]

Therefore, since international law as it stands today posits that compulsory treatments or interventions, even if life-saving, are inconsistent and irreconcilable with the right to informed consent, the relevance of this right deserves adequate consideration as apt starting point for determining the legal value of advance directives from an international law perspective, as well as for assessing the consistency of relevant domestic regulation with international standards.

3 The Euthanasia Debate and the Right to Die with Dignity

3.1 Advance Refusal of Treatments and Requests for Euthanasia and Physician-Assisted Death

Advance care planning involves communicating one's directives on end-of-life issues, including withholding or withdrawing life-sustaining measures, refusing certain kinds of treatment, abandoning life-shortening pain and symptom management and sedation at the end of life. Such directives may also include requests for euthanasia and physician-assisted death, thus raising both legal and ethical dilemmas.

Actually, advance directives originated as a way to avoid the excesses of life-prolonging measures as provided by advanced medical technology and thus as a means of protecting patients from unnecessary prolonging of the dying process under conditions hard to endure or contrary to their own concept of dignity. This is the reason why instructional directives very often consist in the advance refusal of futile, disproportionate, or aggressive treatments and life-sustaining measures (such

[79] European Parliament, Resolution of 14 January 2009 on the situation of fundamental rights in the European Union 2004–2008, Official Journal of the European Union, C 46E/08, 24 February 2010, pp. 48–69, paragraph 167 (emphasis added).

[80] At least for adult competent patients, and where derogations due to emergency situations and public health interests do not apply, the non-derogable nature of informed consent is no longer controversial: see Wear (1992), p. 1.

as mechanical ventilation or artificial nutrition and hydration) or in DNR orders (i.e. 'do not resuscitate' orders amounting to a refusal of life-saving measures, such as cardiopulmonary resuscitation). Their rationale resides in the patient's will to escape the risk of being subject either to prolonged unbearable suffering or to a condition of mere physical survival devoid of any cognitive functions.

It must be stressed, in this respect, that while it is generally acknowledged that patient autonomy implies that no authority is entitled to deprive the individual of their right to choose what they deem best for themselves, including the right to refuse or halt medical treatments,[81] it is often questioned whether respect for this right should be disregarded when it leads to the patient's death. In this connection, a lively discussion has developed on the legal limits of patient autonomy in the practice of end-of-life care, that is to say whether autonomy encompasses the individual right to choose freely and knowingly to refuse treatment when this choice will have fatal consequences. The debate has focused on two major issues: whether there is a recognised right to die, or to die with dignity, and whether respect for individual autonomy may legitimise passive euthanasia and assistance to suicide at the request of a competent terminally ill or dying patient.

Domestic legislation and practice show that also in this respect the legal regulation of end-of-life issues offers a vast array of solutions differing from one jurisdiction to another[82] and that there seems to be no universal standard, except for the generally agreed view that non-voluntary and involuntary active euthanasia is outright prohibited as amounting to the offence of murder or manslaughter. Also international law, as it stands today, cannot yet provide any exhaustive and clear-cut answer to such challenging issues. It was in fact observed that euthanasia is one of the fields that have "largely eluded efforts of international regulation".[83] Therefore, since there are no existing international biolaw instruments that explicitly address euthanasia nor any human rights convention providing for a right to die, the euthanasia debate has essentially developed within the framework of the universal rights to life and to human dignity.

3.2 Euthanasia and Universal Human Rights

3.2.1 Euthanasia and the Right to Life

As a preliminary observation, it has to be noted that a clear distinction is made between the refusal or withdrawal of life-sustaining, life-prolonging, disproportionate, or futile treatments upon request or by will of the interested person

[81] See Europe Charter on Patients' Rights, Article 4; Amsterdam Declaration, paragraph 3.2; Report 2009, paragraph 28; UN Mental Illness Principles, paragraph 4.

[82] See Byk (2007).

[83] Schabas (2009), p. 445; see also Negri (2011b).

(including passive euthanasia or 'letting die') and the taking of action lacking medical, therapeutic, or palliative justification and the intending solely to terminate life (i.e. active euthanasia that is considered as amounting to an arbitrary taking of life contrary to international human rights law). Although generally agreed upon, such a distinction does not fall short of criticism on grounds that it may build on misleading arguments intended to separate morally justified deaths from morally unjustified deaths.[84]

The scope of self-determination in end-of-life care is deeply intertwined with the universal recognition of the value and protection of human life. Around this theme, two approaches based on different moral and philosophical rationale contrast each other in medical ethics: the 'sanctity of life' approach, according to which life is 'sacred' and valuable per se and is worth protecting independently of any physical disability or psychological deficiency; the 'quality of life' approach, which posits that life can be renounced when physical existence is not supported by mental and social qualities that make living meaningful for the interested person.

International human rights conventions protect the right to life as the "supreme right",[85] which is fundamental, indisposable, and inviolable even in times of public emergency or armed conflict,[86] that is to say a right that enjoys the status of jus cogens. Human rights treaties are couched in terms that clearly recognise that every human being has the inherent right to life, which is protected by law, and that "no one shall be arbitrarily deprived of his life"; they thus envisage only very limited circumstances where a person can be deprived of life (i.e. capital punishment), and no reference is ever made to assisted suicide or euthanasia.[87]

That said, the question was put whether the legalisation of euthanasia in some jurisdictions constitutes a dangerous violation of the most basic rules of human rights, in contrast with the international obligations assumed by those States. This problem was raised at the beginning of the twenty-first century in relation to the first two euthanasia laws adopted in Europe (The Netherlands and Belgium), since it was questioned whether they were compatible with the obligations arising from Article 6 ICCPR and Article 2 of the European Convention on Human Rights (ECHR).

As far as the Dutch law on euthanasia and assisted suicide of 2001 is concerned, its alleged incompatibility with Article 6 ICCPR was discussed at the UN Human Rights Committee on the occasion of its consideration of the periodic reports sent

[84] See Orentlicher (1998).

[85] The Human Rights Committee interpreted the right to life as "the supreme right from which no derogation is permitted": Human Rights Committee, CCPR General Comment No. 6: The right to life (art. 6), 30 April 1982, paragraph 1.

[86] See, in this respect, Article 15 of the European Convention on Human Rights, Article 4 of the International Covenant on Civil and Political Rights, and Article 27 of the American Convention on Human Rights.

[87] See, for example, Article 6 of the International Covenant on Civil and Political Rights, Article 2 of the European Convention on Human Rights, Article 4 of the American Convention on Human Rights, and Article 4 of the African Charter on Human and Peoples' Rights.

by the Dutch government. The Committee considered the ways the law was applied in light of the principle that

> where a State party seeks to relax legal protection with respect to an act deliberately intended to put an end to human life, the Committee believes that the Covenant obliges it to apply the most rigorous scrutiny to determine whether the State party's obligations to ensure the right to life are being complied with (articles 2 and 6 of the Covenant).

In its concluding observations, the Committee expressed its concern in respect of certain critical aspects of the application of the Dutch law (in particular, its applicability to children, the effectiveness of controls, the application of criteria for determining non-punishability), recommending that it be revised in the light of Article 6 ICCPR.[88] In this respect, the approach of the Committee was indeed 'soft', since it chose to avoid addressing the core question at stake and to pronounce itself on the outright incompatibility of the euthanasia law with the Covenant, merely criticising certain aspects of its implementation and the effectiveness of the relevant safeguards.

Also in considering the Swiss legislation on assisted suicide, the Committee limited itself to recommending that Switzerland

> consider amending its legislation in order to ensure independent or judicial oversight to determine that a person who is seeking assistance for suicide is acting with full free and informed consent.[89]

Along with the Committee's mild position, it should be remarked that also other UN human rights bodies (especially the General Assembly and the Human Rights Council) have remained completely silent on this topic, so that the debate on euthanasia and assisted suicide has mainly developed within the Council of Europe, whose organs have instead taken a clear stance against both active euthanasia, physician-assisted death, and the partial decriminalisation of mercy killing.[90] In fact, in the relevant documents approved on the subject, the Parliamentary Assembly clearly stated as early as 1976 that the physician "has no right, even in cases which appear to him to be desperate, intentionally to hasten the natural course of death".[91] It later recommended that States adopt all necessary measures to protect the fundamental rights of the terminally ill and dying patients, especially

[88] Human Rights Committee, Concluding Observations of the Human Rights Committee: Netherlands, CCPR/CO/72/NET, 27 August 2001 and Concluding Observations of the Human Rights Committee, CCPR/C/NLD/CO/4, 11 August 2009, paragraph 7.

[89] Human Rights Committee, Consideration of Reports Submitted by States Parties under Article 40 of the Covenant: Concluding Observations of the Human Rights Committee: Switzerland, CCPR/C/CHE/CO/3, 3 November 2009.

[90] Parliamentary Assembly, Verbatim Records: 2005 Ordinary Session (Second Part), 12th Sitting, Wednesday, 27 April 2005, e Doc.10455 on Assistance to Patients at End of Life, 9 February 2005.

[91] Council of Europe, Parliamentary Assembly, Recommendation 779 (1976) on the rights of the sick and dying, 29 January 1976, paragraph 7; Resolution 613 (1976) on the rights of the sick and dying, 29 January 1976.

> upholding the prohibition against intentionally taking the life of terminally ill or dying persons, while: i. recognising that the right to life, especially with regard to a terminally ill or dying person, is guaranteed by the member states, in accordance with Article 2 of the European Convention on Human Rights which states that 'no one shall be deprived of his life intentionally'; ii. recognising that a terminally ill or dying person's wish to die never constitutes any legal claim to die at the hand of another person; iii. recognising that a terminally ill or dying person's wish to die cannot of itself constitute a legal justification to carry out actions intended to bring about death.[92]

Even recently, it reaffirmed that "Euthanasia, in the sense of the intentional killing by act or omission of a dependent human being for his or her alleged benefit, must always be prohibited".[93]

Unfortunately, the active role played by the organs of the Council of Europe was not coupled with an unequivocal and authoritatively guiding case law of the European Court of Human Rights,[94] which has never declared euthanasia as being absolutely contrary to Article 2 ECHR, rather invoking the "margin of appreciation" doctrine to avoid taking a clear position on such a controversial matter.[95]

In conclusion, international practice, as expressed by the UN human rights bodies and by the Strasbourg Court, suggests that under present international law euthanasia is not to be considered absolutely contrary to the right to life,[96] which means that no universal prohibitive rule has emerged so far.

3.2.2 Euthanasia and the Right to Human Dignity

The role of human dignity in the context of end-of-life choices is crucial.[97] It is considered the unique universal value that inspires the major common bioethical principles, and it is therefore considered the noyau dur of both international biolaw

[92] Parliamentary Assembly, Recommendation 1418 (1999) Protection of the human rights and dignity of the terminally ill and the dying, 25 June 1999, paragraph 9.c.

[93] Parliamentary Assembly, Resolution 1859 (2012), supra note 77, paragraph 5.

[94] This aspect was highlighted also by the Committee of Ministers: see Parliamentary Assembly, Doc. 9404, 8 April 2002, Protection of the human rights and dignity of the terminally ill and the dying, Recommendation 1418 (1999), Reply from the Committee of Ministers, adopted at the 790th meeting of the Ministers' Deputies (26 March 2002), paragraph 11.

[95] See Schabas (2009), p. 445. In principle, the Strasbourg Court excluded the admissibility of derogations from Article 2 different from those expressly provided therein (McCann and others v. the United Kingdom, no. 18984/91, judgment of 27 September 1995, paragraph 147); however, the Commission had previously found that the failure of the Swiss legislator to criminalise passive euthanasia was not incompatible with Articles 2 and 8 of the Convention (European Commission on Human Rights, Widmer v. Switzerland, no. 20527/92, decision of 10 February 1993). The relevant cases decided by the Court are Pretty v. the United Kingdom, no. 2346/02, judgment of 29 April 2002; Haas v. Switzerland, no. 31322/07, judgment of 20 January 2011; Koch v. Germany, no. 497/09, judgment of 19 July 2012, Gross v. Switzerland, no. 67810/10, judgment of 14 May 2013.

[96] Focarelli (2009), paragraphs 30–31.

[97] See Andorno (2005a, 2009); Di Stasi (2011).

and international human rights law. Nevertheless, human dignity is a difficult concept to be defined, since it is often used in a rather vague and under-conceptualised sense.[98] Also in this context, dignity is invoked in support of contradictory arguments and rights claims, since both supporters and detractors of euthanasia appeal to the notion of human dignity arguing from completely different assumptions and pursuing opposite purposes. Following their arguments, dignity could justify both respect for life in the name of the principle of the sanctity of life and the right to euthanasia in the name of the principle of quality of life (which is translated into the right to live and die with dignity).

The vagueness of human dignity becomes problematic when it is put forward as a standard to evaluate individual conduct or public policies; it is deemed a potentially useful concept, but it calls for elaboration of more specific criteria that make it more meaningful for evaluative purposes.[99] Dignity as such does not provide any objectively assessable standard; to the contrary, it is a subjective, relative, relational, and holistic concept that provides an evaluation criterion that builds on the "lived experience" of the right holders and how they feel that their dignity is being affected. Therefore, since the interpretation and application of the right to human dignity in the context of euthanasia do not fall short of ambiguities,[100] it is claimed that the notion of dignity should be given a more concrete and less equivocal meaning in relation to end of life choices, especially in light of the fact that most of the legal considerations are developed around the question of whether or not there is freedom to give up one's life in the name of a right to a dignified death. In conclusion, the effective relevance of human dignity to the emergence of a "right to die with dignity" is highly debated and often considered overstated.[101]

3.3 The Controversial Emergence of a "Right to Die with Dignity" as Part of the Right to Personal Autonomy and Privacy

The recognition of the "right to die with dignity" is advocated with strength by those who claim that restrictive legislation is undemocratic, violates an individual's basic rights, discriminates unfairly against people who do not share certain religious beliefs, is inappropriate in a multicultural society, causes unnecessary pain and suffering, and is inhumane.

[98] According to Chapman (2011), pp. 3–4: "[w]hile human dignity is a powerfully evocative and widely accepted concept, it is elusive as to its precise meaning and requirements... there is the distinct possibility that not only the term human dignity may convey a multiplicity of understandings, it may even be referring to different things. ... A lack of clarity about the meaning of human dignity can relegate the concept to be used as little more than rhetorical dressing."

[99] Chapman (2011), p. 5, 10, and 12.

[100] Mathieu (2005), p. 72.

[101] See, in this sense, Amarasekara and Bagaric (2002).

Advocates of the right to a dignified death also try to add further strength to their arguments by referring to personal autonomy and private life. This approach was substantially supported by the Strasbourg Court in the case of Pretty v. UK when it found that "a person may claim to exercise a choice to die by declining to consent to treatment which might have the effect of prolonging his life",[102] conceding that personal autonomy may lead to choices that are not necessarily respectful of the concept of the inviolability of life:

> Without in any way negating the principle of sanctity of life protected under the Convention, the Court considers that it is under Article 8 that notions of the quality of life take on significance. In an era of growing medical sophistication combined with longer life expectancies, many people are concerned that they should not be forced to linger on in old age or in states of advanced physical or mental decrepitude which conflict with strongly held ideas of self and personal identity.[103]

These considerations led the Court to conclude that it was "not prepared to exclude" that the existence of a law preventing individuals from exercising their personal choice to avoid what they consider as an undignified and distressing end to their life would constitute an interference with their right to respect for private life.[104] The Court further developed this case law in Haas v. Germany and expanded on the relevance of the right to private life by acknowledging that an individual's right to decide in which way and at which time their life should end, provided that they he is in a position to form freely their own will and to act accordingly, is one of the aspects of the right to respect for private life within the meaning of Article 8 of the Convention.[105] This consideration was however 'mitigated' by the Court's placing special emphasis on two elements: the need to interpret Article 8 in light of Article 2 (right to life) and the absence of a general consensus among the Members of the Council of Europe as to the existence of a right to choose how and when to put an end to one's life. However, the Court concluded that, even assuming that States may be under an obligation to adopt measures facilitating a dignified suicide (and therefore to guarantee a "right to die with dignity"), this obligation had not been violated in the circumstances of that specific case (shifting again the attention to the States' margin of appreciation).[106]

The latest decision delivered in the case of Gross v. Switzerland was the object of fierce criticism because it was interpreted as opening up the door to the official recognition of a right to assisted suicide. In this case, the Court stated that the Swiss law does not provide sufficient guidelines ensuring clarity as to the extent of the right to obtain on medical prescription a lethal dose of a suicide drug. It accordingly found that there had been a violation of Article 8 of the Convention since this lack of clarity had caused the applicant a considerable degree of anguish in a situation

[102] Pretty v. the United Kingdom, supra note 95, paragraph 63.

[103] Pretty v. the United Kingdom, supra note 95, paragraph 65.

[104] Pretty v. the United Kingdom, supra note 95, paragraph 67.

[105] Haas v. Switzerland, supra note 95, paragraph 51.

[106] Haas v. Switzerland, supra note 95, paragraph 61.

concerning a particularly important aspect of her life. In this respect, the Court considered that the applicant's wish to be provided with a lethal dose of medication allowing her to end her life fell within the scope of her right to private life, though it did not take a stance on the merits of the question of whether she should have been granted the possibility to acquire that drug in consideration of her personal situation and health conditions.[107]

It follows from this case law that while a strict domestic criminal prohibition of euthanasia and assisted suicide is in accordance with the Convention, the question of whether the legalisation or decriminalisation of assisted suicide amounts to a human rights violation depends on a careful balancing of the State's positive obligation to protect the right to life and its obligation to respect the right to die with dignity, which can be derived from the right to respect for private life. It must be stressed, however, that this position only reflects the European perspective as expressed by the Strasbourg Court, and it cannot be considered as reflecting any general consensus on this issue, given that the variety of domestic legislations still testifies that there are no universally accepted norms to justify euthanasia or assisted suicide.

4 Palliative Care and the Right Not to Suffer

4.1 Objectives of Palliative Care

Palliative care is a specialised form of health care that aims to enhance the quality of life of patients who are faced with serious illness. In recent decades, the issue of pain treatment has reached worldwide recognition, especially in the framework of end-of-life care.

In the early 1980s, the Cancer Unit of the World Health Organization (WHO) began to develop a global initiative aimed to promote pain relief and opioid availability worldwide.[108] Some important achievements were reached, such as the progressive expansion of a worldwide network of national and international organisations designed to respond to the urgent need to develop and implement comprehensive programs of palliative care. Since then, enhanced cooperation between such organisations, health professionals, and the civil society has played a key role in promoting the development of these programs.[109]

[107] Gross v. Switzerland, supra note 95, paragraphs 63–69.

[108] Sepúlveda et al (2002).

[109] In fact, dissemination of palliative care and pain management has been conducted for several years through the work of both governmental organisations and NGOs, such as the WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the International Association for the Study of Pain (IASP), the International Association for Hospice and Palliative Care (IAHPC), the Global Alliance for Palliative Care (WPCA), the European (EAPC), Latin-American (ALCP) and African (APCA) Palliative Care Associations, and many other national associations operating in this sector. See Astudillo et al (2009).

In 1990, the WHO adopted a definition of palliative care according to which "palliative care is the active total care of patients whose disease is not responsive to curative treatment", also stressing that "control of pain and other symptoms, and of psychological, social and spiritual problems is paramount".[110] In 2002, the official definition was expanded pursuant to the idea that palliative care should not be relegated only to the later stages of care:

> palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.[111]

According to the WHO, palliative care's objectives are to improve the quality of life of the patient, to reaffirm the importance of life, to consider dying as a normal process without lengthening or shortening life, to provide relief from pain and other symptoms integrating the psychological and spiritual aspects of patient care, to offer a support system to help patients live as actively as possible until death, to support the family during the illness and bereavement.

As it can be inferred from the WHO definition and the basic principles that complete it, palliative care endeavours to provide a professional, scientific, and human response to the needs of all patients in advanced and terminal stages of illness. Its scope has extended from the treatment of patients affected by cancer to all medical contexts where there is a need to provide services to persons suffering from irreversible diseases, such as AIDS, neurological diseases, specific organic failures (kidney, heart, liver, etc.) in their final stages.[112] It follows that the primary purpose of palliative care is to provide comfort and improve or maintain the quality of life for patients not amenable to cure, that is to say terminally ill and dying patients. Its aim is to prevent or treat as early as possible the symptoms and side effects of serious illness, as well as all relevant psychological, social, and spiritual problems related to it. Moreover, although it is generally acknowledged that palliative care may have as side effect the acceleration of death (indirect euthanasia), it is not intended to hasten death and excludes active or passive euthanasia, nor is it to be equated to physician-assisted suicide. Rather to the contrary, it is argued that improvements in palliative care in fact render assisted suicide unnecessary and lessen requests for euthanasia.

4.2 A Human Rights Approach to Palliative Care: The Relevance of Universal Rights

As illustrated before, the concept of palliative care includes comprehensive, individualised, and continuous treatment of people with a limited life expectancy

[110] WHO (1990).

[111] WHO (2002).

[112] Fernández (2007), p. 145. See also Stjernswärd and Clark (2005).

through a holistic approach respectful of the dignity of patients and their right to self-determination.[113] A key point of this approach is the belief that every human being has the right to be treated with dignity and to die with dignity (although, as discussed before, this latter right is still considered controversial) and that the relief of pain—physical, psychological, spiritual, and social—is a crucial element in this process. A human rights approach to palliative care is therefore advocated to better understand which obligations are incumbent on States under international human rights law and which international standards are by now consolidated.

4.2.1 Palliative Care and the Right to Health (Including the Right to Access to Essential Medicines)

In order to examine palliative care in the human rights perspective, the first relevant norm is Article 12 ICESCR, notwithstanding this provision does not include any expressly mentioned 'right to palliative care'. According to the interpretation provided by the UN Committee in General Comment No. 14, "States are under the obligation to respect the right to health by, inter alia, refraining from denying or limiting equal access for all persons . . . to preventive, curative and palliative health services" and has also noted, with respect to the elderly, the importance of "attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with dignity".[114] In this regard, the UN Special Rapporteur on the right to health—who considered palliative care to be an issue requiring "urgent attention"[115]—asserted that palliative care "is absolutely crucial in order to prolong the lives of older persons affected by life-threatening diseases and to ensure their death in dignity".[116]

Furthermore, in accordance with General Comment No. 3,[117] the parties to the Covenant on Economic, Social and Cultural Rights have a core obligation to ensure the satisfaction of minimum essential levels of each of the rights enunciated therein, including essential primary care health. In light of this clear guidance, the

[113] The holistic approach that characterises palliative care is consistent with the definition of health provided in the WHO Constitution: "Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity". See Preamble of the Constitution of the World Health Organization, adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States in force from April 7, 1948, and amended by resolutions WHA26.37, WHA29.38, WHA51.23 WHA39.6 and the World Health Assembly

[114] General Comment No. 14, paragraphs 34 and 25, respectively.

[115] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/63/263, 11 August 2008, paragraph 50.

[116] Thematic study on the realization of the right to health of older persons by the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, A/HRC/18/37, 4 July 2011, paragraph 60.

[117] CESCR, General Comment No. 3, The nature of States parties obligations (Art. 2, paragraph 1 of the Covenant), 14 December 1990, paragraph 9.

Committee considered that the non-derogable core obligations stemming from Article 12—for which a State party cannot, under any circumstances, justify its non-compliance—include, inter alia:

> (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; … (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs; (e) To ensure equitable distribution of all health facilities, goods and services; (f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population ….[118]

With specific reference to palliative care, this means that States should ensure universal access to palliative care services, provide basic medications for pain relief, and implement specific policies of palliative care as a public health problem.[119] Therefore, governments should adopt and implement a strategy and action plan aimed to extend the treatment of pain and palliative care services, which, according to the WHO, should have priority status within public health programs of disease control. Furthermore, States are required to ensure an appropriate policy and regulatory system, develop plans for the implementation of these services, and take all necessary and reasonable measures, within the available resource, to carry out the plan.

As part of these basic obligations, States have to guarantee access to palliative medicines and provide opioid analgesics—which are included in the WHO List of Essential Medicines and are completely under governmental control—ensuring not only that these drugs be available in sufficient quantities but that they be also physically and financially available to those who need them. To achieve this goal, States should implement an effective system of supply and distribution and create a regulatory framework that allows public health systems, both in the public and private sectors, to obtain, prescribe, and dispense these drugs.[120]

The availability of opioid analgesics, such as morphine and codeine—which WHO has included in its Model List of Essential Medicines[121]—also depends on

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[118] General Comment No. 14, paragraph 43.

[119] See also Brennan (2007), p. 495.

[120] Lohman et al (2010). Since access to medicines is an integral and fundamental element of the right to health, governments and the international community as a whole have a responsibility to provide such access to everyone. The primary responsibility for expanding access to medicines rests, in any case, on the States. See Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health—Expert consultation on access to medicines as a fundamental component of the right to health, A/HRC/17/43, 16 March 2011; Human Rights Council, Resolution 15/22, The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/15/22, 6 October 2010. See also Brennan et al (2007), pp. 207–209; Gwyther et al (2009), pp. 770–771. For a comprehensive analysis of the obstacles to the provision of pain treatment and palliative care, see Human Rights Watch, "Please, do not make us suffer any more…" Access to Pain Treatment as a Human Right, 3 March 2009, pp. 19–43, 47–50, available at http://www.hrw.org/reports/2009/03/02/please-do-not-make-us-suffer-any-more.

[121] De Lima et al (2007).

the regime of international narcotics control, regulated by the UN Conventions.[122] The Single Convention on Narcotic Drugs of 1961[123] recognises in its preamble

> that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes.

Article 4 provides that

> The parties shall take such legislative and administrative measures as may be necessary. . . to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.

The Convention on Psychotropic Substances of 1971[124] used more or less the same terms in Article 5. But while the UN treaties on narcotics assert that the medical use of these drugs is legal and 'indispensable' to alleviate pain, in practice, many governments have implemented strict laws and policies that focus on drug abuse and ignored their obligation to ensure legitimate access to pain-relieving drugs. This problem has been addressed at different levels. The International Narcotics Control Board, the body charged with overseeing the implementation of the UN convention, stated in 1995 that the 1961 Convention

> establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs.[125]

In 1999, it recognised that

> outdated restrictive regulations and, more frequently, uninformed interpretations of otherwise correct regulations, misguided fears, and ingrained prejudices about using opioids for medical purposes continue to prevail in many countries.[126]

In the same direction, the Board stated in 2007 that it

> remain[ed] concerned about seriously low levels of consumption of opioid analgesics for the treatment of pain in many countries, particularly in developing countries. The Board again urge[d] all Governments concerned to identify the impediments that may exist in their respective countries with regard to the usage of appropriate opioid analgesics for the treatment of pain and to take measures to increase the availability of these drugs for medical purposes, in accordance with the recommendations of the WHO.

In the same year, in consultation with the INCB, the WHO established the Access to Controlled Medications, aimed to address all the identified obstacles to

[122] Heilmann (2010, 2011).

[123] Single Convention on Narcotic Drugs, signed in New York on March 30, 1961, in force since December 13, 1964.

[124] Convention on Psychotropic Substances, signed in Vienna on 21 February 1971.

[125] INCB, Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs, available at http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf.

[126] INCB, Report of the International Narcotics Control Board for 1999: Freedom from Pain and Suffering, available at http://www.incb.org.

the accessibility of controlled medicines, with emphasis on regulatory, attitudinal, and knowledge barriers.[127]

Other international bodies such as the Economic and Social Council of the United Nations and the World Health Assembly also called on countries to ensure an adequate supply of opioid analgesics. In its resolution 2005/25, the Economic and Social Council recognised the importance of improving the treatment of pain, including through the use of opioid analgesics, especially in developing countries, and called on Member States to remove barriers to the use of such analgesics taking fully into account the need to prevent their diversion for illicit use.[128] In May 2005, the World Health Assembly adopted Resolution 58.22 on the prevention and control of cancer, urging Member States to ensure the medical availability of opioid analgesics and requesting the WHO Director General to explore funding mechanisms for cancer prevention, control, and palliative care and to examine, together with INCB, how adequate pain treatment with opioid analgesics can be facilitated.[129] In addition, the special session of the Commission on Narcotic Drugs of the United Nations Office on Drugs and Crime, which took place on March 11, 2009, addressed the lack of access to medicines for pain relief in many countries, firmly stating the commitment of States to ensure an adequate supply of drugs for palliative care while preventing their diversion into illicit channels, in accordance with the treaties of international drug control.[130]

Also the Special Rapporteur on the right to health, in his 2010 report on international drug control, noted that

> Restricted access to opioids has an obvious impact on the availability of OST [Opioid Substitution Treatment] . . . However, there are three other primary areas in which access to controlled medicines is essential: (a) management of moderate to severe pain, including as part of palliative care for people with life-limiting illnesses.[131]

The Rapporteur therefore recommended to Member States to amend laws, regulations, and policies to increase access to controlled essential medicines and to the United Nations drug control bodies to "integrate human rights into the response to drug control in laws, policies and programmes" and to "formulate guidelines that provide direction to relevant actors on taking a human rights-based

[127] Joint report by WHO and INCB, Assistance Mechanism to Facilitate Adequate Treatment of Pain with Opioid Analgesics, 2 March 2007.

[128] Economic and Social Council of the United Nations, Resolution 2005/25, Treatment of pain using opioid analgesics, 22 July 2005.

[129] World Health Assembly, Resolution WHA 58.22, Cancer Prevention and Control, 25 May 2005.

[130] UNODC, Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem, 12 March 2009.

[131] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/65/255, 6 August 2010, paragraph 42.

approach to drug control, and devise and promulgate rights-based indicators concerning drug control and the right to health".[132]

4.2.2 Palliative Care and the Right to Freedom from Torture and Cruel, Inhuman, or Degrading Treatment

The concern of UN bodies and their insistence to adopt a human rights approach to international drug control are grounded on the consideration that non-compliance with the basic obligation to ensure access to palliative medicines constitutes both a violation of Article 12 ICESCR and a breach of the fundamental right to be free from torture and inhuman or degrading treatment as provided by Article 7 ICCPR.[133]

In this respect, the UN Special Rapporteur on torture explicitly stated that "the de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment".[134] In the same wake, together with the Special Rapporteur on the right to health, he issued a joint statement addressed to the Commission on Narcotic Drugs affirming that

> The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines – which include, among others, opioid analgesics – as part of their minimum core obligations under the right to health. Governments also have an obligation to take measures to protect people under their jurisdiction from inhuman and degrading treatment. Failure of governments to take reasonable measures to ensure accessibility of pain treatment, which leaves millions of people to suffer needlessly from severe and often prolonged pain, raises questions whether they have adequately discharged this obligation. Lack of access to essential medicines, including for pain relief, is a global human rights issue and must be addressed forcefully.[135]

The relevance of this approach is testified by the subsequent steps taken by the Special Rapporteur on torture. In particular, it is noteworthy that he issued a specific

[132] Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/65/255, 6 August 2010, paragraphs 76–77.

[133] The right to freedom from torture and inhuman or degrading treatment is also recognised by regional conventions: see Article 3 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950; Article 5 paragraph 2 of the American Convention on Human Rights of 1969; Article 5, paragraph 2 of the African Charter on Human and Peoples' Rights of 1981; Article 4 of the Charter of Fundamental Rights of the European Union of 2000. According to Somerville, failure to treat pain is also a violation of patients' autonomy and their right to self-determination: Somerville (1994); Amon and Lohman (2011).

[134] Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Manfred Nowak, A/HRC/10/44, 14 January 2009, paragraphs 72, 74 e).

[135] Joint Statement of the Special Rapporteur on the question of torture and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health to the Chairperson of the of the 52nd Session of the Commission on Narcotic Drugs, 12 December 2008, paragraph 3, p. 4.

Report on Torture in Health Care Settings that focuses on certain forms of abuses that may cross a threshold of mistreatment that is tantamount to torture or cruel, inhuman, or degrading treatment or punishment. In this report, the Special Rapporteur applied the torture and ill-treatment framework to the issue of denial of pain treatment and concluded that

> not every case where a person suffers from severe pain but has no access to appropriate treatment will constitute cruel, inhuman, or degrading treatment or punishment. This will only be the case when the suffering is severe and meets the minimum threshold under the prohibition against torture and ill-treatment; when the State is, or should be, aware of the suffering, including when no appropriate treatment was offered; and when the Government failed to take all reasonable steps to protect individuals' physical and mental integrity.[136]

Such an approach also finds support in some important statements of principle by the European Commission and Court on Human Rights, according to which lack of medical care in cases where someone is suffering from a serious illness or is exposed to 'severe or prolonged pain' could in certain circumstances amount to inhuman treatment contrary to Article 3 ECHR.[137]

4.3 The "Right Not to Suffer" as an Emerging International Human Right

In the last decade, there has been a widespread and growing support for recognition of palliative care status as a human right and States have been urged to fulfil their relevant obligations under international human rights law.

International organisations and the civil society advocate that palliative care be not considered a privilege for a few people but a right guaranteed at universal level. This view is based on the conviction that there is a basic right of the terminally ill and dying that guarantees respect for the fundamental and non-derogable right to human dignity. In this sense, although palliative care is generally described as an "inalienable element of the right of citizens to health care",[138] it is called for a

[136] Human Rights Council, Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez, A/HRC/22/53, 1 February 2013, p. 13, paragraph 54.

[137] European Commission on Human Rights, Tanko v. Finland, no. 23634/94, decision of 13 May 1994; European Court of Human Rights, McGlinchey and Others v. the United Kingdom, no. 50390/99, judgment of 29 April **2003**; see also N. v. the United Kingdom, no. 26565/05, judgment of 27 May 2008, where the Grand Chamber stated that "a lack of medical and palliative care . . . might be equally relevant to the finding of a separate potential violation of Article 3 of the Convention" (paragraph 21).

[138] Council of Europe, Recommendation Rec(2003) 24 on the organization of palliative care, adopted by the Committee of Ministers on November 12, 2003; see also Recommendation 1418 (1999), supra note 92.

consideration of palliative care in medical ethics not only as good medical practice but also as an imperative based on patients' rights,[139] including the right to a dignified death.[140]

It should also be noted that, following the seminal work of Margaret Somerville, a broad consensus has grown on the idea that the alleviation of suffering of the terminally ill is a human right[141] and that "the unreasonable failure to treat pain is poor medicine, unethical practice, and is an abrogation of a fundamental human right".[142] In the medical and legal literature an intense debate has developed to demonstrate effectively that this statement has a sound legal basis beyond rhetoric[143] and soft law.[144]

Still, it seems that the debate has focused in most cases on the assertion of a right to palliative care as a derivation of the right to health—and thus primarily based on Article 12 ICESCR, supported by the existence of the corresponding binding obligations clarified by the UN Committee in its interpretation of the normative content of the provision—while it seems clear that a broader right has emerged, that is to say the "right not to suffer", which is based on the inviolable principles of dignity, universality, and non-discrimination. According to a holistic approach, this right represents the synthesis of some fundamental rights applicable in the field of health care—human dignity, psychophysical integrity, health, freedom from torture or inhuman or degrading treatment—and is associated with the other basic patients' rights as recognised and protected by international human rights law.

[139] Brennan et al (2007), pp. 210–211: "Frustrated by the slow pace of medical, cultural, legal, and political change, many within the community of pain clinicians have begun to promote the status of pain management beyond that of appropriate clinical practice or even an ethic of good medicine. They advocate nothing less than a paradigm shift in the medical professions' perspective on pain management from simply good practice to an imperative founded on patient rights."

[140] Veronesi (2011), pp. 18–19. According to Brennan et al (2007), p. 210: "If there is a clear ethical duty to relieve suffering or to act virtuously by doing so, then one may argue that from that duty springs a right. The moral right to pain management emerges from, and is directly founded upon, the duty of the doctor to act ethically".

[141] Somerville (1992); "to leave a person in avoidable pain and suffering should be regarded as a serious breach of fundamental human rights" (Somerville 1995); "the relief of severe, unrelenting pain would come at the top of a list of basic human rights" (Cousins 1999).

[142] Brennan et al (2007), p. 205.

[143] Brennan (2007), p. 494.

[144] See, for example, The Declaration on the promotion of patients' rights in Europe of 1994; the European Charter of Patients' Rights of 2002; the Cape Town Declaration of 2002; the Declaration of Korea of 2005; the Montreal Statement on the Human Right to Essential Medicines of 2005; the Joint Declaration and Statement of Commitment on Palliative Care and Pain Treatment as Human Rights of 2008.

5 Concluding Remarks

Universal human rights like dignity, health, physical integrity, and freedom from torture or inhuman treatment have special relevance to the end-of-life debate. Indeed, exploring biomedical, ethical, and legal issues surrounding the end of life through a human rights approach is pivotal to assessing the emergence or affirmation of new international biorights.

In the domains of patient autonomy and end-of-life decision-making and care, such rights as the right to informed consent, the right to die with dignity, and the right not to suffer have emerged over the last decades and gained increasing importance in the international legal order, also imposing specific obligations on States in respect of any and all individuals under their jurisdiction. These rights have also contributed to the setting of generally accepted human rights standards that offer authoritative guidance to both domestic legislators (in their difficult attempt to provide a satisfactory normative regulation to bioethical questions) and judges (in interpreting national law in harmony with international biomedical and human rights law).

However, it is to be questioned whether they are merely aspirational or legally enforceable rights. Several scholars have criticised the lack of appropriate jurisdictional guarantees associated to the so-called rights of fourth generation, and many share the view that it is the national judge who is best entitled to satisfy the need for justiciability of bioethical rights.[145]

Despite the absence of specific protective machineries devised by the relevant instruments of international biolaw, international biorights are not completely devoid of protection. At the regional level, for example, it has to be stressed that while the Oviedo Convention does not confer any contentious competence on the Strasbourg Court, the jurisdiction of this Court can nonetheless be exercised every time the violation of the rights protected by the Oviedo Convention also amounts to the breach of one of the rights guaranteed under the European Convention on Human Rights (as the several cases concerning informed consent and assisted suicide show).[146]

The same paradigm may apply at the universal level, although it is to be noticed that the contribution offered by the UN treaty-based bodies so far is almost non-existent, given the paucity of relevant case law developed by the Human Rights Committee with regard to Article 7 ICCPR and the complete absence of case law on

[145] Chapter VIII of the Oviedo Convention articulates the obligations incumbent on States Parties to guarantee a right to justice through the provision of an appropriate judicial protection for unlawful infringements and threats of infringement of the rights and principles set therein (Article 23), the adoption of sanctioning measures (Article 25), and the effective guarantee of redress (Article 24). Article 29 only confers on the European Court the competence to deliver advisory opinions on general legal questions concerning the interpretation of the Convention independently of any judicial proceedings pending before national courts (see also the Explanatory Report, paragraphs 164–165).

[146] See, for example, Negri (2013).

Article 12 ICESCR due to the fact that the Optional Protocol to the Covenant only entered into force on 5 May 2013. In the alternative, relevant violations of international biorights could be denounced through recourse to the "special procedures" of the Human Rights Council and of the Special Rapporteurs on the right to health and on torture. Although unable to reach a binding decision, these mechanisms may contribute significantly to the promotion and protection of these rights, which mirror not only the ethical and legal imperatives shared by the entire human community but also the values accepted by the international community as a whole, as embodied in universal human rights instruments.

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Advance Health Care Directives Under European Law and European Biolaw

Charter of Fundamental Rights of the European Union, European Convention for the Protection of Human Rights and Fundamental Freedoms and Oviedo Convention

Angela Di Stasi and Rossana Palladino

Abstract This chapter focuses on Advance Directives at the "end of life" under European Law and European Biolaw with a special reference to some selected normative sources, namely the Charter of Fundamental Rights of the European Union (Article 3, paragraph 2, and Article 1), and to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) (Article 6 and Article 9), together with the undeniable contribution of the case law of the European Court of Human Rights concerning the application (and often only a request for application) of some articles of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR). In this respect, the Oviedo Convention represents the first attempt to provide a common binding framework at a European level in the field of Advance Directives. Although such Convention was drafted in the context of the Council of Europe (and has not been signed by the European Union), the work tries to highlight the importance that it may have in achieving a "European common approach" in the context of EU law, thanks to the "bridging role" played by the Strasbourg Court. The Human Rights approach—which is adopted in this work—is based on the conviction of the necessary interface between Bioethics and Human Rights, considering that biomedical issues, when they deal with fundamental values and rights, not only concern the biomedical field but also require the conceptual support of International Biolaw.

Professor Angela Di Stasi is the author of the Introductory remarks, of Part I and of Some conclusive remarks. Dr. Rossana Palladino is the author of Part II and of Some conclusive remarks.

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1 Introductory Remarks

The scientific and technological process—showing the extraordinary potentials that the new sciences have provided to men—and the partial overcoming of the so-called paternalistic model of physician–patient relationship have caused a sort of "eagerness of lawfulness" in relation to several needs of human beings, which are halfway between life and death.[1] It may influence the process of enlargement of the international "catalogues" of human rights[2]: it is indubitable, in fact, that the

[1] It is our translation of that "insistent eagerness of lawfulness" referred to by Amato (1988), p. 69. It is then one of the aspects of the wider problem about "what is the role of law in the age of technique". See, on this point, a well-known passage taken from the interview to Heidegger published in Spiegel on September 23, 1966, which is referred to by Resta (1999). For an investigation of this subject from the constitutional point of view, see, with special reference to euthanasia, Tripodina (2004), especially the Introduction. With specific reference to the living will and the proxy consent, see the same text on p. 103ff. About the necessity of continuous adaptation of law to the new scientific knowledge, see Feldman (2009). On the different meanings of science, see Boladeras (2004). On the idea of coproduction between science and law, see Jasanoff (2004).

[2] At least according to the prevailing approach of the European doctrine that includes those rights pertaining to Bioethics and Life Sciences among the so-called rights of third generation. As it is well known, the borders of the category of human rights have undergone significant reconsiderations in the context of a marked relativisation in a space-time sense. Once the rights of the individualistic tradition of the so-called first generation (i.e. civil and political rights) have been

categories of human rights, both of an internal and international source, represent an evolving list[3] continuously subject to modifications according to the new needs of human beings in the universal[4] and, with reference to the present work, in the regional European contexts.[5]

recognised, those of the "socialist" tradition of the so-called second generation (i.e. economic, social, and cultural rights) have been added, as well as further subcategories, among which there is first of all the one concerning the rights of the so-called third (and fourth) generation. See, in particular, Bobbio (1992), p. 27ff., and Barile (1991), p. 36. On "human rights between universalism, regionalisms and multiplicity of constitutions", we dare refer to Di Stasi (2011a), particularly on p. 125 and the following, as well as to Di Stasi (2004), particularly the introduction.

[3] It does not close the "catalogue" of human rights as the very new rights consecrated in a variety of international instruments issued over the last year (from the right to inhabiting to the right of protection of the young as regards compulsory education in the social Charter revised by the Council of Europe, from the prohibition of eugenic practices to the right of protection of personal data in the Charter of Fundamental Rights of the European Union, joining the rights already codified some decennia before). It is not meaningless that the "lists" of rights themselves, included in some international conventions on human rights, are usually enlarged by the State parties through the execution of additional protocols that enrich the original catalogue of rights. Let us remember, with reference to an extra-European agreement, that the American Convention on Human Rights was integrated by the Protocol of San Salvador concerning economic, social and cultural rights as a meaningful proof of the overcoming of the old dichotomy between these rights and the civil and political rights already consecrated in the conventional text. Art. 26 of the Convention of San Josè occupied the whole chapter III with a discipline merely programmatic as regards economic, social, and cultural rights. But within a European context, too, we refer to a large number of protocols that have enlarged the catalogue of rights included in the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) dating back to 1950.

[4] The indivisibility of human rights, together with universalism, represents one of the most significant achievements of the World Conference on Human Rights, Vienna, 14–25 June 1993. See United Nations, Doc. A/CONF.157/PC57, Doc.A/CONF. 157/PC58, Doc.A/CONF. 157/PC59. In the Universal Declaration of Human Rights (1948)—on which see below—the search for a common vision of human rights that can be accepted by all the States of the international community had led to the adoption of the western catalogue of rights. Based on the relationship of State–individual, it was linked only to the respect of civil and political rights, with the inclusion of the right to ownership and the exclusion of peoples' rights. The International Covenants—the drafting of which had started, as it is known, together with that of the Universal Declaration—by specifying the categories of rights included in it, overcame the opposition of a hierarchical kind between the category of civil and political rights and that of economic, social and cultural rights, hoped for by an intense normative activity of the General Assembly. The conception of human rights as "indivisible, interdependent and intrinsically connected with each other" (as it is underlined in the Word Conference on Human Rights of 1993) is also assumed within the normative activity of the institutions of the European Union. This is witnessed, in particular, by the catalogue of human rights included in the Charter of Fundamental Rights of the European Union (Nice 2000—Strasbourg 2007)—to which we refer below—which, by completely overcoming the bipartition between the two macro-categories of rights that characterised the original Project, classifies them as fundamental "values" corresponding to the headings of dignity, freedom, equality, solidarity, citizenship, and justice. The statement of the indivisibility of human rights within the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) appears to be harder, since it privileged only civil and political rights in the original text.

[5] See Andorno et al. (2009); Campiglio (2012); Sassi (2012), in particular pp. 326–328. As it is well known, among the European countries, The Netherlands was the first country to legalise assisted suicide and euthanasia (law dated April 12th 2001, come into force since April 1st 2002).

Moreover, the constant progress of medical science and health technologies implies big opportunities, as well as big challenges to the health systems of the Member States also in terms of the best scientific evidence derived from sound data and information and relevant research.[6]

In the mingling between public and private demands and needs, which distinguishes such sectors, the new frontiers of (Bioethics and) Biolaw are characterised in general by a strong need for normativisation implying a difficult definition of the limits to be imposed on the so-called sovereignty of the individual over his body.[7]

With reference to the "end of life" choices and with specific regard to the debate on Advance Directives[8] Regulations, such call for normativisation could not but have to do with a search for a consultation of a wide range of stakeholders and for a more or less "shared" social consensus.[9] In particular, aside from the recourse to more or less structured deontological norms,[10] the lack of such

[6] So White Paper, Together for Health: A Strategic Approach for the EU 2008–2013, COM (2007), 630 final, para.1.

[7] In the Italian law literature see, among others, Bompiani et al. (2001); Boschiero (2006); Marini (2013); Francioni (2007). See, particularly Saulle (1997). For an interdisciplinary approach, see the huge treatise directed by Rodotà and Zatti (2010), and with regard to the subject of this chapter see especially volume V, edited by Ferrara (2010).

[8] In the present work, we use the expression "Advance Directives", being fully conscious that scholars also refer to them as "Advance Declarations" or "Advance Decisions". See, on this question, the opposite position of Marini (2009), introduction, pp. XXIV. On the different meanings of these wordings, see Barni et al. (2004). In the civil law and common law systems—which have provided normative solutions to the problem—many "generations" of advance directives can be identified (from the first living wills to a prototype of "third generation directive").

[9] If the juridical norm generally "acknowledges needs, spurs and evaluations coming first and outside the world of law, according to a preliminary building process of social consensus" (so in Il riconoscimento e la tutela dei diritti fondamentali dell'uomo rilevanti in ambito biomedico, in Bompiani et al. (2001), p. 81) even more in the field of the Sciences of Life, the production of norms requires a larger democratic participation and "sharing". On shared or "by intersection" consent, see Prodromo (2010), p. 180 (referring to Rawls). On the necessity that the questions raised by the developments of biology and medicine can be the subject of a public debate, see Article 28 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine (see below). It provides that:"Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation". About the contrast between law in books and law in action, see Madoff (2005).

[10] The Italian Code of Medical Ethics recognises the principle of informed consent and the duty to a patient's previously expressed wishes. Article 30 stipulates that physicians must fully inform patients about proposed treatments. Article 32 specifies that physicians are to stop diagnostic testing and/or medical treatment upon receipt of a patient's documented refusal. Article 14 specifies that physicians must not provide futile treatment (i.e., treatment that fails to improve health or quality of life). Although deontological norms are now considered as real, binding juridical norms (and might also be reversed by the Court of Cassation), they only apply to the members of the relevant professional associations.

consensus delays or hinders the "legislator's" activity, at both the international and national levels.[11]

As it is well known, European States share a substantially uniform position as to the exact definition of the notion of death, which is considered as brain death.[12] However, the aspiration of individuals (and of their relatives) to orient "end of life" choices by extending the decision-making autonomy even to such a really delicate moment of a man's existence does not find any univocal solution either in national or in international and European legal systems. The situation in the European States is very diverse, ranging from no legislation whatsoever on Advance Directives to specific legislation that confers binding effect on them.[13]

This lack of univocity is the consequence of the necessary collocation of such question within the wider context of the respect of the "sacred nature" of life[14] or, at

[11] As it is shown—just like it happens in other legal systems—by the difficult course followed by the Italian Draft Bill concerning "Disposizioni in materia di alleanza terapeutica, consenso informato e dichiarazioni anticipate di trattamento", which has been approved by the Senate and amended by the Chamber of Deputies. See, as regards the normative solutions experimented in other countries, dossier no. 104/2009 drawn up by the Servizio studi del Senato della Repubblica (available online at the web site www.senato.it) and entitled "La disciplina sul testamento biologico in alcuni Paesi (Francia, Germania, Regno Unito, Spagna e Stati Uniti)". At present, therefore, the only law in force (since May 16, 2003) is Law No. 41 of Novembre 14, 2002, concerning "Disposizioni di legge per la regolamentazione dell'autonomia del paziente nonché dei diritti e degli obblighi in materia di informazione e documentazione clinica". Moreover, Law No. 6 of January 9, 2004, concerning "Introduzione nel libro I, titolo XII, del codice civile del capo I, relativo all'istituzione dell'amministrazione di sostegno e modifica degli articoli 388,414, 417, 418, 424, 426, 427 e 429 del codice civile in materia di interdizione e di inabilitazione, nonché relative norme di attuazione, di coordinamento e finali", permitted a judicially appointed guardian ("amministratore di sostegno") to make decisions for an individual. Some scholars (see Carlassare (2009)) argue that a law about the Advance Directives is superfluous "dal momento che, come hanno riconosciuto non solo i giudici ma la stessa Corte costituzionale pronunciandosi sul conflitto d'attribuzione sollevato dal Parlamento (ord.n. 334/2008), il diritto è sicuro e . . . una esplicita legge sulle dichiarazioni anticipate di trattamento. . .non è strettamente necessaria per poter riconoscere validità a quanto una persona abbia precedentemente dichiarato per farlo valere nel momento in cui dovesse perdere per sempre la capacità di intendere e volere". In the same way, much perplexity about a possible "intervento legislativo affrettato e non condiviso", taking into account the fact that "l'attuazione di una futura legge in materia difficilmente potrà fare a meno del contributo interpretativo del giudice", is expressed by Marini (2009), p. XXVI. For a quite critical point of view on the so-called Italian Draft Bill, see Carusi et al. (2012). See also Agosta (2009) and Penasa and Corn (2010).

[12] See art. 1 of Law No. 578 dated 29 December 1993, concerning the "Norms to ascertain and certify death".

[13] As it is provided by Resolution 1859 (2012) of the Parliamentary Assembly of the Council of Europe (para 5), of which see below part II, para 4.2. For an International, European and Comparative examination of Advance directives, see Negri (2011a). In the same collection, see Andorno (2011).

[14] Both in the light of the moral Hebrew-Christian tradition and of the laic idea of the "sacred character" of biological life.

least, of the collocation of "life" between the self-determination and the dignity of the human being.[15] It is undoubted, in fact, that Advance Directives at the "end of life" affect those fundamental rights and values of the individual that are potentially even opposed to each other and, above all, the respect of dignity and identity of the human being.[16] Among others, there are the prohibition of degrading treatment, the right to life, the right to privacy, and the right to make individual choices (self-determination). In particular, they state a suitable consideration of a free and informed consent, a fundamental principle concerning health protection whose sources have by now overcome the borders of the national legal system as also witnessed by the Italian Constitutional Court.[17]

How is it possible to strike a fair balance,[18] under European Law and European Biolaw, within the context of a right that is defined as "hard"?[19]

The purpose of this work is to examine the Advance Directives at the "end of life" under European Law and European Biolaw with a special reference to some selected normative sources, namely the Charter of Fundamental Rights of the European Union (Article 3, paragraph 2, and Article 1) and to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) (Article 6 and Article 9), together with the undeniable contribution of the case law of the European Court of Human Rights concerning the application (and often only a request for application) of some articles of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR).

In this respect, the Oviedo Convention represents the first attempt to provide a common binding framework at a European level in the field of advance directives.

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[15] See, for a mostly internal perspective, Mirzia (2011).

[16] We dare refer to Di Stasi (2011b) and to Di Stasi (2013).

[17] See Constitutional Court, Judgment No. 438 of 15 December 2008, available online at www.cortecostituzionale.it. In this judgment (drawn up by Judge Saulle), the need for the patient's informed consent to medical treatments is traced by referring not only to domestic sources but also to Article 24 of the Convention on the Rights of the Child, of Article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, of Article 3 of the Charter of Fundamental Rights of the European Union. The Constitutional Court refers to then jurisprudence of the Court of Cassation (sentence dated October 16th 2007, nr. 21748) that had based the informed consent on the same articles, basing it on the legitimisation of any medical intervention. On free and informed consent, see a wide account in Negri (2011b).

[18] Balancing is a necessity in the complex bioethical questions surrounding the beginning and end of life. See Chieffi and Giustiniani (2010), p. 8. They argue that " Il biodiritto, in particolare, mostra le difficoltà di pervenire ad un giusto punto di equilibrio tra legittimo esercizio della libertà di scienza e il doveroso ossequio ai cosiddetti diritti fondamentali dell'essere umano che i rinvii alla dignità, e soprattutto alla persona, del nostro edificio costituzionale ribadiscono".

[19] This unusual term is used by Rodotà (2007), p. 375, where the term "hard" right stands for a right that "does not send life off from itself, but tries to penetrate it, a right which does not fix an unchangeable rule but outlines a procedure for the continuous and joint involvement of different individuals" (our translation from the original into English). About the limits of the International Law as regards euthanasia, see Negri (2011c).

Although such Convention was drafted in the context of the Council of Europe (and has not been signed by the European Union), we will try to highlight the importance that it may have in achieving a "European common approach" in the context of EU law, thanks to the "bridging role" played by the Strasbourg Court.[20]

The Human Rights approach—which is adopted in this work—is based on the conviction of the necessary interface between Bioethics and Human Rights, considering that biomedical issues, when they deal with fundamental values and rights, not only concern the biomedical field but also require the conceptual support of International Biolaw. It states the overcoming of oppositions between the progress of science and knowledge and the protection of human rights; it also identifies, in the existing and—above all coming—instruments of (International and) European Law and Biolaw, the attitude to generate a dynamic process giving an increasing role to individuals in the international society,[21] a dynamic process that for countries with no specific legislation in matter involves "consultation of all the stakeholders before the adoption of legislation in parliament and foreseeing an information and awareness-raising campaign for the general public" while for countries with a specific legislation in matter involves "that the general public ... is sufficiently aware of it and implements it in the practice".[22]

This work, within a general context, is the product of a joint research at the same time branching off in different investigation fields.

[20] See European Parliament resolution of 14 January 2009 on the situation of fundamental rights in the European Union 2004–2008, para 167, which contains the invitation " ....to those Member States who have not yet done so to introduce legislation on living wills to ensure that, according to Article 9 of the Oviedo Convention on Human Rights and Biomedicine, "The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account" and to ensure the right to dignity at the end of life".

[21] We refer to an international society as universal society where "a continuous relationship of material and spiritual exchanges exists, through which the whole mankind shows itself to be a society that civil development tends to make more intense" or a society that identifies itself "in order to find its own raison d'être or to portrait its way of being according to the existence of independent or sovereign entities" and therefore international society or community in its own sense (our translation from the original into English). Then the classical realistic approach of Quadri (1968), p. 19. See the enlightened reflections by Ziccardi (1964), p. 1004, where, with reference to a pluralistic conception, the distinguished Author defines a legal system as "any environment of social coexistence, both among individuals, and groups of already associated individuals, admitting their unlimited multiplicity", and also by Ziccardi (1962), p. 79, where the existence of "a universal, naturally juridical community, the norms of which are meant both for single individuals and States" (our translation from the original into English) is emphasised. About the mixed international community, as society of States and individuals, see particularly Leanza and Caracciolo (2012), with specific reference to chapter 4: "Oltre la soggettività internazionale: i beneficiari delle norme internazionali". See also Di Stasi (2011c).

[22] See Resolution 1859 (2012) of the Parliamentary Assembly of the Council of Europe, para.6.

2 Part I

2.1 The Predictable Lack of Norms That Attribute Explicit Competence in the Field of Advance Health Care Directives in the Treaties of the European Union

In the treaties of the European Union, as it is well known, there is the lack of a norm attributing some competence to the European institution in the field of Advance Directives and, more in general, in the sector of bioethics. The references themselves to the protection of health, contained in the primary law of the EU (Article 168 of the Treaty on the Functioning of the European Union/TFEU), do not allow a primary attribution of competence coming from them to EU institutions; indeed, the primary responsibility for the organisation and delivery of health care is still left to each Member State.

On the other hand, the theme of the Advance Directives can be hardly referred to the "modern" right to health, as positive right, frequently termed as "social-economic" right. More easily such issues can be referred, instead, to a "negative" right as the right to personal integrity or the right to life (in all its implications).

It is the logical consequence of the exclusion of such fields of the so-called Sciences of life from the range of objectives of a possible international organisation action, like the European Union, aiming at privileging, up to date, the economic dimension of integration or just some forms of political integration that leave these material fields out.

However, the increasing importance of the protection of fundamental rights within the legal system of the European Union[23] and the emerging area of "health and human rights", as a new area of human rights law,[24] is bound to make such sectors a subject to be focused on by the law of the European Union. In addition to this, there is an increasing attention given, in the legal system of the European Union, to the person as an entity having needs over and above the field of economic integration. The individual, from being a "productive factor", in the first stage of the European integration process, aims at assuming importance as person involved in subjective juridical situations, even not strictly linked to the working of the market.

As it is well known, the Treaty of Lisbon provides the respect for human rights as founding principle of the European Union, according to Article 2 of the Treaty on European Union (TEU), a value influencing the adhesion of the new member States (Article 49 of the TEU), to be promoted in all fields of international relations (Article 21 TEU). Moreover, the same Treaty identifies such respect in the whole of "rights, freedoms and principles" set out in the Charter of Fundamental Rights of

[23] See Di Stasi (2011a), part II, cap. 3.

[24] See, inter alia, Rothmar Herrmann and Toebes (2011); Mchale (2010). As it is well known, the EU has a mandate to complement national action on health, while an effective health policy must involve all relevant policy areas.

the European Union being in force by now[25]: a Charter that the European Union recognises (Article 6, para. 1, TEU) through a material or receptive reference to it.[26] In the same Treaty, the adhesion of the European Union to the ECHR is also provided, with the consequence, after this adhesion has been completed, of being forced to respect, as "high contracting party", the catalogue of rights and to guarantee the freedoms contained in it.

Within a more general attention of the European Union, which "places the individual in the heart of its activities",[27] a circumstance being particularly useful to develop some innovation characteristics, as regards the Advance Directives, represents the coding of a catalogue of fundamental rights concerning all aspects of an individual: the Charter of Fundamental Rights of the European Union.

2.2 *The Charter of Fundamental Rights of the European Union (Article 3, n. 2, and Article 1)*

As it is well known, the equalisation of the legal value of the Charter of Fundamental Rights of the European Union with that of the TEU and TFEU (Article 6, para. 1) gives a full normative relevance to its articles.[28] Moreover, the potential of the EU's accession to the European Convention of Human Rights to achieve a more harmonious and convergent human rights system in Europe likely causes effects even as regards the interpretation of the few norms of the EU that can be referred to as regards the "Sciences of life".

The Charter consists of a Preamble and seven titles, the final of which is devoted to the General Provisions Governing the Interpretation and Application of the Charter.[29]

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[25] The Charter was published for the first time in Official Journal of the European Communities C 364, 18 December 2000, which regards, as it is well known, non-binding acts. In a modified version, it has been again proclaimed by the European Union, the Council and the Commission, in Strasbourg on December 12th 2007, and it has been published together with the "Explanations" in Official Journal of the European Union C 303, 17 December 2007. In the huge literature existing about the Charter, see de Kerchove et al. (2000); Bond (2001); Ferrari et al. (2001); Panebianco (2001); Pocar (2001); Comba (2002); Rossi (2002); Toniatti (2002); Walker (2002); Siclari (2003); Peers (2004); Ruggiero (2004); Bisogni et al. (2009); Di Federico (2012). See, infra part 3, para 3.1 and 3.3.

[26] Here it can be considered as receptive reference; after that Article 6, para. 1, is shown as not being possible to represent a norm on juridical production, Daniele (2009), at p. 243.

[27] So Preamble to Charter of Fundamental Rights of the European Union.

[28] See the treaties in Official Journal of the European Union, C 83/389, 30 March 2010. See, as regards a selection of jurisprudential decisions on the subject, Panebianco (2001), pp. 50–60; Panebianco and Buonomenna (2005), p. 249 and the following.

[29] Within it 54 articles can be found, while, in the light of the consciousness of the indivisible character of human rights, the previous conception of the Project as being double divided into articles about civil, political, and citizens' rights and economic and social rights has disappeared.

The titles, numbered one to six, are focused on some fundamental values: dignity (I), freedom (II), equality (III), solidarity (IV), citizen's rights (V), and justice (VI).

The "statute" of fundamental rights, developed in the Charter, undoubtedly shows an intention of reaffirmation, as the Preamble says, of the fundamental rights deriving from five normative sources and two jurisprudential "sources", which are expressly referred to. It is a Charter that does not want to be an autonomous source of production but rather of review of rights consecrated in other sources[30]: in this sense it intervenes as a "reinforced" source, with clear reference to jurisprudence, by making recourse to a method of common law that, being not only a fixed but also a moving reference, ensures its permanently developing condition.

Also the Charter not only shows a reaffirmation character. From one side the reviewing activity, made according to five normative sources and two jurisprudential "sources", also causes ius novum. At the formal level, a sui generis "legislator" could not but cause a sui generis receptivity: a catalogue of rights that, even if it was the reproduction of other pre-existing catalogues, distinguishes itself for its "added value".[31] Moreover, just the influence of the development of jurisprudence the European Courts and of the national Courts, and in general of the Community acquis, would be reason for the inclusion of some "new" rights, at least as regards the drawing up of the expressed juridical positions (and, among them, particularly some rights concerning the Sciences of Life).

A non-complete receptivity is also confirmed by the strong developing character that, as the Preamble of the Charter says, distinguished the Charter itself, according to the so-called historical character of rights, intended as their changeability as an effect of their gradual differentiation and specification, "in the light of changes in society, social progress and scientific and technological development".

The Charter is not only a substantial catalogue of rights. It is also the result of the purpose, already characterising the works of the Convention, of laying down a text "as it had to be integrated within the Treaties". This explains the existence, in Title VII, of the General Provisions that seemed to aim, still before the Charter became binding, to guarantee its coexistence within the national-Community-European-international acquis.[32]

These substantial and procedural characteristics of the Charter—and above all its being the result of a positivisation of the fundamental rights of the European Union based on the reception of the above-mentioned development of law renewal—ensure, in relation to the subject under discussion, some of its application potentials.

In particular, in consecrating "the right to respect for his or her physical and mental integrity" (para. 1) in the fields of medicine and biology (para. 2), Article 3

[30] See, in particular, Barbera (2001). On the sources of the Convention, we dare refer to Di Stasi (2011a), pp. 250–252.

[31] Communication of the Commission about the nature of the Charter dated 11 October 2000.

[32] V. art.51, 52, 53, 54. See, inter alia, Garcia (2002).

of the Charter provides "the free and informed consent of the person concerned, according to the procedures laid down by law" (first alinéa).[33] The innovative character of this norm cannot go unnoticed, since its difficult aim is that of making controversial subjects fall within the range of the fundamental rights of the European Union, even if they are the subject of a recommendation or of special conventions binding more or less large groups of States (as the above-mentioned Convention on Human Rights and Biomedicine that is expressly referred to in the Explanations of Article 3).[34]

The general character of the article may understate the regulation's innovative character; when the Charter faces highly controversial and ethically sensitive subjects, "it has to be limited to the formalization of those few principles on which all legal systems of the Member States converge".[35]

If its content does not greatly wander off the provision of the already-mentioned Convention, the inclusion of such norm in the Title devoted to dignity is very meaningful. The right to respect physical and mental integrity (Article 3, para. 1) becomes (in para. 2 of the same norm) the guarantee of a number of corollaries of human dignity, among which there is "the free and informed consent of the person concerned", as influence of the government on its body; however, as regards the ways in which it is manifested, we refer "to the procedures laid down by law".[36]

As a matter of fact, in the Charter of Fundamental Rights of the European Union the Advance Directives at the "end of life" can find a broader framework just in the protection of dignity: it becomes part of Title I, while human dignity becomes the heading of Article 1, which states "Human dignity is inviolable. It must be respected and protected".[37] It is not consecrated as a right to dignity, but it is set up as a general clause, implying the recognition of the character of an inviolable, juridically protected, good.[38] In the same Title 1 dignity is specified, with reference to the specific subject of this work, as the "Right to the integrity of the person" (Article 3), which, at no. 2 (para. a), includes "the free and informed consent of the person concerned, according to the procedures laid down by law". It also appears in

[33] See Bifulco (2001) and Patrone (2009).

[34] While the provisions of art.3 are based on the mentioned Convention on Human Rights and Biomedicine, they are similar to the character of the Charter being more general and of a perfunctory kind. See below part 3, para 3.1–3.3.

[35] See Bifulco (2010), in particular p. 20.

[36] About the link between dignity and respect of the oneness of the individual, his identity, and self determination, see Rodotà (2006), p. 40.

[37] See the vibrant criticism expressed by Grossi (2003) on the editing technique adopted, which would make some provisions of the Charter merely rhetorical. See also Palermo (2003); Bifulco (2004); Resta (2010a), p. 287, where the EU Charter is considered as "one of the most advanced international instruments as regards human rights and a . . . necessary point of reference for the construction of a European system of biolaw".

[38] We must not forget that the respect for human dignity assumes, in the same treaties, the role of a founding value of the European Union (Article 2 TEU) and also a principle of the Union's external action (Article 21, para. 1).

the Preamble, where human dignity is mentioned as the first value among the "indivisible (and) universal values" on which the European Union is founded.

It is evident that in devoting the heading of Title 1 to dignity (before the Title II "Freedoms" and the Title III "Equality")[39] and adding to it, as incipit, Article 1 in its wide conception, the Charter of Fundamental Rights of the European Union confers on it an almost "holy character": it makes it become a sort of "sanctuary" implying that the human person, since it is a unique and unrepeatable being, able of self-determination, is the holder of a value transcending any condition in which he could find himself.[40] But the Charter does not limit itself to assigning to dignity the rank of character indelebilis,[41] that is, to recognise it, as the Explanations to Article 1 of the Charter of Fundamental Rights state, "not only [as] a fundamental right in itself but [as] … the real basis of fundamental rights".[42] Besides, its peculiar systematic choice of assigning to it "the axiological presumption of fundamental rights"[43] (thus anticipating its provision, compared with the same "right to life" provided in Article 2), apart from using the category of inviolability only for itself, adds a specification of such value through the following norms and, with reference to the subject of this writing, to the already-mentioned "right to the integrity of the person".

The norms referred to, within the above-mentioned limits of the content, represent a reference normative ground, also referring to the Advance Directives. However, we cannot forget, in any case, that the Charter does not create new competencies but imposes certain restrictions on the EU's institutions in exercising the competencies allocated to them by the Treaties; it imposes certain restrictions on States when acting within the scope of EU law, i.e., when implementing EU law or applying it.[44]

[39] On the so-called triangle of Constitutionalism, see Baer (2009).

[40] See Olivetti (2001). The term "sanctuary" is used in this work. It is not to be forgotten that in the Charter there are further references to dignity concerning its disciplined applications, with reference to specific categories of individuals: see Article 25 devoted to "the rights of the elderly", which also provides … "to lead a life of dignity".

[41] For this definition, see Pistorio (2009), in particular, p. 39.

[42] See Official Journal of the European Union, C 83/02, 30 March 2010. On the Explanations, we dare refer to Di Stasi (2010a, b). On the subject, see a specially critical comment by Sciarabba (2008), section V "Il problema delle "spiegazioni" della Carta", p. 229, and Sciarabba (2005). A really different opinion is that expressed by Sandro (2009).

[43] So Silvestri (2007), p. 2.

[44] So art.51 of the Charter.

2.3 The Derivative Character of the Charter from the Main Source of Reference (European Convention for the Protection of Human Rights and Fundamental Freedoms) and from Its Case Law. The Guidelines of the Jurisprudence of the European Court of Human Rights About the "End of Life"

As we have noticed in the foregoing paragraph, the Charter, because of its characteristic of adopting normative contents within a whole of international acts, finds its main source of reference in the ECHR. The above-said Explanations, mostly containing references to the ECHR and its case law, show that. Such characteristic of the Charter—which has also allowed kinds of "anticipated"[45] application—also distinguishes the above-mentioned norms of the Charter, referring, lato sensu or stricto sensu, to the choices at the "end of life".[46]

It is for this reason that the jurisprudence of the European Court of Human Rights (ECtHR) can be an important source of inspiration in the application of such norms of the Charter.[47]

As it is well known, the jurisprudence of the ECtHR has had an impact on the development of health care and on dealing with some controversial issues not directly referring to health (as the "right" to a particular medical treatment) across Europe.

Such case law, since the first statements in the case Pretty,[48] has come to a significant enhancement of the principle of self-determination, from a "pro-choice" point of view, which gives a fundamental importance to the will of the concerned person. In it an evolution approach to the issues of the "end of life" can be seen, which leaves the door open to further "updatings" of the approach to such issues. It is a logical consequence of the high evolutionary character distinguishing the issues concerning the "Sciences of Life", thus continuously questioning even the big certainties of law."[49]

The general approach taken by the ECtHR to issues (like those concerning the "end of life") illustrates the difficulty in utilising a human rights approach according to the differences in religious and ethical perspectives across states.

The ECtHR has been offered a number of opportunities to issue its opinion on the subject, but only a few claims on the subject have been examined, while some even well-known cases on the subject, like the Spanish case of Ramón Sampedro

[45] We dare refer to Di Stasi (2011a), p. 257ff.

[46] See Azoux-Bacrie (2010).

[47] See Brosset (2011).

[48] European Court of Human Rights, Pretty v. the United Kingdom, no. 2346/02, judgment of 29 April 2002. See Sanderson (2002); De Schutter (2003); Hale (2003); Keown (2003); Nugent (2003); Merkouris (2011).

[49] Our translation of Resta (2009), p. 51.

and another one connected with the story of Eluana Englaro, have been judged as being inadmissible ratione personae, since they are based on "non transferable rights".[50]

In the most recent case law of the ECtHR, we notice a more suitable gradual balancing between values (even opposed with each other) on which the regulation of the Advance Directives is based, with an interpretation of the ECHR not only as a "living" convention[51] but also, in a joint sense, of various articles of the Convention.[52] The interpretation of it as a "comme un tout" (as it is affirmed in the case Haas in para. 54) means, from the point of view of the ECtHR, to read at the same time Article 8 and Article 2 of the ECHR[53] or Article 13 in conjunction with Article 8 (although in the context of a decision as to the admissibility).[54]

It is not strange that in the case law of the ECtHR, besides the above-mentioned articles, alleged violations of Article 3 of the ECHR have also been referred to (as inhuman or degrading treatment), as well as of Article 5, para. 1 (as right to liberty) and of Article 9 (as freedom of conscience and thought).

If the ECtHR can perform an essential role in harmonising the cultural differences inside the juridical systems of the other State members of the ECHR, such differences, however, account for the reference, by the ECtHR, to the so-called margin of appreciation of states.[55] It allows discretion to each state (and its domestic jurisdictions) to interpret Convention provisions, taking into account its particular national circumstances and traditions, such as cultural practices or religious or historic traditions. However, even as regards a so delicate subject, we

[50] As everybody knows, the ECHR does not admit actiones populares. See European Court of Human Rights, Sanles Sanles v. Spain, no. 48335/99, decision of 26 October 2000; Ada Rossi and Others v. Italy, no. 55185/08, 55483/08, 55516/08, 55519/08, 56010/08, 56278/08, 58420/08 and 58424/08, decision of 16 December 2008. In the recent decision of 19 July 2012, Koch v. Germany, no. 497/0 the European Court of Human Rights, in declaring the application partly admissible, "considers … that the complaint raises serious issues of fact and law under the Convention" (referring to "Alleged violation of the applicant's *own rights* under article 8 of the Convention"). Emphasis added.

[51] "À la lumière des conditions d'aujourd 'hui" (European Court of Human Rights, Haas v. Switzerland, no.31322/07, ECHR 2011, Section 1, Judgment of 20 January 2011, para 55).

[52] It is shown by some debated judgments. See, recently, the comments by Campiglio (2010) and Resta (2010b) to the judgment of 25 June 2010 issued by the German Supreme Court (Bundesgerichtshof).

[53] See also European Court of Human Rights, Haas v. Switzerland.

[54] See European Court of Human Rights Koch v. Germany.

[55] The ECtHR recognises generally (see Handyside v. United Kingdom, 24 Eur.Ct. H.R. (ser. A) at 22 (1976) that, by reason of their "direct and continuous contact with the vital forces of their countries", the domestic authorities in each states are, in principle, better placed than an international court to interpret domestic law, assess the fact of a case, or decide on the measures necessary in a particular area and will, depending on the circumstances, grant a state a certain degree of latitude in balancing rights and interests. Also in the judgment Handyside v. United Kingdom, we find the confirmation of the margin of appreciation of states. See Arai-Takahashi (2002). Inter alia, also Sapienza (1991).

cannot forget that the ECtHR has also repeatedly stated that the margin of appreciation "goes hand in hand with European supervision".[56]

2.4 The Influence of the European Court of Human Rights' Case Law on European Law in the Light of the Adhesion of the EU to the ECHR

As it has already been said above, the still existing lack of efficiency and cohesion resulting from the parallel application of two systems of human rights will most probably be reduced by the accession of the EU to the ECHR. Until the entry into force of the Lisbon Treaty, human rights were being regulated by two distinct and independent regional regimes: the so-called Luxembourg system and the so-called Strasbourg order. Within the so-called Luxembourg system fundamental rights, first developed by the ECJ, as general principles of EU law, were then enshrined in the EU treaties; within the Strasbourg system, human rights were based on the ECHR, as interpreted by the ECtHR. The two regimes have coexisted for all these years with no major conflicts of authority even though some divergences of approach existed in relation to specific areas. One of these can be surely represented by the regulation of the issues concerning the "end of life", existing in the ECtHR Jurisprudence, non-existing in the ECJ Jurisprudence.

In the Treaty of Lisbon, Article 6, para. 2 of the TEU has changed the general power provided in the Treaty establishing a Constitution for Europe (Article I-9)[57] to a real obligation of result for the European Union, which causes, as a corollary, an obligation for the institution, the Council included, which keeps, also according to the provisions of the TFUE, a key role within the final signing procedure of the Union's agreements. The advancement of this process—which also finds its normative basis in Article 59 ECHR, particularly in para. 2 introduced by Protocol XIV—will actually determine a transition of a jurisdictional system based on the simple coexistence of two autonomous and independent Courts (the Court of Justice of the European Union/ECJ and the ECtHR) and of two catalogues of rights not perfectly comparable/through more advanced forms of integrations between the two subsystems.[58]

[56] Handyside v. United Kingdom, at 23.

[57] About predictions, within the Treaty establishing a Constitution for Europe, concerning biomedicine, see Krajewska (2005).

[58] As for the procedure, the Council of the European Union adopted, on June 2, 2010, a Decision authorising the Commission to negotiate the accession of the European Union to the Convention following the provisions of art. 218 TFUE. In the framework of the Council of Europe, after the meeting of May 26, 2010, the Minister Delegates gave a mandate to the Steering Committee for Human Rights (CDDH) to elaborate, in cooperation with the EU representatives, one or more legal instruments that could set the EU accession modalities to the ECHR. The CDDH has in turn entrusted the task to an informal working group (CDDH-EU) composed of 14 experts specially

It is the end of the very long debate that had occurred within the institutions, which had led to the conviction that only a formal participation by the adhesion of the EU to the ECHR would have ensured an efficient coordination between the two systems.[59]

Then in the Treaty of Lisbon there is the overcoming of the previous consideration of the joining of the European Union to the ECHR, as a hypothesis alternative to the building of a catalogue of rights binding for the Union itself. The substantial equalisation of the Charter to the primary law of the Union does not eliminate the necessity of an international level of guarantee and control of the conduct of the institutions; therefore, joining the ECHR gives place to a consistent international guarantee of individual human rights, as regards both the violations of member States and the institutions of the Union. It is my opinion that, just as regards the latter typology of violations, the expected adhesion to the ECHR could fill the gap already becoming smaller and smaller, represented by a certain resistance of the Court of Justice of the European Union (ECJ) to supervise, within this context, the normative activity of the above-said institutions.[60] It could also help the overcoming of that disputable jurisprudence of the ECtHR asserting the only liability of

chosen for their experience. In June, after the eighth meeting, the members of the informal working group have transmitted "il progetto di Accordo per l'adesione, il progetto di modifica al Regolamento del Comitato dei Ministri per la sorveglianza sull'esecuzione delle sentenze e dei termini dei regolamenti amichevoli, e il progetto di rapporto esplicativo dell'Accordo di adesione" to the Steering Committee for Human Rights, which, in an extraordinary meeting held from 11 to 14 October 2011, have examined and approved these legal instruments, with some amendments. See "Projet d'instruments juridiques pour l'adhésion de l'Union européenne à la Convention européenne des droits de l'homme". CDDH-UE(2011)16, on the internet website http://www.coe.int/t/dghl/standardsetting/hrpolicy/cddhue/CDDHUE_documents/CDDHUE_2011_16_final_fr.pdf. See also the Report to the Committee of Ministers on the elaboration of legal instruments for the accession of the European Union to the European Convention on Human Rights (CDDH (2011)009en), namely the report transmitted by the Steering Committee for Human Rights to the Committee of Ministers on October 14, 2011, by which the latter was asked to provide guidelines for pursuing the process. When the draft was being considered for adoption by the CDDH, several States have expressed their objections so that the European Commission has thought further debate was necessary within the EU. The negotiation was in a stalemate following the objections of some governments, including Great Britain. In June 2012, the negotiations between the Council of Europe and the European Commission reopened (Doc. 47+1(2012)R01, 21 giugno 2012). About the issue on accession, see, ex multis, Ivaldi and Tuo (2012); Fiengo (2011); Jacqué (2011); Lock (2011); Potteau (2011); Sanz Caballero (2011); Szymczak (2011); Tizzano (2011); Artino and Noël (2010); De Schutter (2010); Dollat (2010); Mengozzi (2010); Bultrini (2009); Gianelli (2009); Zagrebelsky (2007).

[59] For a synthesis of the issue of accession, we dare refer to Di Stasi (2012).

[60] Such resistance finds, on the other hand, some elements helping to overcome it, where the Court of Justice has cancelled some measures adopted by the European institutions as regards the issue of terrorism. Let us refer to the judgment of 3 September 2008, joint law cases C-402/05 P e C-415/05 P, Kadi and Al Barakaat International Foundation, ECR I-6351, in which the affirmations of the Court of First Instance (see the judgment dated September 21st 2005, T-315/01, Kadi, ECR 2005, as well as the judgment bearing the same date, T-306/01, Yusuf, ECR 2005), have been completely reversed; these judgments acknowledged a sort of "jurisdictional immunity" for those acts that are only meant for representing a mere execution of resolutions of the Safety Council.

member States for violating fundamental rights by acts imposed by EU obligations.[61]

With specific reference to the Advance Directives, their regulation, under European Law, will benefit from a more harmonious and convergent human rights system in Europe.[62] In this sense the EU Charter, which includes several references to the ECHR (both norms and case law), appears to be one of the "vehicles " that could connect the two systems.

3 Part II

3.1 The Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Oviedo Convention)

As mentioned in the introduction, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine represents the first attempt to provide a common framework at a European level in the field of bioethics. Drafted in 1997[63] by the Council of Europe and entered into force in 1999,[64] the essence of the Oviedo Convention is to lay down the necessary legal measures in order to protect human rights and freedoms in the context of medicine.

[61] See, in particular, the judgment dated June 30th 2005 Bosphorus Hava Yollari Turizm, as it is reported in the Rivista di diritto internazionale, 2005, p. 778 and the following, in particular paragraphs 155 and 156. In such judgment, by making recourse to a topic by illustration technique of a "substantialist" character, it is underlined that since "it is well assumed that the concerned organization [the Community] grants the fundamental rights a protection at least equivalent to that ensured by the [CEDU] (. . .) we must conclude that a State respects what is required by the CEDU when it only gives execution to the juridical obligations deriving from its adhesion to the European Union"". In the judgment, it also said that "such a presumption can be however overcome within a specific law case, if the protection of the human rights guaranteed by the CEDU was clearly inadequate. In this case the role of the CEDU as "constitutional instrument of the European public order" would prevail over the interest into the international cooperation". In the doctrine, among others, see Cannizzaro (2005) and Lebeck (2007).

[62] See in particular Varju (2011).

[63] European Treaty Series No. 164.

[64] On the "history" of the Oviedo Convention, see Bompiani (2009a); Bompiani (2009b); Zanghì and Panella (1996). On the Convention of Oviedo in more general terms see Bompiani et al. (2001); Gevers et al. (2005); Pavone (2009); Gros et al. (2009); Taupitz (2002); Bompiani (1997); Byk (2001); Cataldi (2000a; 2000b; 2006); De Vel, (2003); Den Exter (2009); Dommel and Alexander (1997); Dubouis (1998); Hendriks (1997); Loreti (1999); Piciocchi (2001); Roscam (1996), (1998); Sapienza (1998); Saulle (2003).

The title, the Preamble, and Article 1 of the Convention put the light on the context in which it moves, namely the protection of human rights in a particular field (biology and medicine). These references recall the relevant activities of the Council of Europe for the promotion and protection of human rights in general.[65]

In particular, the Oviedo Convention aims to address the potential conflict between the protection of the human and the new frontiers of scientific and medical research.

In this sense, the key provision on which it is based is Article 2, which states that "the interests and welfare of the human being shall prevail over the sole interest of society or science". As pointed out by the Explanatory Report,[66] the whole Convention, the aim of which is to protect human rights and dignity, is inspired "by the principle of the primacy of the human being, and all its articles must be interpreted in this light" (point 22).

It is well known that the Biomedicine Convention turns around the founding principle of human dignity.[67] Thus, the human dignity of the person not only is a fundamental right in itself but also constitutes the real basis of fundamental rights,[68] although neither the Oviedo Convention nor the Explanatory Report specifies the concept of human dignity, which remains very broad and vague.[69] As such the Convention is in line with other international and European documents on human rights, like the Universal Declaration on Human Rights; the International Covenant on Economic, Social and Cultural Rights; the International Covenant on Civil and Political Rights; and the Charter of Fundamental Rights of the European Union.

The Oviedo Convention is a legally binding instrument and therefore embodies legal, enforceable rules that serve as a basis for a more common approach to patients' rights in Europe,[70] strengthening, at an international level, the legal position of the patient in setting a minimum level of protection.

Among other features,[71] the Biomedicine Convention is structured as a framework Convention. In other words, the norms and principles laid down are to be

[65] See Di Stasi (2011a), part 3, chapter 3.2.

[66] Explanatory Report to the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human rights and biomedicine, Doc. DIR/JUR, Strasbourg, May 1997.

[67] See Andorno (2009a). The right of protection for human dignity and identity is part of the "leading principles", together with the right to respect for one's integrity, the right to (equal access to) health care, and the prohibition of non-discrimination. See Dute (2005).

[68] The Explanatory Report confirms that human dignity "constitutes the essential value to be upheld" (point 9).

[69] On the role of dignity in the fields of human rights, bioethics, and biolaw, see Di Stasi (2011b) and also Andorno (2009a, 2009b).

[70] The Convention has been qualified as a real "patient's rights treaty". See Nys (2001).

[71] The main characteristics of the Oviedo Convention have been summarised as follows: "binding instrument", "comprehensive approach to bioethics", "framework instrument", "minimum common standards", "implementation at a national level", "judicial protection by national courts", "relative rights". See Andorno (2005).

regarded as "minimum requirements" with which States must comply and short of which they must not legislate. Instead, States are allowed to grant under national legislation "a wider measure of protection" with regard to the application of biology and medicine than it is stipulated in the Convention (Article 27).

The difficulties in finding consensus among States, which is behind the "framework structure" of the Oviedo Convention, flow into the structure and content of the provisions. In fact, most of them have a low degree of detail and often a certain degree of abstractedness.

To overcome this, the Convention (Article 31) calls for additional protocols[72] in which the basic norms set out are defined in greater detail with regard to specific fields of action in the areas of medicine and biotechnology. Moreover, Article 32 provides the possibility to propose amendments and also a periodic review of the Convention.

3.2 Relationship with the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)

In the previous paragraph was not said that the Oviedo Convention has a "universal vocation"[73] that places it at an international level and, together with the UNESCO Declaration on Human Rights and Bioethics,[74] as the main tool for the achievement of a "global bioethics".[75]

A general analysis of the relationship of the Oviedo Convention with other legally binding or non-binding international instruments is beyond the purpose of this work,[76] which will focus only on the close relationship with the European

[72] Up to now, four Protocols entered into force: Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Paris, 12 January 1998; Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 January 2002; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Strasbourg, 25 January 2005; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, Strasbourg, 27 November 2008.

[73] Apart from the Council of Europe member states, non-member states, including US, Japan, Mexico, Australia, Canada, and the Holy See, have participated in its drafting. Moreover, the Convention is accessible to non-member states of the Council of Europe.

[74] Adopted by UNESCO's General Conference on 19 October 2005, it is inspired by the Oviedo Convention.

[75] On the concept of "global bioethics", see Andorno (2007); Gadd (2005); Nys (2006). With specific reference to the issue of advance health care directives, see Beširević (2010).

[76] For further details, see Roucounas (2005).

Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR).

Scholarship has highlighted the link between the two Conventions and has assumed that the Oviedo Convention operates in principle as a "*lex specialis* vis-à-vis the Convention on Human Rights".[77] Several elements can be taken in support of such a framework.

First of all, according to the Preamble of the Oviedo Convention the parties "bear in mind", among other instruments, the ECHR. This is due to the fact that the Oviedo Convention operates in the field of human right protection, in which the ECHR represents the main instrument created by the Council of Europe.

Moreover, the close relationship with the ECHR appears in at least two specific fields. First, the Explanatory Report stresses the parallelism in the use of the term "human rights" in the two Conventions. Thus, the term "Human Rights" used in the Biomedicine Convention has to be referred "to the principles laid down in the Convention on Human Rights, which guarantee protection of such rights". The Explanatory Report also states that

> The two Conventions share not only the same underlying approach but also many ethical principles and legal concepts. Indeed, this Convention elaborates some of the principles enshrined in the European Convention for the Protection of Human Rights (point 9).

Furthermore, although the Oviedo Convention does not provide any jurisdictional mechanism of guarantee, Article 29 entitled "Interpretation of the Convention" enshrines that "the European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions[78] on legal questions concerning the interpretation of the present Convention".

However, the role of the European Court of Human Rights is not limited to this advisory competence. Although the Biomedicine Convention itself does not give individuals a right to bring proceedings before the European Court, infringement of the rights contained in the Biomedicine Convention "may be considered in proceedings under the European Convention of Human Rights, if they also constitute a violation of one of the rights contained in the latter Convention".[79]

As aptly noted by scholarship, the above-said elements imply not only that the Convention

> operates within the orbit of the *European system of human rights protection* but also that for *reasons of harmony* the Convention ought to be interpreted and implemented in the light of a/ the principles and the rules on human rights as laid down by the ECHR and b/ the case law of the European Court of Human Rights (in a sense this could be qualified as the *evolutionary principle of interpretation*.[80]

[77] Roucounas (2005), p. 26, and Panella (1996), p. 14.

[78] It is noted that the provision is not clear about the legal nature and the value to be attached to these advisory opinions. Doubts about their legally binding value are raised by Gitti (1998).

[79] Explanatory Memorandum, paragraph 165.

[80] Roucounas (2005), p. 27.

In this respect, in the following pages (paragraph 5) there will emerge a certain overlap existing between the two Conventions. Especially, Article 8 (protection of private life and family life) of the ECHR functions as a bridge between both Conventions.

3.3 Article 9 of the Oviedo Convention

The Oviedo Convention contains the only European legal framework on living wills, provided by Article 9. It is given in Chapter II, entitled "Consent", containing Articles 5–9. Thus, such provision is part of the set of rules inspired by the patient's right to "self-determination" and "autonomy" in relation to medical interventions and research.

This principle is realised through the free and informed consent,[81] to which in general terms Article 5 of the Convention is dedicated; said Article provides that "an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it".

Articles 6, 7, and 8 contain a specific provision on "protection of persons not able to consent", "protection of persons who have a mental disorder", and "emergency situation", while Article 9 concerns itself with "previously expressed wishes". In essence, the "advance care planning" can be considered as the "projection in time" of the self-determination in relation to one's own health.[82]

This norm is of great importance as it embodies the first significant effort made by the European institutions to set up a binding legal framework relating to "advance health care directives". Such term is used to indicate instructions given by individuals specifying what action should be taken for their health in the event that they are no longer able to make decisions due to illness or incapacity.[83]

Such instructions, demonstration of the exercise of the "precedent autonomy",[84] are intended to acquire value only if the person is no longer able to give consent.[85] As well known, the advance health care directive's topic has greater importance in case they contain instructions to refuse treatment at the end of life, although they could indicate acceptance to treatment. Moreover, the doctrine classifies advance health care directives in the following way:

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[81] On the right to informed consent in the International Biolaw and International Human Rights law, see Negri (2011b).

[82] D'Aloia (2010), p. 15.

[83] See Fischer et al. (2004).

[84] Davies (2002). On the link between self-determination and advance health care directives, especially in the Italian law, see also Alpa (2006) and Franzoni (2009).

[85] Andorno (2011); Andorno et al. (2009); Berger and Haarhoff (2002); Bompiani (2004); Nys (1997); Pascalev and Vidalis (2010); Stefanini (2006).

(a) the "living wills", which are written documents designed to allow people to express their preferences regarding the provision—or the withholding—of specified treatments in the event that they become unable to make decisions in the future;
(b) the "lasting (or durable) power of attorney for health care", which allows individuals to appoint someone as a "health care proxy" (for example, a trusted relative or friend) to make health care decisions on their behalf once they lose the ability to do so.[86]

Indeed, the Oviedo Convention does not incorporate such a distinction; Article 9 is limited to establishing that the previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes "shall be taken into account".

In line with the overall approach of the Convention, Article 9 is not detailed and leaves many open questions to the interpreter.

In primis, using a vague expression, the provision states that the advance health care directives "shall be taken into account". This seems to indicate that advance directives are not binding and they have only an advisory effect. This interpretation is confirmed by the Explanatory Report, which provides that "taking previously express wishes into account does not mean that previously expressed wishes should necessarily be followed" (point 62). As a consequence, the physician maintains a certain degree of discretion regarding the choice of treatment at the end of life.

The Explanatory Report only provides two examples to illustrate why in some circumstances the physician may have good reasons not to follow the patient's wishes on the grounds that they do not apply anymore to the situation at hand: a) when they have been expressed a long time before the intervention, b) when medical technology has made significant progress since the time where the advance directive was signed and it can be reasonably assumed that, in the present circumstances, the will of the patient would have been different.

Moreover, the article provides no details on the way in which wishes should be expressed or how the physician should ascertain those wishes. The Explanatory Report to the Convention does not resolve the ambiguity of Article 9.

Also the concept of "medical intervention" is ambiguous. Does this expression include medically supplied nutrition and hydration for individuals who are in a permanent vegetative state?[87]

Moreover, the provision makes no mention on how the physician has to reconstruct the patient's wishes in the case of advance directives formulated in vague or ambiguous terms. In these cases, who will be responsible for interpreting the will of the patient?

As will be seen in the following paragraphs, the further instruments adopted by the Council of Europe only partially help to solve these doubts.

[86] For such classification, see Andorno et al. (2009), p. 208.

[87] In a positive sense, see Santosuosso (2001).

3.4 Council of Europe's Recommendations and Resolutions on Advance Health Care Directives and Continuing Powers of Attorney

In 1999, the Council of Europe set again in the field of advance health care directive. In particular, the Parliamentary Assembly adopted Recommendation 1999(1418)[88] on the Protection of the human rights and dignity of the terminally ill and the dying. By this Recommendation, the Assembly advises that the Committee of Ministers encourages the member states of the Council of Europe to respect and protect the dignity of terminally ill or dying persons, taking the necessary measures, among others, to ensure that a currently incapacitated terminally ill or dying person's advance directive or living will refusing specific medical treatments is observed; that criteria of validity as to the scope of instructions given in advance, as well as the nomination of proxies and the extent of their authority, are defined; and that surrogate decisions by proxies based on advance personal statements of will or assumptions of will are only to be taken if the will of the person concerned has not been expressed directly in the situation or if there is no recognisable will. In this context, there must always be a clear connection to statements that were made by the person in question close in time to the decision-making situation, more precisely at the time when he or she is dying, and in an appropriate situation without exertion of pressure or mental disability. Furthermore, the member states must ensure that surrogate decisions that rely on general value judgements present in society should not be admissible and that, in case of doubt, the decision must always be for life and the prolongation of life; that—notwithstanding the physician's ultimate therapeutic responsibility—the expressed wishes of a terminally ill or dying person with regard to particular forms of treatment are taken into account, provided they do not violate human dignity; and that in situations where an advance directive or living will does not exist, the patient's right to life is not infringed upon.

Afterwards, the Council of Europe adopted two other Recommendations, which will be analysed in the following paragraphs, taking into account the limited value of such instruments. As it is well known, Resolutions and Recommendations are the typical instruments through which international organisations operate in international relations. In general, the recommendations with an international organisation are to provide guidance on how to behave in relation to a given question. Thus, they are acts of soft law and do not require the recipient States the obligation to comply.[89] In essence, they only have an "exhortative" value.

However, by these documents the Council of Europe continues its engagement to promote patients' self-determination that had started with the adoption of the Biomedicine Convention. Even if non-binding, such recommendations are likely to

[88] Adopted by the Assembly on 25 June 1999 (24th Sitting).

[89] See Malintoppi (1958).

have an impact on the domestic legislation of European countries, at least by drawing their attention to the possibility of introducing or refining these new means for making health care decisions in advance.

3.4.1 Recommendation 2009(11) of the Council of Europe's Committee of Ministers

Influenced by the fact that only a minority of member States already had legislation or draft proposals on continuing powers of attorney and advance directives and recognising that there were considerable disparities between national legislation as regards these issues, the Council of Europe drafted a new Recommendation.

The Recommendation of the Council of Europe's Committee of Ministers 2009 (11) "on principles concerning continuing powers of attorney and advance directives for incapacity"[90] aims to "promote self determination for capable adults in event of future incapacity by means of continuing powers of attorney and advance directives" (principle 1). It is based on the principles of self determination and subsidiarity and has as its objectives the promotion of coherence as regards the basic principles in the legislation of European countries on this matter.

The Recommendation dedicates Part II (Articles 3–13) to "continuing powers of attorney" and Part III (Articles 14–17) to "advance directives".

In some sense, Part II fills up the "legislative gap" left by Article 9 of the Oviedo Convention, which does not deal with this topic.

According to principle 2, a "continuing power of attorney" is a mandate given by a capable adult with the purpose that it shall remain in force, or enter into force, in the event of the granter's incapacity.[91] It should be noted that the content of the power of attorney could be broader and not limited to matters of health: it could cover "economic and financial matters, as well as health, welfare and other personal matters" (principle 3).[92]

In the Recommendation's perspective, the continuing power of attorney is conceived as an alternative to public representation, as that possibility is less restrictive of the person's rights. It permits, and even encourages, adults to prepare for what shall happen if and when they are no longer able to take care of their own

[90] Adopted by the Committee of Ministers on 9 December 2009 at the 1073rd meeting of the Ministers' Deputies. See Andorno (2010).

[91] The "granter" is the person giving the continuing power of attorney. The person mandated to act on behalf of the granter is referred to as the "attorney" (principle 2, paragraph 2).

[92] This is the reason why principle 2 uses two different expressions ("remain in force" and "enter into force"): it is due to the fact that "the definition includes the point of time in which the power of attorney will become operative, and this varies depending on the purpose of the document: those for economic and financial matters may become effective immediately, and remain valid after the granter's incapacity; those for health, welfare and personal matters only will be in effect in the event of the granter's incapacity". See Andorno (2011), p. 83. See also Explanatory Report, point 57 and the following.

interests (Explanatory Memorandum, point 47). So, granters may appoint as attorney "any person" who they consider "to be appropriate".[93]

Principle 5 of the Recommendation establishes the written form. Rectius, it provides that continuing power of attorney "shall be in writing" and leaves to States to determine other formal requirements for the validity of the power of attorney.[94] The latter is revocable at any time.

Regarding the role of the attorney, principle 10, paragraph 1, provides that "he acts in accordance with the continuing power of attorney and in the interests of the granter". As well noted by scholarship, such a provision has to be harmonised with principle 10, paragraph 2, according to which the attorney must also take into account, "as far as possible", the "wishes and feelings" of the patient and give them "due respect".[95] Moreover, it is required that the attorney acts impartially: thus, principle 11 establishes that "States should consider regulating conflicts of the granter's and the attorney's interests".[96]

What happens if the proxy acts inconsistently with these requirements?

As provisions regarding the granting of powers of attorney are intended to replace public representation, the use of the power of attorney is thereafter regulated only to a limited extent, and public authorities are rarely involved in the monitoring and supervision for the protection of the interests of the incapacitated adult. According to principle 12, paragraph 1, the granter may appoint a third party "to supervise" the attorney. This is defined by Explanatory Memorandum (point 161) as a "private supervision system" to ensure that the attorney takes proper care of the interests of the granter, that he or she does not act in situations where there is a potential conflict of interests, and that there is no misuse of power. Moreover, paragraph 2 deals with the involvement of public authorities. Thus, States should consider introducing a system of supervision under which a competent authority is empowered to investigate. When an attorney is not acting in accordance with the continuing power of attorney or in the interests of the granter, the competent authority should have the power to intervene. Such intervention might include

[93] "One or more persons from among their family members or friends, or a professional such as a lawyer, notary or accountant" (Explanatory Report, point 48). When the granter appoints more than one person, it should indicate how the attorneys are to act (jointly, concurrently, separately, or as substitutes).

[94] In particular, according to principle 8, States should consider introducing systems of certification, registration, and/or notification when the continuing power of attorney is granted, is revoked, enters into force, or is terminated.

[95] See Andorno (2011), p. 82. According to him, a possible way out to this dilemma is to consider that the best interest of the patient, which is mentioned in the first paragraph and without any particular condition, is a general principle that should always guide the proxy's decision. This standard embodies the basic guiding value for surrogate decision-making and offers the conceptual framework for the proxy's decision. On the contrary, the "wishes and feelings" of the patient are an element, among others, that the proxy must take into account "as far as possible" to determine what is in the best interest of the patient.

[96] The Explanatory Report (points 156–159) shows some examples of conflict of interests.

terminating the continuing power of attorney in part or in whole. The competent authority should be able to act upon request or on its own motion.

As mentioned above, the Recommendation also deals with advance directives defined in principle 2, paragraph 3, as "instructions given or wishes made by a capable adult concerning issues that may arise in the event of his or her incapacity".[97]

The principle uses two terms ("instructions" and "wishes"): the word "instructions" is used to refer to advance directives that are legally binding, while "wishes" is employed to indicate that such documents have a merely advisory value.[98] This double terminology, which also appears in principle 15, shows well the deep disagreement between European countries concerning the legal effect to be given to advance directives.

Interestingly, the terminology used in Principle 15 to refer to previously expressed wishes is slightly different from the one found in Article 9 of the Oviedo Convention. While the latter provides that such wishes "shall be taken into account", the Recommendation stipulates that they should be given "due respect".[99]

Such directives may or may not be addressed to particular persons such as representatives appointed by a competent authority, attorneys, medical staff, or other persons who make decisions on behalf of or affecting the author during incapacity. They are always unilateral documents that do not establish a contract with any such person (Explanatory Memorandum, point 177) and shall be revocable at any time and without any formalities.

Advance directives do not necessarily have to be in writing, even if States should consider whether advance directives or certain types of advance directives should be made or recorded in writing if intended to have binding effect (point 16, para. 1).

[97] The Explanatory Report clarifies that the term "living wills" is commonly used in national legislation, even if it covers two different types of decisions, the binding instructions, as well as wishes to be given due consideration (and therefore often called "advance statements"). Paragraph 3 uses only the term "advance directives", but as described in the definition and expanded in Principle 15, paragraph 1, the term covers both instructions with binding effects and wishes (point 79).

[98] See Andorno (2010), p. 123, and the Explanatory Memorandum, point 178.

[99] According to Andorno, "this latter wording is certainly stronger than the one of the Biomedicine Convention". In this regard, he notes that some countries employ the verb 'to respect' precisely in order to make advance directives binding by law. See, for instance, the new Article 372.2 of the Swiss Civil Code, adopted in December 2008 and which will enter into effect in January 2013. The French version is available at http://www.admin.ch/ch/f/ff/2009/139.pdf. Cf. Andorno (2010), p. 123. The Author also notes that "it is difficult to determine whether this difference in the wording was deliberate or simply an oversight, especially because it only appears in the English version of the recommendation: the French text employs the same verb that is used in the Biomedicine Convention ("prendre en compte")".

3.4.2 The Parliamentary Assembly's Resolution 1859(2012)

Although the Committee of Ministers recommended States to promote continuing powers of attorney and advance directives and laid down a number of principles to guide member states in regulating them,

"the situation in Europe is very diverse, ranging from no legislation whatsoever on advance directives, to specific legislation which confers binding effect on them. Even where specific legislation does exist, it is not always fully implemented. Thus, today, only a tiny minority of the Council of Europe's 800 million citizens actually have advance directives, living wills and/or continuing powers of attorney – making it difficult, if not impossible, to take their previously expressed wishes into account, and thus effectively to protect their human rights and dignity".

Starting from these considerations, the Parliamentary Assembly adopted Resolution 1859(2012),[100] aiming at soliciting States to adopt provisions on advance directives, living wills, and continuing powers of attorney, considering them as an expression of the fundamental principle of personal autonomy and of the principle of consent. At the same time, the Parliamentary Assembly broadly highlights that the Resolution is not intended to deal with the issues of euthanasia or assisted suicide. Euthanasia, in the sense of the intentional killing by act or omission of a dependent human being for his or her alleged benefit, "must always be prohibited".

The Parliamentary Assembly exhorts especially States with no specific legislation on the matter by putting into place a "road map" towards such legislation, promoting advance directives, living wills, and/or continuing powers of attorney and also recommending it to countries with specific legislation on the matter by ensuring that the relevant Council of Europe standards are set in the Biomedicine Convention and in the 1999 and 2009 Recommendations.

Furthermore, the Parliamentary Assembly lays down a set of new principles that should be followed by national Parliaments (contained in point 7 of the Resolution), which are specifications of the Oviedo Convention's provisions.

In particular, point 7, paragraph 2, is interesting since in it the idea of creating "state registries" to register advance directives, living wills, and/or continuing powers of attorney emerges. Such advance directives, living wills, and/or continuing powers of attorney, when properly validated and registered, should be "fully taken into account". One wonders if such a terminology has to be interpreted in the sense that the patient's wishes have to be always followed by physicians, decreasing discretion left by Article 9 of the Oviedo Convention.

Another way to avoid that the physician can easily find justifications for departing from the patient's wishes is to make sure that the patient's will is as current as possible. This seems the aim of point 7, paragraph 6, in providing that capable adults should be encouraged to review at regular intervals (for example, once a year) the advance directives, living wills, and/or continuing powers of attorney they have made.

[100] Assembly debate on 25 January 2012 (6th Sitting).

With Recommendation 1993 (2012), the Parliamentary Assembly advises that the Committee of Ministers bring Parliamentary Assembly Resolution 1859(2012) to the attention of member states, with a request for implementation.

The Assembly further believes that Council of Europe standards in this field should be developed further. It thus recommends that the Committee of Ministers instructs its relevant steering committees (in particular, the Steering Committee on Bioethics) to continue developing such standards and to promote and monitor their implementation based on the principles enshrined in Committee of Ministers Recommendation (2009)11 and those developed in paragraph 7 of Assembly Resolution 1859(2012).

3.4.3 Linked Issue: The Council of Europe's Recommendations and Resolutions on Palliative Care

The Council of Europe adopted acts on palliative care, to which we make some mention, this topic being closely linked to advance health care directives.

The main document is the Committee of Ministers' Recommendation on the organisation of palliative care, adopted in 2003.[101]

The Committee of Ministers recommends that the governments of member States adopt policies, legislative and other measures necessary for a coherent and comprehensive national policy framework for palliative care. This is defined as

> The active total care of patients with advanced, progressive disease. Control of pain, of other symptoms, and of psychological, social and spiritual problems, is paramount. The goal of palliative care is the achievement of the best possible quality of life for patients and their families.[102]

Palliative care policies should be based on values propounded by the Council of Europe, such as human rights and patients' rights, human dignity, social cohesion, democracy, equity, solidarity, equal gender opportunities, participation, and freedom of choice.

Considering palliative care as a "vital and integral part of health services", Council of Europe sets out some principles on the issue: palliative care services and policies must offer a wide range of resources, such as home care, inpatient care in specific or conventional units, day hospital and outpatient clinics, emergency

[101] Recommendation Rec(2003)24 of the Committee of Ministers to member states on the organisation of palliative care.

[102] This Resolution uses a slightly revised version of the definition formulated by the World Health Organization (WHO) in 1990 and revised in 2002 "Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual". See WHO, Cancer Pain Relief and Palliative Care. Technical Report, Series 804, Geneva, Switzerland, 1990, p. 11 and WHO, National Cancer Control Programs: Policies and Managerial Guidelines, 2nd ed., Geneva, Switzerland, 2002.

call-out, and respite care facilities. These should be comprehensive and appropriate to the health care system and culture and should focus on the changing needs and wishes of patients—informal caregivers should be supported in their caregiving and should not incur major social setbacks, such as job loss, as a consequence of caregiving. A formal right to "care leave" may be desirable; all professionals involved in the care of patients with advanced, progressive disease should have easy access to specific expertise if and when they need it; specialist palliative care should be available for all patients when they need it, at any time and in any situation; it should be ensured that there is leadership in the development of palliative care at national level and proper coordination of services with a clear allocation of responsibilities. The formation of regional networks is recommended as a good means to reach this goal; patients should be guaranteed access to palliative care without undue financial barriers. Financial and other arrangements should be such that continuity in palliative care is guaranteed and is adapted to the needs of the patient; there should be sufficient respite care facilities to offer temporary relief when caregivers in the home become overburdened.

The Recommendation takes into account palliative care–end of life connection. In this case, point 66 of the Annex points out as guidelines orienting Member States legislations, ethical principles of palliative care as formulated by the Hungarian hospice and palliative care association.

These principles give great importance to the will of the patient, especially at the end of life. Patient has the rights to medical care, to human dignity, to personal support, to pain relief and reduction of suffering, to information, to self-determination, and to refuse treatment.

With reference to the right to refuse treatment, point 66 of the Annex refers to the case of advance health care directives. According to it, a person capable to act with regard to his or her later state of incapacity can refuse, in a public instrument (e.g. living will) certain life-supporting or life-saving treatments in a future situation of suffering an illness with no cure, being incapable of psychical self-care due to illness, or having pain that cannot be relieved with appropriate treatment. The patient is entitled to name another person to exercise this right in case of the patient's incapacity. The declaration may be withdrawn at any time. Each act and decision should be documented in written form.

It has to be noted that even in cases of treatment refusal, the patient does not lose the right to benefit from palliative care, being patients refusing treatment "fully entitled to pain relief and the easing of suffering" (annex, point 66).

These issues are also addressed in a Resolution of the Parliamentary Assembly of the Council of Europe, adopted in 2008.[103]

This Resolution recognises that the limits of any medical intervention are determined by the autonomy of the individual patients in so far as they express their will not to receive curative treatment or, regardless of any medical assessment of their state of health, have done so explicitly in a living will, for instance.

[103] Resolution on Palliative care: a model for innovative and social policies, 29 January 2008.

Finally, the Assembly hopes that palliative care also offers individuals who have given up hope of dying in dignity if they are allowed to turn down curative medicine but accept pain relief and social support.[104] Thus, the realisation of the Parliamentary Assembly's "hope" is left to the Member States' legislation on the matter.[105]

3.5 Legal Effects of the Oviedo Convention within the Italian Legal System

In 2001, Italy adopted Law No. 145 on the ratification and execution of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.[106]

Article 1 of this Law provides that "The President of the Republic is authorized to ratify the Convention for the Protection of Human Rights and Dignity ...."[107] and "full and entire execution is given to the Convention".

Although Italy is among the first signatories to the Convention and adopted Law 145/2001, it is not in the list of States having ratified the Convention.[108]

This is due to the fact that until now the Italian instrument of ratification has not been deposited to the General Secretary of the Council of Europe.[109]

Thus, the issue is, what value has to be paid in the Italian legal system to the Oviedo Convention and, in particular, to Article 9 discussed above?

While the instrument of ratification is not deposited, Law 145/2001 could be regarded as a "normal law" in force that provides independently provisions similar to those contained in the Oviedo Convention.[110] This argument is not acceptable, having into account the Law and the Oviedo Convention combination. As a matter

[104] Points 12 and 13 of the Resolution.

[105] Among practical recommendations, Parliamentary Assembly with regard to legal regulations on living wills recommends: "avoid creating legal arrangements which could lead to interpretation problems in practice; 22.5.2. conduct a comprehensive assessment of the legal consequences, taking account of possible legal side effects such as asset liability ("care as a financial loss")", points 22.5.1 and 22.5.2 of the Resolution.

[106] Law of 28 March 2011, no. 145, published in the Official Gazette of 21 April 2001, no. 95.

[107] In accordance with article 80 of the Constitution of the Italian Republic, stating that the "Parliament shall authorise by law the ratification of such international treaties as have a political nature, require arbitration or a legal settlement, entail change of borders or new legislation". Scholarship qualifies the act of ratification as a manifestation of will, put in place by the representatives of the State in international relations, such as to produce the effect of a treaty in the international order. See Monaco (1958), p. 174; Labriola (1991), p. 2. See also Cannizzaro (1992).

[108] See http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=03/02/2013&CL=ENG

[109] Italy is not the only State that has not ratified the Convention yet. On the reasons not motivating some States to ratify, see Goffin et al. (2008).

[110] As absurdity as this hypothesis is proposed in Casonato (2006), p. 174.

of fact, Article 2 of the Italian Law states that full and entire execution is given to the Oviedo Convention as of the date of entry into force, "in accordance with Article 33 of the Convention . . .".

According to Article 33, paragraph 4 of the Oviedo Convention:

> In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Therefore, failure to deposit the instrument of ratification involves a substantial relief and stands as a necessary element for the completion of the ratification process. The latter cannot be considered concluded, and therefore Italy is not bound by the provisions of the Oviedo Convention, not being effective in the Italian legal system.

However, this conclusion is in line with the theoretical arguments of the international law scholarship,[111] as well as with the case law of the Italian Constitutional Court. The latter ruled with reference to the Italian law[112] ratifying the European Convention on the International Validity of Criminal Judgements.[113] Since the instrument of ratification had not been deposited, the Constitutional Court considered that the Convention had not come into force for Italy and the law of ratification was "not operative".[114]

Despite these conclusions, the Convention has a strong influence in the Italian legal system.

For example, with reference to Article 9 of the Oviedo Convention, it has clearly inspired Article 34, paragraph 2 of the Italian Code of Medical Ethics of 2006, stating that the physician, when the patient is not able to express his will in case of danger of life, "cannot but take into account" what has been previously expressed by the patient.

That is to say that the physician "must" take into account the patient's previous wishes and justify his departing from the patient's wishes. Thus, the Italian Code of Medical Ethics uses a wording certainly stronger than the one in Article 9 of the Biomedicine Convention.

Moreover, the Supreme Court of Cassazione considered that the Convention of Oviedo has some effects on Italian law. The reference is to the Englaro case judgment,[115] where the Supreme Court states that the Oviedo Convention has an "auxiliary function" for the interpretation of internal dispositions: it succumbs when it conflicts with internal provisions, but it can and should be used in the

[111] Conforti (2010), p. 324. Specifically on the Oviedo Convention, see Bompiani (1998).

[112] Law of 16 May 1977, no. 305, published in the Official Gazette

[113] Council of Europe, The Hague, 28 May 1970.

[114] Decree no. 202 of 21 September 1983, in http://www.giurcost.org/decisioni/1983/0282o-83.html.

[115] Supreme Court of Cassazione, judgment of 16 October 2007, no. 21748.

interpretation of national rules in order to give them a reading as much as possible in accordance to the Convention.[116]

Furthermore, the Supreme Court reminds that Italian Constitutional Court implicitly considered the Oviedo Convention's principles as part of the Italian legal system such not be regardless.[117]

Recently, the National Bioethic Committee has submitted a motion[118] calling on the Italian government to complete the process of ratification, eventually making reservations as allowed by Article 36 of the Convention.[119]

Once the Biomedicine Convention is ratified, it will be necessary that the Government adopt the decrees for its implementation in Italian Law.

As a matter of fact, Article 3 of Law 145/2001 provides that the Government is authorised to adopt, "within six months from the date of entry into force" of this Law, one or more legislative decrees bearing additional provisions required for the adaptation of the Italian legal system to the principles and provisions of the Oviedo Convention. These decrees have never been adopted, even after another Parliamentary delegation.[120]

However, the failure to adopt such decrees does not seem to be relevant to the effectiveness of Article 9 of the Biomedicine Convention in the Italian legal system. This provision, indeed, falls into the core of the directly applicable provisions of the Oviedo Convention. According to paragraph 20 of the Explanatory Report, the Biomedicine Convention contains a number of provisions "which may, under the domestic law of many States, qualify as directly applicable ("self-executing provisions"). This is the case, particularly, of the provisions formulating individual rights".

Article 9 certainly formulates individual rights, and as it is written it is qualifiable as a self-executing provision.[121]

[116] Point 7.2 of the judgment Englaro.

[117] Constitutional Court, judgments of 2005, no. 46, 47, 48, 49. On the value of the Oviedo Convention in the judgments of Italian Tribunals and Courts, see Palombino (2011).

[118] http://www.governo.it/bioetica/mozioni/mozione_24_02_2012.pdf

[119] Article 36, paragraph 1: "Any State and European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article".

[120] See article 1, paragraph 3, Law of 26 February 2007, no. 17. On this topic, see Pizzetti (2007).

[121] On this point, see Guillod (2005), p. 32, and Andorno (2005), p. 135.

4 Some Conclusive Remarks: Impact of the Oviedo Convention Within EU Law

Analysing the European regulatory system, the first attempt to provide a common binding framework at a European level in the field of advance directives is the Oviedo Convention.

However, from the above-said analysis it emerges that the Council of Europe's instruments have twofold limits: a "structural" limit and a "content" limit. They are both linked and a result of differences between the European States on bioethical issues.

Despite its limitations, although the Oviedo Convention does not create a real "harmonised legislation", persisting a "patchwork"[122] of different regulations on the subject of advance treatment and end of life choices,[123] it could open to a "virtuous process" of "rapprochement" between States that also involves those countries that have not ratified it yet.[124]

Likewise, the Biomedicine Convention could concur to create a "common approach" at EU level that, de iure condendo, could lead to the adoption of acts at "supranational" level.

This approach might have been accelerated by the signing of the Oviedo Convention by the European Union (formerly European Community), which, however, has never acceded to the Convention.[125]

However, the Biomedicine Convention is able to find other "access channels" to European Union law, to exercise such a "virtuous effect". In primis, it is well known that the Convention has played a key role on the writing of certain substantive provisions of the European Charter of Fundamental Rights.[126]

Furthermore, the Strasbourg Court's judicial activity embodies another "access channel" in a twofold way.

Some preliminary remarks are necessary. First of all, in order to be effective, international legislation on human rights ought to be accompanied by an appropriate enforcement system, preferably the court jurisdiction. In providing for a reporting procedure only, and lacking an international judicial complaint procedure, the Convention risks to fall short of legal effect.

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[122] This terminology is used by Hervey and Vanhercke (2010).

[123] For comparative legal perspectives, see Negri (2011a), part 3, and also Andorno et al. (2009), para. 3; Casonato (2011); Delbon and Conte (2006); Pizzetti (2008), part II, charter III.

[124] An example of this is France because its Law of 22 April 2005 relating to patients' rights and end of life issues, which provides that advance directives "must be taken into account by the doctor" (Art. 1111-11 of the Public Health Code), uses virtually the same wording of Article 9 of the Biomedicine Convention. Interestingly, France has signed but not ratified the Convention yet. France has recently (13.12.2011) ratified the Convention, which entered into force on 1.04.2012.

[125] On this topic, see Cot (1997).

[126] See Azoux-Bacrie (2010) and also Editorial (2004), p. 340; Krajewska (2005); Piciocchi (2001).

However, as mentioned above (paragraph 2), the Strasbourg Court has a role in implementing the Oviedo Convention. In particular, the jurisprudence of the European Court of human rights, which deals with complaints arising under the ECHR in relation to health, is relevant in this respect. In other words, although the Oviedo Convention has failed to harmonise the laws of the Member States relating to bioethics, the Strasbourg Court, interpreting the rights contained in the ECHR in the light of the Oviedo Convention, has in part filled this gap by giving it a legal value greater than that emerging from its limited subjective scope.

Without making explicit reference to the Oviedo Convention, this phenomenon has occurred primarily in the already mentioned Pretty case, where for the first time the Strasbourg Court approached the issues of euthanasia and assisted suicide, relying on Article 8 of the ECHR.

Along the same line is the Glass v. U.K. case, in which the Strasbourg Court referred to Article 6 of the Oviedo Convention, although UK has neither signed nor ratified the Convention.[127]

That said, what are the effects on EU law (not a member of the Oviedo Convention)?

European Union is passing through new trends introduced by the Lisbon Treaty (the already-mentioned legally binding nature of the Charter and the provision of the EU's accession to the ECHR) offering new development possibilities for the protection of human rights in the field of "Life sciences" too.

Such possible developments in the field of bioethics—and especially of Advance Directives—imply that any attempt at more invasive normative solutions would have entailed a forced simplification of the ethical pluralism existing on the point.[128]

If, then, the issues concerning end-of-life choices resist a complete normative consecration under the European Law and the European Biolaw, it can be expected that the different courts will continue carrying out a significant activity, also of a "creative" kind. Even if the jurisprudential source lacks the exhaustiveness and the certainty of the legislative intervention, it is certainly possible for it to meet the need for a "new" law and to reduce the spaces of the normative gap.

[127] In Glass v. UK, the European Court considered: "It does not consider that the regulatory framework in place in the United Kingdom is in any way inconsistent with the standards laid down in the Council of Europe's Convention on Human Rights and Biomedicine in the area of consent". By doing so, the Court is reviewing the British regulatory framework on parental consent under the Biomedicine Convention, although the UK has neither signed nor ratified the Convention. Among further cases, in the case of Evans v. UK (10 April 2007) and R.R. v. Poland (28 November 2011), the European Court referred to article 5 of the Biomedicine Convention (requirement of free and informed consent); in the case of Mouvement Raëlien Suisse v. Switzetland (13 July 2012), the Court of Strasbourg referred to the Additional Protocol to the Oviedo Convention of 12 January 1998 on human cloning, and in the case of Costa and Pavan v. Italy (28 August 2012) to article 12 of the Oviedo Convention on predictive genetic tests. For further details on this topic, see Lawson (2009).

[128] See Bifulco (2010), p. 20.

As it is well known, the Court of Justice of the European Communities has had an important "creative" role in interpreting and applying the founding treaties with regard to the protection of fundamental human rights. This development was nurtured and developed in the subsequent case law of the Court of Justice.

The ECtHR played and plays a dominant role in the interpretation of a substantial catalogue of (especially) civil and political rights with regard to the ECHR and all the system of the Council of Europe (the Oviedo Convention included).

Since the mid-1990s, in particular, the Court of Justice has increasingly looked at the ECHR for inspiration as to the nature and scope or even existence of fundamental rights in Community law.

Now the European Union itself could become a signatory to the ECHR, as the Lisbon Treaty mandates and the jurisprudence of the ECtHR may have an enhanced impact on European law.

Thus, first the Biomedicine Convention could guide the EU Court of Justice's interpretation of the European Charter of Fundamental Rights. This is due to the fact that the Strasbourg Court functions as a bridge between both Oviedo and ECHR Convention and the EU Charter of fundamental rights. As seen in Part I, as the Charter contains rights that correspond to rights guaranteed by the ECHR (like Article 7, which corresponds to Article 8 of the ECHR), "the meaning and scope of those rights" shall be the same as those laid down by the ECHR.

It is also true that such an "osmotic process" undergoes a slowdown if we consider that the Charter's provisions apply in respect of the subsidiarity principle and within the limits of the Union. Thus, this weighs the absence of a competence in the field of bioethics and, in particular, in the sector of end-of-life choices.

A similar "osmotic process" is also produced by the future adhesion of the EU to the ECHR.

We think that the EctHR and the EU Charter represent a "bridge" or a "trait d'union" between the Oviedo Convention and the EU law, which could contribute to the achievement of a "European common approach" on end-of-life choices. De iure condendo, this approach could lead to greater sharing of values, to a decrease of differences between EU member States and, finally, to the convergence within a "common European policy" on the issue of Biolaw.

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Advance Directives Regulation in Italy: Between Consent and Legal Rules

Vitulia Ivone

Abstract Decision-making for medical care at the end of life is closely related to the broader subjects of patients' self-determination and informed consent. This chapter explores both issues from the perspective of the Italian legal order in the light of the principles of the Italian Constitution and the standards set by the Codes of medical ethics. It also expands on Italian case law, especially the recent Englaro and Welby cases, both testifying to the important role played by the Italian courts in the absence of a law regulating advance directives. The chapter also offers an overview of the contents and a critical assessment of the Italian draft law, which first attempted to regulate advance directives, also known as Calabrò Bill.

Contents

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1 Introduction

To identify and verify the existence of a corpus of fundamental individual rights pertaining to individuals in our society, each and every sector of life should be looked at closely. End-of-life issues are an integral part of this consideration and as such must be reflected in the entire Italian legal system. The Living Will and its implication to philosophical and ethical issues must encourage law practitioners to place the value of human dignity as the foundation of any legal system and its laws. Also known as a "Health Care Advance Directive", the "Living Will"[1] is a document stipulated by a person of sound mind by which he can instruct his family and future health care givers of his wishes to accept or deny resuscitation and/or life-support treatments if that same person falls into a permanent vegetative state (PVS) or is terminally ill.[2] It appoints the person's health care trustee/proxy and eventually communicates whether he wishes to donate organs and whether he has an existing health care power of attorney. It also stipulates the person's wishes with regard to accepting/denying future medical treatments that could prolong his life if the person becomes incapacitated and unable to make or communicate decisions regarding his medical care. Such a Living Will is also known as a "right to die" document because it allows a person to direct his personal physician to deny him life support if he is diagnosed as being brain dead and therefore has no chance of recovery. From a legal point of view, the definition of "Living Will" is unclear because, according to the Italian legal system, a final will and testament represents

[1] Andorno (2011), p. 73: "The living wills, . . . are (usually written) instructions that specify ahead of time personal preferences regarding the provision—or the withholding—of particular treatments in the event that the individual becomes unable to make decisions in the future". However, he stresses that there is yet no minimum consensus among European countries as to the "minimal formal requirements for the validity of advance directives such as for instance the individual's legal capacity and freedom of choice at the time of its drafting; his/her incompetence at the time of its implementation, absence of revocation in the meantime; the need of a previous consultation with a health care professional, etc" (p. 78).

[2] Gigli (2002): "Vegetative state can occur at the exit from the coma and is characterized by a prolonged condition of supervisory without apparent awareness by the patient or of the surroundings. The patient seems unable to interact with others or to respond to specific stimuli. The pathophysiology of this disorder is not yet clear and the brain damage that can support it are of different types and in different locations. The patient, while alternating sleep to wakefulness, does not show responses with apparent meaning. He is not terminally ill and in no need of machinery for the support of vital functions. However, he needs care, in particular to be hydrated and nourished". This is the opinion of Gian Luigi Gigli, Head of the Federazione Internazionale delle Associazioni Mediche Cattoliche. The patient in a vegetative state can stay alive for years with minimal assistance. Therefore, the patient in a vegetative state cannot be identified in any way with a terminally ill patient, the former case being characterised as a severe disability that requires only an accurate basic assistance, similar to what happens in many other situations of serious injury to some parts of the brain that limit the ability of communication and self-sustenance.

the after-death wishes of a person.[3] As such, it is a mortis causa act with which a person establishes partly or fully what will happen to his body and his property after his death. The considerations addressed, however, in a Living Will are different—they deal with what the person wants to happen to his body before his death.[4]

The Living Will is not optimal because it is impossible to predict all the circumstances that will terminate the life and also because, when a patient is hospitalised in an intensive care unit, the circumstances described in advance directives "in life" may not necessarily be those recorded by the physician. Therefore, the most likely hypothesis is that health professionals draft a template form for advance directives, containing declarations of intent against the application of medical treatment in terminal conditions of life that can be considered as aggressive medical treatment, provided that they do not constitute active or passive euthanasia. Compared to the "living will"[5]—intended as a declaration by which it is determined how physicians should behave in the terminal phase of the illness of a patient when he is not in possession of mental faculties or is unable to take such decisions—advance treatment directives widen the scope of the principle of informed consent in relation to medical treatment of persons who, for whatever reason, have lost their ability to express themselves or suffer from a medical condition that precludes the possibility of providing for their own interests. The Italian legal system lacks a rule that identifies the kind of declaration or conduct that might properly and effectively represent the expression of the wish to avoid medical care once the person is up to the total loss of consciousness. This determines the need to identify the boundaries of informed consent. Article 5 of legislative decree no. 211/2003 or Article 6 of the Oviedo Convention relies on a legal representative to decide in place of the incapacitated person, acting in his interest.

These provisions exist solely to ensure "therapeutic alliance" as the ideal model of a physician–patient relationship. Therefore, the basis of informed consent as an act of exercising the constitutional right to consent to or refuse medical treatment must be sought elsewhere.

The Italian legal system, as yet, has been unable to adapt its laws to encompass the intentions and implications of a Living Will. A draft proposal known as Draft Law No. 10 has been sitting on the drawing boards of the Italian Parliament, waiting for the latest amendments to be discussed and accepted. The absence of a law and

[3] D'Angelo (2011), p. 444, writes "... bioethical issues and advance directives regulation represent, in essence, a significant test of the tendency of the Catholic Church to assume a more direct role in Italian politics or, if you prefer, clear evidence of the real importance that the dictates of the Church's hierarchy have in the institutional practice of political decision-making, first of all in Parliament".

[4] Marino (2005), p. 88; Rodotà (2006), p. 111.

[5] Bailo and Cecchi (1998), pp. 490–501; Campone (2009), p. 11; Casonato (2008); Cendon (2002); Cosmacini (2010), p. 45; Englaro and Pannitteri (2009), p. 63; Girolami (2010), p. 78; Neri (1996); Piana (2010), p. 81; Santosuosso (1990).

recent events involving two cases of euthanasia[6] received extensive media coverage and triggered a serious public debate. The participants in this debate have involved not only those immediately affected by this topic (the families, the national health service, civil rights lawyers, the Italian legal system) but also the civil society, fully aware that this is an "ethically sensitive" subject that forces the people to consider what side they would take if it were them. Generally speaking, any new law is usually founded on an established one that is then modified, only to be modified again as each epoch dictates future modifications. Every law therefore fits into a larger context, that is to say, into a "system" with which and from which the law receives its directions. And so, to take on the issue of Advance Directives, it is necessary to analyse the issue of informed consent as it is treated in Italian law.

2 Informed Consent According to the Italian Constitution

The practice of free and informed consent[7] is a form of respect for individual freedom and a means to attain the person's individual best interests. The principle of informed consent expresses a choice of value in the way of understanding the relationship between physician and patient, which appears to be based first and foremost on the rights of patients. Consent pertains to the moral freedom of the patient, his self-determination and physical ability, understood as the right to respect the individual's bodily integrity: that said, then the patient's right to be treated by the physician is being taken away and is replaced by a general "right to cure", which may not reflect the will of the sick person. In the Italian legal system, the right to self-determination allows the person to dispose of assets of a personal nature, such as his physical integrity.

The analysis of two documents, one presented by the Italian National Bioethics Committee and the other being the Code of Medical Ethics, helps our understanding of the topic.

The National Bioethics Committee (established by the Italian Presidency of the Council of Ministers) has declared that "The Advance Directives can be written on a document duly signed by the interested party and, subsequently, health care givers must not only take these directives into account, but must also justify in writing any actions on their part which violate the stated directives". Underlining the free and voluntary character of health care, the Code of Medical Ethics (CDM)[8] states that

[6] This refers to Welby v. the State and Englaro v. the State, infra Sect. 3.

[7] The issue of informed consent has been fully covered in legal scholarship. See, in particular, Nannini (1989), p. 74; Santosuosso (1996); Ferrando (1998); Pinna (2006), pp. 590–594; Calderai (2005), pp. 325–330; Guerra (2005); Facci (2006); Cacace (2007); Moccia (2007), p. 87.

[8] The Code of Medical Ethics was approved by FNOM-CeO on December 16, 2006. A study of the Codes of Medical Ethics, which followed one another over time, shows the progressive evolution undergone by this subject. The first Code of Ethics of 1954—known as Frugoni Code and never made official—discussed the issue of consent, stating that "consent may be validly given only by

physicians are bound by the free and conscious will expressed by the person to receive medical care. When a patient refuses this care, the physician "must desist" from acts of diagnosis or treatment. If the patient is incompetent, the health care giver is invited to "take account" of his earlier will, in the absence of a law on advance directives. Article 13 of the CDM recognises the autonomy of the physician in planning decisions and implementing diagnostic and therapeutic methods,

> except when the patient's will is to reject or refuse taking responsibility for himself in the observance of the fundamental rights of the person, the Code sought to avoid any exhaustive manner of using coercion against a patient able to decide for themselves. It is necessary to emphasise the role of physicians within the constitutional framework of the right to receive health care. The Code of Medical Conduct states at Article 34 that

The physician, while respecting their own dignity, freedom and professional independence, must adhere to the freely expressed wishes of their patients with regard to medical treatments. The physician or health care giver must not ignore any previously stated wishes if a severely ill patient is unable to communicate their wishes. Both these documents, even though not binding, represent an important parameter of reference not only because they both place the patient at the centre of all considerations but above all because they bind the physician to declare the justification for any violation of the patient's wishes and directives. Such behaviour, while not mandatory, appears to be in line with the fundamental principles at the basis of the Italian legal system: with reference to Articles 2, 13, and 32 of the Italian Constitution, a document that safeguards our basic inviolable human rights and, in particular, the freedom of the individual who seeks the realisation also of his personal health choices. In particular, Article 32 of the Constitution establishes that

> The Republic shall safeguard health as a fundamental right of the individual and as a collective interest and shall guarantee free medical care to the indigent. No one may be forcefully submitted to medical treatment unless provided for by law. In no case may the law violate the limits imposed by respect for the human being.

The first sentence of Article 32 highlights the good of public interest and that of community interest, while the second part establishes the criteria of assessing an individual's willingness to undertake health treatments, thus emphasising the private sphere of the individual.

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those who know exactly the scope and consequences of consent itself, which can occur only exceptionally in the physician-patient relationship". It is thus established that consent may be requested only by the physician. In the Code of Ethics of 1978, this topic is dealt with in Articles 30 and 39: the latter rule states that the patient's consent is required when in the proposed treatment there is an inherent risk and that consent must be valid. In Article 30, the problem of disease with poor prognosis is dealt with: it could be hidden from the patient but had to be disclosed to the family. A new Code of Ethics was published in 1989, first replaced in 1995 and again in 1998: in this new text, it is shown that consent is now well established in the medical culture. In particular, Article 30 refers clearly and simply to the kind of information that is required for consent to treatment, stating that it must be appropriate and consistent with reality, taking into account the capacity of understanding of the patient in order to promote maximum adhesion to the proposed diagnosis and therapy.

An important limit to an individual's right to make decisions about his own body is found in Article 5 of the Civil Code, which prohibits the individual from performing any acts of disposition of his own body that may cause a permanent diminution of his physical integrity. The same rule, even if frequently invoked by those who deny the right of self-determination, encounters however in standard applications at least two important limits that create doubts about its absolute relevance: the consent to donate organs and the hypothesis of ius sepulcri. In both cases, the individual can make arrangements for the disposal of all or part of his body for a time when he will be unable to make such arrangements; the noticeable difference being that the individual would already be dead when his wishes were carried out. In this hypothesis, then, the legal system offers examples of situations in which the obligation not to dispose of one's body leaves space for the wishes of the person, determined by his own situation. Such power not only refers to one's actions but could also express itself in a declaration to palliative health care givers of the patient's wishes in the event of being terminally ill. The imperative limit imposed on this decisive action of the patient results from the application of the Penal Code, which in Article 579 ("murder by consent") considers killing a person who has consented to being killed as manslaughter and in Article 580 ("instigation to suicide") considers the actions of those who assist and/or encourage others to commit suicide as criminal. This provision clearly proves that euthanasia is forbidden. Therefore, the protection of an individual's rights appears to be less effective than the imperative rules when the individual chooses an action that leads or might lead to his death. With no doubt, this prohibition contrasts with the rights of a person to refuse medical treatment on the ground that such refusal would inevitably result in the person's death.[9] For this reason, the hardest thing in identifying the correct conduct in such situations can be found in the fine line dividing the patient's refusal of treatment and the patient's suicide. In particular, in the distinction between "active" and "passive" euthanasia, consider that the "active" form is illegal, while the second form is permissible.[10] The fundamental difference between the two forms of euthanasia can be found in the fact that in the hypothesis of active euthanasia the health care giver actively contributes by providing and using lethal drugs, while in the case of passive euthanasia the health care giver avoids using or stops using all life-support treatments that all keep the patient alive. While such cases of active euthanasia are easily identifiable, other cases of passive

[9] Giunta (1997), p. 108 ff.; (2001), p. 380 ff.

[10] The terms "euthanasia" and "assisted suicide", present above, all in the political and social debate linked to the draft legislation on "advance treatment directives", do not appear in the Italian Criminal Code due to the already-mentioned semantic and phenomenological variance of the words, which generates undoubted difficulties of standardising them. The 1930 Criminal Code does not provide a specific regime for euthanasia, but the relative conduct can be considered, certainly with some difficulty, by reference to the paradigmatic cases of "murder by consent" (Article 579 of the Criminal Code) and "instigation or assisted suicide" (Article 580 of the Criminal Code), as well as, obviously, "murder" (Article 575 of the Criminal Code). See the chapter by Corn, in this book.

euthanasia go unseen, above all in situations of complex therapies, when it is difficult to distinguish between 'death from natural causes' and 'death from medical intervention'. We should keep in mind that the Italian legal system, in line with European principles, prohibits aggressive therapy in which life-support treatments are disproportionate and unjustifiable.

3 Comments on the Right to Health as a Fundamental Human Right: The Evolution of Article 32 from Its Original Formulation to the Current Definition of Health

As said before, Article 32, para. 1 of the Italian Constitution confirms that "The Republic shall safeguard health as a fundamental right of the individual and as a collective interest and shall guarantee free medical care to the indigent".[11] In the 1947 Italian Constitution, Article 32 was hindered by various members of Parliament, a fact that continued to create practical consequences up until the 1970s, when its effect on Italian legal rulings was clearly felt. In fact, it was not until 1970 that the sense of the Article was applied across the boards.[12]

With the legal reconstitution of the phenomenon "Health", it appeared to "benefit the community" while limiting individual freedoms.[13] This profile is clearly reflected in the same Italian Constitution, which mentions health as a limit to private freedom. The Constitution authorises such limitations that are not covered by a court decision: limits to the inviolability of home for reasons of public health and safety (Article 14), limits to the freedom of movement and residence for reasons of health (Article 16), and limits to the freedom of assembly in the name of public safety (Article 17).

Within this perspective of health as a community benefit (whereby it appeared to be a duty to be and remain healthy rather than have the right to be healthy), two other elements became evident—the right to well-being and the right to health care—which emerged in the Constitution with the birth of the social state during the first half of the twentieth century and in the consequent legalisation of social rights.

It was only in recent decades that a more sensitive legal doctrine has considered health as being an autonomous fundamental individual right.

[11] The Italian legal literature on these topics is very wide: Lessona (1950), p. 336; Pergolesi (1961), p. 112; Mortati (1961), p. 1; Carlassare (1967), p. 14; Merlini (1970), p. 78; Bessone et al. (1974), p. 67; Vincenzi Amato (1976), p. 32; Busnelli and Breccia (1978), p. 89; d'Alessio (1981), p. 536; Modugno (1982), p. 303; Pezzini (1983), p. 21; Caravita (1984), p. 14; Luciani (1986), p. 439; Romboli (1988), p. 81; Bottari (1991), p. 79; Modugno (1995), p. 40; Teresi (1998), p. 114; Bottari (2001), p. 112; Balduzzi and Di Gaspare (2002), p. 108; Chieffi (2003), p. 18; Rodotà (2006), p. 112; Zatti (2009), p. 313.

[12] Cheli (1997), p. 51.

[13] Bartole et al. (2001).

With respect to freedom, the right to health can be divided into several parts and, as such, presents many complex legal positions.

The physical and psychological integrity of an individual is of the utmost importance in the protection of health, without excluding other considerations. Since the 1970s, Italian courts, and then the Constitutional Court, have identified a perspective to protect this integrity in the form of redress for direct and autonomous damage—"biological damage"—combining Article 32 of the Constitution with Article 2043 of the Civil Code. With the historical decision No. 88 of 1979, the Constitutional Court ruled that Article 32 protected health not only

> as a community interest, but also, and above all, as a fundamental right of the individual, so that it represents a basic and absolute right, fully applicable also in inter-individual relationships … indeed to be included within the subjective positions directly protected by the Constitution.[14]

The difficult balance is highlighted between the right of the patient to be treated effectively and the right to be respected as a person in his physical and mental integrity: this right is enshrined in Article 32, para. 2, as the insurmountable limit event to medical treatment that may be imposed by law in order to protect public health.[15]

Paragraph 2 provides that "no one may be forcefully submitted to medical treatment unless provided for by law" and shows the insuperable limit of respect for the human person: in this way, it brought the issue of the existence, under Italian law, of a right to refuse health care. This issue falls within the broader context of the liberty rights granted to the individual, especially when the pathology only affects the sick person, without any involvement of other members of the community.[16]

Medical treatments referred to in Article 2 have been interpreted by the doctrine as "any therapeutic or diagnostic activities, to prevent or treat diseases".[17] These activities have been divided into several categories: compulsory, coercive and non-binding treatments. The first are those characterised by a compulsory treatment provided by law and punished with the use of a variety of measures (such as the inability to travel to countries where certain vaccinations are not practiced); coercive treatment is that imposed by force; non-binding treatments are not provided by any provision, for which there is the other problem with the role and limits of

[14] Constitutional Court, 14 July 1986, n. 184, available at http://www.cortecostituzionale.it.

[15] Mantovani (1990), who states that "collective health cannot be conceived as a good in contrast to that of individual health". In the event of a clash between those two interests, "the collective interest of health cannot prevail over that of the individuals and therefore the imposition of the sacrifice of those goods would be in breach of the principle of protection of the human personality in its intangible rights".

[16] Luciani (1980), pp. 669–679; Modugno (1982). In particular, in cases where the need to protect the health of the individual joins the equal need to protect the entire community, the right of the individual must be balanced with that of the community to the extent available, regarding health treatment, mandatory or coercive (paragraph 2 of article 2 of the Constitution).

[17] Amato (1976), pp. 176–472; Sandulli (1978), pp. 507–518; Anzon (1980), p. 1449; Perlingieri and Pisacane (2001), pp. 202–208.

consent in relation to Article 5 c.c.[18] Determining the legitimacy of health treatment poses a problem of coordination between Article 32, para. 2, and Article 13 of the Constitution. Legal scholarship is not unanimous: according to some authors,[19] medical treatment applies only to Article 32, para. 2; according to others,[20] bearing in mind the distinction between compulsory and coercive medical treatment, Article 13 is deemed to apply to the latter. Thus, this rule would arise as a general framework for all forms of limitation of personal freedom and therefore for any coercive measures affecting the freedom of the individual to decide for his own.

In reference to the Italian Constitution, there is a guarantee that it is not possible to read Article 32 as a rule that expresses primarily the duty to preserve the health in the exclusive interest of the community, legitimating a power of public intervention, nor can it be thought to accentuate only the individual moment, transforming the personal inviolability as designed by the Italian Constitution.

4 The Psychophysical Integrity of the Person and Health as a "State of Complete Physical, Mental, Social and Spiritual Well-Being"

Health, as an essential profile of the human person,[21] cannot be reduced only to the absolute right to respect for the physical integrity of the person: first, health is not just about the physical integrity of the person but also about his psychic integrity, in a vision that emphasises the unity and indissolubility of the human person. Second, health is not just a static and individual aspect, but it is also connected to the healthy and harmonious development of the person.[22]

Moreover, the right to health cannot be reduced to health care: health care is the bureaucratic apparatus of the State in which the National Health Service (SSN) is articulated. This is because health is very important in the relationship between people.

Thus, the human person is a psychophysical unit: therefore, it is impossible to separate the health from the complex value of the person. Consequently, it is not possible to identify a conceptual autonomy of health because it is inseparable from the human person. Health, therefore, although independently provided in the Constitution (Article 32), must be considered together with the disposition that, as the general provision of individual protection, recognises and guarantees the rights of the person (Articles 2 and 3, para. 2).[23]

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[18] On the specific issue of vaccination, see Panunzio (1979), pp. 890–902.

[19] Crisafulli (1982), pp. 557–566.

[20] Pace (2008), p. 87.

[21] Mortati (1961).

[22] Perlingieri (2005a), p. 104; Perlingieri (2005b), p. 137; Capizzano (1974), p. 1002.

[23] Perlingieri (2005b), p. 185; Capizzano (1974), p. 1004.

This means that the protection of human dignity must be realised with regard to all aspects of the person.The autonomy of "health" is not considered only by assessing the injustice of its violation, especially because it can occur that a value legally relevant on an existential level does not result in a corresponding patrimonial evaluation. Health, as an aspect of the human person—and so as an existential value by definition—cannot achieve a protection through the use of dispositions inspired by an exclusive patrimonial logic, or its protection can be exhausted in a valid criterion for the problems of property and production.

The central problem is the identification of the legitimacy and worthiness of protection of the instances in the concrete circumstances.[24] The opinions are not uniform. Someone has said that the foundation of reflection is to be found in Article 13 of the Constitution, while others have expanded the constitutional principle of solidarity and theorised a correlation between the right and duty to health—expressed in Articles 32 and 2 of the Constitution—and the presence of an inescapable duty to provide for their own preservation.

The other dimension of the right to health, as a social right or as a right to receive a benefit, may be exercised in public and private structures. It is important to distinguish the right to be treated and the right to receive free medical care: Art. 32 of the Constitution provides protection only to the first, forcing the State to prepare the organisational apparatus in order that the right to be treated can be guaranteed. The right to free treatment is instead provided by the Constitution only to "the indigent."

The Italian Constitution prescribes a minimum threshold. Subsequent laws have in some phases provided more extensive protection. The reform of 1978 has provided a system based on free general care. This system was later partially abandoned for cost reasons. In general, this is a problem of social rights, which involves cost because they require a complex administrative apparatus, as opposed to the rights of freedom. The Italian Constitutional Court has recognised in the 1990s that the protection of social rights can be linked to the availability of financial resources, and therefore social rights are rights that are configured as "financially affected".

However, the Court later stated that the core of social rights, and in particular the right to health, cannot be compressed and therefore cannot be balanced with the needs of public finance. The core of the right to health is rooted in the need for protection of human dignity.

Dignity is at the core of fundamental rights and represents a limit to the exercise of other rights, for the protection of those situations that cannot sometimes be directly placed under specific subjects fully capable of self-determination, but they refer more generally to vulnerable persons and to would-be human beings (the embryo, the foetus) or to what is human without being attributable to a subject (think of the problems of research on the human genome, genetic manipulation, or cloning).

[24] Carnelutti (1968), p. 202; Cataudella (1991), p. 161 ff.; Lonardo (1993); Russo (2001), p. 573.

In this perspective, we can also analyse the freedom of treatment, understood as a social right to choose between treatment options, the economic costs of which are borne by the National Health Service.

5 The Evolution of Consent in the Context of the Codes of Medical Ethics

The principle of informed consent expresses a choice of value in the way of understanding the relationship between physician and patient. Consent pertains to the moral freedom of the subject, his self-determination, and his physical ability, understood as the right to respect the individual's bodily integrity. The patient cannot be considered a person in a position of awe: it is more appropriate to recognise the physician's right or the power to heal and also the patient's right to choose or refuse or terminate therapy at all stages of life, even the terminal one. It honours the personal principle enunciated in the Italian Constitution that interprets the human person as a value in itself, prohibits any manipulation of it, and notices the intervention of solidarity only on the basis of the person and his harmonious development.[25]

The principle of informed consent to medical act is configured as a "person's real right".[26]

In the present time, the physician cannot always justify his choices on the basis of implied and presumed consent but must communicate all the information to the patient, who—independently and consciously—must decide without any external influences. In this perspective, the sick person may refuse medical intervention for many reasons, inspired by moral norms or rules of prudence, even if the choice can favour or indirectly cause death.[27] The physician is obliged to comply with these decisions.

To understand the evolution of the issue of informed consent and the decline of medical paternalism, it is very useful to analyse the Italian Codes of Medical Ethics (CDM).[28]

[25] The function of Article 2 Constitution, considered in the totality of its systematic articulations, is that of a general "open" clause aimed to protect the person. Through the statement of the unique value of the human person, the rule "requires that the person is protected in all its manifestations essential to its development, even when they have not been made explicit through a type of regulatory legislation". In this way, "the protection of personality can be considered unitary, undefined, unlimited, flexible and adaptable as far as possible to the concrete situations and to the cultural and environmental problems in which it occurs".

[26] Constitutional Court, 23 December 2008, n. 438.

[27] Gracia (1993), p. 22 ff.; Gorgoni (2009), p. 126 ff.

[28] Formaggio (1958); Norelli and Dell'Osso (1980).

5.1 The History of the Italian Codes of Medical Ethics

The Code of Medical Ethics is the official position taken by the Medical and Dentists Organization (FNOM-CeO) on the behaviour of the physician in various professional fields. The Code deals with the most important ethical issues, for each of which the rules of good behaviour of the physician are given.

Since 1954, in the Code of Medical Ethics, the issue of consent was dealt with by stating that "consent may be validly given only by those who know exactly what are the object and the consequences of the agreement itself, which would occur only exceptionally in the relationship between physician and patient".

It is established that consent may be requested only by the physician.

The following statement implies very serious consequences: "At the time of conclusion of the contract between physician and patient there is a manifestation of will which implicitly includes the consent to use the means that the physician deems appropriate". The issue of consent to medical act, in the ethical code in 1978, is dealt with in Articles 30 and 39. In particular, Article 39 establishes that the patient's consent is required if the proposed treatment implies an inherent risk. Furthermore, it must always be expressed in a valid way. The code does not establish, however, what is meant by "valid". In cases where refused consent is necessary, the physician should ask for a release by the person or his family. It is clear that the freedom of choice of treatments to the patient up to that point had not yet been acknowledged by the medical culture.

The new Code of Ethics was published in 1989 and contains the results of many reflections and debates.

In fact, Article 40 makes a sort of revolution: the request for consent becomes a duty for the physician, to be implemented for therapeutic and diagnostic activities, and thus not only when there is a risk. In these cases, consent must be given explicitly, in writing. In the Code of 1989, there is also a better clarification of the formal and substantial requirements of consent, and for the first time there is a reference to the information to be given to the patient. Article 39, in fact, is very clear in pointing out that it is the physician's duty to provide information on diagnosis, prognosis, and therapeutic perspectives and on their consequences. It also shows the way in which the information must be given (taking into account the level of culture and capacity for discernment of the patient), and the physician must make it clear to the patient that medical knowledge is limited and must respect the rights of the patient.

The physician–patient relationship becomes an equal relationship, where the patient is no longer the man who relies on medical attention (paternalistic relationship) but instead the one who asks for and expects from the physician all the necessary information to decide, with all the available elements, to which treatment he wishes to adhere.[29]

[29] Fineschi (1996), p. 28.

Currently, the physician–patient relationship revealed some critical issues, especially in relation to the refusal of treatment. In fact, the patient is the one who needs the physician and starts a relationship with him dictated by the need to be informed. This is a helping relationship, particularly complex for the kind of help needed, where the personal aspect meets the material aspect. From here, the two aspects of medicine, scientific knowledge and technical ability living together, needs to act on the patient's body.

These considerations have led to informed consent that, while calling for greater medical attention, relates to the patient and places him on a plane of consciousness. However, there is still the possibility to hide a poor prognosis from the patient—differently from countries that do not admit it—even "in relation to the responsiveness of the patient".[30]

The Code of Ethics of 1995 refines the information contained in Article 39 of the previous Code: concerning the information for valid consent, it states that the physician must take account of the patient's emotions, along with his level of education, when giving the information and ensure that the information given is the less psychologically traumatic, as well as the most suitable, avoiding to provide a false information on the reality of the disease. In addition, the text acknowledges that the information may be "limited to those items that culture and psychological condition of the patient are able to understand and accept, avoiding unnecessary details of data on scientific aspects". This represents the implementation of the recommendations issued by the CNB in the document Information and Consent to Medical Act in 1992, which provided that the physician should provide the information according to the so-called medium standard model, which

> requires to say what a reasonable person, considered as average within of a community, would like to know and could understand of the medical procedure that will affect her (with the benefit of the popular level of exposition, but with the ambiguities related to the notions of reasonable and average).

5.2 From the Code of 1998 to the 2006 Code

With the publication of a Code of Ethics in 1998, the subject of consent was accepted in medical culture. Article 30 states clearly and simply the requirements of information to be provided for the consent to treatment (diagnosis, prognosis, prospects, possible therapeutic alternatives, the expected consequences of the choices made). In that article, it is stated that the information must be

[30] Article 44 states that "if it is accompanied by lack of conscience"—and this is the first step towards the situations for which today we discuss about the advance directives treatment—"the physician shall act in good faith and consciousness continuing in therapy until fairly useful". It is left, therefore, to the physician to decide what the useful therapy to the patient is. The importance of this rule lies in the fact that it, for the first time, takes into account the quality of life as a parameter of behaviour in the case of terminally ill patients.

appropriate—close to reality—and should be given taking into account the understanding of the patient, in order to promote maximum adhesion to the diagnostic and therapeutic proposal.

It is also confirmed that in cases of poor prognosis the information should be given with caution and not in traumatising terms, directly to the patient, unless (and this is a new fact) it is himself who asks, in writing, to give the information to a third person. This introduces for the first time the concept of "proxy", a person who is not necessarily linked to the patient by blood and to whom the information can be supplied.[31]

Title II (General Duties of a Physician) takes care of the "Findings of diagnostic and therapeutic treatments". Here, the Code explicitly declares the prohibition on aggressive treatment, if it is the opinion of the patient to be such and it cannot be expected that it benefits the patient's health or at least that it causes an improvement (Article 16). It also reiterates the prohibition on euthanasia (Article 17), and concerning the treatments that affect physical and mental integrity, their viability is dependent, on the one hand, on therapeutic assessment and, on the other hand, on effective clinical benefit for the patient, in terms of reduced suffering (Article 18).

Article 34 of the Code states that "the physician must follow, in respect for their dignity, freedom and professional independence, the freely expressed will of the person", which allows the physician to comply with the wishes expressed by the patient, but always respecting his own professional independence.[32] Therefore, in the presence of an explicit will of the subject, the physician is obliged to abide by it, provided that this does not conflict with the principles of independence and dignity of the medical profession.

In case the patient is not able to express his will, the physician must take account of what has been previously expressed, in adherence to the European Convention on Human Rights and Biomedicine of 1997. This principle is in line with recent legislative trends that led Italy to adopting the law on organ transplants (Law of 1 April 1999, n. 91), in which the principle of silent consent is expressed.

In the Code of 16 December 2006, the sections devoted to General Duties of physicians and Relationship with citizens are very important.

The prohibition on aggressive treatment, if requested by the patient, is explicitly stated, and the ban on euthanasia is reiterated.

The Code devotes six articles to the subject of information and consent. Standing out is the general information to citizens as distinguished from information to third parties. The general information to the public must have as content "diagnosis, prognosis, prospects, possible therapeutic alternatives, the expected consequences of choices made". Moreover, the physician must not engage in diagnostic and therapeutic activities without explicit and informed consent of the patient, and in

[31] Cecchi, (2006), p. 113.

[32] This article, innovative in relation to the text of the previous Code, stresses the need for respect by the physician of the clearly expressed will of the subject about his choices in order to protect his own health.

the presence of a valid refusal of a competent person the physician should desist from any diagnostic and curative activities. There can be no medical treatment against the will of a person: from this we deduce the new concept of freedom of self-determination of the patient.

6 Outdated Laws Versus Updated Medical Technology

When the Italian Constitution was written, medical research and development were in their first stages of existence. Not even antibiotics had been invented, let alone the incredible recent advances in medical research and its associated technological revolution that has taken place in the area of health care. The average life expectancy was almost half that of today's. As such, the miracles possible today were inexistent, and therefore patients then died earlier and faster. Now, thanks to medical advances, a person can hope to live long and well. But when a person is unable to hope for recovery, or to wake from a brain-dead coma, this same technology becomes his prison and his torturer. This was the case with Eluana Englaro (in a PVS for 15 years) and Piergiorgio Welby (perfectly lucid and able within a completely paralysed body).

6.1 The Welby Case and the Degenerative Pathological State

This section discusses in particular detail these two separate cases that have been responsible for bringing to the Italian people the need to consider the issue of patients' rights and their "best interests".

Piergiorgio Welby had suffered from a serious degenerative pathological state, inhibiting any movement of the body, for which there was no medical treatment that could halt the development of the disease. Despite this condition, Welby had retained all his full mental faculties and had interested himself in the evolution of his illness and had expressed his conscious opinions about the treatments themselves. On 16 December 2006, the Court of Rome deposited the order that declared inadmissible the appeal of Piergiorgio Welby, who had asked to be separated from the ventilator that kept him alive. Indeed, after asserting the constitutional nature of the rights and freedoms of the person in relation to his body and the right to self-determination, the Court of Rome stated conclusively that these rights cannot be implemented because "the underlying principle inspiring the legal system is the inviolability of the right to life". The reference is Article 5 c.c., which prohibits any acts of disposal of the body that can cause permanent damage, and Articles 575; 576; 577, § 3; 579; and 580 of the penal code, punishing murder by consent and assistance to suicide. The decision upholds two principles: first, the rights and freedoms of the person in relation to his body are affirmed, but exclude the right to refuse life-saving treatments; second, these rights and freedoms, while having

constitutional status, are outweighed by the right to life, which is prevalent as the basis and precondition of all other rights. Finally, the greater weight of the right to life is inferred from the systematic position of Article 2 of the Constitution, which, being a general close, necessarily comes before Articles 13 and 32 of the Constitution, as well as the position of guarantor of the physician and the prohibition of acts of disposal of the body. This legal reasoning is identical to the one applied in the case of Eluana Englaro: the Court of Appeal of Milan—as will be seen—in its decision of 16 December 2006 first, recognised that "under the right to health and self-determination in health, the competent subject can refuse also the treatment necessary to keep him alive" and that in case of incompetent person, there must be a balance between the right to self-determination and right to life and that it "can be resolved in favor of the right to life". This fundamental analogy made by the courts leads to the conclusion that, although we have two totally different situations—Eluana Englaro in a PVS for 15 years and Piergiorgio Welby perfectly lucid and capable—it clearly appears the idea of life as a "super-right" that does not allow any distinction on a case-by-case basis and cancels the important distinction between conscious and capable patients and incompetent patients. In particular, Welby's request was to detach the ventilator under terminal sedation to avoid suffering. The hospital and the physician denied Welby's request: while the right of freedom and to the conscious wishes regarding the acceptance or denial of any medical therapy was recognised, there was a limit: the protection of the right to life was not removal, not even by the person concerned.[33] Welby's motivations were based on the principle of informed consent as the basis of any therapy, on the consequential configuration of a full and informed right of self-determination in rejecting any intrusive activities of a medical nature, including the right to discontinue therapy for which his consent had been revoked. Welby's request for urgent action by the court to ensure the right to validly express the refusal of unwanted medical treatment was in part accepted by the judge,[34] who stated that he could not command the physician not to reinstate the therapy because that choice fell within the physician's discretion to assess the usefulness of a therapy, as enshrined in Article 37 of the Code of Medical Conduct. This rule states that

> in case of diseases with certainly unfavorable prognosis, or at least in the terminal stage, the physician should guide their actions for the purposes of moral support and of administration of any pain therapy by providing those in need, as far as possible, with treatments appropriate to the preservation of the quality of life.

On 23 July 2007, the Court of Rome recognised Welby's "right" to refuse treatment and the "duty" of the physician to respond to the request of the patient. In this way, a very important role in the Welby case was played by his physician, Dr. Riccio, who was finally acquitted on the criminal charge of manslaughter at the

[33] Specifically, if the patient has been sedated and is therefore no longer able to decide, the physician and the hospital are required to reattach the ventilator to restore breathing and avoid the risk of life.

[34] Procura di Roma, opinion 11 December 2006, Bioetica, 2010, p. 34.

end of a very complex trial,[35] which showed that the heart of the problem was the relationship between physician and patient in their separate roles, thus freeing this situation of all external and instrumental intrusions.[36] The importance of informed consent is enormous not only from a legal viewpoint but also under the ethical and deontological profiles. The power to heal is limited by the patients' will of self-determination in relation to their health needs, except for cases of compulsory treatment provided by law or emergency situations that pose a serious hazard to community health. Therefore, informed consent to medical acts not only has ethical and contractual relevance to the provision of medical assistance, but it is also a precondition for the legitimacy of medical and surgical treatments.

6.2 The Englaro Case

The Englaro case[37] raised the issue of the scope and limits of patient autonomy and the problem of defining the status of the legal guardian of the incapacitated person and the sense of the expression "personal care". The story concerns the young Eluana, who remained in a PVS following a car accident in January 1992 and since then was nourished and hydrated through a nose feeding tube. Eluana's father, her legal guardian, asked the court for permission to stop "treatment which allowed her body to prolong the vegetative state":[38] in particular, in his submissions to the Court of Appeal of Milan of 8 October 1999, Eluana's father stated how difficult it was "in such conditions to bring back the subject to the concept of the human person and even to that of a living person". This was because Eluana had stated many times, when she was healthy, that she did not want "to be held in such undignified conditions". Therefore, the refusal of treatment expressed by the guardian was the expression of a wish expressed by the girl when she was in "a state of total capacity". In 1999, the Court of Lecco stated that "any form of euthanasia" is an unacceptable attempt to justify the tendency of the community—unable to provide adequate support for individuals forced to extreme dedication toward the sick in the hope of recovery—to neglect the rights of its weakest members and particularly of those who are no longer in a position to lead a conscious, active, and productive life. In rejecting the appeal, the Court of Appeal of Milan in 2003 emphasised the role of the legislator to identify and develop the correct tools for the effective protection of

[35] Having noted that his request to the President of the Republic "to obtain euthanasia" could not be upheld, Welby had spoken to two physicians so that they could satisfy his request. While Dr. Casale had preferred to wait for the intervention of the judiciary, Dr. Riccio considered it to be his duty to grant the request of the patient and to accompany him in the short period of time between the plugging off of the ventilator and death.

[36] Riccio (2008), pp. 11A–17A.

[37] The case of Eluana has a difficult qualification: this is due to its strong symbolic power and the fact that, for the first time, the issue of the interruption of artificial hydration is addressed.

[38] Court of Lecco, 18 January 1999, Foro italiano, 1999, p. 1306.

the person and the respect of his right to self-determination. By decision of October 16, 2007, no. 21748, the case was referred to the Court of Appeal of Milan to determine whether the statements made by Eluana before falling into unconsciousness were able "to draw [. . .] her personality and her way of conceiving [. . .] the very idea of personal dignity, in light of her values and the ethical, religious, cultural and philosophical beliefs which guided her will".[39] The reasoning of the Court led it to extend the scope of its final determination, expanding on other major issues concerning the effectiveness of advance directives and also the limits within which a patient in full possession of his capacity may refuse treatment. The key part of the decision is its reference to the principle of informed consent as a direct result of Articles 2, 13, and 32 of the Italian Constitution: as a principle, which is accepted in several rules of national[40] and international law,[41] has to be construed as "inclusive of the possibility for the patient to request cessation of treatment even when that involves his death". Before the ruling of 2007, the courts had always rejected the request of the applicant, although for different reasons. The decree of July 9, 2008, endorsed the option to terminate artificial feeding via a nose feeding tube, enunciating the following principle:

> When the patient has been for many years in a permanent vegetative state, resulting in a radical inability to relate with the outside world, and when they are kept artificially alive by a tube that provides nutrition and hydration, at the request of the guardian representing them, and heard the 'tutor ad litem', the court may authorize the withdrawal of such medical practice only on the following conditions: a) when the condition of vegetative state is, according to a rigorous clinical appreciation, irreversible and there is no medical fundament, according to internationally accepted scientific standards, which suggest even the slightest possibility of some, although weak, recovery of consciousness and return to a perception of the world, b) provided that such application is really expressive, on the basis of clear, unequivocal and convincing evidence, of the voice of the patient themselves, as drawn from their earlier statements or from their personality, lifestyle and beliefs, thus corresponding to their way of conceiving, before falling into unconsciousness, the very idea of human dignity.

This principle is at the basis of the judgment delivered by the Court of Appeal of Milan on July 9, 2008, by which it authorised the discontinuation of life support through an artificial feeding tube after having verified consistency with the parameters set by the Court of Cassation. On November 11, 2008, the Supreme Court declared inadmissible the action brought by the public prosecutor of Milan against the order of July 9, 2008, of the Court of Appeal of Milan, considering that the classification of the case put in place in that judgment was correct. On February 9, 2009, Eluana died because of discontinuation of life support.

[39] Nivarra (2010).

[40] The reference is to Articles 1 and 33 of Law No. 833/1978, which established the National Health Service.

[41] The reference is to Article 5 of the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) and to Article 3 of the Charter of Fundamental Rights of the European Union.

6.3 Recent Case Law by Administrative Courts

The close relationship between the Englaro case and the issues related to the subject of human dignity is reinforced by the decision of the TAR (the Regional Administrative Court) of Lazio, on September 17, 2009, no. 8560, according to which

> Patients in a permanent vegetative state (PVS), who are not able to express their will about the health care being practiced, or to be practiced on them, should not in any case be discriminated in comparison to other patients who are able to give their consent, and they may, where their will has been reconstructed, avoid that certain medical treatments be practiced on their body.

Also, the patient "has a constitutionally qualified right to be healed according to their desires, since it is entirely up to them to decide which treatment to undergo". In the same direction also moves the decision issued on appeal by the Movement in Defense of the Citizen

> against the directive by the Secretary Mr. Sacconi ordering all facilities of the national health service to always forbid the interruption of artificial feeding and hydration in PVS patients, and thus even to prohibit it when the reconstruction of the patient's wishes indicate their rejection of such practice.

The TAR, after stressing that the issues at stake involved the "constitutional right to personal freedom that Article 13 (the Constitution) qualifies as inviolable"—enhanced by the entry into force of the International Convention on the Rights of Persons with Disabilities,[42] which requires for the same situations the guarantee of informed consent—stressed that

> the importance of the constitutional rights involved prevents that they be limited by the exercise of power of the public authority. As a consequence, they are excluded from the jurisdiction of the administrative judge and in case of violation of the principles set out by the TAR, it is up to ordinary courts to ensure full respect of dignity and personal freedom.

The importance of this decision lies in the fact that the TAR has established the jurisdiction of ordinary courts just after stating the constitutional nature of the individual right to choose which medical treatment or intervention should be practiced on one's body. With reference to persons who are unable to express their will, such as PVS patients, the TAR has made it clear that they cannot be discriminated against. Therefore, it is very important to grasp the scientific and legal aspects related to the definition of a PVS,[43] regardless of the different

[42] The Convention on the Rights of Persons with Disabilities was adopted on December 13, 2006, during the sixty-first session of the General Assembly of the United Nations by resolution A/RES/61/106. The Convention and its Optional Protocol were opened for signature on March 30, 2007. Until May 14, 2007, there were 92 signatures to the Convention, 50 signatures to the Optional Protocol, and one ratification to the Convention. This is the first major human rights treaty of the twenty-first century.

[43] The official definition of permanent vegetative state was coined in 1972 (Jennett (2002), pp. 12–31). Unlike the coma, PVS is a state or condition in which there is no real disease: the subjects may not have precise pathologies but are still in situations characterised by the loss of

positions expressed over time.[44] In the case of Eluana, by decree of July 9, 2008, the Court of Appeal of Milan reconstructed her wishes, highlighting that the continuation of nutrition and hydration had to be considered as an (unlawful) aggressive medical treatment, hence consenting to its suspension. Even taking into account the precedent set by this deliberation whereby nutritional therapies are subject to the principle of informed consent and could represent aggressive treatment, Article 3 of the Draft Law "Calabrò" (to be discussed below in Sect. 4), concerning the content of advance treatment directives, expressly bans the withdrawal of hydration and nutrition, which cannot be the object of living wills.[45]

7 The Guiding Principles of the "Calabrò" Draft Law

The Draft Law of March 26, 2009, No. 10, entitled "Dispositions in matter of therapeutic alliance, informed consent and advance treatment directives", is composed of nine articles. Article 1 recognises and protects human life as an inviolable right guaranteed even in the terminal phase of life, in cases where the person is no longer capable of discernment, until his death as established by existing law. This draft law clearly prohibits all acts of euthanasia, including the suspension of nutrition and hydration. The above-mentioned Article 3 of the draft law regulates "the contents and limits of advance directives of treatment": which represents only guidelines about therapy and about accepting or refusing medical treatment and/or dispensing with special medical treatment, also if disproportionate or experimental. With regard to the existence of a trustee/proxy, who can "substitute" the person, Article 6 of the Calabrò Bill provides for the appointment of a trustee who, in case of acceptance, must sign the statements and position himself as the sole legitimate interlocutor with the physician in the case of the patient's incapacity to communicate. In this sense, the trustee/proxy has a key role in protecting the declared "best interests" of the patient: he carries out the will of the patient at a time when the

upper and sensory functions. The PVS is distinguished from brain death: this requires, instead, a complete and irreversible injury throughout the brain that is equivalent to the death of the body. A study group of the Italian Society of Neurology proposed to consider lawful the suspension of any life-sustaining treatment, including artificial nutrition and hydration, giving reasons for this opinion in the substantial identification of the essential condition of PVS and the death of the person. This conclusion was criticised by the National Bioethics Committee, which noted that the legal system does not foresee any "cortical" criterion for ascertaining death.

[44] Ferrando (2006), p. 149.

[45] The Draft Law provides that "nutrition and hydration, in the various forms in which science and technology provide them to the patient, are forms of life support and physiologically designed to relieve suffering until the end of life. They may not be the subject of an advance treatment directive"; it justifies this prohibition as being in compliance with the UN Convention on the Rights of Persons with Disabilities, which states, at Article 25, alinea f), that States Parties shall "Prevent discriminatory denial of health care or health services or food and fluids on the basis of disability".

patient is not capable of discernment and prevents situations of aggressive therapeutic treatment or patient neglect. It is possible to express waivers and later amendment to the living will in writing. In fact, the trustee would also be the person to whom is entrusted the difficult task of expressing the will of the patient if there are no advance directives.[46] According to Article 5, where it is not possible to call on previously communicated wishes in order to reconstruct the wishes of the patient:

> the trustee, if appointed, is the only person legally authorized to work with the health care givers and who can undertake to act in the best interest of the patient, always working within the intentions stipulated by the patient in their earlier declarations.

In this sense, the task of the trustee is reduced to a mere executor of the advance directives of treatment. Referring to the position of the ethics committee of a hospital, Article 7 of the bill merely states that any contrast between differing views must be evaluated by this committee, without specifying the role of this intervention: there is doubt that it will offer mere opinions and, as such, will not be binding. Another important question is related to the creation of an adequate Living Will model and its accompanying guidelines.

7.1 Open Questions About the Legislative Text

The analysis carried out so far highlights some pressing questions, including the preliminary question whether informed consent, as expressed in the draft law Calabrò, respects the principle of self-determination that originally inspired it. In other words, was the practice of informed consent already in the system, or are we trying, through legal instruments, to define its borders? Could it be questioned whether the bill is not too unbalanced in favour of the reaffirmation of medical paternalism? Can a document, albeit circumstantial, grasp the deep meaning of a directive that looks at a highly pathological stage of the life of a human being? When the civil lawyer comes to informed consent and correlates it with a contract of an economic character, it is easy to find in the legal system the rules for its implementation and the sanctions for any violations. The displacement of such a framework in the personal field demands a reflection on alternative ways in which bureaucracy certainly is not the answer. Reducing information to its minimal contents lessens the main objective, namely the protection of human dignity as a general assumption, which can never be derogated from, even by laws of circumstance. It is dignity—not survival at all costs—that defines human life and

[46] The rule is very clear on this point because it highlights how it takes a will substitute in case of lack of advance directives obliging the trustee or, in the absence of this figure, the guardian or "the spouse unless legally separated or de facto, the unmarried, the children, the relatives within the fourth degree". The Supreme Court in 2007 has extended the powers of the legal representative, subjecting them to two constraints: the exclusive interest of the patient and best interests for him.

represents the imperative limit for the legislator itself according to the wording of Article 32 of the Constitution. It is the ultimate value to be served by advance treatment directives. Although there are academic positions and interests in conflict, we cannot allow that bioethics becomes a field of political struggle and of intervention of religious authorities. The increased awareness of physicians of the need to analyse the moral problems raised by technological progress has been, over the years, a great enrichment to the debate.[47]

Draft Law No. 10 provides for "therapeutic alliance" between physician and patient, which is expressed in a document of informed consent, signed by the patient, which becomes part of the medical record. When requested, a patient may refuse at any time but explicitly, with a document that he must sign, in whole or in part the information concerning him. Moreover, this informed consent to medical treatment may be later revoked, even partially. In the advance treatment declaration, the person does not express his will, but the guidelines regarding the medical treatment in the event the person will be no longer capable of understanding. The person declares his decision to adhere or not to a medical treatment, according to the existing legal rules and the code of medical ethics. The waiver of the person can be expressed in relation to some forms of medical treatment, "disproportionate or experimental". The nutrition and hydration, "in various forms in which science and technology can provide to the patient, are forms of life support and physiologically designed to alleviate the suffering until the end of life. They are not subject to declaration to advance treatment". An important question is related to the directives' structure: the importance of the "vital" character leads us to prefer the written form by persons of full age and who are competent, informed, independent, and not subject to any family, social, or environmental pressure. The function of the form is certainly inspired by reasons of security and promotion

[47] The aid of anaesthesiologists and neurologists has provided opportunities for closer examination and comparison. For patients in PVS, the physician cannot avoid taking into account the previously expressed wishes of the patient when the patient is no longer able to express his will. About the lawfulness of the denial of a life support measure such as artificial feeding, a new study by two research teams from Cambridge and Liège has highlighted the possibility that some individuals held in a vegetative state are not entirely without conscience. In other words, the use of modern methods has shown metabolic responses and possible emergence of conscience. From this we can deduce the overcoming of the schematic pattern of vegetative state, understood as a medical condition in which the cortex is completely devoid of functions. The possibility of any residual mental activity calls into play the principle of self-determination of the patient. In view of these scientific breakthroughs, the debate has stalled in Italy, both in the progress of the analysis of the bill and in the debate within civil society. This situation of intellectual stagnation is likely to miss the opportunities offered by the biomedical revolution and is likely to confer only to the legislator the task of making law an instrument that does not meet the expectations of those who suffer. The contingent circumstances of the low degree of authority that the research enjoys in Italy do not help the debate: all this does not open up the door to a serene view of the near future.

of interests and values of protection of individual interests.[48] The validity of the ATD is 5 years, after which it "loses its effectiveness". The advance declaration of treatment can be renewed several times and can be revoked or modified at any time: "the waiver, even partial, of the declaration must be signed by the interested person". The advance declaration of treatment must be inserted in the medical record "at moment that is relevant from a clinical perspective"; in "emergency conditions or when the subject lives in danger of his life, the advance declaration of treatment does not apply". The Draft Law consents to appoint a trustee of adult age, "capable of discernment, which accepts the appointment by signing the declaration: they are the only entity legally authorized to work with the patient's physician" and committed to act exclusively for the patient's best interests, always acting lawfully and only following the intentions explicitly declared by the person in his advance directive, and is also committed to ensuring that the patient is given the best palliative care available, and prevents aggressive treatment or therapeutic abandonment and checks carefully that the proxy does not lead to situations that integrate—for the patient—cases referred to in Articles 575, 579 and 580 of the Penal Code. One major point of conflict during the parliamentary debate has focused on the desires expressed by the persons in the advance declaration of treatment—"their desires are taken into account by the physician who, after hearing the Trustee, notes in the medical record the reasons why they believe they should follow them or not": thus, they are not binding. In addition,

> the physician not may consider signs oriented to cause the death of the patient or otherwise contrary to law or medical ethics. The indications are evaluated by a physician, heard the trustee, knowledge and belief, under the principle of inviolability of human life and health, according to the principles of precaution, proportionality and prudence. In case of dispute between the trustee and the treating physician, the matter is submitted for assessment by a panel of physicians consisting of a coroner, an anesthesiologist-intensive and a neurologist, hearing submissions from the physician and the medical specialist of the disease. These physicians, with the exception of the treating physician, are appointed by the health department's shelter structure or the local health jurisdiction. The opinion of the panel is not binding on the physician, who is not required to perform contrary to the beliefs of science and ethics.

8 Concluding Remarks

The Draft Law was inspired by the creation of a so-called therapeutic alliance between physician and patient, which devalues the legal effect of a so-called advance declaration of treatment, since the choice of treatments to be administered does not depend on the will expressed in the document but on the importance the physician would give to it. The text seems to allude to some sort of agreement

[48] In this sense, it should be read that Article 9 provides for the creation of a registry of advance directives for treatment at the national level. In addition to having found inspiration in the American register of living wills: this register is in the ownership of the Ministry of Labor.

between the physician and the patient's wishes, but it is not clear how this could happen since one of the two wills (the patient's will) has been crystallised into a document, and therefore there lacks the elasticity and flexibility necessary to reach such an agreement. In fact, the will of the physician and that of the patient cover different intentions and objectives because each one works in his own field of competence: the first ensures and declares a terminal medical condition; the other expresses a choice on the basis of that condition. In particular, in an advance declaration of treatment, the wishes of the patient are placed on the same level as those of the physician, which in fact should not be the case: the patient does not express his will but simply his own intention in relation to the medical treatment he wants or not to receive. With this approach, the physician could simply "take into account" or "reflect" instead of "take note". The difference between the two expressions is significant, since the term "take account" means that the physician can make a choice that could differ from that expressed in the advance declaration of treatment. Conversely, when the expression "taking note" is used, the physician would be much more limited in his activity. In this line, it is not surprising that the Draft Law no longer contains the provision—present in an earlier bill—that allowed the physicians to disregard the treatment, always motivated by the previously expressed wishes of the patient in cases when considerable time has passed or there have been significant developments of scientific and technical knowledge and treatment. Another question that arises appears to clearly refer to the patients in PVS and natural incapacity. It seems appropriate to ask what happens then in case of patients able to discern but whose health conditions require the assistance to perform even the most basic life functions. The bill keeps silent on that matter. It is not clear whether this omission is to be interpreted as inadequacy of the tool in such cases or merely admits of an analogous interpretation. Regarding the issues of nutrition and hydration, the regulations—contained in the bill—provide that they constitute "forms of life support" and no medical treatment, consequently, they cannot form the object of an advance declaration of treatment. This particular aspect would have been adopted in accordance with ethical and moral criteria rather than medical science. In fact, on this point, experts are divided between those who do not agree and believe that nutrition and hydration are considered medical treatment and those who agree with the position adopted in the bill. With regard to the documentation required by the bill to guarantee the validity of the advance declaration of treatment, the form must bear the signature of the person and the physician, and both signatures must be witnessed before a notary. In many other countries, Living Will forms can be freely downloaded from the internet, to be completed by the patient and witnessed by a Justice of the Peace. One might wonder whether the reason for such a complex Italian procedure reflects the importance of the advance declaration of treatment or whether it is, in fact, an attempt to dissuade the patient from drafting the document by making it so difficult to have witnesses.

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Patient's Autonomy According to German Law

Jochen Taupitz

Abstract During the last two decades, various options have been developed to enable competent persons to influence, in advance, the decision-making process concerning their medical treatment in case they become incompetent. At the same time, this raised the question about the legal status of such statements, asking if they are fundamentally different from actual consents or refusals to consent regarding medical treatment. The Act that has come into force on September 1st, 2009, regulates living wills and the duties and role of surrogate decision-makers in the scope of civil law, but leaves quite a lot of questions unanswered.

Contents

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1 Informed Consent as the Basis

1.1 No Treatment Without Consent

Any health care measure that intervenes into the physical integrity of a person (article 2 II 1 of the German Constitution—GG[1]) is legally considered to contain elements of the legal offence of bodily harm as defined by section 223 et seq. of the German Criminal Code (Strafgesetzbunch—StGB)[2] and section 823 I of the German Civil Code (Bürgerliches Gesetzbuch—BGB).[3] The Federal Court of Justice (Bundesgerichtshof—BGH) consistently maintained this position, already developed in 1894 by the Imperial Court of Justice (Reichsgericht—RG).[4] Therefore, every medical professional must obtain a valid consent from the patient through a personal dialogue before starting medical treatment, informing him[5] of the nature, significance, implications, and risks of the measure or treatment (informed consent).[6] This means that it is not enough just to take account of a "formal" consent but much more to enable the patient to make a free and self-responsible decision based on the necessary information for or against a specific medical measure ("materialisation of the consent"[7]). Patients who refuse this measure must be informed about the consequences of their refusal.[8] This dialogue may be condensed or even skipped only in exceptional cases, for example when an immediate treatment is necessary and any delay would pose a serious threat to the

[1] "Basic Law for the Federal Republic of Germany" (Grundgesetz für die Bundesrepublik Deutschland—GG) of 23 May 1949 (Federal Law Gazette p. 1), in the revised version published in the Federal Law Gazette, part III, class. no. 100-1, as last amended by Art. 1 of the Law of 11 July 2012 (Federal Law Gazette I p. 1478)", English unofficial translation available at http://www.gesetze-im-internet.de/englisch_gg/index.html (Last accessed: 1 October 2013).

[2] "Criminal Code" (Strafgesetzbuch—StGB) of 15 May 1871, in the version promulgated on 13 November 1998 (Federal Law Gazette, part I, p. 3322), last amended by Art. 1 of the Law of 24 September 2013 (Federal Law Gazette, part I, p. 3671). Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_stgb/index.html (Last accessed: 1 October 2013).

[3] "Civil Code" (Bürgerliches Gesetzbuch—BGB) of 18 August 1896, in the version promulgated on 2 January 2002, last amended by Art. 1 of the Law of 20 September 2013 (Federal Law Gazette I p. 3642); unofficial English translation available at http://www.gesetze-im-internet.de/englisch_bgb/index.html (Last accessed: 1 October 2013).

[4] Repeated judicial decisions of the German Federal Court of Justice (BGHSt 11, 111; 16, 309; 35, 246; BGHZ 29, 33; 106, 153) based on judicial decisions of the Imperial Court of Justice dating back to 1894 (RGSt 25, 375; 38, 34).

[5] In order to improve readability, only the male form is used in the text; nevertheless, all data apply to members of both genders.

[6] Section 630 d BGB. For further information on informed consent, see Parzeller et al. (2012), pp. A576–586.

[7] Taupitz (2000a), pp. A28 et seq.

[8] Taupitz (2000a), p. A28.

patient's life.[9] These exceptions must be well justified and documented. Any medical measure carried out against the patient's will is prohibited and would therefore lead to prosecution.[10]

The right of a competent patient to give informed consent to medical treatment is also guaranteed by the German Constitution (Grundgesetz—GG) dated 1949. According to the right to self-determination in regard to one's body, constitutionally enshrined in the guarantee of human dignity (art. 1 I GG), the general right of personality (art. 2 I in conj. with art. 1 I GG) and the right to physical integrity (art. 2 II 1 GG), every person, if mentally competent, has the right to refuse any medical treatment.

1.2 Capability of Consent

However, based on the individual right to self-determination, this concept naturally becomes problematic when a person is incapable of consent. Decisional capacity in the context of health care is not the same as contractual capacity in the terms of civil law. There is no legally binding chronological moment (such as the age of majority) constituting the patient's capacity to decide about health care issues by giving, refusing, or withdrawing consent to medical treatment. A person who can understand the nature, relevance, impact, and risks of a certain medical measure, weigh them up and create a will of his own on this basis is considered to be capable of consenting.[11] Minors (aged at least 14[12]) and even patients who are under custodianship due to health matters are potentially capable of consenting in all areas, provided that they possess the "mental and moral maturity" to assess the "significance and extent of the intervention and its development".[13] It is an individual issue that the medical professional should prove in every single case.[14]

In practice, assessing the capability of consent often causes difficulties. On the one side, humans can 'understand', 'weigh up', and 'create a will' to varying extents; additionally, according to the prevailing view the extent of the necessary capability to consent depends on the type of encroachment as well. On the other side, disregarding the gradual differences and specifics of the individual cases, legislation demands a 'yes-no-decision' regarding the capability of consent: either the one concerned is capable of consent or he is not. A legally certain authoritative

[9] For an overview of exceptions to the physician's duty of informing the patient, see Parzeller et al. (2012), p. A581.

[10] Compare: BVerfG decision from 25 July 1979 no. 2 BvR 878/74 = BVerfGE 52, 131; BGH decision from 5 July 2007 no. 4 StR 549/06 = MedR 2008, 158.

[11] BGH decision from 5 December 1958 no. VI ZR 266/57 = BGHZ 29, 33.

[12] Taupitz (2000a), pp. A60 et seq.

[13] BGH, decision from 10 February 1959 no. 5 StR 533/58 = BGHSt 12, 379.

[14] More information: Taupitz (2000a), pp. A58 et seq.

assessment of an incapability of consent, as was possible under past legislation with the incapacitation of adults, is not possible anymore. Thus, it must be noted that legislation does not sufficiently determine the required capabilities (and probably is not able to either), leading to the responsibility being shifted to medicine most of the time (more exact: to the physician responsible).

1.3 Emergency Cases: Presumed Consent

As far as a person is incapable of consent, his legal representative can under certain circumstances consent to the medical procedure (Section 630 d BGB), but the person concerned may also have made an anticipatory decision beforehand. However, before going into these questions (see below 2.2, 2.3, and 2.4), it is necessary to depict the legal situation when a person incapable of consent needs to be treated immediately (e.g. due to life threatening injuries) yet neither a legal representative is present or reachable nor a decision has been made by himself.

In such an emergency, so-called presumed consent is used as a legal justification. Within reasonable bounds, one must try to identify the will the person concerned would have expressed if it would have been possible to ask him. Presumed consent is assumed when medical procedures are both urgent and objectively appropriate according to the interest of the person concerned, so that the physician may act accordingly. Legally, the entire emergency medicine is dealt with this way; thus, consent is formally (still) necessary, but the individual will of the patient gives way to an objectively orientated evaluation of reasonableness: anyone who urgently needs medical care is taken care of because it is appropriate according to their objective interest; thus, a reasonable patient would agree to the procedure. It does however depend on the individual expectations of the person concerned if his individual expectations are brought to the physician's attention (say, by relatives or through a living will). Should the physician know of the individual expectations of the person concerned, and should this person not want to be treated, the physician is bound thereby. So he must also follow the patient's individual volition in emergency situations, even if it might be unreasonable.

However, while assessing the presumed will, several questions arise. In regard to the wishes of the patient, it is always problematic to assess which wishes, when expressed and towards whom, with what intensity and based on which advance information, are relevant. Further questionable is if these earlier expressed wishes can be projected unto the specific (later occurring and perhaps unforeseeable) situation. Problematic is also how much effort must be put into the assessment of the patients' will. In the face of these insecurities,[15] the presumed will easily becomes a fiction and a practical instrument to depict the decision most acceptable

[15] See LG Oldenburg decision from 16 March 2010 no. AZ 8 T 180/10; crit. remark on the decision from Tolmein (2010).

to the acting person[16] (the physician) as a decision corresponding to the patient's presumed will and therefore legitimised by the high-ranking right to self-determination. The criterion of presumed will therefore has been criticised as a "gateway for heteronomy".[17] But there is no other solution if one takes the principle of human autonomy seriously. An objective balancing of interests would certainly entail heteronomy.

2 Anticipatory Decisions of the Person Concerned

2.1 Introduction

Not least because of the portrayed insecurities in referring to the presumed will, various options have been developed during the last two decades to enable competent persons to influence, in advance, the decision-making process concerning their medical treatment in case they become incompetent. At the same time, this raised the question about the legal status of such statements, asking if they are fundamentally different from actual consents or refusals to consent regarding medical treatment. It's an issue that has been passionately debated in Germany for several years[18] and that has come to an end for the time being with the new Act that has come into force on September, 1st 2009.[19] The German Parliament voted in favour of the law, which regulates living wills and the role of surrogate decision-makers in the scope of civil law.[20] The legislator intentionally missed the opportunity to regulate the associated criminal law issues that have dominated the end-of-life debate for years.[21]

[16] In the end critical on the use of presumed consent (especially regarding existential questions): Laufs (1998), p. 3400; Seitz (1998), p. 421; Höfling (2000), p. 116 et seq.; van Oosten (1999), pp. 673, 680 (considering South Africa), with further references.

[17] Höfling (2009), p. 2851; same position: Diederichsen in: Palandt (2012), sec. 1897 BGB, recital 16, sec. 1901a, recital 6.

[18] The parliamentary debate started back in 1985, after a publicity campaign of assisted suicide proponents. Accordingly, the public hearing held by the Committee on Legal Affairs of the German Bundestag focused mainly on criminal law provisions. For more information on this initial debate, see Stenographisches Protokoll über die 51. Sitzung des Rechtsausschusses des Deutschen Bundestages (1985), protocol no. 51.

[19] "3rd Act Changing the Custodianship Law" (3. Gesetz zur Änderung des Betreuungsrechts—3. BtÄndG") of 29 July 2009 (entered into force on 1 September 2009), in: Federal Law Gazette I, p. 2286.

[20] This law was supported by different members of all parties, even though mainly by members of the Social Democrats, the Greens, and the Liberals. In this case, the usual practice to vote in line with their own party was skipped, since this issue was considered to be a matter of conscience.

[21] Nevertheless, an indirect impact on criminal law occurred due to the recognition of the primacy of the patient's will over the physician's position as the guarantor of life (sec. 323c of the Criminal Code). See also BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963 (2966).

Under strong influence of the debate on patient autonomy and anticipatory decision-making, a number of instruments have been developed to enable competent persons to express their wishes in advance, thus striving to ground all medical decisions in autonomy, even when the patient is no longer able to express his real-time volition. All these instruments that provide guidance or rules for medical decisions to be made after the person becomes incapacitated are called advance directives (Vorausverfügungen). European comparative studies usually differ between two main types of advance directives,[22] instructional and proxy directives. An instructional directive provides particular details about wishes and preferences for treatment decisions that might be anticipated (for example, living wills, the more specific physician orders to limit care,[23] and even organ donation instructions), while a proxy directive designates one or more individuals—health care agent, attorney, or proxy—to make surrogate medical decisions for the patient if he becomes incapable of making them on his own. Nevertheless, the German literature traditionally differs between three main types of advance directives; thus, this paper will maintain this tripartite division differing between a **living will** (Patientenverfügung), a **power of attorney** (Vorsorgevollmacht), and a **custodianship directive** (Betreuungsverfügung), which may also be combined. Powers of attorney and custodianship directives might be described as "proxy directives" in the above-mentioned sense, but the term "proxy" might be misleading in the case of custodianship directives that are strongly influenced by custodianship (former guardianship) courts and are specific legal instruments. However, just like proxy directives, powers of attorney and custodianship directives focus on who will make the decision rather than on what those decisions should be, although all advance directives might overlap. In this sense, this paper uses the umbrella term "surrogate", therewith meaning any person who has been, according to German law, properly designated to make health care decisions on behalf of another adult person unable to give consent to or refuse medical treatment.

2.2 Custodianship and Custodianship Directives

According to the German custodianship law, if a person of full age, by reason of a mental illness or a physical, mental, or psychological handicap, cannot in whole or in part take care of his affairs, the custodianship court, following his application or

[22] Brauer et al. (2009), p. 227; Clements (2009), p. 276; Emanuel (2008), p. 198; Loewy (2004), p. 416; Gillick (2004), p. 8.

[23] There are different such orders or requests, such as DNR ("do not resuscitate"), CPR ("cardiopulmonary resuscitation"), DNAR, ("do not attempt resuscitation"), AND ("allow natural death"), "comfort measures only", "no tube feeding", "no IV-fluids", etc. For further information: Gillick (2006), p. 133; Burns et al. (2003), p. 1550; Mirachi (2007), p. 305; Schmidt (2009), p. A-1511/B-1292/C-1260; Rinofner-Kreidl (2010), p. 32; Schweizerische Akademie der Medizinischen Wissenschaften (SAMW) 2008, etc.

of its own accord, appoints a custodian for him (sec. 1896 I BGB), unless the patient has issued a power of attorney to a trusted person while being mentally competent to still do so (sec. 1896 III 2 BGB). Despite the widespread misbelief among the German population, in Germany there are no default legal representatives or health care proxies for adults, like for example in England,[24] which would automatically empower the next of kin to make any decisions on behalf of an adult who lacks decisional capacity. Even though in practice they often act as legal representatives, especially in emergency situations, the next of kin must be authorised as legal representative first—either as custodian by the custodianship court or as proxie/attorney by the person on whose behalf he is supposed to act, thus becoming legally valid surrogate decision-maker.[25]

The most common representatives are the court-appointed custodians[26] (sec. 1896 I 1 BGB), who may be appointed only for specific groups of tasks in which the custodianship is necessary (sec. 1896 II 1 BGB). These groups are not explicitly listed in the law. Therefore, the judge of the respective custodianship court is free to decide how to name them in a concrete case.[27] The scope of tasks should be phrased as precise as possible and relate to the current life situation of the person concerned. Exceptionally, it is also possible to appoint one custodian for all groups of tasks,[28] but this is an extremely rare exception.[29] If the custodian is supposed to meet decisions in health care issues, he must be explicitly appointed to do so.[30]

When deciding about the person of the custodian, the court has to take into account the currently or previously expressed wishes of the person who is supposed to be put under custodianship (sec. 1897 IV BGB). The expressed wishes can be

[24] Jox et al. (2008), p. 163.

[25] A bill presented to the German parliament regarding this issue and suggesting that relatives should be considered as standard surrogate decision-makers for incompetent patients was rejected at this point (Bundestag printed paper no. 15/4874 p. 26, in conj. with Bundestag printed paper no. 15/2494). For further information: Bundesrat printed paper no. 865/03; 2003, p. 97, http://www.dnoti.de/DOC/2005/abschlussbericht.pdf (Last accessed: 20 June 2012); crit. Strätling et al. (2003), p. 379; in favour of a default system, Sahm and Will, (2005), p. 20.

[26] Bundesamt für Justiz: Betreuungsverfahren—Zusammenstellung der Bundesergebnisse für die Jahre 1992 bis 2011, available online at: http://www.bundesjustizamt.de/DE/Themen/Buergerdienste/Justizstatistik/Betreuung/Verfahren__Betreuungsgesetz,templateId=raw,property=publicationFile.pdf/Verfahren_Betreuungsgesetz.pdf (Last accessed: 17 July 2012).

[27] Usually they cover property and financial or personal welfare matters, but they can also be more detailed like, e.g., "apartment clearing out" (BayObLG decision from 19 June 2001 no. 3Z BR 125/01 = NJW 2002, 381), etc.

[28] Compare sec. 276 I no. 2 of the Law on the Proceedings regarding Family Matters and Voluntary Jurisdiction (Gesetz über das Verfahren in Familiensachen und in den Angelegenheiten der freiwilligen Gerichtsbarkeit = FamFG).

[29] Bundestag printed paper no. 11/4528, p. 122; BayObLG decision from 3 June 2002 no. 3Z BR 94/02 = FamRZ 2002, 1225 et seq.; BGH decision from 4 August 2010 no. XII ZB 167/10.

[30] Compare: BayObLG decision from 3 August 1995 no. 3 Z BR 190/95 = BtPrax 1995, 218; BayObLG decision from 24 August 2001 no. 3 Z BR 274/01 = FPR 2002, 203.

positive or negative, proposing or even rejecting one or more persons to be appointed as custodians. Positive suggestions have to be accepted, unless the person does not meet the legal requirements or such an appointment would be contrary to the best interests of the person to be under custodianship.[31] Negative suggestions aren't obligatory but only proposing.[32] In order to make any suggestions, the person who is nominating or rejecting potential candidates does not necessarily have to be legally competent.

If a (still) capable individual wanted to propose or reject somebody as his custodian in advance, he would need to create a custodianship directive (Betreuungsverfügung),[33] which is not subject to any formal requirements. For provability reasons though, it is advisable to put it into writing or even get it verified by a notary. If the person suggests no one who may be appointed as a custodian, the court has to consider his family and other personal ties, in particular the ties to parents, to children, to the spouse, and to the civil partner and the danger of conflict of interests (sec. 1897 V BGB). Only if no other suitable person is available, who is prepared to perform the task of a custodian on a voluntary basis, the court can appoint a person who conducts custodianships on a professional basis (sec. 1897 VI BGB). In practice, most custodians—either suggested by the person itself or appointed by the court according to sec. 1897 V BGB—are usually close family members. Despite this fact, the German legislator deliberately did not introduce a system of default legal representatives for adults and retained the obligatory court appointment procedure in 2005.[34]

The content of a custodianship directive is not limited to nominations or rejections of potential custodians. It can also contain wishes on how to manage the affairs of the person under custodianship, which the custodian must comply with to the extent that this, firstly, is not inconsistent with the best interests of the grantor and, secondly, can be expected of the custodian (sec. 1901 III BGB). In this regard, the content of a custodianship directive might overlap with the content of a living will.

2.3 Power of Attorney

The entire German custodianship law is dominated by the principles of necessity and subsidiarity (1896 II BGB). In the interaction of these principles, they are deemed to protect the individual's privacy against state interferences or minimise their impact as much as possible. In accordance with these principles, private

[31] Diederichsen in: Palandt (2012), sec. 1897 BGB, recital 16.

[32] Bundestag printed paper no. 11/4528, p. 128.

[33] For more information see: Lipp (2007), p. 48.

[34] Bundestag printed paper no. 11/4528, p. 122; BayObLG decision from 3 June 2002 no. 3Z BR 94/02 = FamRZ 2002, 1225 et seq.; BGH decision from 4 August 2010 no. XII ZB 167/10.

precautions explicitly override any state-ordered or -provided support.[35] For this reason or in order to avoid the above-mentioned very formal and costly court procedure,[36] it is possible to grant a trusted person power of attorney (Vorsorgevollmacht—sec. 1896 II 2, alt. 1 BGB). This is a legal instrument that gives this person the legal authority to act on behalf of the grantor and to make legally binding decisions for him.[37] Since it is a legal act, the grantor must be legally competent at the time of the issuance.[38] Similar to custodianship directives, it can be granted for specific groups of tasks, dealing for example with property and financial or personal welfare matters. According to the principle of subsidiarity, if there is an existing power of attorney for personal welfare matters, there is no need to appoint a custodian for this group of tasks and the authorised attorney is entitled to make legally binding health care decisions on behalf of the grantor. The grantor is free to establish restrictions or conditions on the power of the donee. However, if an individual limits the power of attorney to specific groups of tasks, there is a high risk that a custodianship would become necessary for other groups. If possible, a coexistence of a custodianship and a power of attorney should therefore be avoided.[39]

Unlike the custodians, authorised attorneys are not under the direct control of public courts, thus evading direct state interference and control of the private sphere of the person who's granting the power of attorney. Therefore, it is advisable to grant a trusted person a "general" power of attorney (Generalvollmacht), enabling this person to act on one's own behalf in all matters (Vertretung in allen Angelegenheiten) where a custodianship might become necessary. Generally, a power of attorney is not required to be in writing. It can also be granted orally or even implicitly.[40] Since there are some very important exceptions from this general rule, inter alia considering health care issues, it is absolutely recommendable for reasons of legal certainty to set it up in writing, preferably with a notary. According

[35] Roth 2010, part C, recital 2 et seq.

[36] Powers of attorney "are also in the public interest as they avoid costly guardianship proceedings as well as the appointment of guardians who, if the ward is poor, have to be paid for by the general public" (Lipp 2007, p. 30). See also Bundestag printed paper no. 11/4528, p. 122.

[37] More information: Lipp (2007).

[38] A legally incompetent person may apply to the custodianship court to appoint a trusted person as his custodian. For more information, see Taupitz (2000a), p. A 102; Roth 2010, part C, recital 125; partial legal capacity sufficient according to, e.g., Baltz (2009), p. 77, with further reference; capacity to give informed consent sufficient according to, e.g., Diederichsen in: Palandt (2012), sec. 1904, rectial 26.

[39] Information brochure on the custodianship law of the German Federal Ministry of Justice 2012, p. 31, http://www.bmj.de/SharedDocs/Downloads/DE/broschueren_fuer_warenkorb/DE/Das_Betreuungsrecht.pdf (Last accessed: 17 July 2012).

[40] Winterstein in: Jürgens (2010), sec. 167 BGB, recital 3; the content of such instruments is hardly provable and therefore cannot be verified; compare OLG Hamm decision from 12 May 2009 no. I-15 Wx 1-4/09 = FGPrax 2009, 217 (219). For this reason, some authors argue that a power of attorney for health care has to be in writing in any case; for example: Dodegge (2010a), p. 2630.

to the new law, if there is a justified risk that the represented person would die or suffer serious and long-lasting detriment to health due to a medical measure, an attorney may consent to this measure only if the power of attorney expressly includes these measures and is given in writing (sec. 1904 V 2 in conj. with sec. 1904 I BGB). This also refers to non-consent or revocation of the consent if the suggested measure is medically indicated and there is justified reason to fear that the represented person will die or suffer serious and long-lasting detriment to health if the measure is not carried out or is discontinued (sec. 1904 V 2 in conj. with sec. 1904 II BGB). The same applies to putting the represented person in accommodation that is associated with deprivation of liberty (sec. 1906 BGB).

With the new Act regulating the custodianship law, the German legislator also intended for equality between the court-appointed custodians and the patient-designated attorney (sec. 1901a III, 1904 V 1 BGB), with the already-mentioned exception that an attorney can only consent or refuse consent to life-sustaining or -prolonging treatment when explicitly and in writing authorised by the grantor to do so (§ 1904 V 2 BGB).

2.4 Living Wills

2.4.1 Introduction

Within the context of the new regulation, sec. 1901a BGB is the key provision, stipulating legal requirements and the scope of living wills and regulating the duties and the role of a surrogate decision-maker. The law differentiates between immediately binding "living wills" (sec. 1901a I BGB) and indirectly binding "wishes with regard to treatment or the presumed will" (sec. 1901a II BGB). In this sense, a "living will" is defined as a written determination of a competent adult, for the event of his becoming unable to consent, as to whether he consents to or prohibits specific examinations of his state of health, treatment, or medical interventions not yet directly immanent at the time of determination. Accordingly, to be binding a living will must meet all formal and content-related requirements specified by law. According to the explicit wording of the law, it is not the physician but the custodian or the person given power of attorney who must examine whether the determinations written in the living will correspond to the current life and treatment situation. If it does, such a living will must be followed and the surrogate decision-maker (custodian or the person given power of attorney) must see to it that the will of the patient is attended to (sec. 1901a I BGB). The other constellation—if there is no living will or if the determinations of a living will do not correspond to the current life and treatment situation—stipulates that the custodian or attorney must determine the wishes with regard to treatment or the presumed will of

the represented person and decide accordingly whether he, meaning the surrogate decision-maker, consents to or prohibits a medical measure (sec. 1901a II BGB).[41]

2.4.2 Living Will: Legal Requirements

Written Form

According to the new sec. 1901a I 1 BGB, a living will must be set up in writing (sec. 126 BGB), thus changing the previous prevailing opinion that binding living wills can be in written or oral form.[42] This new formal requirement is aimed to warn the individual, who is making the will, of potential "hasty and injudicious determinations".[43] In contrast to a last will that must be handwritten (holographic) (sec. 2247 I BGB), a living will must not. It just must be signed personally. The signature or the living will does not necessarily have to be authorised or certified by a notary or witnessed by someone else. Only when the individual cannot sign personally or has lost the ability to sign, the attendance of a notary and a witness, who has to sign the notary report, is compulsory.[44] Many organisations provide various standardised forms for different kinds of advance directives and living wills,[45] but there are no official statutory forms, like, for example, in Israel.[46] Such standardised forms should be treated with high caution, especially when a medical professional was not consulted prior to filling out the form. In situations where a patient might die, due to compliance to his own written living will, it would be preferable and in accordance with the idea of sec. 1904 V BGB to acknowledge this living will as immediately binding, only if preceded by a professional medical consultation.[47] In contrast to the execution, the revocation of a living will implies no formalities and may be withdrawn at any time without any specific formal requirements (sec. 1901a I 3 BGB).

[41] Bundestag printed paper no. 16/13314, p. 4.

[42] LG Fulda decision from 30 April 2009 no. 16 Js 1/08 - 1 Ks = BeckRS 2010, 06420; LG Waldshut-Tiengen decision from 20 February 2006 no. 1T 161/05 = NJW 2006, 2270.

[43] Bundestag printed paper no. 16/8442, p. 13.

[44] Sec. 25 of the Certification Act (Beurkundungsgesetz) from 28 August 1969 (Federal Law Gazette I, p. 1513), as last changed by art. 2 of the Law of 22 December 2010 (Federal Law Gazette I, p. 2255).

[45] May (2012).

[46] Schicktanz et al. (2010), p. 365; Shalev (2010), p. 141.

[47] Taupitz (2000a), p. A111 et seq.; compare also Decision III 2.3. of the Civil Law Section of the 63. German Jurists Forums 2000 = FamRZ 2000, 1484 (1485); Nationaler Ethikrat 2005, p. 33, different in cases of dementia, p. 34.

Age of Majority and Decisional Capacity

Contrary to the previous legal position and the commonly held opinion in the German legal literature,[48] an individual who wants to set up a valid living will now must be of legal age, beginning at the age of eighteen (sec. 2 BGB). Unfortunately, the parliamentary documents give no answers concerning the reasons or the purpose of this formal requirement. Before the reform, the basic tenet of the German law was that a minor may be able to give fully binding consent independently, provided that he is deemed to have the necessary "mental and moral maturity" to assess the "significance and extent of the intervention and its development".[49] Decisional capacity was unanimously considered to be the basic requirement to give, refuse, or withdraw consent considering health care issues. In this sense, the new rigid age limit for living wills caused reasonable doubts that this formal requirement infringes the constitutionally guaranteed right to self-determination (art. 2 I in conj. with art. 1 I GG) and the principle of equality (art. 3 GG). Moreover, the German Federal Court of Justice (BGH) also modified the mentioned tenet in 2006, denying the competent minor patient exclusive authority to decide on his own health care issues but acknowledging him the right to "veto" the consent given by his legal representatives.[50] Nevertheless, a living will usually, but according to German law not necessarily, contains a refusal of consent to certain medical measures or treatments, which in the end means that even according to the mentioned BGH ruling, minors can refuse unwanted medical measures, though only by vetoing. On this account, decisional capacity remains to be a mandatory requirement for all health care decisions, including living wills. Admittedly, this prerequisite is not undisputed. On the one hand, it is already questionable where to draw the line between decisional capacity and incapacity,[51] especially in cases when it is progressively diminishing, like it is the case with dementia. In addition to this, it remains questionable if the person concerned had (still) been capable of consenting when signing the living will. In order to avoid such concerns, it should be ensured that witnesses are able to confirm decisional capacity afterwards. This problem has certainly been reduced with the legal age requirement, since adults are presumed competent to consent.[52]

[48] Lange (2009), p. 539; Spickhoff (2009), p. 1951, each with further references.

[49] See above 1.2.

[50] BGH decision from 10 October 2006 no. VI ZR 74/05 = MedR 2008, 289, with a comment by Lipp. Providing parents with information required also by OLG Karlsruhe, decision from 07.04.2010 no. 7 U 114/09 = BeckRS 2010, 08386. Further crit. comments: Kern ((2007)), p. 220412. One part of the literature had already demanded a similar system of "co-consent" of the minor capable of consenting and his parents; see Taupitz (2000a), pp. A 63 et seq.

[51] More detailed: Taupitz (2000a), pp. A 58 et seq.

[52] Lipp (2009), sec. 17, recital 127.

Content-Related Requirements

Besides the very few formal prerequisites, a valid living will is required to contain "determinations" showing if its signer consents to or prohibits "specific" examinations concerning his state of health, treatments, or medical interventions "not yet directly immanent" at the time of determination. Since the legislator did not define how specific these determinations must be in order to be directly binding, this requirement has been highly discussed shortly after the reform.[53] Nevertheless, the regional court of Kleve rightly notices that it "is not decisive to anticipate one's own biography as a patient" but to loosely determine one's own wishes regarding specific life or treatment situations. The living will, therefore, must merely contain determinations that make it possible to conclude a decision for or against a treatment in question.[54] In this sense, accepting depictions of "the main treatment situations and symptoms"[55] or completely renouncing "concrete detailed listings"[56] entail the risk of creating a too vague living will, giving space for misinterpretations, or even a written document that does not meet the legal requirements for a directly binding living will. There is, however, unanimous agreement that general wishes and guidelines do not meet the legal requirements for a valid living will.[57] Notwithstanding, the surrogate decision-maker must take them into consideration when deciding on the basis of the patient's wishes or presumed will pursuant to sec. 1901a II BGB. In practice, it will certainly prove difficult to assess if a determination is precise enough or not.

Living wills that have been set up before the new law entered into force on 1 September 2009 remain valid provided that they meet the above-mentioned legal requirements.[58] Many of them probably do not fulfil the required level of accuracy stipulated in sec. 1901a I BGB[59] and are likely to be implemented according to sec. 1901a II BGB.

[53] Roglmeier and Lenz (2009), p. 239; Schmitz (2009), p. 64; Diedrichsen in: Palandt (2012); Najdecki (2009), p. 2602.

[54] LG Kleve decision from 31 May 2010 no. 4T 77/10 = NJW 2010, 2666 (2668). Accordingly, Diederichsen in: Palandt (2012), § 1901a, recital 18 with further references.

[55] Najdecki (2009).

[56] Schmitz (2009).

[57] Bundestag printed paper no. 16/8442, p. 13.

[58] During the parliamentarian debate, the German legislator relied on the number of 8.6 million living wills (ca. 10 % of the total population) that has been estimated by the German Hospice Foundation; compare Bundestag printed paper 16/8442, p. 8.

[59] The legislator explicitly recognised this risk in Bundestag printed paper no. 16/8442, p. 14. See also Albrecht and Albrecht (2009), p. 428.

2.4.3 Living Will: Optional Elements

In order to prevent unnecessary barriers of the right to self-determination, there are no other formal requirements for living wills apart from the written form. A medical or legal consultation is not necessary,[60] even though the legislator has emphasised the valuable consulting role of a medical professional prior to the execution of a living will.[61] According to general principles, a physician is obliged to inform the patient in a personal conversation about the nature, benefits, and risks associated with the treatment. The concept of informed consent aims at protecting patients from acting under pressure or as a result of misleading information. Within this concept, it is incumbent upon physicians to ascertain whether the person is able to make his own health care decisions. In spite of these general rules, the legislator has refrained from making a medical consultation a mandatory requirement for advance directives. It suffices that the patient is legally competent at the moment of his decision (sec. 1901a BGB).

A valid living will may be revoked at any time without a specific form, and it does not have to be renewed periodically, which by implication means that it has no expiry date like in Austria. Nevertheless, it is absolutely advisable to add a date, since the individual life situation or treatment options might essentially change between the moment of execution of a living will and the moment of its potential application.

2.5 Treatment Wishes and Presumed Will (Sec. 1901a II BGB)

The right to self-determination is certainly the key element considering legal aspects of health care issues. As long as the anticipated situation actually happened, the living will is binding, unless there is evidence or a reason to assume that a patient has changed or revoked his will (sec. 1901a I BGB). If there is no living will or if the living will does not meet the legal requirements, it is the duty of the surrogate decision-maker to determine the treatment wishes or the presumed will of the patient and decide respectively (sec. 1901a II BGB). The presumed will (see above 1.3) must be ascertained "on the basis of concrete indications", considering "in particular patient's prior oral or written statements, ethical or religious convictions and other personal values of the patient".[62] In order to fulfil this task, the surrogate decision-maker should communicate with the patient's close relatives and other persons enjoying the patient's confidence, as far as this is possible without any considerable delay. If none of this is possible, the decision is to be made upon values deemed to be universally shared, acting in the patient's best interest, thus

[60] Critical on this: Höfling (2009), p. 2852; Lange (2009), p. 537; Olzen (2009), p. 362.

[61] Bundestag printed paper no. 16/13314, p. 20. Compare also: Taupitz (2000b), p. 116.

[62] Bundestag printed paper 16/13314, p. 5.

taking the risk to act in accordance with one's own values. However, if there are any doubts about what is in the patient's best interest, the principle **in dubio pro vita** must prevail.[63] This is to prevent that surrogate decision-makers meet any decisions based on "mere speculations about the will".[64] For the sake of the patient's safety, the custodianship court has to prove the decision of the surrogate decision-maker in cases when the treating physician and surrogate decision-maker disagree if the met decision to conduct or omit a specific measure is in accordance with the wishes or presumed will of the patient (sec. 1904 IV BGB).

2.6 Implementation of a Living Will and Its Addressee

According to the wording and systematisation of the new law within the provisions of custodianship law, the role of surrogate decision-makers has substantially increased. If a person makes any health care determinations for the case of becoming unable to give consent, it is the surrogate decision-maker who—first of all—must prove if there's a valid living will at all. The following step is to "examine whether these determinations correspond to the current living and treatment situation" (sec. 1901a I 1 BGB). If this is the case, he must see to it that the will of the respective person is attended to (sec. 1901a I 2 BGB). Legally, the contained determinations are being treated as equals to real-time decisions. However, if the determinations differ only slightly, the surrogate decision-maker faces a great challenge. Especially the question where to draw the line between an immediately binding living will and an indirectly binding wish or presumed will is bearing a huge responsibility, but this is the basic problem when interpreting "anticipative" declarations. In this context, the content-related requirement of "specific determinations" plays a major role.[65] Where there's no immediately binding living will, it is the surrogate decision-maker who plays the central role, since he's supposed to determine the patient's treatment wishes or his presumed will.

However, the new wording should not belie the fact that the role of the physician is still absolutely essential and inevitable. The patient's representatives cannot make any decisions until the physician examines "which medical measure is indicated with regard to the patient's overall condition and prognosis" (sec. 1901b I 1 BGB). If a medical measure or its continuation is not medically indicated (anymore), the physician has to withhold or withdraw it. Neither the patient nor his representative or next-of-kin can require that the doctor performs a non-indicated measure.[66] The reality, however, is often quite different. A typical case where

[63] Id. at p. 4.

[64] Seichter (2010), p. 162.

[65] See also Taupitz and Weber-Hassemer (2006), p. 1117.

[66] "Empfehlungen der Bundesärztekammer und der Zentralen Ethikkommission bei der Bundesärztekammer zum Umgang mit Vorsorgevollmacht und Patientenverfügung in der ärztlichen Praxis" 2010, p. A 882.

patients are systematically provided with non-indicated life-sustaining measures is that of artificial nutrition or hydration in the case of patients with advanced dementia. "Recent studies demonstrate that there is no proof of any benefit, that tube-feeding often results in further harm to the dementia patient and that the patient's will is not sufficiently taken into consideration."[67] Nevertheless it is performed over 100,000 times a year in Germany.

Once the physician decides that a measure is medically indicated, he must discuss it with the patient's representative in order to ascertain the patient's will. Any decision met pursuant to the aforementioned rules must be approved by the custodianship court "if the justified danger exists that the person under custodianship will die or will suffer serious and long-lasting detriment to his health due to the measure", unless the then caused delay would entail this danger (sec. 1904 I BGB). The same counts for "non-consent to or revocation of the consent" to a measure that is medically indicated (sec. 1904 II BGB).[68] According to sec. 1904 IV BGB, approval is not required if the surrogate decision-maker and the physician agree that the granting, non-granting, or revocation of consent corresponds to the will of the patient established pursuant to section 1901a BGB. In accordance with general principles, any person may turn to the custodianship court in cases of suspected abuse.

The new law gives no specific answer concerning the question whether a physician is allowed to decide on his own when there is no surrogate decision-maker yet. This loophole in the law already caused a new debate about which person is the addressee of a living will—if it is the surrogate decision-maker, the physician, or even other medical staff. Having in mind that the German custodianship law is dominated by the principles of necessity and subsidiarity, giving primacy to patient's volition, it is reasonable to state that concrete determinations stated in a living will should be immediately binding, even when there is no valid surrogate decision-maker. In this sense, the physician and other medical staff can be considered to be addressees of a living will,[69] despite the explicit wording of the law.[70] Also the amendment of the Civil Code that recently (in 2013) included provisions for the (medical) "treatment treaty" into the Civil Code[71] says in sec. 630 d I 2 BGB that, concerning a patient incapable of consent, the decision of a surrogate decision-maker has to be obtained by the physician "unless a living will according to sec. 1901a I 1 allows or prohibits the examination, treatment or medical intervention". That means, that the physician is directly bound by a living

[67] Synofzik (2007), p. 428, with further references; see also Public experts hearing of the Judicial Committee of the German Bundestag on living wills from 4 March 2009: expert opinion of Borasio, p. 8.

[68] Procedural rules contained in sec. 287 and 298 FamFG (Diederichsen in: Palandt (2012), sec. 1897 BGB, recital 16); see also Taupitz (2010), p. 176.

[69] Accordingly, Bundestag printed paper no. 16/8442, p. 11, 15.

[70] Diederichsen in: Palandt (2012), sec. 1901a BGB, recital 20; Coeppicus (2010), p. 9.

[71] Law of 20 February 2013 (Federal Law Gazette, part I, p. 277).

will if the living will meets the legal requirements and the situation actually happend. But one has to see that this is contrary to the very formal procedure in the provisions concerning living wills (§§ 1901a, 1901b BGB) aiming to protect the incompetent patient.[72,73] The first step is the duty of the physician to examine if a measure is medically indicated with regard to the patient's overall condition and prognosis. If it's not, all other steps are dispensable. If it is indicated, then "he and the custodian must discuss this measure, considering the patient's will as a basis for the decision to be taken pursuant to section 1901a" (sec. 1901b I BGB). This dialogue between the physician and the surrogate decision-maker should not be waived. If this dialogue is required in cases when there is a court- or patient-appointed representative, then it would be a mistake to assume that the physician can forego this dialogue. Only exceptionally, in cases of emergency, physicians and other medical staff should be allowed to act independently. In these cases, it is of utmost importance to decide if a measure is medically indicated or not. Like it was the case before the reform, such a measure should be conducted relying on the presumed consent (see above, 1.3). In such a case, a representative of the patient must be included as soon as possible. If there is no indication, there is no need to ascertain the patient's will and therefore there is no need for a representative.

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[72] Diehn and Rebhahn (2010), p. 331.

[73] Lipp (2009), sec. 17, recital 198 in conj. with sec. 16, recital 116; Taupitz (2010), p. 169.

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"Killing Me Softly": New Questions About Therapeutic Self-Determination in the Italian Society and Old Answers from the Criminal Code

Emanuele Corn

Abstract Euthanasia and assisted suicide are both considered criminal offences under Italian penal law. This chapter examines the provisions of the Italian Criminal Code relevant to the end-of-life debate, i.e. articles 575 (murder), 579 (murder by consent), and 580 (aiding or abetting suicide), and the practical difficulties arising in their application to complex end-of-life cases, where these norms prove to be to some extent inadequate and outdated. It also offers an overview of recent case law, especially the Englaro and Welby cases, from the criminal perspective and highlights the shortcomings of the Calabrò Bill on advance directives regulation.

Contents

1 Introduction: The Role of Comparative Criminal Law in Biolaw

The juristic comparison is a set of techniques to study how two different countries deal with some social and legal problems. Using comparative law in approaching the legislations is very important in a globalised world in order to make every kind

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of international relationship easier. In the European Union, the juristic comparison is not only helpful but also necessary.[1]

Recent history tells us that the laws of European countries share common foundations and values, converging over the common objective of a more similar legislation. However, the speed of this historical process is different, depending on the branch of law: it is higher in private law, especially in commercial law, and it is slower in a few sectors of public law, in particular in criminal law.[2]

The convergence of the criminal norms of European countries began just a few years ago. The more widespread explanation of this lateness is the decision of national governments against losing the political and media power that characterises criminal law. For this reason, the convergence process began with the Euro and the financial interests of the EU[3]: i.e., objects that are impossible to protect without a shared interest. In 2008, a first-pillar instrument with criminal norms came about with the Directive 99/EC. This is an environmental protection law through criminal law, and it is interesting that at the moment European penal norm projects on biolaw do not exist. It may be that the convergence of the penal norms about liability of physicians, euthanasia, or assisted reproduction in EU countries is not necessary, but, for example, we cannot say the same with norms about stem cell research or use of biotechnology in agriculture.[4]

Anyway, the juristic penal comparison is important in every sector of biolaw, even though it generates only mutual knowledge of the juristic reality. It is interesting to know how different countries, which share the same values in the EU context, balance the interest in play in the most important bioethical questions. At the same time, it is necessary that the differences between the countries' legislations be limited, even if a convergence of norms is not indispensable. On the contrary, we have two different problems: one is practical, and the other is political.

The practical problem is medical tourism. At the moment, Italy suffers from two important phenomena based on its very restrictive legislation. The first one is fertility tourism: today, thousands of Italians travel every year to Spain or other countries for fertility treatments, especially the strictly banned sperm-egg donation.[5] The second one is "assisted-suicide tourism": in this case, the "most popular" destination is Switzerland,[6] depending on the money that the sick person can spend and on how much his friends and family want to help him. The present and the recent past offer other grim examples of travel in Europe based on the legal regulation of the procedure sought in the home country: it is the history of the

[1] Sacco (1992), pp. 6–26, 154–168; Gambaro and Sacco (2008), chapters I and II.

[2] Bernardi (2004); Cadoppi (2004), pp. 44–54; Fornasari (2006), p. 270.

[3] Bernardi (2005).

[4] See e.g.: Vagliasindi (2012), pp. 246–247.

[5] Dolcini (2008), p. 64.

[6] As far as the Netherlands is concerned, officially only Dutch residents should receive medical assistance to commit suicide. But the law does not prohibit doctors from administering euthanasia to non-residents.

regulation of abortion in Ireland and Germany, among others. All these important examples are connected with criminal law.

The political problem is based on a question: if there is a remarkable difference between national legislations concerning the most important bioethical problems, does that mean that there is no real sharing of values in the EU context? It does not indeed, since each country respects the European Union Fundamental Rights Charter (especially art. 3) and the ECHR case law. This is not a detailed law, of course, but it defines the framework guiding national Parliaments when passing laws on bioethical-sensitive issues. For example, the ECJ and the ECHR could not now admit an act of Parliament strictly prohibiting fertility tourism because this law would infringe not only the four EU freedoms but also, and mainly, the fundamental rights.

For this reason, the juristic comparison in criminal law is necessary today in the EU: the more European judges from different countries evaluate the compliance of the acts of a national Parliament with EU law, in criminal topics too, the more the EU national Parliaments must consider what happens abroad. These judges, these members of Parliament, and all the people working with them need juristic comparison in criminal law.

2 "A Law from (and for) the Past": Presentation and Discussion of the Most Relevant Articles of the Criminal Code

I The existing legal provisions concerning end-of-life-related crimes are actually to be found in the Criminal Code. They have never been changed since the adoption of the Code in 1930. We find these norms within three articles: murder, murder by consent, or assisted suicide (Articles 575, 579, 580 C.C.).

The first one is the general norm concerning murder. It punishes with imprisonment from 21 to 24 years whoever kills another person. According to Article 40, para. 2 C.C., the law punishes the person who did not prevent the event as if he had provoked it, being obliged to do so according to the law (for example, the physician must prevent the patient's death).

The second one—and most important in this paper—is Article 579 C.C.: murder by consent. The only different element between the conducts of these articles is the element of consent. Punishment is, according to Article 579, imprisonment from 6 to 15 years.

This provision is an innovation of the 1930 Penal Code. With this rule, the legislator intended to resolve a dispute that had arose in the Courts concerning the enforcement of the articles on murder or on assisted suicide in the previous Criminal Code.[7] Even though Article 579 does not give any justifying role to

[7] Cagli (2001), pp. 105–106.

consent, this element is very important. The Report for the final Bill of Penal Code in 1930 affirmed it too, in particular, in relation to malice and the personality of the guilty.[8]

However, Article 579 C.C. was considered from the very beginning a rule that affirmed the principle of the absolute unavailability of human life. Until now, this norm—with Article 580 C.C. and Article 5 of the Civil Code—expresses a kind of fundamental principle de facto and it influences the scale of values of the 1948 Constitution, even though it is a lower level source.[9]

The Doctrine and the Courts say that the written form is not necessary to express consent. So it can be a tacit agreement,[10] but it must be real: in a case that happened in the 1960s, the Court didn't consider that the expressions of discouragement of a sufferer were an authentic consent.[11]

Another important characteristic of Article 579 C.C. is the inapplicability of the common aggravating circumstances (Article 61 C.C.). This means that the legislator considered the consent of the offended person dominant over every other circumstance that may be able to extend the punishment.[12]

Moreover, the mentioned Report suggested that the judge has to apply an attenuating circumstance (Article 62 n. 1 C.C.) if the motive of the murder was mercy on the sufferer. However, the Courts always interpreted restrictively this norm (which affirms that the punishment must be attenuated if the subject acted for reasons of special moral and social value). For example, in 1989[13] the Corte di Cassazione (the Italian Supreme Court) stated that these reasons must have the wholehearted approval of society at the moment the act is committed. It is the special moral and social value—expressed in that society in that moment—that attenuates the antisociality of the criminal offence and that gives the general approval of the community.

However, Article 579 C.C. is a kind of "short blanket". The questions about euthanasia were the same in 1930 as today, but the present medicine turned a problem concerning only a few people into the destiny of a large part of society.[14]

The right to therapeutic self-determination is well established today. The Corte di Cassazione recognised it by a direct interpretation of Articles 32 and 13 of the Constitution,[15] which override the civil and criminal statutes without need for other

[8] Relazione al progetto definitivo del codice penale e di procedura penale, in Mangini et al. (1930), p. 462.

[9] Cagli (2010), p. 1983.

[10] Antolisei (2008), p. 64; Corte d'Assise di Roma, 10.12.1983, in Foro italiano, 1985, II, 4891983.

[11] Corte d'Appello di Ancona, 06.02.1969, in Giurisprudenza di Merito, 1969, II, 173.

[12] Mantovani (2008), p. 173.

[13] Cassazione Penale, Sezione I, 7.04.1989 in La Giustizia penale, 1990, II, 459 (a commentary on the sentence: Bellotto 1993).

[14] In her most important book, Maria Beatrice Magro states that she doubts that Article 579 C.-C. complies with the Italian Constitution; Magro (2001), passim.

[15] Cassazione Penale, Sezioni Unite, 18.12.2008–21.01.2009, n.2437 http://www.altalex.com/index.php?idnot=44514.

specifications. The doctrine decisively supports this interpretation,[16] which seems to have definitively prevailed.[17]

Thus, killing by consent is nowadays a crime in Italy too, but refusing medical treatment is a right, even if the physician has to switch off a ventilator or another life-sustaining machine.

That means that the right to therapeutic self-determination can make the conduct of active murder allowable[18]; this is a very conflicting debate, that the media often used to support the legal ground of the Calabrò Bill (the last draft bill—with a liberticidal approach—with dispositions on the Advance Treatment Directives (ATDs), infra paragraph 4).

The rise of the Constitution's predominance is winning against this position, but there is another helpful argument that does not need to resort to the sources of the theory of law because it is based on penal dogmatic. Hence, we have to shift the attention from the objective element of the crime to the mens rea. If the physician considers that the sufferer consciously and unconditionally wishes his death, then the doctor wants to help the patient commit suicide, whether he acts as an active or passive conduct. Thus, the mens rea is not that of murder by consent but of assisted suicide, and it would be impossible to punish on the strength of Article 579 C.-C. because the correspondence between conduct and mens rea is necessary to arrive at a guilty verdict in a legal system based on the culpability principle.[19] This shows one more time that the norms in force today are inadequate.

II Assisted suicide is a crime in Italy, according to Article 580 C.C. This norm also punishes soliciting suicide. The punishment is imprisonment from 5 to 12 years; therefore, it is slightly milder than murder by consent, but only if suicide happens. If it does not occur, the punishment is imprisonment from 1 to 5 years, but only if the attempt causes serious or very serious injuries.

It is a complex and ambiguous system of punishments that does not clarify the attitude of the legal system with regard to suicide.[20] One more time, the 1948 Constitution is indispensable for a correct interpretation: on the strength of its norms, not punishing suicide (and attempted suicide) is a Hobson's choice and it is not simply a choice of political opportunity. Moreover, the right to self-determination is so important that not only it warrants the lawfulness of suicide,

[16] Donini (2007), p. 903; Risicato (2009); Viganò (2007).

[17] Before that, the Ordinanza of Tribunale Civile di Roma on 2006, December 16th—concerning the famous "Welby case"—goes in the opposite direction (a commentary in Donini (2007), p. 903).

[18] One more time: Sentence GUP Roma, 23.07.2007, n. 2049 (on the Welby case, see in Rivista Italiana Diritto e Procedura Penale 2008, p. 437). With this statement, the sentence set a question about the right of the physician to refuse to turn the switch off in accordance with his conscientious objection (Giunta 2008, p. 868).

[19] A similar argument is used by certain authors who would charge with temporary embezzlement rather than normal embezzlement situations of loss or destruction of assets before restitution in the case of acts of God (cfr. Fornasari 2008, p. 113).

[20] Bertolino (1999), p. 113.

but it even justifies the punishment of the person who strengthens or creates another subject's intent to commit suicide.

So, in the case of refusal of medical treatment, even if the mens rea is the one required by Article 580 C.C., the physician cannot be punished according to this norm because the conduct does not correspond to that described in the precept. Moreover, the Corte di Cassazione expressly said that the difference between Article 579 C.C. and Article 580 C.C. rests on the responsibility over the act.[21] In the conduct of assisted suicide, responsibility over the act must be of the person who is going to die, whereas in murder by consent it is of the other person.

Therefore, it is plain that it is impossible to resolve the legal questions about the end of life with the penal norms currently in force in Italy. These provisions were created for a country that has changed. We believe that in Italy the majority of people die in a hospital when the physician and the relatives decide that they have done "enough".

The provisions in force today have only one thing in common: these norms are an expression of the approach that the 1930 legislator had towards the right to life. It was an absolutely unavailable right, and its real holder was not the person but the State and the community. As we showed, this old conception influences contemporary discipline regardless of the Constitution. For this reason, it is not positive that the Calabrò Bill did not introduce any change in the penal norms: today, Articles 579 and 580 C.C. are useless and detrimental. It is clear that the provisions of the Criminal Code must recover their role of regulating the country's real situation. At the moment, this is not the case, unfortunately. In the last passage of the Calabrò Bill (from the Camera dei Deputati to the Senate), the members of the Lower House changed the word volontà (will, wishes) of the patient to the word orientamenti (tendency) (cf. Article 7, para. 1)!

3 "Today": A New Lexicon for Discussing the End of Life. The Rules Established in Court

I What has been written until this point shows that in Italy there is no corpus of specific norms dedicated to the decisions concerning the end of life, living wills, or advanced treatment directives; there is a jumble of generic norms in the Italian Constitution and in the Penal Code. In the twenty-first century Italian society, the former are insufficient, while the latter are also inadequate.

This lack of regulation has forced the Courts to solve the concrete cases by employing constitutional principles directly, using a very unusual method in a civil law country.

For this reason, the solutions for the most internationally renowned cases (Englaro, Welby, Nuvoli), as many more less famous ones, are similar to those

[21] Cassazione Penale, Sezione, 6.02.1998, n. 3147, in Rivista Penale, 1998, p. 466.

given by other European countries, including Germany. However, since Italy is a civil law country, those verdicts, even though famous and eminent, do not establish a solid precedent.

First of all, they do not give to physicians, patients, and relatives the serenity to decide what to do in critical situations, serenity that they would have if there were a specific law on the matter. The physicians are above all afraid of being forced by the threat of a legal punishment to justify their actions before a Court.

Second, the verdicts give answers only to a few aspects of the legal problems surrounding the "end of life", while many important issues have to be dealt with in the Italian Parliament: among those issues, living wills and proxies.

II What does this law "based on the jurisprudence" say?

Before presenting it, it is necessary to clear the role that the words have within the Italian debate on the end of life.

First of all, has the word "euthanasia" been de facto banned?[22]

As Giunta mentions, the first few times this word was used in the past there was an intention of unmasking collective fears about end-of-life decisions; he underlines that today, thanks to technical progresses, "to die" is increasingly a human decision rather than an unexpected event.[23]

Those who consider this fact an attack on the idea that only God has the right to decide about human life[24] succeeded in imposing the idea that the word "euthanasia" had only a negative meaning similar to "legalised murder". Quoting the Nazi euthanasia program, they affirm that every concession to the contrary position will put society on the infamous slippery slope.

The expression "right to life" is nowadays also less used, as is "right to die", the dark side of the moon. In Italy, the idea that the right to life is a kind of "super-right" that impedes a trade-off with every other right is still very strong. Nevertheless, also those who strongly endorse the freedom of self-determination never allow a complete freedom of suicide.

This does not occur because there is no faith in the freedom of the people but because of the consequences of the recognition of this freedom.

The first consequence is the freedom, without exceptions, of assisted suicide, perhaps the most admissible because these conducts will be a cooperation with the practice of a constitutional right.

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[22] A good example: Canestrari (2012), pp. 45–49 and 83. The Calabrò Bill states (Article 1 para. 1 c)) that "any form of euthanasia is banned", but it is a norm without content. In fact, the Bill does not give any definition of euthanasia, and the prohibition is a simple link to the norms of the old Criminal Code. To give a definition of euthanasia is impossible in Italy today, for Parliament too, because the meaning is different according to the ideology of the person who writes it. See also Cagli (2011) p. 1819.

[23] Giunta (2008), p. 866.

[24] Only when thinking this could one consider meaningful norms that do not give people the freedom to decide about their lives, even though, from a secular point of view, making available the right to live means not automatically recognising a right to die. This right, as we say later, has potentially very negative consequences.

However, further consequences are the following: to impede the suicide of another person could, in a few cases, establish the crime of violenza privata (private violence) (art. 610 C.C.), and the reaction, also violent, of the suicide victim against the aider should be justified as self-defence. Finally, the hardest consequence: if a person physically prevented from killing himself had the right to die, he could demand the State to help him and the State would have to help him in order not to discriminate the subjects physically able to kill themselves from those who are not able to.[25]

In the Italian debate, the words are thus different. As Zatti affirms,[26] people do not speak about the conflict between a right and a duty to live or to die but about therapeutic self-determination.

To die is an individual experience that concerns the body of the person and is paradoxically more related to the concept of health than to that of life.

The Courts also contributed to this evolution of the meaning of the words, using in their verdicts references to norms that, like the very important Article 32 of the Constitution or other provisions from international agreements, do not speak about euthanasia but specify the limits and contents of the right to health. Whichever is the point of view taken, to debate about the right to health is preferable because nobody doubts it exists, as occurs with the right to die, and it is certainly an available right.

Thus, there are not in this debate those ideological prejudices that impede the development of a fruitful debate about the right to life.[27]

III The starting and ending point norm for all the verdicts about Italian judiciary cases about the end of life is Article 32 of the Constitution.[28] The first sentence of the second paragraph is very important because it states that nobody can be forced to undergo a medical treatment.[29] For this reason, the Italian judges do not discuss if there have been cases of active or passive euthanasia, rather if a refusal of medical treatment or a request for palliative therapies provoked the death of the patient.

Now we will proceed to present the different cases solved in the Italian case law, from the simplest situations that should be called passive euthanasia to the most complex cases of what abroad is still defined as active euthanasia.

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[25] Magro (2012), p. 52.

[26] Zatti (2007).

[27] The references to "dignity", above all to a respectable death, do not help the debate. There is no consent on the meaning of "respectable death", and each person has a different opinion according to his ideological prejudices. Piciocchi (2012), p. 41.

[28] I. The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. II. No one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person.

[29] The sentence ends with the words "except under the provisions of the law". This reference to norms that impose medical treatments relates to children's vaccinations, to epidemics, and to quarantine (as for public health problems) or to the investigation about fatherhood or biological evidence in the case of crimes.

(a) The simplest case is that of a patient who refuses ab initio a therapy or interrupts it without the need for material help from anyone.

In the face of the right of a person to deny health care or to live the last stages of his life according to a criterion of dignity not imposed by anyone, the physicians have the duty to cure.

The conscious rejection of the treatment by the patient eliminates this duty and turns it into its opposite, that is, the duty to respect the will of the patient. The physician's conduct is atypical and therefore loses any relevance within criminal law.[30]

(b) This case becomes more complicated if the ill person, due to a physical problem, needs the active help of the physician or of another subject to interrupt the therapy. This was the case of Piergiorgio Welby.

Piergiorgio Welby became sick with progressive muscular dystrophy, and in order to end his life he needed the help of an anaesthetist to remove the automatic ventilator that allowed him to live after a respiratory crisis in 1997. In this case, the physician actually carried out an action and did not just make an omission: with his own hands, he interrupted a "life-saving" therapy by intervening on the causal progress of the illness that, without residual obstacles, killed the patient.

The German doctrine speaks in these cases of interruption of a causal rescue process (Abbruch einer Rettungscausalität). German are also the authors who first proposed to interpret such cases as an omission rather than an active action, even if this is evidently a counterintuitive interpretation.

With a normative interpretation of the physician's conduct, these authors invented the juridical type of the crime of omission through active conduct (Unterlassung durch Tun).[31] According to this theory, if the patient asks for it, the active behaviour of the physician is considered an omission, which is not legally prosecutable for the reasons explained in point (a): basically, the respect of the patient's will. It focuses on the patient's will and leaves the difference between active conduct and omission in the background.

The majority of the Italian doctrine refused this theory, which was judged as too overblown because it imposes, in fact, to upset reality.[32]

In the minority doctrine, we recommend the opinion of Maria Beatrice Magro, who declares that in these cases the aliud agere would identify with an omission.

[30] Pulitanò and Ceccarelli (2008), p. 330.

[31] The theory appeared almost 50 years ago, but it acquired new strength just for the solution of complex end-of-life cases; cf. Meyer-Bahlburg (1968), p. 49; Roxin (1969), p. 380; in particular: Schöch (1995), p. 153.

[32] Fausto Giunta considers unclear the reasons for the equivalence between active conduct and omission, which are from the naturalistic point of view very different. Giunta (1997), p. 93. The theory does not deal with the problem of the right of the physician's conscience's objection, who could refuse to act. Cf. supra nt. 17; for all: Donini (2007), p. 911.

According to her opinion,[33] the action of the physician would not be contrary to the normative duties, but it would establish a behaviour with the will of a patient who refuses a therapy. Magro states that there is no difference between the interruption of already-begun therapies and the ab initio refusal because in both situations the physician does not start the natural process that leads to the patient's death, but it is included in a pre-existing and autonomous process. This is, in the opinion of the author, the ontological difference between the situation in which the patient asks to be killed or to be left to die.

In our opinion, the majority of Italian authors refuse this theory because they have simpler reasons to answer the problem. In fact, Article 32 of the Constitution does not make any difference between active conduct and omission because the norm uses the point of view of the patient: the facere or non facere of the physician is not relevant for the interpretation of the norm.[34]

The decision about the case of Piergiorgio Welby is proof of this assertion.

The murder case against the physician ended in a pretrial hearing. The judge considered that the anaesthetist played a role in the causal sequence of the death but his conduct was permissible. In fact, the judge enforced article 51 C.C. (concerning exercise of a right), together with Articles 2, 13, and 32 of the Constitution, the Oviedo Convention, and the case law of the Corte Costituzionale. In other words, the judge considered that the conduct of the physician conformed to what Article 579 C.C. describes as murder by consent (from 6 to 15 years' imprisonment) but was not a criminal offence because the patient's conscious will has to be respected.[35]

Lucia Risicato asserted that in this way Article 32, para. 2 of the Constitution entered the group of provisions justifying Article 51 C.C, not only because it is a case of exercise of a patient's right but also because the physician must perform the duties imposed by the constitutional norm.[36]

In our opinion, the decision of the Roman judge is correct and very important. Magro writes that it is not necessary to use the theory of the justifying act if it is possible to demonstrate that the conduct is not typical (according to the theory of the crime of omission through active conduct). But that means that any relevant fact happened. We do not believe that to remove the automatic ventilator that allowed Welby to live has the same legal meaning as killing a fly. We believe that the conduct of the anaesthetist is licit, but it is nonetheless a relevant conduct. And this is not a simply dogmatic discussion.

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[33] Magro (2012), pp. 59–60; the Author alludes to Engisch (1973), p. 163.

[34] Cupelli (2008), p. 1824.

[35] Sentence GUP Roma, 23.07.2007, supra nt. 17; among others is the same opinion: Donini (2007), p. 902; an alternative but less linear solution is proposed by Gibernat Ordeig (2006), p. 1573. From a technical juridical point of view, the solution would be different in the case of ab initio refusal because in this case there is no typical fulfilment of the penal circumstances and, consequently, the guarantee position of the physician does not work (Article 40, para. II C.C.); along these lines: Brignone (2009), p. 924.

[36] Risicato (2010), p. 250.

(c) Even more complicated is the case of the interruption of care received by an unconscious person.

In a civil law country like Italy, only a law could give a clear answer to these difficult cases and this law does not exist nowadays. Nevertheless, throughout the jurisprudence concerning the case of Eluana Englaro, the Italian high Courts gave partial leanings.[37] In order to do this, they could only resort to the Italian Constitution, even in this case, by directly applying the above-mentioned articles.

Although Eluana Englaro's case has been commented by several criminal law authors, it is substantially a private law case. Within the Englaro 2007 verdict, the Corte di Cassazione fixed the two fundamental requirements to allow the proxy to order the interruption of the therapy: first of all, the fact that the vegetative state of the patient was irreversible and, second, that it is therefore impossible for him to communicate his will and that his better interest could be followed in a subjective and individual perspective.

This means, according to the judges, that the proxy must retrace the patient's will.

Written documents are not necessary in this case: if these are not present, the will could also be retraced through generic and past declarations. Even the declarations made without the awareness that they will have been applied in order to solve future cases of unconsciousness are valid.

We do not comment on the verdict in detail because others have already done so in depth in this book. We only express two considerations.

First: the case of Eluana Englaro established these important principles only because it was a case of private law. Only the courage and the persistence of the girl's parents forced the Italian courts to speak up on this case, and this occurred because in Italian private law the non liquet prohibition is in force.

If, as it often happens even nowadays, the parents had decided to say "enough" shortly after the accident, speaking in the aisle with physicians, Eluana Englaro would have died many years ago and no jurist would have spoken about her case.

If, after years of vegetative state, the parents had cut off the machine in a moment of desperation, they would have been charged with murder. But even if they would have been sentenced to a few years in prison (with all the possible extenuating circumstances), they would certainly have received an absolute pardon from the President of the Republic.[38]

The parents of Eluana Englaro decided to respect the law and to seek justice from the relevant Italian Courts. They did not cut off the machine in hiding, but they

[37] Among the many verdicts about the Englaro case, the most important is the Cassazione Civile, Sezione I, 04.10.2007–16.10.2007, n. 21748, in Rivista italiana di diritto e procedura penale, 2008, p. 384 (a commentary of the decision: Barbieri (2008); see also Iadecola (2008); Viganò (2008); Seminara (2007); one of the most critical commentaries is authored by Eusebi (2008)).

[38] As it happened in 2011, when President Napolitano granted pardons to Calogero Crapanzano, who in 2007 killed his 27-year-old son (suffering from autism) with a rope.

asked from the Italian justice system the authorisation to do so. After 9 years of waiting, the judges gave them this authorisation.

For this reason, Eluana Englaro' s case is not a case of criminal law.

After the girl's death on 9 February 2009, many associations and persons charged the father of Eluana, Beppino Englaro, and the physicians who cut off the machines with murder.

For this reason, on 27 February 2009, the prosecutor began an investigation against them. The medical examination confirmed that Eluana died because of a heart attack due to dehydration, and this was compatible with the sanitary protocol authorised by the judges. The prosecutor consequently asked the investigating magistrate to dismiss the investigation. The request was accepted (GIP Udine, 11 January 2010, unpublished).

(d) The issue of pain relief and palliative care still needs to be dealt with.

Fortunately, Italy nowadays has a law that regulates this matter: Law no. 38 of 15 March 2010, specifically commented on in this book too. Palliative care consists, as is known, in giving very powerful analgesic medicine to patients with inauspicious prognosis. This definition is compatible with the cited law, in particular with Article 2 para. 1 a).

This therapy can have as secondary effect the shortening of the patient's life, and so palliative care is considered active indirect euthanasia.

Law no. 38/2010 does not deal with the issue. Not only does it not use the "banned word" "euthanasia", but it does not modify the criminal law in force either. To change the criminal law or to use the word "euthanasia" would have impeded approval of a law requested and supported by many terminal patients' support groups, many of which are admittedly Catholic. Active indirect euthanasia, in the form of palliative care, is thus legal and has a specific regulation. Even though it is applied every day in many Italian hospitals, it cannot be called by its name. To say whether this is hypocrisy or real politik is not up to the jurist. The penal law author must nevertheless expose the cost of this choice, which is potentially very high.

The lack of penal rules has not caused problems until now because no physician has been sued by a patient's relative.

Let me give an example: two brothers have a sick, incurable father, and they agree with a physician to giving palliative care to him in a hospice. Let's imagine that one of the two brothers lets the other one convince him to give his consent, but after the father's death he changes his mind and decides to sue the physician.

According to the criminal law in force, in these cases there are all the elements in order to condemn the physician, and the easy way to absolve him would be to bring into question, case by case, the certainty of the proof. In a real trial, it would be very difficult to prove that the last dose of anaesthetic, which killed the patient, had only been administered in order to reduce his pain by killing him or if the death was a predictable, but not wished, consequence.

The difficulty of providing proof does not cancel the legal problem: in the absence of a clear legislative position, it is necessary to resort to dogmatic in order to absolve the physician.

Canestrari states that the self-legitimacy of the medical activity performed with the person's consent makes the fact atypical because it is socially useful and adequate for its scope.[39] This argument is nevertheless debatable for the reasons expressed at the end of section 3, sub b).

Magro maintains instead that it is necessary to use the theory of the defences as grounds for excluding criminal responsibility, in particular necessity (Article 54 C.C.) and consensus (Article 50 C.C.).[40] It is an attractive hypothesis, even though the author only dedicates a few lines to it. We unfortunately believe that it is not usable within the law in force. Article 54 C.C., in fact, states that the conduct of the person who acts forced by the need of saving himself or others from a present danger of serious injury is not punishable. It is contrary to logic to state that a person was killed in order to be saved from serious injury. Even Article 50 C.C. does not really help in solving the problem because the concept of consent suffers from all the issues we have discussed at length. In order for consensus to prevail on it, it would be necessary to resort again to the direct application of Article 32 of the Constitution. This is correct, but why meddle with the defence's theory elsewhere?

A third possible solution is based on the content of the intent. In order to exclude the criminal responsibility of the physician, some authors use the principle of the double effect as a practical principle that guides moral reasoning.[41] This principle is used in order to decide upon the goodness of an action in cases in which reaching a good and intended effect on the direct protection of an essential right of a person is necessarily followed by reaching a collateral unintended effect, but which can damage other essential rights. According to these Authors, the double effect principle would be usable in the case in which the physician accepts the risk of shortening the patient's life in order to mitigate his pain. This theory does not seem to be adequate either. In order to state that there is intent, in fact, the Italian interpretation does not retain sufficient that the physician consider the patient's death as a possible or at least probable consequence of his own action nor that the physician accept the risk of causing it.[42]

We believe that a more persuasive solution is within guilt, not in such a specific element like intent but strictu sensu as principle of guilt. We think, in particular, about the inesigibilità principle (Unzumutbarkeit Prinzip).[43]We cannot in fact expect a different conduct from the physician: he has to cure a patient whose destiny consists only in very painful days before death.

[39] Canestrari (2006).

[40] Magro (2012), p. 76.

[41] Miglietta and Russo (2011), p. 922.

[42] Gallo (1951–1952; 1964); Canestrari (1999), passim; Fiandaca and Musco (2009), pp. 367–370.

[43] To suggest an English translation of this word is quite difficult. The origin of the word inesigibilità is the verb esigere, which can be translated as "to expect" or "to require". Thus it could be said: "Principle of unexpectedness".

The physician stands before crossroads: he can either do nothing or, with the knowledge and means at his disposal, limit the pain as much as possible, even shortening the wait for death.

Can the State threaten the physician with a penalty if he decides to intervene? We believe not.

It is a hypothesis[44] that certainly has a weak point in responding to a penal doubt with a principle instead of a specific norm. Nevertheless, we believe that this hypothesis is more adequate than the three ones presented beforehand.

We repeat that the best solution would be a clear and explicit law.

4 "What About the Future?"

I During the last legislature, the Senate of the Republic approved on 26 March 2009 a Draft Bill (S. 10) consisting of 9 articles, with the title "Dispositions on the Subject of Therapeutic Alliance, Informed Consent and Advance Treatment Directives (ATDs)" (Disposizioni in materia di alleanza terapeutica, di consenso informato e di dichiarazioni anticipate di trattamento). It was amended and passed by the Chamber of Deputies on 12 July 2011. To become a law, the Draft (consisting now of eight articles) needed another vote without modification by the Senate. It was discussed in Commission XII as Draft Bill S. 10 B,[45] with the unofficial name of Calabrò Bill (from the name of the first proposer). The dissolution of the Italian Parliament in December 2012 interrupted this process.

In this paper, we are going to write only about the criminal aspects of the Draft Bill, but it is necessary to give some general information.

The core of the Draft is art. 3, "Content and restrictions on the Advance Treatment Directive" (Contenuto e limiti della dichiarazione anticipata di trattamento). In the first sub-paragraph we read: in the Advance Treatment Directive, the declarant expresses his wishes and information about the activation of therapeutic treatments, as long as they are in compliance with the text of this law.

The heart of the new legislation is the rule that imposes to respect the law when writing ATDs. The ATD is, in fact, an act with a strict and heavy procedure to be followed and, at the same time, a document with a lot of restrictions in its contents.

Many norms of the Bill prevent the wishes of the patient from being part of the document that contains the ATDs.

First of all (art. 3, para. 3), the Bill affirms that in the ATD the person cannot express instructions corresponding to the crimes of murder, murder by consent, or assisted suicide (Articles 575, 579, 580 C.C.). The Bill does not introduce new

[44] Thanks to suggestions from the book Fornasari (1990), passim.

[45] Website of Senato della Repubblica. In these last months, we found a few references about this draft bill in itinere: Carusi (2012); Magro (2012), p. 113; Manna (2011); Pelissero (2012); Penasa and Corn (2013).

criminal norms, but it mentions two more times these articles of the Criminal Code: Art. 1, para. 1, al. c) and Art. 6, para. 6.

The first mention is included in the general principles of the Bill, where we read that, according to Articles 575, 579, 580 C.C., every form of euthanasia and every form of help in suicide or assisted suicide is banned. The medical activity can only be aimed at saving and protecting human life and health or alleviating pain.

II The second mention applies to the proxy (fiduciario), who is the person whom the patient can empower to speak with the attending physician when he becomes unconscious. So, Art. 6, para. 6, affirms that the proxy undertakes to carefully check that the patient does not come across a situation corresponding to the crimes of murder, murder by consent, or assisted suicide.

There is a third point where the legislator shows the will to block every action that brings the patient closer to the end of life; it is Art. 7 (Role of the physician), para. 3. It affirms that the physician cannot take into account instructions aimed at causing the death of the patient or, in any case, considered to be against the law or medical ethics. This norm appears to be correct in changing the law that resolved the Welby case.

Moreover, Article 3, para. 4, affirms—again about the restrictions in the contents of the ATDs—that the physicians must maintain nutrition and hydration until the end of life. They can be interrupted only if they are not effective and they no longer give what the patient needs for the most important physiological bodily functions. The person cannot write an ATD about nutrition and hydration.

Besides the contents of the ATDs, it is necessary to consider at which moment the document, in which the subject wrote his wishes, begins to take effect.

Article 3, para. 5, affirms that

> The ATD takes effect in the moment in which the subject is permanently unable to understand information about the medical treatment and its consequences, because of a proved absence of cortical and subcortical brain activity, and for this reason he cannot decide about him/herself.

The original Senate's disposition was not so precisely formulated because it simply referred to subjects in a vegetative state. This point has been strongly criticised because it did not offer a necessary (and clear) definition of one of the most important elements of this project, i.e., what does it mean to be in a vegetative state.

Thus, it seems that the new law will leave out a huge part of the population involved in the problem[46] because the second part of the third article, fifth sub-paragraph, declares that the evaluation of the clinical state of the subject has to be made by a medical board composed of an anaesthetist/resuscitator, a neurologist, the attending physician, and the specialist of the pathology. This process will clearly take much time, and it is evident that the moment in which what the subject wrote will be read will not coincide with the moment in which the subject will lose conscience.

[46] Brignone (2009), pp. 927–928.

Finally, we have to consider that, according to Article 7, para.1, the physician cannot be forced to act according to the will of the subject if he prefers to use different medical treatments. He only has to declare which treatment will be used and the reason for his decision in the medical records, but this cannot be contestable before a judge.

The situation described is complicated. With all these exceptions, we have to ask ourselves what a person can write into his ATDs and in which moment what is written will be taken into consideration.

A healthy person with a good education is hardly able to clearly imagine what medicine he will or will not wish to assume when he will be in a vegetative state (if he will ever be in it), even with the help of a physician. It is easier to imagine that this person is going to wish giving an ATD with general instructions about the treatments over his body when he is going to be unconscious. Not allowing to write dispositions about feeding and hydration is clearly like emptying them of content.[47] The only utility could be to name a proxy, when he is not a relative, for example in the case of common law marriage.

Another question is, which laws could be applied to the situations that are not covered by the Bill?

The enforcement field of this law is really narrow because it only refers to persons who are in a vegetative state, without being in danger of dying. The Italian Health Ministry has declared that it does not know the exact number of these cases but that it supposes it to be nowadays about 3,000. The prestigious review Nature[48] has written that it is just a law for cases like Eluana Englaro's. It is partially true.

In addition, it is clear that a law about ATD should embrace a wider sector of the population. The number of people who nowadays end their lives in Italy due to a serious illness that causes them disability and severe pain is in the tens of thousands. These people, the Corte Costituzionale affirmed, need a clear law, but this is not what the Italian Parliament is doing.[49]

However, the message the media are communicating is quite different. The public opinion is informed about the debate on feeding and hydration, but it thinks that the Parliament has to work on a wider law about the possibilities of listening to the declarations, out of the vegetative state cases.

One more time, the Italian Parliament is doing a "manifesto" law in order to show to the media that it is working on important concerns, but without saying anything or almost anything.[50] The majority of "end of life" situations in Italian hospitals will be resolved exactly like today, i.e. in a "grey area", with the physician and the relatives deciding the destiny of the patient in the corner of a corridor, speaking softly so that people who pass there will not realise the subject of the conversation.

[47] Pulitanò and Ceccarelli (2008), p. 337; Brignone (2009), p. 928.

[48] Our direct source is the newspaper Internazionale (n. 790: 13).

[49] Canestrari (2012), p. 47.

[50] Bobbio Pallavicini (2012).

This is happening despite the messages of the Corte Costituzionale to the Italian Parliament, despite the constitutional principles and of the secular nature of the State of Law, despite the respect of the person's will and despite the flag that everyone claims as their own, i.e., the principle of human dignity.

III From the penal jurist's point of view, penal dispositions limiting the individual freedom of people refer to the distinction between law and ethics.[51]

The situation created by the Calabrò Bill is paradoxical even if we consider the official Catholic Church documents, first of all the 1992 Catechism and especially number 2,278 (therapeutic obstinacy). Transforming the part of the Catechism dedicated to euthanasia[52] into a State law would paradoxically protect people's freedom of choice over the destiny of their life better than the Calabrò Bill.

It is very interesting that, according to what the Jesuit Mario Beltrami (one of the most important experts on this part of Catechism) says, the basis of what is declared in numbers 2,276–2,279 is on purely rational subject matters and not on religious reasons.[53]

The Bill does not introduce new criminal norms, we repeat, but since 1978 (Abortion Act) Italian legislators have not modified the penal norms regarding

[51] In Spain: Mir Puig (2005), p. 129, who speaks about this issue in relation to the principle of exclusive protection of juridic goods; in the Italian interpretation, this principle is a different way to intend an aspect of the principle of the fragmentary nature of criminal law: cf. Fiandaca and Musco (2009), p. 33, following the theories, in Germany, Maiwald (1972), p. 9.

[52] Euthanasia 2276 Those whose lives are diminished or weakened deserve special respect. Sick or handicapped persons should be helped to lead lives as normal as possible. 2277 Whatever its motives and means, direct euthanasia consists in putting an end to the lives of handicapped, sick, or dying persons. It is morally unacceptable. Thus an act or omission which, in of itself or by intention, causes death in order to eliminate suffering constitutes a murder gravely contrary to the dignity of the human person and to the respect due to the living God, his Creator. The error of judgment into which one can fall in good faith does not change the nature of this murderous act, which must always be forbidden and excluded. 2278 Discontinuing medical procedures that are burdensome, dangerous, extraordinary, or disproportionate to the expected outcome can be legitimate; it is the refusal of "over-zealous" treatment. Here one does not will to cause death; one's inability to impede it is merely accepted. The decisions should be made by the patient if he is competent and able or, if not, by those legally entitled to act for the patient, whose reasonable will and legitimate interests must always be respected. 2279 Even if death is thought imminent, the ordinary care owed to a sick person cannot be legitimately interrupted. The use of painkillers to alleviate the sufferings of the dying, even at the risk of shortening their days, can be morally in conformity with human dignity if death is not willed as either an end or a means, but only foreseen and tolerated as inevitable. Palliative care is a special form of disinterested charity. As such it should be encouraged. (Available via http://www.vatican.va/archive/ENG(0015)/__P7Z.HTM).

[53] Beltrami (2008). There are also other official documents in which these concepts are more clearly expressed, for example the declaration on euthanasia Iura et Bona of the Congregation for the doctrine of the faith 1980 (Available via www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19800505_euthanasia_sp.html) and the Charter for health care workers 1995 by the respective Pontifical Council, which affirms para. 120 that artificial hydration and feeding are considered cures and can be suspended when painful for the patient (available via http://www.vatican.va/roman_curia/pontifical_councils/hlthwork/documents/rc_pc_hlthwork_doc_19950101_charter_en.html).

crimes against life. In the opening document to its annual Conference,[54] the prestigious Franco Bricola Association ("Eighty years of the Rocco Code", "Gli ottant'anni del Codice Rocco"—Bologna—19/20.3.2010) wrote that there is a political inability to write norms about these crimes in a new way: this is a meaningful example of the parliamentary sloth about a key topic, in which the tensions between lay and Catholic people represent a historical impasse rather than a will to mediate. If we consider life the most important among universal values, only when we can update its protection according to the needs of history will we be able to rewrite the whole Code, which from that good draws the axiological basis of the hierarchies of the penal system.

The Calabrò Bill was discussed in the Senate Commission XII, but the senators have stopped working on this project since November 2011, shortly before the collapse of the last Berlusconi Government. Now we know that the Calabrò Bill will never become law. In 2012, the priorities of the Government concerned the economy and the parties of the big government coalition had very different ideas about the end of life.

The task of passing a bill on living will directives will be left to the next Parliament, and the subject matter of the new draft will depend on the new majority.

Unfortunately, years of discussion within the Parliament and processes too exposed to the media left deep wounds. The hope is that the new members of Parliament[55] leave their ideologies aside and seek concrete and sharable answers. The hope is that they remember that everyone has a date with death; they too.

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[54] Stortoni and Insolera (2012), pp. 21–22; also Pulitanò (2010).

[55] The new legislature has begun working in the second half of March 2013, and Members of Parliament have already proposed various bills concerning the end of life. Till May 1st, none was inserted in the agenda.

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The German Law on Euthanasia: The Legal Basics and the Actual Debate

Anna Zwick

Abstract This chapter focuses on the German criminal law in regard to euthanasia. Referring to the traditional classification, active indirect euthanasia, passive euthanasia, and assistance in suicide are legal in Germany, whereas active direct euthanasia is a crime. As criminal law is to be interpreted in the light of the Constitution, the most relevant Constitutional principles such as human dignity, the right to life and physical integrity, and the right to self-determination are presented.

This legal overview is complemented by some of the currently most controversial issues within the topic. These include the impact of the new German law on living wills on the criminal law on euthanasia. Among other relevant debates, the issue of the criminalization of commercial assistance in suicide is discussed.

The chapter concludes that despite the difficulties in the practical differentiation, the law on euthanasia is rather clear in Germany. The problem that remains, however, is the legal insecurity still largely found among the population and also among physicians and even lawyers. This insecurity leads to a frequent circulation of unqualified warnings, for one of a discussion concerning the legalization of active direct euthanasia, which currently is not at all being considered.

Contents

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1 Introduction

1.1 Introductory Remarks

The issue of euthanasia is extraordinarily complex and concerns extremely difficult ethical, medical, cultural, and religious questions. The German legal framework of euthanasia is inconsistent and anything but clear. Affecting anybody on a very personal level, the topic is emotionally and existentially distressing.

Since it is occasionally claimed that because of historical reasons a thorough debate on euthanasia cannot be held in Germany with the same openness as in other countries, it should be said that euthanasia is discussed as broadly in Germany as in other countries.[1] The German discussion is not (or no longer) fundamentally different in content, and argument from discussions led in other European countries or in the United States.[2]

Already in the year 1986 the amount of German literature related to euthanasia was described as "threatening".[3] Nearly 30 years later, the amount has obviously not become less threatening. This article shall give a short overview of the current legal situation of euthanasia in Germany and focus on the presentation of the latest development and the current debates.

[1] Oduncu and Sahm (2010), p. 380.
[2] Oduncu and Sahm (2010), p. 371.
[3] Otto (1986).

1.2 Structure

This article has the aim to give the reader an overview of the German law and legislation on euthanasia and to point out the mostly undisputed basic principles. Based on this overview, inconsistencies will be presented in order to explain the actual debate on euthanasia.

In the last years, the debate has become more heated because of an accumulation of incidents related to euthanasia. In addition to the continual natural interest in the topic of euthanasia, both the concerned professionals and the general public have shown a steadily increasing interest in the issue because of the new German law on advance directives, which came into force in 2009. This article will explain the emerging implications of the new civil law on living wills for the criminal law on euthanasia. It will also analyze whether the new law can provide the necessary clarity. For this purpose, two rather new judgments, which are seen as the new German milestone judgments, shall be taken into consideration. The change of the medical professional code and the proposition of a highly controversial bill on commercial killing shall be presented as further new developments.

Presenting the basic legal principles and the actual debate in Germany shall enable the reader to gain a picture of the legal framework of euthanasia in Germany in order to evaluate the situation and compare it to other nations' situation.

1.3 Terminology

This article uses the expression "euthanasia" in order to describe decisions and actions at the end of life, which directly or indirectly affect the dying process and the onset of death.[4] It should be noted, however, that euthanasia is not the exact translation of the German term. Due to the indissoluble connotation of the German word "Euthanasie" with the racial mass murder of the sick, the disabled, and certain minorities under the German National Socialist regime, the word "Euthanasie" is mostly avoided in the German language. The word "Sterbehilfe" is used instead, which literally means "help in dying".

In accordance with international literature, the term euthanasia will be used in the following text, even though it is not a straightforward translation of the German technical term. In this context, it is useful to refer to the sensible distinction suggested by the German National Ethics Council between the terms "euthanasia", used here, and the historical "criminal euthanasia".[5]

[4] Definition by the German National Ethics Council, which rejects the usage of the word euthanasia: German National Ethics Council (2006), p. 48.

[5] As the word "euthanasia" still carries sensitivity, the German National Ethics Council distinguishes between "euthanasia" and the historical "criminal euthanasia" under the Nazi regime: German National Ethics Council (2006), p. 88.

2 Which Forms of Euthanasia Are Legal in Germany?

As the German Criminal Code does not contain any specific regulation on the issue of euthanasia (whether performed by a physician or by anybody else), it is to be referred to the general norms of the German Criminal Code and their interpretation by the German courts.[6]

In addition to the legislation, further guidelines are to be consulted. Although these guidelines are not compulsory, they are influential for the public and legal debate on euthanasia. The German Medical Association (Bundesärztekammer) has been publishing opinions regarding the issue of the physician's role in euthanasia since 1979.[7] Its latest opinion was published in January 2011.[8] The German Medical Association also publishes the Model Professional Code for Physicians (Musterberufsordnung für Ärzte), which is not binding but is taken into account by the State Chambers of Physicians when they compose the binding professional Codes at the federal state level (level of the Bundesländer). Furthermore, the Opinion of the German National Ethics Council (Nationaler Ethikrat) on euthanasia from 2006[9] and the opinions (Gutachten) and decisions (Beschlüsse) of the Association of German Jurists (Deutscher Juristentag)[10] play a very important role in the debate.

Taking all this into consideration, a short overview of the basic legal principles of euthanasia shall be presented as follows.

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[6] A clear analysis of the legal conditions of euthanasia is difficult as many judgments only refer to a very specific situation and only rarely give a greater overview. Like in any other legal system, many German cases on euthanasia have only clarified individual aspects on the basis of mostly different and often unusual case constellations.

[7] The German Medical Association (Bundesärztekammer) is the joint association of all 17 State Chambers of Physicians (Landesärztekammern) and thereby the central organization in the system of medical self-administration in Germany. By representing the physicians' interests, it plays an important opinion-forming role in matters of professional health and social policy, even with regard to legislative procedures. Even though its Opinions are not binding, they do have an enormous effect on the opinion-forming process. Physicians are compulsory members of the local State Chambers of Physicians and therefore indirect members of the German Medical Association, which is an unincorporated association (unlike the local State Chambers of Physicians, which are registered corporations under public law). See http://www.bundesaerztekammer.de/ (English version available) (accessed 29 March 2012).

[8] German Medical Association (2011).

[9] German National Ethics Council (2006).

[10] The Association of German Jurists (Deutscher Juristentag e.V.) is an organization with about 8,000 members of all legal professions that organizes the German Jurists Forums (Deutsche Juristentage) every 2 years. See http://www.djt.de/index.php?id=57 (accessed 20 June 2012). It has discussed euthanasia three times in the last years. Even though their decisions are not binding, the opinions (Gutachten) and the decisions (Beschlüsse) give a rather good impression of the German lawyer's view on the issues of euthanasia. The latest conference on euthanasia was in the year 2006—where the majority of the lawyers voted for a special regulation of euthanasia, in addition to the civil law regulation.

2.1 General Principles

Although the details of the legal forms of euthanasia have always been extremely controversial, it is clear that no form of euthanasia can be legally performed against the wish of the patient concerned.[11]

The only exception is the case of a lack of medical indication. Where there is no indication for a medical measure, the physician does not act illegally if he refrains from a medical measure although the patient asked for it.[12] There is generally no duty to perform a medical measure that is not medically indicated.[13] Only comfort care (Basisbetreuung), which means body care, alleviation of pain, dyspnea and nausea, decent housing, and the alleviation of hunger and thirst, but not necessarily by artificial nutrition and hydration, must always be provided.[14]

As an aspect of the right to self-determination, the patient can refuse any treatment. He is, however, not entitled in any case to insist on a certain treatment.[15] The physician may—due to his occupational freedom (guaranteed in Article 12 of the German Constitution)[16] and his right to self-determination (guaranteed in Article 2 (1) of the German Constitution)—refuse the provision of medical measures that are not medically indicated.[17] Therefore, the medical indication restricts the scope of the physician's duties.[18]

2.2 Traditional Classification

In order to describe the legal forms of euthanasia under German law, the traditional classification shall be outlined in the way it has been developed by the legislation within the last decades. A distinction is made between illegal "active" euthanasia and legal "passive" and "indirect" euthanasia (see Fig. 1). This traditional terminology is also common to other legal systems but is broadly criticized both in the

[11] Decision of the German Federal Court (BGH) from 8 May 1991 no. 3 StR 467/90 = BGHSt 37, 376; Engländer (2011), p. 513.

[12] Section 1901 b (1) of the German Civil Code; Schulze (2012), Sec. 1901b, recital 3; Bamberger and Roth (2012), Sec. 1901b, recital 2; Salkić and Zwick (2012), p. 291.

[13] BGH decision from 4 July 1984 no. 3 StR 96/84 = NJW 1984, 2639, p. 2642; Engländer (2011), p. 513, with further references; extensive discussion at Duttge (2006).

[14] Grundsätze der Bundesärztekammer zur ärztlichen Sterbebegleitung, in its version of promulgation from 21 January 2011, Deutsches Ärzteblatt 108(7) (2011) A 346; Engländer (2011), p. 517.

[15] Decision of the Regional Court Karlsruhe (LG Karlsruhe) from 30 August 1991 no. 10 O 291/91 = NJW 1992, 756; Taupitz (2000), p. A23; Verrel (1996), p. 226.

[16] Basic Law for the Federal Republic of Germany (Grundgesetz für die Bundesrepublik Deutschland—GG) of 23 May 1949 (Federal Law Gazette, p. 1), in the revised version published in the Federal Law Gazette, part III, class. No. 100-1, as last amended by Article 1 of the Law of 21 July 2010 (Federal Law Gazette, part I, p. 944). Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_gg/index.html (accessed 29 March 2012).

[17] Taupitz (2000), p. A 24, with further references.

[18] BGH decision from 17 March 2003 = NJW 2003, 1588, p. 1593.

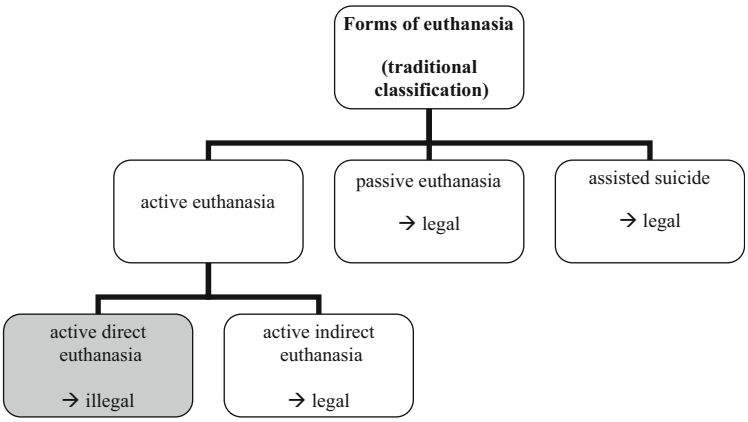

Fig. 1 Traditional classification of euthanasia

international and in the German debates because of its ambiguity and of its little use.[19] However, it is still used in the German literature and legislation, at least as a basis for a possible new development of legislation that is to be presented further on.

2.2.1 Active Direct Euthanasia

Active euthanasia means any mode of ending life with the intention to cause the person's death—with that person's explicit or presumed consent.[20] An example for active euthanasia would be the killing of a person by a lethal injection in order to alleviate his pain and suffering.

Generally, the active deliberate termination of another person's life is a crime under Section 211 et seq. of the German Criminal Code.[21] The act causally linked with the patient's death either constitutes the crime of manslaughter (Section 212 of the Criminal Code) or murder (Section 211 of the Criminal Code). Even if the actor only shortens the patient's life by minutes, he remains criminally liable. Also his motives are irrelevant. A compassionate killing constitutes a crime under Section 211 et seq. of the Criminal Code too.[22]

[19] Borasio (2012b), p. 166; Oduncu and Sahm (2010), p. 373; Schicketanz et al. (2010), with further references.

[20] German National Ethics Council (2006), p. 46.

[21] Criminal Code (Strafgesetzbuch—StGB) of 15 May 1871, in the version promulgated on 13 November 1998 (Federal Law Gazette, part I, p. 3322), last amended by Article 5 (3) of the Law of 24 February 2012 (Federal Law Gazette, part I, p. 212). Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_stgb/index.html (accessed 29 March 2012).

[22] BGH decision from 8 May 1991 = BGHSt 37, 376, where the Court had to decide whether "active euthanasia" performed against the patients' wishes was murder or manslaughter. As the accused nurse acted out of compassion, she was convicted not of murder but of manslaughter.

Section 216 of the Criminal Code states that killing remains criminal even if it is performed on request. The patient's explicitly and seriously expressed wish does not make the act of killing lawful. It rather only mitigates the threat of punishment for the actor from a possible lifelong imprisonment to an imprisonment of 5 years at the utmost. Section 216 of the Criminal Code therefore is an express provision that mitigates the punishment because the motive of killing on request is considered an integral element in determining culpability.[23] On the other hand, Section 216 of the Criminal Code clearly states that killing on request remains a crime.

The reasons given for the illegality of active direct euthanasia are diverse. The main reasons referred to in Germany are that the protection of life must not be relativized, that there must be no room for purely economic reasons in end-of-life decisions, that there would be no way to protect patients from the dangers of misuse, and that the relationship of trust between physician and patient would be jeopardized.[24] In the early 1980s, when German politicians discussed a new legislation on euthanasia, there was a discussion about the legalization of active direct euthanasia. The German institution "Deutsche Gesellschaft für Humanes Sterben" had suggested changing Section 216 of the Criminal Code by adding an exception for the killing in order to allow a humane death.[25] After the hearing of many experts, the plans were abandoned. The reasons were both still the impacts of the euthanasia practice in the German Third Reich and the fact that the different approaches seemed irreconcilable.[26] Even though some authors and some politicians still call for a general legalization of active euthanasia,[27] they are clearly outnumbered and it can be stated that Germany does not aspire towards the legalization of active euthanasia. In 2002, the Bundestag Enquete Commission on Law and Ethics of Modern Medicine (Enquete-Kommission "Recht und Ethik der modernen Medizin") and, in 2005, the Conference of the German Ministers of Justice (Justizministerkonferenz) confirmed their refusal of the legalization of active euthanasia.[28]

2.2.2 Active Indirect Euthanasia

Indirect euthanasia describes cases where the physician's medically indicated treatment of a patient involves the administering of a pain-killing medication that has the known but unwanted possible side effect of shortening the patient's life.[29]

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[23] Sayid (1983), p. 534.

[24] Kutzer (2007), p. 61; Deutsch and Spickhoff (2008), p. 422; Wagner (2005), p. 63.

[25] Schreiber (2006), p. 474.

[26] Schreiber (2006), p. 474, referring in fn. 23 to the stenographical protocol of the hearing.

[27] Czerner (2004), p. 11; Kusch (2007), p. 436; Kusch (2006), p. 261.

[28] Enquete-Kommission "Recht und Ethik der modernen Medizin" (2002); Herbstkonferenz der Justizministerinnen und Justizminister 2005, TOP II.3, http://www.mj.niedersachsen.de/portal/live.php?navigation_id=3810&article_id=10280&_psmand=13. (accessed 13 August 2012).

[29] This chapter does not deal with the question raised by experts in palliative care who argue that a correctly performed sedation of a patient did not shorten the patient's life and who therefore question whether indirect euthanasia did have any practical relevance at all. See Borasio (2012b), p. 163, with further references.

In the described constellation, the physician does not commit a crime. Indirect euthanasia is accepted as a legal form of euthanasia under German law.[30]

Although it is beyond dispute that indirect euthanasia is not a punishable crime, there are both dogmatic and practical uncertainties.

The dogmatic construction for the exemption from punishment is controversial.[31] Some authors argue that even the definition of homicide is not satisfied in these cases classified as indirect euthanasia.[32] They argue that the physician's social conscience predominates in these cases. As the physician's only aim is to make the dying process as tolerable as possible, his act should not be classified as an act of killing at all.

The legislation and the majority of the literature argue, however, that an act of killing has been committed but that this act is not to be seen as unlawful, either because it is justified or excused.[33] Authors who argue in this context that the patient's presumed or actual consent was a justification for indirect euthanasia however cannot find a convincing argument to how the consent could serve as a justification in regard to Section 216 of the Criminal Code, which states that killing on request is a crime. Therefore, it is probably more convincing to argue as the Federal Court of Justice (BGH) does. It has stated that a physician's act of indirect euthanasia can be justified according to Section 34 of the Criminal Code (rechtfertigender Notstand) because "facilitating a painless and dignified death in accordance with the patient's wishes is a higher-level object of legal protection than the prospect of having to live a little longer in severe and in particular agonizing pain".[34]

Because of these uncertainties, experts have often called for a legal clarification of the legality of indirect euthanasia. In 2005, a revised version of an Alternative draft with regard to euthanasia attracted a lot of attention, not least because of a Section 214a that clearly stated that a physician's action, which would traditionally have been classified as indirect euthanasia, was not unlawful.[35] The need for a clear regulation was also emphasized by the Association of German Jurists (Deutscher Juristentag e.V.) in their expert opinion for the 66th German Jurists Forum (Deutscher Juristentag).[36]

[30] BGH decision from 15 November 1996 no. 3 StR 79/96 = BGHSt 42, 301.

[31] For an overview of the dispute, see Dreier (2007), p. 322.

[32] Herzberg (1996), p. 3048; Jähnke et al. (2005), prior to Sec. 211, recital 16, with further references; Krey and Heinrich (2008), Sec. 1, recital 14; Tröndle (1987), p. 30.

[33] Laufs and Kern (2010), § 149 Ärztliche Sterbehilfe, recital 12; Kühl and Lackner (2011), prior to Sec. 211, recital 7; BGH decision from 15 November 1996 no. 3 StR 79/96 = BGHSt 42, 301, p. 305; BGH decision from 07 February 2001 no. 5 StR 474/00 = BGHSt 46, 279, p. 285.

[34] BGH decision from 15 November 1996 no. no. 3 StR 79/96 = BGHSt 42, 301, p. 305. See also German National Ethics Council (2006), p. 58.

[35] Schöch et al. (2005), p. 553.

[36] Verrel (2006).

2.2.3 Passive Euthanasia

Passive euthanasia describes situations of letting someone die. The person concerned dies because life-sustaining measures are not or no longer performed. According to the definition of the German National Ethics Council, this denotes cases

> in which, where a disease is expected to have a fatal outcome, treatment that is still possible is withheld—that is to say, potentially life-prolonging measures are either not initiated or are withdrawn. The patient is allowed to die.[37]

An example would be the case of a physician refraining from or disconnecting the artificial respiration of a patient with the consequence that the patient dies.

It is to be emphasized that a patient's artificial feeding or artificial hydration is a medical measure. These provisions are no longer seen as basic care that must always be provided but rather as medical measures that are not always beneficial for the dying patient. Therefore, it can be a legal form of passive euthanasia if the physician discontinues or refrains from an artificial feeding of the patient.[38]

There is a general agreement that certain forms of letting someone die must be legal. The exact scope of this legal form of euthanasia, however, is not clear. Dogmatically, such an omission could constitute a crime in the form of killing by omission (Sections 212 et seq. and 13 of the Criminal Code) or in the form of a failure to render assistance (Section 323c of the Criminal Code).

It was especially discussed whether letting someone die could only be a legal case of passive euthanasia when the patient was in the *final phase of his life*. The uncertainty became even worse when a Civil Panel of the Federal Court of Justice (BGH) decided in 2003 that even though relevant advance directives must be followed, the power to refuse medical life-sustaining treatment was restricted to situations where the patient was suffering from a terminal disease that was "irreversibly leading to death".[39] Even though this decision differed from prior judgments, many courts thereupon referred to this judgment and decided that legal passive euthanasia could not be performed because the requirement of a terminal and irreversible disease was not (yet) fulfilled.[40] As, therefore, many advance directives were overruled, a lively debate was triggered. Especially for cases of persistent vegetative state and dementia, this issue was decisive for the question whether the advance directive was binding or not and therefore also whether euthanasia could be legally performed in these cases or not.

Another important problem is the question of how to distinguish between legal passive and illegal active euthanasia. The distinction was traditionally made by the

[37] German National Ethics Council (2006), p. 46.

[38] Borasio (2012a), p. 152.

[39] BGH decision from 17 March 2003 no. XII ZB 2/03 = BGHZ 154, 205.

[40] Decision of the District Court Siegen (AG Siegen) from 28 September 2007 no. 33 XVII B 710 = NJW-Spezial 2008, 103; decision of the Regional Court Fulda (LG Fulda) from 30 April 2009 no. 16 Js 1/08—1 Ks = ZfL 2009, 97, p. 107.

classification *as an act or an omission*. Only an omission could be classified as passive euthanasia, whereas an act could only be classified as illegal active euthanasia.[41]

However, this classification led to uncertainties, especially in cases where a mechanical medical device was switched off. Switching off a machine is obviously an act rather than an omission. However, if the act of switching off a machine was seen as an act, this would mean that the physician's behavior could be no case of legal passive euthanasia but only a case of illegal active euthanasia.

Therefore, these cases were to be seen as omissions. This was traditionally achieved by the dogmatic construction of judgmentally reclassifying the physician's act into an omission (omission by action—Unterlassen durch Tun).[42] This construction was broadly criticized, especially because of its dogmatic uncertainties, but nevertheless accepted as necessary. As the patient's right to self-determination guarantees the patient's freedom to refuse any medical measure at any time and as there is never a duty for the patient to continue to live, the physician even has the duty to interrupt the medical treatment as soon as the patient refuses his consent. Therefore, classifying the physician's behavior as illegal euthanasia would impose two conflicting duties on the physician in these case constellations. On the one hand, the physician would have the duty to interrupt the treatment, and on the other hand he could not lawfully switch off the life-sustaining machine because his action would result in illegal active euthanasia.[43] This dogmatic and logical contradiction is the reason why the cases in which the physician dismisses or refrains from life-sustaining measures must be classified as legal passive euthanasia. This was achieved by the reclassification of the physician's act into an omission.

As presented below, both the new law in living wills and further legislation have led to some more clarity recently.

2.2.4 Assisted Suicide

Suicide is the act of a person who kills himself on his own responsibility and, in doing so, actually controls the events leading to death.[44] Under the German law, suicide itself does not constitute a criminal act because Section 211 et seq. require the killing of another person.

For lack of a criminal principal offense, the assistance in suicide is not automatically a crime. Considering that assistance in suicide is not a particular punishable offense according to the German Criminal Code either, assistance in suicide is not forbidden under German law. It can therefore be legally performed.[45] However, it is

[41] Roxin (1999), p. 6; Schroth (2006), p. 551, with further references.

[42] Czerner (2005), p. 96; Roxin (1969), p. 395; Roxin (1987), p. 349.

[43] Engländer (2011), p. 514.

[44] BGH decision from 14 August 1963 no. 2 StR 181/63 = BGHSt 19, 135, p. 139.

[45] German National Ethics Council (2006), p. 61.

to be mentioned that, regardless of the legality of suicide and assisted suicide, the use of certain drugs is punishable under the German federal narcotic law (Betäubungsmittelgesetz).[46]

Even though it is non-controversial that assistance in suicide is not a crime, some uncertainties cannot be avoided.

The distinction between cases of legally assisted suicide and illegal killing on request causes practical problems. Only if the act of killing that directly ends the suicide's life is carried out and controlled by the suicide himself can the aiding person be a legally acting aider, abettor, or instigator. The assistant may solely provide subordinated support, and the person who wants to die must be in control of the situation. It must be obvious that the assistant is not the deciding and therefore truly acting agent.[47] That this distinction involves practical difficulties is evident.

Another issue is physician-assisted suicide. As the German Criminal Code does not constitute any exception for physicians in this context, the general rule that assistance in suicide is not a crime also applies to physicians. Thus physician-assisted suicide is (again apart from the misuse of certain drugs forbidden by the German federal narcotic law) not a crime under the German Criminal Code.[48]

However, there are other limits. The Model Professional Code for Physicians (Musterberufsordnung für Ärzte, MBO) in the version promulgated in 2011 by the German Medical Association (Bundesärztekammer) clearly states in Section 16 that physicians may not kill patients on their request and that physicians may not provide assistance in patients' suicide.[49]

If this was implemented in the binding professional Codes at the federal state level (level of the Bundesländer), physician-assisted suicide would be forbidden by professional law, with the consequence that a violation of this prohibition could lead to a penalization according to professional law or even to the loss of the physician's license to practice medicine.

Furthermore, the fact that assisted suicide is legal whereas killing on request constitutes a crime may lead to contradictory results in certain situations. If, for example, a person is physically no longer able to perform suicide, there is no legal

[46] German Narcotic Law (Betäubungsmittelgesetz—BtMG) of 1 August 1981, in the version promulgated on 1 March 1994 (Federal Law Gazette, part I, p. 358), last amended by Article 2 of the Law of 10 June 2013 (federal Law Gazette, part I, p. 1497). Available at http://www.gesetze-im-internet.de/bundesrecht/btmg_1981/gesamt.pdf (accessed 18 June 2013).

[47] Oduncu and Sahm (2010), p. 375.

[48] Obviously, it must be taken into consideration that the physician generally has a duty to provide medical treatment to the patient. The illegal omission of medical treatment, despite a duty to act, remains a crime, according to Sections 13 and 211 et seq. Penal Code. Legal assistance in suicide can therefore generally only be provided by a physician if he does not have the duty to provide medical treatment. Such a duty does no longer exist when the physician is released by the patient, which is always in the patient's competence; decision of the Higher Regional Court München (OLG München) from 31 July 1987 no. 1 Ws 23/87 = NJW 1987, 2940.

[49] Musterberufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte (MBO-Ä 1997) in der Fassung der Beschlüsse des 114. Deutschen Ärztetages 2011 in Kiel, available at http://www.bundesaerztekammer.de/downloads/MBO_08_20111.pdf (accessed 16 August 2012).

possibility to receive any help in dying. It is being discussed how to solve this problem within the existing criminal law as there is a great consensus that the crime of killing on request loses its justification in certain constellations.[50] This problem is also recognized by the courts.[51] However, a possible modification of the legal protection of those people is rather a matter for the legislative power.[52]

3 Critics of the Classification of Euthanasia

The presented classification of acts of euthanasia is highly criticized. As shown, the terminology is both misleading and open to misunderstanding. The German National Ethics Council therefore suggested the use of other terms. The term "therapy at the end of life" was suggested as the new term for any medical measure adopted in the terminal phase with the aim to prolong life or at least to relieve suffering.[53] Therapy at the end of life would also include medical measures that hasten the natural process of dying and that are currently classified as cases of indirect euthanasia. As the patient's death is neither an indirect nor a direct aim of the relevant action, the term therapy at the end of life is favorable.[54] The German National Ethics Council furthermore suggested the terms "letting die" instead of passive euthanasia and "killing on request" instead of active euthanasia.[55] It remains to be seen whether this suggested terminologies will prevail.

4 The German Legal Basis

In order to present the actual debates and the latest development of the law and of the legislation, the first step must be to give an overview of the legal basis. It is mainly the criminal law, interpreted in the light of the Constitution, that is relevant for the issues of euthanasia.

[50] Dreier (2007), p. 320; German National Ethics Council (2006), p. 64.

[51] BGH decision from 20 May 2003 no. 5 StR 66/03 = NJW 2003, 2326, p. 2327.

[52] German National Ethics Council (2006), p. 64.

[53] German National Ethics Council (2006), p. 49.

[54] German National Ethics Council (2006), p. 49.

[55] German National Ethics Council (2006), p. 50.

4.1 Constitutional Law

The Constitution must be considered as the basis for any interpretation of the existing law and provides the legal frame for any change of the statutory law or the legislation.

The most relevant constitutional principles in the context of euthanasia are human dignity, the right to self-determination, and the right to physical integrity.

The guarantee of **human dignity** is laid down in Article 1 (1) of the German Constitution and is considered the major fundamental constitutional principle.[56] The individual must be protected in his subjecthood and in his autonomy.[57] Human beings "must not become the object of third parties' decisions even in matters of life and death and in particular when dying".[58] Self-determination and physical integrity are the innermost core of human dignity.[59] Life as such is obviously part of human dignity. However, not any termination of a person's life automatically violates this person's dignity.[60] It can therefore certainly not be concluded that euthanasia is generally a violation of human dignity. Neither, however, is there a claim to receive active euthanasia based on Article 1 (1) of the Constitution.[61]

In any case, human dignity is inviolably protected. Therefore, no violation of human dignity can ever be justified. Both the rigorous application of intensive care and the failure to perform appropriate measures of pain alleviation can be a violation of human dignity.[62]

The right to life and the right to physical integrity are guaranteed in Article 2 (2) of the Constitution. The individual is protected in his biological and physical integrity and existence. Life as such is protected as a "maximum value of the constitutional order".[63] That does, however, not mean that life in its biological sense is to be protected by all means.[64] Of course, a person needs to be protected from being killed by third parties as part of his right to life. But at the same time, this person is to be protected from any medical intervention that is performed without a valid consent as part of his right to physical integrity. That means that a competent patient may refuse any medical treatment. That also means that any

[56] Decision of the German Constitutional Court (BVerfG) from 16 January 1957 no. 1 BvR 253/56 = BVerfGE 6, 32; BVerfG decision from 19 October 1971 no. 1 BvR 387/65 = BVerfGE 32, 98.

[57] German National Ethics Council (2006), p. 52.

[58] German National Ethics Council (2006), p. 52.

[59] Hufen (2005), p. 83.

[60] Hufen (2005), p. 82.

[61] Spickhoff (2011), Art. 1 GG, recital 13.

[62] Hufen (2005), p. 83.

[63] BVerfG decision from 25 February 1975 no. 1 BvF 1/74 = BVerfGE 39, 1, p. 42; BVerfG decision from 16 October 1977 no. 1 BvQ 5/77 = BVerfGE 46, 160, p. 164.

[64] Hufen (2005), p. 86.

person may place his right to be free from pain over the protection of his life.[65] Article 2 (2) of the Constitution must not be turned into a duty of the individual to live, still less to live a life in degrading pain or other demeaning circumstances.[66] This becomes even more obvious if life-sustaining measures involve an intervention in the patient's physical integrity, for example by a feeding tube.

The Constitution guarantees in Article 2 (1) that every person shall have the right to free development of his personality insofar as he does not violate the rights of others or offend the constitutional order or the moral law. This law contains the **freedom of action** and **the right to free deployment of the personality.** The freedom of action is an "extensive expression of the freedom of individuals and at the same time the origin of any citizen's subjective right of defense against the state".[67] It is understood as an overall freedom of action. Any possible human activity falls within its scope. The "entire range of possible human activity" is protected "without the application of qualitative criteria".[68]

The **freedom of personality**, derived from Article 2 (1) in combination with Article 1 (1) of the German Constitution, protects the individual development of the personality by shielding the personal sphere of the individual, so that he may have a space "where he is left to himself, unobserved, and able to interact with others of his confidence without having to regard social expectations".[69] The freedom of personality protects the individual's integrity and all aspects, including distortion and falsification, created under the freedom of action.[70]

The **right to self-determination** is also guaranteed by Article 2 of the German Constitution and is most fundamental in the context of euthanasia. It is not explicitly mentioned in the Constitution. While it is generally undisputed that the right is laid down in Article 2, it is subject to controversial discussions wherein exactly. Some argue for Article 2 (1), others for Article 2 (2). Again, others place it under the freedom of personality, derived from Articles 1 (1) and 2 (1).[71] It is however irrelevant for the present consideration because the right is undisputedly recognized and belongs to the core area of the rights of human dignity and freedom overall protected by Articles 1 and 2 of the Constitution.[72] Any patient has the

[65] Hufen (2005), p. 86.

[66] Hufen (2001), p. 852.

[67] BVerfG decision from 1 August 1978 no. 2 BvR 123/76 = BVerfGE 49, 15, p. 23.

[68] German National Ethics Council (2006), p. 52.

[69] Dreier (2006), Art. 2 I, recital 70; BVerfG decision from 12 September 1994 no. 2 BvR 291/94 = NJW 1995, 1477.

[70] Dreier (2006), Art. 2 I, recital 23.

[71] Spickhoff (2011), Art. 2 GG, recital 13 argues for Article 2 (2) referencing a decision of the Constitutional Court: BVerfG decision from 22 September 1993 no. 2 BvR 1732/93 = BVerfGE 89, 120, p. 130; Knopp (2003), p. 384 argues for Article 2 (1); others argue in favor of the general right of personality, derived from Articles 1 (1) and 2 (1): Damm (1998), p. 926, Taupitz (2000), p. A 12; Maunz and Dürig (2012), Art. 2, recital 204, argues in favor of the general right of personality in combination with Article 2 (2).

[72] Hufen (2001), p. 851.

constitutionally guaranteed right to decide over his own body.[73] In the medical context, it guarantees the right of the patient to decide if and how he is to be medically treated.[74] The patient is not an object of the medical art of healing but a self-determined partner of the physician. He may consent to and also refuse any medical measure. Any refusal is obliging—also if the refusal of the medical measure may lead to the patient's death and also if the refused medical measure could probably cure the patient.[75] Any medical measure that is carried out against the patient's will violates the patient's constitutionally guaranteed rights. It is accepted that any person has a so-called right to illness.[76] This right extends until the right to self-abandonment and self-destruction,[77] which can in certain circumstances be interpreted as a "right to one's own death".[78] The patient's right to self-determination is, however, not guaranteed without restriction.[79] It is restricted especially by the constitutional legal system that protects the common good, as well as the rights of third parties, all considering the principle of proportionality.[80]

The right to self-determination is a right of defense, not an entitlement to a certain medical measure. Although active euthanasia may, for example, be in accordance with the will of the person wishing to end his life, there is no right to obtain this form of euthanasia. It is controversial whether there is a right to commit suicide. Such a right could be part of human dignity[81] or be contained in the right to self-determination.[82] It could also be guaranteed as a negative right in the right to life.[83] However, it is not generally recognized.[84]

Generally, two important principles are opposed to each other. On the one hand, any individual's life is to be protected. On the other hand, patient autonomy is to be guaranteed. However, any person has the guaranteed right to self-determination in respect of his body, which means that he is allowed to let any sequence of events take its course, even if this leads to death.[85] Hence, the right to self-determination in respect of one's body precedes anyone else's duty to protect this life. In the context of euthanasia, the autonomy of a human being (as a right to defense against interference by others) is the most fundamental right and therefore better protected by the Constitution than life as such.[86]

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[73] BVerfG decision from 25 July 1979 no. 2 BvR 878/74 = BVerfGE 52, 131, p. 168, 173.

[74] Spickhoff (2011), Art. 2GG, recital 12.

[75] Taupitz (2000), p. A12.

[76] BVerfG decision from 23 March 1998 no. 2 BvR 2270/96 = NJW 1998, 1774, p. 1775.

[77] Hufen (2001), p. 851.

[78] BGH decision from 8 May 1991 no. 3 StR 467/90 = BGHSt 37, 376.

[79] Maunz and Dürig (2012), Art. 2, recital 205.

[80] Knopp (2003), p. 386.

[81] Maunz and Dürig (2012), Art. 1 I, recital 89.

[82] Knopp (2003), p. 384; Sachs (2011), Art. 2, recital 211.

[83] Maunz and Dürig (2012), Art. 2 II 1, recital 47.

[84] Taupitz (2000), p. A13.

[85] Taupitz (2000), p. A13.

[86] Taupitz (2000), p. A13.

Related to euthanasia, the following concrete results can be drawn based on the Constitution:

Human dignity is to be protected by all means. No violation can ever be justified.

Passive euthanasia can not only be justified, but its omission can even be a breach of constitutional rights in certain cases.[87]

Indirect euthanasia is most often not even an intrusion of constitutional rights.[88]

Active euthanasia is an intrusion of the right to life, which cannot be justified according to present criminal law. However, the Constitution does not impose a duty on the legislator to criminalize active euthanasia.[89]

4.2 Criminal Law Aspects Related to Medical Treatment

In order to legally evaluate any form of euthanasia performed by a physician, one must refer to the general rules of a physician's criminal liability in regard to medical treatment.

The physician's liability is not regulated through a special law. In order to determine the physician's liability, not only in regard to euthanasia but also in regard to any problems related to medical treatment, it is necessary to refer to the general norms of the German criminal law and their interpretation by the courts.

Since 1894,[90] the German jurisdiction has affirmed that any medical measure conducted by a physician, which affects the patient's physical integrity, is an assault.[91] It is irrelevant for this classification as an assault whether the medical measure was performed de lege artis or improved the patient's health. Generally, any medical measure is only justified and may be performed if the patient has given his informed consent after being fully informed about its nature, significance, implications, and risks.[92] If an explicit consent is not possible because of the patient's condition, the patient's consent may also be presumed or hypothetical.

Therefore, any medical measure that is conducted without the patient's valid consent is a punishable infliction of bodily harm and therefore a criminal offense, punishable under Section 223 et seq. of the Criminal Code—even if the measure is necessary to keep the patient alive. To give an example: as the insertion of a feeding

[87] Hufen (2001), p. 854.

[88] Hufen (2001), p. 854.

[89] Hufen (2001), p. 854.

[90] Decision of the Supreme Court of the German Reich (Reichsgericht) from 31 May 1894 = RGSt 25, 375.

[91] Constant jurisprudence: BGH decision from 9 December 1958 no. VI ZR 203/57 = NJW 1959, 811, p. 812; BGH decision from 07 February 1984 no. VI ZR 188/82 = BGHZ 90, 96, p. 99; BGH decision from 14 March 2006 no. VI ZR 279/04 = BGHZ 166, 336, p. 339.

[92] BVerfG decision from 25 July 1979 no. 2 BvR 878/74 = BVerfGE 52, 131; BGH decision from 5 July 2007 no. 4 StR 549/06 = MedR 2008, 158.

tube affects the patient's physical integrity, it is an assault if it is performed without the patient's valid consent.

On the other hand, the physician has a duty to provide appropriate medical care as soon as a relationship with a patient exists. An omission of a medical measure generally is a breach of duty, which constitutes a criminal offense by omission. Depending on the outcome for the patient, the physician's omission may be either an infliction of bodily harm by omission (Sections 223 et seq. and 13 of the Criminal Code) or a form of killing by omission (Sections 212 et seq. and 13 of the Criminal Code). There are only two reasons that justify the omission. The first possible justification is a lack of medical indication, and the second possible justification is a lack of the patient's consent to treatment.[93]

4.3 Civil Law Aspects[94]

After years of a very controversial debate, the German Parliament passed an Act in 2009[95] explicitly regulating living wills and the decision-making process for cases in which the patient becomes incapable of giving or refusing his consent to medical treatment in the scope of civil law.[96] The new law particularly gave an important role to the surrogate decision-maker.[97] Although the law does not explicitly refer to euthanasia, there are obviously implications regarding the issues of euthanasia, which are to be discussed in the following sections.

5 The Influence of the New Law on Living Wills: A New Concept of Euthanasia?

5.1 The Law on Living Wills

This new law on living wills is exclusively a civil law. Regulating the proceeding in cases in which the patient becomes incapable of giving or refusing consent to medical treatment, it provides clear rules on the end-of-life decision-making process and gives primacy to the principle of patient autonomy.[98]

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[93] For more detailed information, see Salkić and Zwick (2012).

[94] For the details, see the precedent contribution of J. Taupitz.

[95] 3rd Act Changing the Custodianship Law (3. Gesetz zur Änderung des Betreuungsrechts—3. BtÄndG) of 29 July 2009 entered into force on 1 September 2009 (Federal Law Gazette, part I, no. 48).

[96] For a more detailed description, see Taupitz and Salkić (2011).

[97] Precedent contribution of J. Taupitz; for further information: Beckmann (2009), p. 585; Taupitz and Salkić (2011), p. 331.

[98] Salkić and Zwick (2012); Taupitz and Salkić (2011).

The criminal law issues related to the end-of-life debate are not regulated by this law. However, already due to the fact that the new civil law states that certain living wills are binding, it has a clear influence on the criminal law issues discussed here.

A valid living will must comply with the State law, which means that the enforcement of the patient's will is only possible within the legal scope that the criminal law provides. Active euthanasia remains illegal—even if requested.

Within the legal scope of criminal law regulations relevant for euthanasia, the new law led to some clarification. As presented above, some courts had stated in civil law cases that passive euthanasia could only be legally performed when the patient was in the terminal phase of his life. When the German Parliament passed the law on living wills, the restricting requirement of a terminal and irreversible disease was dismissed with the consequence that the scope of applicability of advance directives was broadened towards any situation acquiring a medical decision concerning the incompetent person.[99] This was explicitly confirmed in following judgments.[100] Thus, the controversial debate on the applicability of living wills in cases of vegetative state or dementia is solved. Passive euthanasia can be legally performed as long as it is in accordance with the patient's living will, regardless of the question whether the patient is in his final phase of his life or not.[101]

However, due to the lack of regulations in criminal law, the new law still leaves uncertainties, which are to be clarified by the legislation. Mainly two judgments, presented in the following, are seen as "milestones" in this sense.

5.2 The Case of "Putz" from 25 June 2010[102]

On 25 June 2010, the German Federal Court of Justice gave an important and since then constantly cited judgment in the context of passive euthanasia.

5.2.1 The Facts

The judgment was based on the following facts: a 77 year-old lady (Erika E.) became comatose after a cerebral hemorrhage. She had been in a persistent vegetative state for 5 years and had been artificially fed by a stomach tube. Many years

[99] Taupitz and Salkić (2011), p. 336.

[100] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963.

[101] Furthermore, the living will does not have to be objectively reasonable, which means that the living will of a Jehova's witness, in which a blood transfusion is rejected, is obligatory. So, the new law clearly states that euthanasia can be legally provided in any case when there is a valid living will. See Standl (2010); BVerfG decision from 2 August 2001 no. 1 BvR 618/93 = NJW 2002, 206.

[102] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963.

before, she had told her children that she did not want to be kept alive artificially. The daughter became the mother's surrogate decision-maker.

According to the treating physician, there was no longer a medical indication for artificial feeding. The daughter therefore agreed with him that the artificial feeding should be discontinued according to her mother's wish.

The nursing staff agreed, and the feeding was interrupted. However, when the management of the care home learned about the case, the nursing staff was instructed to continue the artificial feeding. For refusing consent, the daughter was threatened to be banned from entering the care home.

In consequence, the daughter cut off her mother's feeding tube by herself. She was advised to do so by her lawyer, Wolfgang Putz, a rather well-known German expert specialized in medical law. The purpose was to prevent Erika E. from an unwanted resumption of artificial nutrition. Though the feeding tube was reinserted, Erika E. died 2 weeks later of natural causes.

Both the daughter and the lawyer were accused. The Regional Court Fulda (Landgericht Fulda) acquitted the daughter.[103] She was excused because of the fact that she trusted the legal advice of her lawyer, who explained in detail why the act was not a criminal offense. There was no duty for the daughter to further investigate the advice given to her; she was allowed to trust her lawyer.[104] The lawyer was convicted of attempted manslaughter by the Regional Court. The sentence of 9 months was suspended. However, in the second instance the German Federal Court (BGH) acquitted him too.

5.2.2 The Meaning of the Judgment

The judgment of the German Federal Court (BGH) received a lot of attention and is considered to be a landmark ruling.[105] It is broadly appreciated as it is said to have provided necessary legal clarity.

The judgment defined the scope of legal euthanasia based on patient autonomy.[106] Patient autonomy was strengthened again. Moreover, the German Federal Court confirmed again in this judgment that the removal of artificially provided nutrition and hydration may be a legal form of euthanasia, which implies that the artificial provision of nutrition and hydration is not comfort care.[107]

[103] LG Fulda decision from 30 April 2009 no. 16 Js 1/08—1 Ks = ZfL 2009, 97.

[104] LG Fulda decision from 30 April 2009 no. 16 Js 1/08—1 Ks = ZfL 2009, 97, p. 107.

[105] Gaede (2010), p. 2926; discussed by Verrel (2010), p. 675; negated by Höfling (2012), p. 462.

[106] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2965; Engländer (2011), p. 516.

[107] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2964; Engländer (2011), p. 517.

The civil law aspects of the case were rather clear.[108] The discontinuation of the artificial feeding was in accordance with the conditions imposed by the new civil law on living wills. First, there was a lack of medical indication, so that the patient's wish would have been irrelevant anyway. Apart from the missing medical indication, the treating physician and the daughter, as the surrogate decision-maker, agreed that the continuation of the artificial feeding was against the patient's wish expressed some years before. The discontinuation of the artificial feeding was therefore in accordance with the civil law on living wills, so that the continuation of the artificial feeding was in fact illegal and should have been stopped.

The problem of the case was rather embedded in criminal law. Although the persons acted according to civil law, their behavior could not be classified as a legal form of euthanasia. Cutting off the feeding tube was no omission and could also not be reclassified into an omission. According to the traditional classification, an act, instead of an omission, could not be a form of passive euthanasia. This would have had the consequence that the accused would have been punishable because of the crime of active euthanasia, although their act was in accordance with the new civil law on living wills.

In order to avoid this legal inconsistency, the Court took this case as a cause to revise the traditional distinction between the different forms of legal and illegal euthanasia in criminal law.

The Court explicitly stated that the distinction between an act and an omission in regard to passive euthanasia was artificial and no longer convincing; it did not make sense that the patient's wish could be a justification for an omission but not for an act.[109] The court said that it was not reasonable that the classification as an act or an omission should be the justification for a distinction between legal euthanasia and illegal euthanasia, irrespective of the fact that the patient's wish was fulfilled in both cases. It is rather only decisive that any patient is entitled to refuse medical treatment with the consequence that this medical measure (be it an act or an omission) should be omitted or refrained from or done if this meets the patient's consent.[110]

Uncertainties and inconsistencies in the former legislation were emphasized by the Court, and a new generic term was introduced: "end of treatment" (Behandlungsabbruch) in the form of "help to die by omitting, limiting or forgoing treatment" (Sterbehilfe durch Unterlassen, Begrenzen oder Beenden).[111] The Court developed criteria that must all be accumulatively in place in order to classify a behavior as legal euthanasia in the form of "end of treatment".

Euthanasia in the form of "end of treatment" is justified as help to die by omitting, limiting, or forgoing treatment

[108] Albrecht (2011), p. 40; Ihrig (2011), p. 584.

[109] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2966.

[110] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2967.

[111] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2967.

> if it is in accordance with the patient's wish (according to Section 1901a of the German Civil Code)[112] and if it has the aim to let the process of the patient's particular disease take its course which means that the illness leads to death if no medical treatment is performed.[113]

This means in detail that the following conditions must be fulfilled[114]:

- The patient must suffer from a life-threatening disease.
- The medical treatment in question must be suitable to preserve or prolong the patient's life threatened by this disease. The omission or interruption of this medical measure must directly be linked to this medical treatment—both in objective and subjective ways.
- This condition makes sure that the person performing this sort of euthanasia lets the patient die, instead of killing him.[115] Basically, that means that the underlying lethal disease, which is not or no longer treated, is finally the reason for death. This condition shall, like explicitly stated in the judgment, include the omission and the withdrawal of a treatment and the "so-called indirect euthanasia, where the anticipated death is an inevitable side effect of a medically indicated palliative treatment".[116] A constellation "of a purposeful intervention, which separates death from the course of the disease" can never be a case of euthanasia in the form of "end of treatment".[117]
- The measure in question must comply with the patient's explicit or presumed wish.

If these conditions are fulfilled, it is a legally performed act of euthanasia. The traditional distinction between the different forms of legal euthanasia, indirect and passive euthanasia, might become unnecessary because the court subsumed also indirect euthanasia under the new term "end of treatment" (see Fig. 2).[118]

It is generally appreciated that the Court developed this new form of euthanasia and clarified the conditions for legal euthanasia. This has led to more unity between the new civil law and the existing criminal law. There is hope that the judgment might lead to more selective criteria regarding the distinction between illegal and legal forms of euthanasia and to more justice in each individual case.[119]

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[112] Civil Code (Bürgerliches Gesetzbuch—BGB) of 18 August 1896, in the version promulgated on 2 January 2002 (Federal Law Gazette, part I, p. 42, 2909), last amended by Article 2 of the Law of 15 March 2012 (Federal Law Gazette 2012, part II, p. 178). Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_bgb/index.html (accessed 29 March 2012).

[113] BGH decision from 10 November 2010 no. 2 StR 320/10 = NJW 2011, 161, p. 162.

[114] See also Albrecht (2011), p. 41.

[115] Alberts (2010), p. 430.

[116] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2967.

[117] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2967.

[118] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2967; Rissing-van Saan (2011), p. 551; similar Ihrig (2011), p. 584.

[119] Alberts (2010), p. 430.

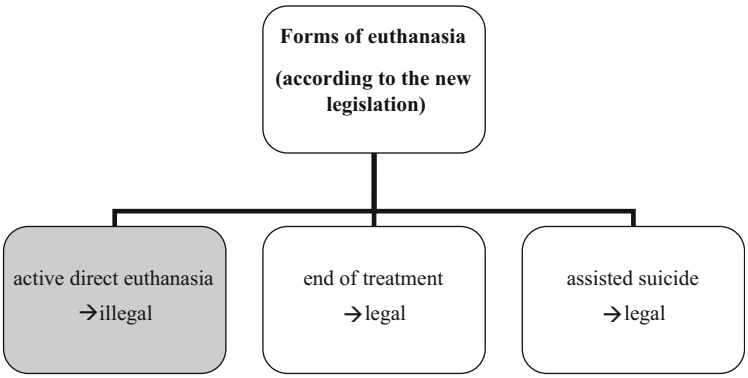

Fig. 2 Possible classification of euthanasia according to the BGH decision "Putz"

However, it is criticized that the dogmatic structure of the newly developed form of euthanasia remains unclear regarding its consistency with Section 216 of the Criminal Code.[120] According to the traditional classification, the underlying case could actually be punishable under Section 216 of the Criminal Code. The Court only stated that "Section 216 of the Criminal Code remains unaffected".[121] It is criticized that a dogmatically correct exception is necessary, which is missing in the judgment.[122] However, according to the argumentation of the court, the described cases would probably be no cases of active euthanasia at all because it would be the underlying condition that would ultimately lead to the patient's death.

Moreover, it remains unclear why former cases of indirect euthanasia can generally be classified as "end of treatment", even when there can be cases where no actual treatment has been performed; consequently, no treatment can be stopped. In these cases, it is the pain-killing medication that leads to death. Only referring to the underlying medical condition as the cause for death is not convincing.

Another issue is the question of who may provide euthanasia in the form of "end of treatment". The Court stated that the described principles applied not only to physicians but also to any third party acting as an assistant to the physician or the surrogate decision-maker ("soweit sie als von dem Arzt, dem Betreuer oder dem Bevollmächtigten [...] hinzugezogene Hilfspersonen tätig werden").[123] Here, uncertainties remain as well. As there is no indication as to the definition of such third parties in the civil law of living wills, the question as to who can provide euthanasia in the form of "end of treatment" remains unanswered.

The court's statement is criticized as both too narrow and too broad.

[120] Gaede (2010), p. 2927.

[121] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2967.

[122] Bosch (2010), p. 911; Brunhöber (2011), p. 404; Duttge (2011), p. 37; Gaede (2010), p. 2927.

[123] BGH decision from 25 June 2010 no. 2 StR 454/09 = NJW 2010, 2963, p. 2968.

Including "third parties acting as assistants to the physician or the surrogate decision-maker" excludes any other third party. This is criticized as too narrow.[124] If a medical measure is, like in the underlying case, conducted against the patient's wish, it is illegal. Only its termination reestablishes a legal state. The result of the act in question (namely the patient's death) is a legal condition—and that means that whoever acts cannot be criticized for the outcome of his behavior. However, such acting can in certain cases already be justified according to general criminal law (Section 32 and Section 34 of the Criminal Code), with the consequence that there might be no need to include third parties in the scope of "end of treatment".[125]

It may, on the other hand, appear rather wrong that any person except for the physician or the surrogate decision-maker is entitled to provide this form of euthanasia at all. It could be problematic that third persons could be justified to end treatment without consulting the physician or the surrogate decision-maker only by referring to the patient's wish.[126] This is obviously a problem as soon as the third person intervenes in the organizational structure of a hospital or a care home.[127] The main problem, however, is that the civil law provides clear procedural rules that have to be fulfilled in order to enforce the patient's wish.[128] These rules might be circumvented. It is generally debatable whether the non-fulfillment of these procedural conditions can justify criminal liability of a crime causing death.[129] Procedural rules would, however, de lege ferenda be necessary to exclude misuse.[130]

It remains an unsolved problem to which extent and under which conditions a "third" person (being neither the physician nor the surrogate decision-maker) can influence a decision made by the physician and the surrogate decision-maker. If their decision appears wrong (for example, because a medical measure is conducted although there is no longer a medical indication), a third person needs a possibility to intervene, which is legal according to both civil law and criminal law.

In conclusion, it can be said that the judgment in the "Putz" case provides much clarity, especially in regard to the implications of the new law on living wills on criminal law. However, many issues remain unsolved, especially questions concerning the procedure of the enforcement of living wills regulated in civil law.

The impact of the civil procedural rules on criminal law was the main subject of the following case.

[124] Engländer (2011), p. 519; Hirsch (2011), p. 39.

[125] Rissing-van Saan (2011), p. 550.

[126] Kubiciel (2010), p. 661.

[127] Schneider (2011), p. 105.

[128] For details, see the precedent contribution of J. Taupitz; Taupitz and Salkić (2011).

[129] Engländer (2011), p. 519; Hirsch (2011), p. 39; Verrel (2010), p. 674.

[130] Kubiciel (2010), p. 661.

5.3 The Case of Cologne "Kölner Fall" from 10 November 2010[131]

The next very important decision of the German Federal Court was a judgment from 10 November 2010,[132] which is seen as the continuation of the above-mentioned judgment and as a further ruling on the impact of the new law on living wills on the German criminal law on euthanasia.

5.3.1 The Facts

The defendant was accused of attempted manslaughter of his mother-in-law. His mother-in-law was brought to the hospital because of suspected pneumonia. Still competent, she agreed to any necessary medical measure and also to a transfer to the intensive care unit. Some days later, she had to be put into an artificial coma because of a serious deterioration of her condition. Even though her condition was serious, it was not hopeless and recovery could not be precluded.

The defendant's wife was her mother's surrogate decision-maker. Nevertheless, only her husband, the defendant, came to the hospital. Being in the hospital, the defendant asked the physicians to turn off the life-sustaining measures. He referred to a living will of his mother-in-law, which he had actually never read. In the living will, it was stated that the mother-in-law refused life-sustaining measures if she was in a terminal phase of life and her situation was irreversibly leading to death. The physician refused to switch off the machines arguing that the actual situation of the defendant's mother-in-law was not hopeless, so that the living will did not meet the situation at stake.

In the following, the defendant himself turned off some medical devices that were necessary to keep his mother-in-law alive. Even though the medical devices were switched on again after some seconds, the defendant's mother-in-law died in the evening. It was not proved that the death was caused by the temporary interruption of the medical treatment.

The defendant was found guilty because of attempted manslaughter.

5.3.2 The Meaning of the Judgment

Similar to the "Putz" judgment, the German Federal Court dealt with the issue of living wills in the context of euthanasia. This judgment built on the above-mentioned court decision and gave further clarity in regard to procedural issues.[133]

[131] BGH decision from 10 November 2010 no. 2 StR 320/10 = NJW 2011, 161.

[132] BGH decision from 10 November 2010 no. 2 StR 320/10 = NJW 2011, 161, p. 161.

[133] Ihrig (2011), p. 583.

As the living will of the defendant's mother-in-law was not relevant (because she was not in a terminal state, which was the premise for the application of the living will), it would have been sufficient to rule that the defendant's act was not in accordance with the patient's wishes written down in the living will. However, the Court used the judgment for further remarks.

Based on the judgment in the case of "Putz", the Court discussed the determination and the realization of the patient's will. It was emphasized that clear procedural rules are stated in Section 1901a et seq. of the Civil Code. These procedural rules are to be followed, also in cases that are, according to the judgment in the case of "Putz", legal as "end of treatment". Only if the clearly defined procedure is followed can it be guaranteed that both the right to self-determination and the right to life are protected.[134] It was emphasized that undergoing the procedure was the only possibility to exclude misuse and to guarantee that the decision was not overhasty but made after a careful examination of the medical condition and according to the patient's will.[135]

Although some unresolved questions remain,[136] the judgment made clear that the civil procedural rules do have an impact on criminal law. Criminally legal euthanasia cannot be conducted by a circumvention of the civil procedural rules but must be performed in accordance with the civil law on living wills.

6 The Actual Debates on Suicide

Besides the influence of the new law on living wills, different forms of suicide are actually broadly discussed issues in Germany.

6.1 Physician-Assisted Suicide: Regulations in the Model Professional Code for Physicians

Physician-assisted suicide has always been a broadly discussed issue in Germany. The discussion about its actual practice was revived in Germany in the year 2011. As explained above, assistance in suicide does not constitute a crime, so that also a physician assisting in suicide is (except for the misuse of certain drugs) not criminally liable.

[134] BGH decision from 10 November 2010 no. 2 StR 320/10 = NJW 2011, 161, p. 162; Engländer (2011), p. 516.

[135] BGH decision from 10 November 2010 no. 2 StR 320/10 = NJW 2011, 161, p. 162.

[136] For example: Ihrig (2011), p. 584.

However, a clear regulation in the medical professional code of conduct was missing. Until 2011, the Model Professional Code for Physicians (Musterberufsordnung für Ärzte, MBO) did not explicitly state that physician-assisted suicide should be prohibited. It said in the version of 2004 in Section 16 that physicians must not actively shorten a patient's life. The patient's well-being must take the highest priority over both own interests and third parties' interests.[137] In 2011, this Section was changed and now clearly states that physicians may not kill patients on their request and that physicians may not provide assistance in patients' suicide.[138] This clearly formulated prohibition of assistance in suicide is new.

This development was rather **unexpected** because of a relaxation of regulations in the Opinions published by the German Medical Association (Bundesärztekammer). The latest Opinion on the physician's role in euthanasia, which was published in 2011 before the Model Professional Code for Physicians was changed in the same year, seemed to indicate a rather opposite development. In 2011 the Opinion from 2004, in which it was stated that the physician's assistance in suicide could even be criminal,[139] was renewed and the new Opinion was formulated much less strictly, stating that assistance in suicide was not a physician's task.[140]

The Model Professional Code for Physicians (MBO), which now clearly prohibits assistance in suicide, is not binding. It is only to be taken into account by the State Chambers of Physicians when they compose the binding professional Codes at the federal state level (level of the Bundesländer). As a consequence of the change of the Model Professional Code for Physicians (MBO), some of the German State Chambers of Physicians adapted their Codes with the consequence that physician-assisted suicide is now forbidden by the professional law.[141] If a physician nevertheless assists in a patient's suicide, he must expect penalization according to the professional law or even the loss of his license to practice medicine.

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[137] Musterberufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte—MBO-Ä 1997—in der Fassung der Beschlüsse des 107. Deutschen Ärztetages 2004 in Bremen, available at http://www.bundesaerztekammer.de/downloads/Mbopdf.pdf (accessed 16 August 2012).

[138] Musterberufsordnung für die in Deutschland tätigen Ärztinnen und Ärzte—MBO-Ä 1997—in der Fassung der Beschlüsse des 114. Deutschen Ärztetages 2011 in Kiel, available at http://www.bundesaerztekammer.de/downloads/MBO_08_20111.pdf (accessed 16 August 2012).

[139] German Medical Association (2004).

[140] German Medical Association (2011).

[141] The following State Chambers adapted their Professional Codes for Physicians so that physician-assisted suicide is explicitly forbidden: Bremen, 02 March 2012, available at https://www.aekhb.de/data/mediapool/ae_re_rg_berufsordnung.pdf (accessed 11 August 2012); Hamburg, 11 May 2012, available at http://www.aerztekammer-hamburg.de/berufsrecht/Berufsordnung_idF_13022012.pdf (accessed 24 September 2013); Niedersachsen, 1 February 2013, available at https://www.aekn.de/assets/downloadcenter/files/Arzt-und-Recht/Berufsrecht/BO27_11_12.pdf (accessed 24 September 2013); Nordrhein, 1 May 2012, available at http://www.aekno.de/downloads/aekno/berufsordnung.pdf (accessed 11 August 2012); Sachsen, 23 November 2011, available at http://www.slaek.de/de/05/aufgaben/berufsor.pdf (accessed 24 September 2013).

However, the controversial approaches towards this issue have become obvious by the fact that many State Chambers of Physicians have not or not yet implemented the new prohibition of physician-assisted suicide into their binding professional Codes.[142] Two State Chambers of Physicians have even changed their law and have explicitly not implemented the prohibition.[143] The State Chambers of Physicians of Bavaria explicitly refused the implementation of the prohibition and formulated that the physician must assist dying patients with respect to their dignity and their wishes.[144]

The further development remains to be seen. Problems will especially arise due to the fact that there is no longer a consistent regulation in Germany but different regulations in the professional Codes at the federal state level (level of the Bundesländer). Such a sensitive issue should be treated uniformly.

6.2 Judgment of the Administrative Court Berlin[145]

Further confusion was caused by a judgment of the Administrative Court Berlin from 30 March 2012.[146] A physician, who was also member of the German organization of Diginitas, filed a suit against the State Chamber of Physicians of Berlin, which had prohibited the provision of lethal drugs to any suicidal patient.

The court ruled that the concrete prohibition of provision of lethal drugs without exception was not consistent with the Constitution. It is one of the physician's duties to perform his professional duties conscientiously. Generally, the assistance in suicide and the provision of lethal drugs to patients are not tasks of physicians so that the general prohibition was legal. However, in consideration of the right of freedom to exercise a profession guaranteed in Article 12 of the German Constitution, the State Chambers of Physicians must not express a prohibition without any exception. A physician's constitutional rights would be violated if he was generally forbidden to assist in any patient's suicide, even if it was an exceptional case of moral conflict like a long-lasting very close relationship to a patient who was terminally ill and was in unbearable pain without any hope of health improvement.

[142] For an overview see http://sterberecht.homepage.t-online.de/Suizidhilfe.htm (accessed 16 August 2012).

[143] Bayern, 1 April 2012, available at http://www.blaek.de/pdf_rechtliches/haupt/BO_2_16.pdf (accessed 16 August 2012); Westfalen-Lippe, 26 November 2011, available at http://www.aekwl.de/fileadmin/rechtsabteilung/waeb0312_neue_berufsordnung_alles.pdf (accessed 16 August 2012): no explicit prohibition, but a compromise: "shall not" instead of " may not".

[144] § 16 Berufsordnung für die Ärzte Bayerns, available at http://www.blaek.de/pdf_rechtliches/haupt/BO_2_16.pdf (accessed 16 August 2012).

[145] Decision of the Administrative Court Berlin (VG Berlin) from 30 March 2012 no. VG 9 K 63.09.

[146] VG Berlin decision from 30 March 2012 no. VG 9 K 63.09.

In conclusion, the Court stated in this case that a prohibition of the provision of drugs, and with that the prohibition of physician-assisted suicide, can only be justified as far as this concerns patients who are healthy or who are not capable to decide. However, a total prohibition is unlawful if no exception can be made for certain cases of moral conflict.

It should, however, be mentioned that the Court stated that it can generally be legal and compatible with the Constitution to prohibit the commercial assistance in suicide, even in the professional law.

The President of the German Medical Association (Bundesärztekammer), Frank Montgomery, said that the judgment had less impact than generally assumed.[147] It is true that the exact scope and consequence of this judgment are not clear yet and that a decision from a higher court is still expected. Furthermore, it is necessary to take into account the unique characteristic of the underlying case, with the consequence that the decision cannot simply be labeled as a landmark decision.[148]

However, the judgment can be seen as a step against a total ban of physician-assisted suicide in the professional law without exception. It remains to be seen whether the underlying legal dispute leads to a general clarification by a higher Court in regard to the question whether the professional law can prohibit more than the criminal law.[149]

6.3 Commercial Assistance in Suicide

Since 2006, there have been several attempts in Germany to legally prohibit the commercial assistance in suicide (gewerbsmäßige Förderung der Selbsttötung).

Several German States proposed a revision of the actual Criminal Code with the aim of an interdiction of commercial assistance in suicide.[150] None of these proposals was successful. However, in March 2012 the Ministry of Justice proposed a new bill on the matter in order to criminalize the commercial assistance in suicide (see Fig. 3), which was adopted by the Federal cabinet and will now be presented to Parliament.[151]

[147] http://www.aerzteblatt.de/nachrichten/49743 (accessed 16 August 2012).

[148] Tolmein (2012).

[149] Tolmein (2012).

[150] Proposal of the States Saarland, Thüringen and Hessen, 27 March 2006, Bundesrat Drucksache 230/06, available at http://www.bundesrat.de/cln_051/SharedDocs/Drucksachen/2006/0201-300/230-06,templateId=raw,property=publicationFile.pdf/230-06.pdf (accessed 13 August 2012); proposal of the State Rheinland-Pfalz, 23 March 2010, Bundesrat Drucksache 149/10, available at http://www.bundesrat.de/SharedDocs/Drucksachen/2010/0101-200/149-10,templateId=raw,property=publicationFile.pdf/149-10.pdf (accessed 13 August 2012).

[151] Draft Bill of the Ministry of Justice, 9 March 2012, available at http://docs.dpaq.de/1424-refe_18072012.pdf_sterbehilfe.pdf (accessed 16 August 2012).

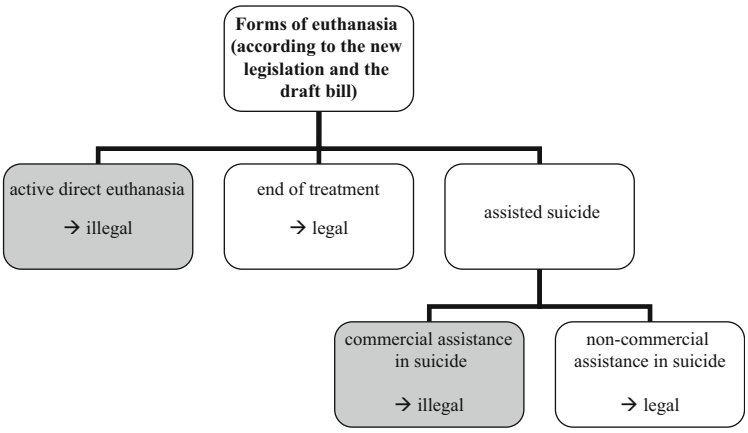

Fig. 3 Commercial assistance in suicide

The official background as mentioned in the draft bill is that some organizations were founded in Germany that commercially offer suicide assistance and that this might lead to a general change in the pattern of assistance in suicide in Germany.[152] It is claimed that in Germany it has become more frequent that persons offer rapid and effective assistance in suicide to a great number of people against payment and that these persons' aim is no longer to give life-affirming advice but rather to organize the suicide quickly in order to make money.[153] Mainly two associations are presumed to be in the focus of this political discussion. Since 2005, there is a German section of the Swiss organization Dignitas.[154] The main focus is, however, on an association called "Assisted Suicide Germany" (SterbeHilfeDeutschland e.V.).[155] Founded in 2009 by the former Senator of Justice of Hamburg, Roger Kusch, it provides information and some form of assistance for its members who seek suicide. According to certain restrictions made by a court decision from 2009,[156] the organizers argue that despite the membership fee the organization is not aiming to make profit.

The original draft of the bill on commercial assistance in suicide from March 2009 simply stated in one new Section 217 that commercial assistance in suicide is to be punished by a fine or a prison sentence of up to 3 years. Due to severe dogmatic criticisms,[157] the draft was amended and a second paragraph, Section 217 (2), was added. It regulates that relatives and other people close to the patient who

[152] Draft Bill of the Ministry of Justice, 9 March 2012, p. 4.

[153] Draft Bill of the Ministry of Justice, 9 March 2012, p. 5.

[154] URL: http://www.dignitate-deutschland.de/ (accessed 16 August 2012).

[155] URL: http://www.sterbehilfedeutschland.de/ (accessed 16 August 2012).

[156] Decision of the Administrative Court Hamburg (VG Hamburg) from 6 February 2009 no. 8 E 3301/08 = MedR 2009, 550.

[157] Deutscher Notarverein (2012), p. 2.

are **participants** in any commercial assistance in suicide provided for the patient are exempted from punishment. This second paragraph has the aim to exclude those people from punishment who have a strong emotional link to the patient and therefore are presumably motivated by altruistic values.

To give an example for the effect of the proposed new law[158]: a woman is fatally ill and wants to die. Her husband brings her to an organization that offers commercial assistance in suicide.

Under the actual legal framework, neither the organization nor the husband is criminally liable. According to the new bill, the person behind the organization would be criminally liable under Section 217 (1). As the husband in this case aids in the commercial assistance, he would also be punishable according to the general rules of participation in criminal law, Sections 26 and 27 of the Criminal Code. In order to exclude this criminalization of the assistance of people close to the patient in commercially assisted suicide, Section 217 (2) is needed.

The bill led to a lively discussion, and both supporters and opponents of euthanasia argued against the bill.

Even though there seems to be a general agreement that certain persons are to be excluded from the liability, it is mainly paragraph 2 that encourages lively discussions. Criticism of the amended bill mainly refers to the uncertainties revealed by paragraph 2. It is very unclear **which persons** are to be defined as people who are close to the patient. Who exactly shall be excluded from the liability? The most controversial issue is that the actual wording of paragraph 2 includes **medical staff and physicians**. That means that a physician who has a rather close relationship to his patient could remain unpunished if he abets commercial assistance in suicide, for example if he recommends a certain organization that provides commercial suicide assistance.

This gave rise to a severe debate about physician-assisted suicide. The President of the German Medical Association (Bundesärztekammer) claimed that the new bill turned physicians into professional suicide assistants.[159] He argued that it was the first time that physicians were explicitly allowed to give assistance in suicide to certain patients that he explicitly refused in the name of the German Medical Association.

In consequence, a public debate on physician-assisted suicide was initiated. However, the fact that the new law would none the less be stricter than the actual law seems to be ignored. As mentioned above, assistance in euthanasia, whether performed by a physician or any close person, is legal under the current Criminal Code.

[158] Official information of the German Ministry of Justice: Strafbare und straflose Formen der Sterbehilfe nach geltendem Recht, 8 August 2012, available at http://www.bmj.de/SharedDocs/Kurzmeldungen/DE/2012/20120808_Strafbare_und_straflose_Formen_der_Sterbehilfe_nach_geltendem_Recht.html?nn=1356288 (accessed 14 August 2012).

[159] Wir sind erschrocken, Frankfurter Allgemeine Sonntagszeitung, 5 August 2012, Nr. 31, p. 2.

Aside from this, some opponents put into question the **general approach** of criminalization.[160] According to German criminal law, assistance in suicide is not illegal. Commercial interests would have to justify the differentiation between the in itself non-illegal act of assistance in suicide and the illegal commercial assistance in suicide. But can economic efficiency be a sufficient decisive factor, even though any market economy is characterized by the fact that any person strives for an increase of assets? The need for regulation is therefore doubted.[161]

Most opinions on the draft bill question the development towards a commercialization of suicide help in Germany and **criticize the lack of statistics** or of any other proof.[162] Even though some organizations exist, it is neither obvious that they mainly pursue the target of making money, nor is it obvious that there is a general social change of attitude towards assisted suicide.[163] Statics are cited that seem to rather prove the opposite.[164]

Related to this, it is criticized that the organizations that are actually targeted by the new law will not fall under the new law because the condition **"commercial"** (gewerbsmäßig) is too narrow.[165] According to the official justification given for the bill, commercial in the sense of the new law is to be interpreted according to previous legislation in other fields of law,[166] which means that someone only acts "commercially" if he acts with the intention to acquire a continuous source of income of some duration and of some extent in order to make profit.[167] Consequently, non-profit organizations do not fall under the new bill, even if they have an organized structure. It is claimed that a broader prohibition is needed that covers any organized form of assistance in suicide. This could, for example, be progressed by a ban on advertising.[168] Mainly, the churches and Christian organizations are strong supporters of the general idea to prohibit any form of organized assistance in suicide.[169]

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[160] Duttge (2012), p. 2.

[161] See, for example, Dignitas (2012), p. 1, where Montesquieu is cited: "Quand il n'est pas nécessaire de faire une loi, il est nécessaire de ne pas en faire." (If it is not necessary to make a law, it is necessary not to make it.)

[162] Dignitas (2012); Humanistischer Verband Deutschland (2012), p. 1.

[163] Dignitas (2012), p. 6.

[164] Compare the surveys conducted by DGHS (Deutsche Gesellschaft für humanes Sterben), available at http://www.dghs.de/fileadmin/user_upload/Dateien/PDF/Forsa-Umfrage_2012-w.pdf (accessed 24 September 2013).

[165] German Medical Association (2012), p. 3.

[166] Draft Bill of the Ministry of Justice, 9 March 2012, p. 10.

[167] BGH decision from 13 December 1995 no. 2 StR 575/95 = NJW 1996, 1069.

[168] German Medical Association (2012), p. 4; proposal of the State Rheinland-Pfalz, 23 March 2010, Bundesrat Drucksache 149/10, p. 5, available at http://www.bundesrat.de/SharedDocs/Drucksachen/2010/0101-200/149-10,templateId=raw,property=publicationFile.pdf/149-10.pdf (accessed 13 August 2012).

[169] Evangelische Kirche Deutschland (2008), p. 32.

However, it seems to be an everlasting phenomenon that as soon as any issue related to euthanasia in the broadest sense is discussed, experts issue a warning about the slippery slope towards the legalization of active euthanasia. Once more, it would be absolutely essential to explain the legal basis and to precisely make clear which issue is discussed on which basis. A general lack of information and detailed knowledge as a basis for further discussion is obvious.

7 Conclusion

Euthanasia and assisted suicide are issues that always have been broadly discussed in Germany. Today, the discussion is vitalized by the new law and the legislation referring to it. Furthermore, the implications of a legal regulation of commercially assisted suicide are broadly discussed—for the first time on a federal level.

Based on the German Criminal Code and the corresponding legislation, it is rather clear which forms of euthanasia are theoretically legal in Germany. Due to the fact that living wills have now been regulated in a new law, implications on criminal law are evident. The exact scope of these implications is being discussed—both in literature and in legislation. Uncertainties remain. In this context, it is often claimed that a clear regulation in the Criminal Code is needed.[170]

Despite these uncertainties pointed out in this chapter and despite the lack of an unambiguous legal regulation, it must be concluded that the law on euthanasia is rather clear in Germany.

The main problem in regard to euthanasia remains the missing information regarding the legal issues. It is apparent that the legal terms are being confused—not only by laymen but also by physicians and even jurists. In almost any matter related to euthanasia or assisted suicide, there are public warnings of an insidious legalization of active euthanasia—as shown even in the actual debate on commercially assisted suicide, which is in truth concerned with a restriction of the actual law. This claim is unnecessary because there is no actual debate on the legalization of active euthanasia in Germany. By phrasing the claim that active euthanasia should be forbidden, a lot of confusion is caused and wrong information is provoked. Any discussion of such a sensitive topic must remain objective and must be based on correct legal prerequisites.

[170] German National Ethics Council (2006); Schöch et al. (2005), p. 553; Verrel (2006), with further references.

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Access to Palliative Care in the Italian Legal System

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Abstract The current model of palliative care in the Italian legal system is regulated by Law no. 38 of 15 March 2010. The objective of palliative care is to alleviate pain, the fear of which becomes central in a patient's consideration of his pathology. An adequate treatment of pain is provided for in all professional Codes of Ethics according to the logic of protecting the dignity of sedated patients while excluding however any disproportionate treatment that does not preserve the "quality of life". This chapter examines the fundamentals of Law no. 38/2010 and its operational aspects, focusing especially on its implementation at regional level and on the specific area of pediatric palliative care.

Contents

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1 Introduction

The access to palliative care and pain management represent two very important and often relevant aspects of the doctor–patient relationship, given the situation whereby medical science is unable to cure the disease, thereby avoiding the patient's death, and/or any situation that requires adequate pain management to relieve the patient's suffering.[1]

The recognition of the right to receive health care as a Basic Right has reinforced the standpoint of lawmakers—both national and regional—to safeguard the rights of the patient to receive adequate treatment for his pathology while reducing his physical, psychological, and social distress.[2]

The constant advances in medical science, both in the fields of diagnosis and treatments, have allowed the patient suffering from pathology to enjoy not only an improved prognosis and extended life expectancy but also the improvement of his quality of life. In the case of palliative care of terminally ill patients, with its relatively new clinical methods and objectives, the emphasis of the caregivers has shifted from the curing of a pathology to the holistic care of the patient.[3]

It is important to clarify that palliative care, while seeking to improve the quality of a patient's life, does not increase the patient's probability of recovery from a terminal pathology. Palliative treatments, instead, aim to reduce the patient's suffering via adequate pain management and emotional support. At present, cancer sufferers in advanced stages are among the greatest beneficiaries of palliative care, which has proven to be of vital importance in providing support to the patient and his family and friends in facing the pain, anxiety, and depression, which can often aggravate the effect of any necessary medical interventions such as surgery and chemotherapy.

Palliative care is aimed at assisting not only terminal cancer sufferers but also other patients with an incurable illness. For example, many medical conditions may not cause the patient to die but will force him to suffer pain and reduce his quality of life and his sense of well being and autonomy.[4] As such, palliative care steps in when medical treatment can no longer offer a cure for the pathology or guarantee a prolonged life expectancy. Palliative care provides psychological support for the patient and his loved ones who may be suffering from isolation and loneliness while managing a treatment regime whereby the patient does not suffer physically from his pathology.

The objective of palliative care is to try to alleviate pain, the fear of which becomes central in a patient's consideration of his pathology.[5] To understand the

[1] Ferrando (2006), p. 1167.

[2] For a general approach to the topic science law, see Santosuosso and Azzini (2010); Santosuosso (2011).

[3] Corli (1988).

[4] Zatti (2007), p. 1.

[5] WHO defined palliative care as a set of techniques that provide comprehensive assistance and are active to all those people whose disease does not respond to specific treatments.

type of pain and the necessary level of pain management required, the doctor–patient relationship must be one of trust, whereby the caregiver can effectively assess the patient's medical history, the nature and strength of his suffering, and the patient's expected quality of life (interference with sleeping patterns, husband/wife relationship, work commitments/hobby), as well as the effectiveness of past and present pain management regimes.

The most important approach for the management of pain and suffering is the use of pharmaceuticals, which, if used correctly, are able to control most of the forms of pain caused by cancer and other pathologies.[6]

Modern medicine distinguishes the two different phases of a patient's assistance program: the therapeutic phase and the palliative phase.[7]

The therapeutic phase tends to heal the patient or to retard the progression of a disease. When this attempt becomes ineffective, the patient enters the palliative phase in which the control of pathological symptoms is useful in relieving any kind of pain and/or suffering, using treatments that permit the patient to continue his existence without the added burden of suffering and disability. In addition to this type of intervention, the dignity of a terminal patient can be further respected by providing an appropriate level of psychological support to him and his family.[8] Therefore, an adequate treatment of pain relief—as is a doctor's duty—already exists in all professional Code of Ethics according to the logic of protecting the dignity of sedated patients while excluding however any disproportionate treatment that does not preserve the quality of life.

"Quality of life" means not only the subjective dimension of health, of what represents an acceptable and good quality of life in a broader sense, but also the perception of an individual's idea of what is for him an acceptable quality of life

[6] The Three-Step "Ladder" pharmacological approach is recommended by the World Health Organization (WHO). Belonging to the 1st step are NSAIDs (non-steroidal anti-inflammatory drugs), which are accompanied by adjuvant drugs; the 2nd step includes the weak opioids, combined with NSAIDs and adjuvant drugs. In the 3rd step are strong opioids, along with NSAIDs and adjuvant drugs. The first step is expected to be the exclusive use of non-steroidal anti-inflammatory drugs, possibly combined with adjuvant drugs (such as psychotropic drugs, steroids, antidepressants, anticonvulsants and local anaesthetics). If pain is not controlled weak opioids (codeine, oxycodone, buprenorphine) may be administered or, in serious cases, strong opioids, such as morphine. This acts by blocking the transmission of pain, by binding it to specific receptors located in the central nervous system. However, there are possible alternatives to morphine in case of inefficiency or poor tolerability: methadone, fentanyl, and buprenorphine. The WHO ladder for cancer pain is a relatively inexpensive yet effective method for relieving cancer pain in about 90 % of patients.

[7] Santosuosso (1996), p. 206; Neri (2011) p. 1785ff.

[8] This requires the involvement of several professionals. The duty extends even to accompanying the patient in the "process of dying", speaking not only on survival but also on the quality of his remaining life in order to improve it. See Patti (2006), pp. 87–102.

and corresponds to the individual's degree of mental and physical autonomy, to ability to continue working, to ability to participate within his family and society. In other words, the concept of "quality of life" has become increasingly considered as a concept of humanity and as a deciding factor in establishing the rights that protect the patient and the need for society to respect these rights.[9] Therefore, in addition to it being a physician's duty, an adequate pain control therapy should also be considered a patient's right to a dignified end of life, thanks to multidisciplinary support.

Until 2010, the Italian law on this topic was Law no. 12 of 8 February 2001, which established "laws and standards to facilitate the use of opioid analgesics for the treatment of pain", paving the way for a change in the type of pain medication in Italy. In particular, this legislative intervention recognised 'LEA', which means Essential Level of Assistance, considered as the "basic health care and social welfare for the terminal patient". This rule requires the State and the regions to provide, at the expenses of the State, a model of health care networks to guarantee the quality of life and human dignity, even in the terminal stages of an incurable disease.

The regulations referred to is Decree no. 43 of 22 February 2007, on "Defining the standard of palliative treatment care for a terminal patient, according to Article 1 para. 169 of Law 30 December 2004, no. 311". In this decree, eight objectives were set which the Regions need to achieve to demonstrate that they have ensured the activation of LEA throughout the Italian territory.[10]

However, until 2010, the absence of a real national plan for standardising palliative care has led to the increase of differences from Region to Region, without any concrete realisation of an effective system that would assist terminally ill patients. Despite the development of health facilities to provide such care, it is clear that a program of palliative care that provides standard criteria for a patient's access to these facilities is totally absent. Also missing in this plan are the minimum requirements for accreditation of providers, as well as common evaluation criteria and economic assistance to access services, facilities, and pharmaceuticals that the state system is unable to provide.

[9] Faggioni (2005), p. 98.

[10] With the regulation referred to in Decree 22 February 2007, 43, entitled "Defining standards of care for terminally ill patients in the palliative treatment", in the implementation of Article 1, co.169 of Law 311 of December 30, 2004, there are fixed eight standard that the regions must achieve in order to demonstrate that they have secured the delivery of this LEA throughout the Italian territory. Now, the absence of a true national plan for palliative care has generated the increase of the differences from region to region, depending on the level achieved in the delivery of the specific LEA. Despite that the development in the territory of the structures to provide such care is undeniable, the absence of a specific welfare program of palliative care that provides uniform criteria for patient access, minimum requirements for the accreditation of providers, specific standards of care, common evaluation criteria, and rates appropriate to the sustainability of their management in the area is evident.

2 The Right to Pain Relief and the Spirit of Law No. 38 of 15 March 2010: Definition and Clinical Features of Terminal Sedation

The use of sophisticated technology regarding the end of life has now blurred the boundaries between life and death, making new conditions of life for the patient possible. The techniques of resuscitation, artificial respiration, and cardiopulmonary bypass allow the continued life of people suffering from severe brain injury and serious physical ailments.[11]

The debate on pain was not easy in the analysis of legal literature: pain is certainly an "extreme condition of existence".[12]

The issue of defining the limits of care constitutes the central problem concerning the end of human life: it needs to be addressed, by some, in order to bring the choice of treatment or of its suspension to the person capable of understanding and will, the availability of which is dependent on the decision of the person in a position to assume responsibility for the choice.[13] This setting is experienced and viewed as "libertarian bioethics" by an authoritative point of view that can be defined as "Catholic", which defends the inherent dignity of the human being, going beyond the choice of the individual—which is based on a subjective feeling of quality of life—in the sense of a balanced physician–patient relationship.[14]

The contrast between these two positions made the Italian debate extremely lively. The advent of Law no. 38 of 15 March 2010 imposed attention to the issue of palliative care that has been characterised, over time, as a constantly evolving field.[15] The goal of palliative care is to achieve the best quality of life for patients and their families.

Although with some delay with respect to foreign experiences, in Italy the issue of sociolegal status of patients with terminal illnesses has assumed a greater importance with Law No. 38.

This Law—which consists of 12 articles—affirms the right of the citizen to have access to palliative care and pain therapy, on the assumption that these benefits must be included in the essential level of health care provided by the National Health Service.

Law No. 38 has been interpreted as a law capable of improving the quality of life of those who live in a situation of physical suffering and able to support the families in situations of difficulty.

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[11] Andreoli (2003), p. 9; Melazzini (2010).

[12] Andreoli (2003), p. 70.

[13] De Fanti (2007), p. 91; De Mattei (2008).

[14] D'Agostino (1993), p. 675ff.

[15] In 1990, the WHO had provided the following definition: "Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms and of psychological, social and spiritual problems is paramount".

Certainly, this Law—for the first time—protects and guarantees the patient's access to palliative care and pain therapy as part of the essential levels of assistance, in order to ensure respect for the dignity and autonomy of the human person, the need for health, equity in access to care, quality of care, and appropriateness with regard to his specific needs.

In particular, Law no. 38 makes the effort to define some very important words, such as palliative care, pain therapy, ill person, networks, residential care, home care, day hospice, and specialist care pain management.

Palliative care is defined as the set of therapeutic interventions, diagnostic, and care services, dedicated to the sick person and his family, aimed at the active and total treatment of the patients whose underlying disease, characterised by a relentless evolution and a poor prognosis, does not respond to specific treatments.

Pain therapy means the ensemble of diagnostic and therapeutic interventions designed to identify and to be applied to these chronic diseases; suitable and appropriate drug; surgical, instrumental, psychological, and rehabilitation therapies, as variously integrated, in order to develop appropriate diagnostic and therapeutic planes for suppression and control of pain.

Ill means a person suffering from a chronic and progressive disease, for which there is no treatment or, if it exists, which is inadequate or has proved ineffective for the stabilisation of the disease or a significant prolongation of life.

Networks is the national network for palliative care and the national network for the treatment of pain to ensure the continuity of care of the patient from the hospital to his home and includes the whole of territorial health care facilities and hospitals, the professionals, and the diagnostic and therapeutic interventions available in the Regions and autonomous Provinces, dedicated to the provision of palliative care; pain control at all stages of the disease, with particular reference to advanced and terminals stages of the disease; and support of patients and their families.

Residential care means all health interventions, social, and health care in palliative care delivered continuously by multidisciplinary teams at a facility called "hospice".

Home care means all health interventions, social and health care guaranteeing the provision of palliative care, and pain therapy at the home of the sick person, for what concerns both basic interventions, coordinated by the general medicine doctor and those of the specialist palliative care team, in which the general practitioner is in any case part, ensuring uninterrupted continuity of care.

Day hospice means the organisational structure of the hospice that provides services and diagnostic and therapeutic care in the diurnal cycle that cannot be executed at home.

Specialised care pain management means all of the health interventions and of pain therapy provided on outpatient mode, day hospital and hospitalisation, or by specialised teams in the country.

3 Operational Aspects of Law No. 38. The Specific Area of Pediatric Palliative Care

Law no. 38 provides that health structures that provide palliative care and pain therapy should ensure a program of individual care for the patient and his family, in accordance with the fundamental principles of the protection of the dignity and autonomy of the patient, without any discrimination.

Health structures must also be in charge of protecting and promoting the quality of life at every stage of the disease, particularly in the terminal stage, and an adequate medical support and social welfare of the sick person and the family.[16]

One of the most important aspects of Law no. 38 is the provision that, within the medical records, in the medical and nursing care sections used by all health structures, it must be annotated the characteristics of the pain relief and its evolution during hospitalisation, as well as the technical and analgesic drugs used, the relative analgesic doses, and the result achieved (Art. 7).

Following the approach of other countries (such as France), the new law has correctly emphasised the role of the physician in the palliative care system, providing for the duty to make a note in the medical records of the level of pain relief in relation to the characteristics and evolution of the disease in the course of hospitalisation, the analgesic technique, the medications used, and the results eventually achieved.

For an adequate circulation of this idea, the law provides for the achievement of national networks for palliative care and pain therapy. In particular, the Ministry of Health promotes the activation and integration of two separate networks, which provide to patients responsive care on a regional basis and in a uniform manner throughout the country.[17] On a proposal from the Minister of Health, the Standing State-Regions Conference defines the minimum requirements and the organisational arrangements necessary for the accreditation of structures for assistance to terminally ill and palliative care units and pain therapy home in each Region.

One of the innovative effects of Law no. 38 is also the simplification of procedures for access to medicines used in the treatment of pain. In fact, after the previous years of a series of bureaucratic obstacles for families to have access to medicine,[18] the law changes the text of the laws concerning the regulation of narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of drug addiction,[19]

[16] Franzoni (2009), p. 255ff; Busnelli (2001), p. 20.

[17] That, in accordance with Art. 1, para. 2, of Legislative decree of 30 December 1992, no. 502, and subsequent amendments.

[18] The reference is to the previous Law no. 12 of 19 February 2001 entitled "Rules to facilitate the use of analgesic opioids in pain", which substantially modifies Law 309/90, concerning the regulation of narcotic drugs and psychotropic substances that, in the idea to regulate the use of opioids stimulant, did not prescribe any legislation to facilitate the therapeutic use of these drugs.

[19] Mercadante (2011), p. 1254.

simplifying the prescription of non-injectable opioid drugs. In fact, according to Art. 10, the physicians of the National Health Service are allowed to prescribe this class of drugs (not all, however,) rather than on special recipe, but using the simple recipe of the National Health Service.

Such innovations have not met great favour. Many health professionals have thought that the vaunted simplification of procedures for access to opioid drugs would deprive a large number of doctors to prescribe drugs. In fact, according to the wording of Art. 10 we understand how these drugs can be prescribed only by physicians who are civil servants and not by private practitioners.[20]

Art. 6 authorises the expenditure to continue the project "Hospital—Territory without pain". In Law no. 38, this project is called "Hospital without pain". This project was initiated by the Ministry of Health on 24 May 2001 and was aimed at promoting the utility of monitoring levels of pain, providing within each health care facility the establishment of an ad hoc Committee, composed of various professionals.

Finally, a strong question about the training of medical and health staff has led to the creation of specific decrees of the Ministry of Education, University and Research—in consultation with the Minister of Health—to identify specific training in the field of palliative treatment of pain therapy associated with neoplastic diseases and chronic and degenerative diseases. In these decrees, it is also requested to identify the criteria for the establishment of masters and higher education in palliative care and pain therapy.

A further change is the introduction—in Law no. 38—of the definition that establishes the right for patients of less than 18 years of age to receive assistance on palliative care and pain therapy at home.

A particular discipline has been designed for pediatric palliative care. The World Health Organization defines palliative care as the active global care of the body, of the mind, and of the spirit of the child, which includes the active support of the family.[21]

A child with severe chronic pathology without the possibility of recovery and/or with relevant disabilities and/or in a terminal stage is an elective patient for palliative care: the satisfactory control of symptoms, the return home, and the reintegration into his family and in his social life represent for the child and the family a very positive and constantly required achievement.

Progress in medicine and technology has allowed survival of infants, children, and teenagers who are lethal disease carriers but does not always allow the healing. New technologies and the general improvement of care have led to a gradual lengthening of survival in this disease. This fact, together with the increase in the number of new children patients surviving, has led to the growth of prevalence of children in need of palliative care, even for a long period of time and through various stages of life, from childhood to adolescence and adulthood.[22]

[20] Furthermore, it should be clarified that the law does not allow, in any case, the administration of useful substances such as morphine intravenously.

[21] Cancer Pain Relief and Palliative Care in Children, WHO-IASP, 1998.

[22] Viciani (1996), p. 272.

In pediatric age, there is a clear distinction between healing intervention to improve the quality of life and prolong life and purely "palliative" intervention.[23]

The Italian Ministry of Health states that in Italy 11,000 children (7,500–15,000) with an incurable disease and/or terminal illness (1/3 cancer, 2/3 non-cancer) need pediatric palliative care and must be followed by a service network, including a pediatric palliative care team, community services, and hospital nearest to the place of the child's life. This right should not be limited by age, disease, social status, economic conditions, and organisation of the family. The network service must guarantee to each child in need of palliative care the answer to the main evolving health needs of the child and those of the family. In particular, the essential actions as part of the diagnostic assessment and intake should be guaranteed, with the active participation of the family in decision-making and, as far as possible for age and condition, of the child.

The creation of the network of pediatric palliative care included in broader networks of care and pediatric palliative care must be on a regional or supra-regional level, taking into account the need to provide both a home care of the patient and a form of residential assistance. The Regions will choose the models to be implemented, including in relation to the characteristics of different health care systems, in which they are going to be realised, while taking into account the priority need to refocus the use of resources, compressing every misuse of long stays in hospital wards, in particular intensive wards.

4 The Project to Standardise the Care on the Whole Italian Territory: The Regulatory Requirements and the Experiences of Individual Regions

In order to operationalise some of the instructions issued by the regulations, such as those referred to in Article 3 (where it is required to define the guidelines for the promotion, development, and coordination of regional operations within the network of palliative care and pain therapy network), the Ministry of Health, with the support of the National Commission, has issued an official document that was finally upheld by the Conference State-Regions on 16 December 2010.

The agreement is expected to create specific structures at regional level, dedicated to the coordination of the two networks. There are few Regions that have a regional coordination with a deliberate act, although many are working in this direction with the establishment of working groups or organisations dedicated to the two areas.

[23] For this specific segment of the population, the time of employment of palliative care can be significantly different—in some cases, it can be limited to the first year of life (disease congenital); in others, much more prolonged periods (Cystic Fibrosis Pulmonary Heart disease, autoimmune diseases); and still in other cases, concentrated in a short period that precedes death.

In recent years, awareness of the benefits resulting from the practice of comfort cares—very popular in the English-speaking world—has led some Italian Regions to adopt laws for the promotion of instruments to assist the terminally ill.[24]

In particular, the Region Emilia Romagna adopted Regional Law no. 29 of 20 July 1994, on "Home care for the terminally ill"; Sicily approved Regional Law no. 26 of 6 April 1996, on "Interventions in favour of subjects with incurable diseases"; Abruzzo and Umbria have enacted, respectively, Regional Law no. 35 of 7 June 1996 and Regional Law no. 17 of 30 March 1995, on the "Establishment of service of hospital at home for oncologic patients".

Very interesting is the experience of the Veneto Region, which by Law no. 7 of 19 March 2009 has implemented the protection of the rights of the terminally ill, thanks to which, since 1998,[25] a system of dedicated health care in the Region is guaranteed. As mentioned above, care of the terminally ill has been reported—albeit in a generic and limited mode when compared with the experience of other countries[26]—between the essential levels of health care (LEA) in 2001.

[24] Parente (2011), p. 112.

[25] The regional model of care was drawn with the DGR n. 5273 of 1998, in which is defined the overall structure of the system of home care (the so-called Integrated Home Care), with particular attention to the needs of the terminally ill. In 2000 DGR n. 2989 were therefore defined the guidelines for regional legislation with the specification of structural, technological, and organizational requirements of hospice (inside and outside the hospital) ensuring continuity and quality of service.

[26] In 2007, the European Parliament issued a mandate designed to analyse and report on the development of palliative care in the 27 EU member states in order to obtain an overview of the understanding, organisation, provision, and funding of palliative care in 'EU and in individual Member States. Recommendations were made on the implementation policy in the EU and in the Member States and were identified several areas where action is needed: not all interested persons can gain access to palliative care with the same ease, cancer patients must receiving' best service, and the financing of the offer of palliative care is not always ensured, there is a shortage of trained personnel in palliative care, there are no generally accepted standards of quality palliative care. The report also states: Raised to the policy level, this translates to a need for efficient use of resources (both human and financial) to guarantee the best possible quality of care. In particular, in November 2010 the Australian Health Ministers' Conference endorsed the National Palliative Care Strategy. The Strategy is the policy document that the Australian Government and State and Territory governments use to guide palliative care policy development and service delivery across Australia. The Strategy has four goal areas: awareness and understanding, as to significantly improve the appreciation of dying and death as a normal part of the life continuum and to enhance community and professional awareness of the scope of and benefits of timely and appropriate access to palliative care services. The other goals are appropriateness and effectiveness: in fact, appropriate and effective palliative care is available to all Australians based on need. The Australian Health Ministers' Conference identifies leadership and governance among the areas of intervention, to support the collaborative and effective governance of national palliative care strategies, resources and approaches. The last goal areas are capacity and capability, to build and enhance the capacity of all relevant sectors in health and human services to provide quality palliative care.

A demonstration of the new approach of the legislator is the explicit recognition of the right of patients to declare their pain and receive the necessary information regarding the service of palliative care.

It is, evidently, the enunciation of the fundamental principles of our legal system (Article 2 of the Constitution) and the basis for the regulation of health care for the terminally ill that, as such, must guarantee the full rights of personality.

The residential character that qualified the care offered to terminally ill patients in 2001 led to a sharp differentiation in the development of programs to support health within the different Regions.

Some, in fact—such as Lombardy—have preferred to regulate the matter in the complex social and health network; others, however (such as Piedmont), integrate it into the context of health services.[27] It is for this reason that, in order to prevent a manifest and unjust gap between Regions, the Ministerial Decree of 22 February 2007 was approved with the aim of standardising health care across the country, by setting the minimum requirements in terms of quantity, quality, and structure.

On 25 July 2012, there was an agreement between the central government and the Regions, which expressly provided for the establishment of the "discipline of palliative care" for the purposes of competition rules for the medical director of the National Health Service. This agreement refers to art. 5 of the Law of 15 March 2010, no. 38, that is, the definition of minimum requirements and organisational arrangements necessary for the accreditation of care structures to terminally ill and the Units of palliative care and pain therapy.

The Board of the National Health Council (Consiglio Superiore di Sanità), at its meeting of 11 December 2012, expressed a favourable opinion on the establishment of the discipline of "palliative care" for the purposes of competition rules to access medical facilities that are part of the palliative care network. This means the full recognition of the "specificity" of the knowledge and skills of palliative care that are a wealth of knowledge painstakingly built through experience, training, and scientific excellence. Now, after the State-Regions Agreement of 25 July 2012 and the approval by the Board, a new scheme of State-Regions Understanding was set up, completing the procedure provided for in Article 4 of the Decree of the President of the Republic no. 484 of 10 December 1997, which will enable the enactment of the Ministry of Health for detection, between the areas of diagnostic medicine and services, of the new discipline of "palliative care" with the change of the table "a" for the professional category of a physician. This important recognition of the new discipline of "palliative care" represents a further step in the development and application of Law no. 38.

After the approval by the National Health Council of 11 December 2012, at its meeting on 7 February 2013, the Permanent Conference for relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano established the discipline of palliative care.

[27] Zucco (Chief of the Scientific Committee of XV Congress SICP, Director of Palliative Care Unit and Hospice, Azienda Ospedaliera "G. Salvini", Garbagnate-Milano) 2007, p. 438.

The discipline of palliative care is identified among the disciplines in which executive positions of complex structure may be conferred for the professional profiles of the management of health care personnel. This is a historic achievement for the world of palliative care that fits into a positive path for the application of Law no. 38 strongly supported by the Italian Minister of Health.

The approval, in Italy, of a self-discipline in palliative care and the definition of its specific content is the positive result of a wealth of knowledge and expertise that has been painstakingly built by hundreds of workers over 25 years of experience "in the field" and activities at home, the hospice, the hospital.

In Italy, this journey has been long and complex, certainly neither easy nor free of obstacles: the goal achieved, however, is really to be considered essential.

Other good news is the recent establishment, as provided in this understanding of 25 July 2012, of the "mixed table" State-Regions for the identification and definition of fees for the activities carried out within the networks of palliative care and pain therapy, both for adults and children. It is another important step in the application of Law no. 38, with the aim of overcoming the current difference between Regions and ensuring a homogeneous distribution of the LEA palliative care across the country.

5 Concluding Remarks

Modern medicine requires that patient care be conceived not only from the physical point of view but in a global sense. It seems important to distinguish two different stages of a patient assistance program: the therapeutic moment and the palliative care moment. The therapeutic phase tends to heal the sick or slow the progression of the disease. When this attempt becomes impossible, it is necessary to enter the palliative phase, in which it is possible to control the pathological symptoms to relieve every kind of suffering, with treatments that prevent the patient to live in difficult situations of suffering and disability.

In addition to this type of intervention, respect for the dignity of the terminally ill is possible also through proper relational counselling to the dying and their families. Therefore, an adequate pain therapy—being the doctor's duty—permeates the professional Code of ethics, excluding disproportionate treatments. The protection of the dignity of the person is realized also by providing pain relief: which is explicitly confirmed by Article 37, which provides that in the case of diseases with certain poor prognosis, or that at least reached the terminal stage, the doctor will perform his duty with the aim of giving moral support and of ensuring the delivery of any medication against pain, providing those in need, as far as possible, of treatments that are appropriate to preserve the quality of life.[28]

[28] Giulino et al. (2011), p. 123.

Now, the "quality of life" not only is the subjective dimension of health in a broader sense and the perception of one's ideal of acceptable and good life but also corresponds to the degree of psychophysical autonomy, cognitive quality, remaining working capacity, relationship with society, family, and the world of work that can qualify as a life of acceptable quality. In other words, the quality of life tends to become a criterion of humanity and a discriminant to determine the right of protection and the duty to respect.

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Legal Rules on Palliative Care Under German Law

Amina Salkić

Abstract During the last few years, palliative care has gained significant importance at the national, European, and international levels. In Germany, meanwhile, there is a broad consensus crossing all party lines that it is of utmost importance to develop needs-based palliative care. In order to achieve this goal, the legislator passed several laws regulating different aspects of palliative care and thus strengthened its legal basis, in particular, within the Fifth Book of the German Social Code. Other relevant policymaker followed by adopting corresponding substatutory rules and regulations.

Even though palliative care structures are growing steadily and spreading to most areas, their availability remains to be uneven, especially in rural areas. The ambitious goal of full coverage with comprehensive palliative care in patients' homes has still not been achieved.

This chapter aims to provide an overview of the national legislation and existing regulations regarding palliative care under German law, their constitutional basis, and historic background.

Contents

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1 Introduction

According to the most frequently cited WHO definition from 2002, palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial, and spiritual.[1]

Modern palliative care has its roots in the hospice movement, which emerged in England in the 1960s. The total pain/total care approach pioneered by Dame Cicely Saunders and the work of the St Christopher's Hospice in London, which she founded in 1967, became models for many other palliative care initiatives worldwide. She introduced a new way of treating terminally ill patients, emphasizing a holistic and compassionate approach, where more than in almost any other branch of medicine it is the whole person who has to be considered and helped.[2]

She firmly rejected the argument that chronic pain might justify (active) euthanasia. For her, the impending death was no excuse for intentional termination of life. One should rather focus on practical measures to alleviate pain and other symptoms, to make the last moments worth living. The same argumentation was adopted by the later German hospice movement[3] and beyond.[4]

[1] World Health Organization (2002), p. 84. Compare also Scottish Partnership for Palliative Care (2006) p. 9.

[2] Saunders (1961), p. 548.

[3] In March 1998, then German Hospice Foundation initiated the publication of the Dortmund Declaration '*Menschliche Zuwendung statt aktiver Sterbehilfe*' (Human Affection instead of Active Euthanasia). This nationwide campaign was also supported by then Federal President Johannes Rau, Chancellor Helmut Kohl, and Federal Health Minister Horst Seehofer. See further Brenn (1998), pp. 18–19.

[4] See, for example, Bundestag printed paper no. 15/5858, p. 68.

At present, there is no uniform translation of the term palliative care in the German language, which is why it is being translated differently.[5] However, the umbrella term Palliativversorgung seems to be prevailing as the appropriate translation of the term palliative care. It includes palliative medicine, palliative nursing, and also hospice work. Accordingly, in this chapter the term palliative care is being used as a comprehensive umbrella term.

2 Development of Palliative Care in Germany: Historical Background

In Germany, first palliative care structures were created as a result of enthusiastic commitment of volunteers within the hospice movement. Even though there have been some early efforts to spread the hospice idea in Germany, the implementation was very slow and isolated. One of the key reasons for the sluggish development was the broadcasting of a documentary Noch 16 Tage ... Eine Sterbeklinik in London in 1971 about the work in the above-mentioned St Christopher's Hospice.[6] For the first time after the Second World War, it publicly tackled the problem of inadequate care of terminally ill patients. The intention of the filmmaker was to promote hospice work as a good role model for future structures in Germany. However, at that time, it was rather counterproductive. Even the title was confusing, since the term hospice was mistranslated as dying clinic (Sterbeklinik). The majority of the TV audience, who still remembered the Nazi period, got the impression that the hospice idea was just a step towards active euthanasia,[7] which led to a broad rejection of the hospice concept. The public did not recognize that the hospice movement considered itself as a kind of stronghold against the practice of active euthanasia and physician-assisted suicide.

The distrust was also evident in 1978, when the German Federal Government was asked to support the establishment of hospices. Subsequently, the Federal

[5] In Germany, many do not even translate the term palliative care but rather use it in its original English form. Others translate it as Palliativmedizin; Palliativversorgung, or (ehrenamtliche) Hospizarbeit. In Austria, the following terms are also being used: palliative Betreuung/Palliativbetreuung, Lindernde Fürsorge (relief and comfort). Besides the already mentioned terms, in Switzerland the term Palliative Betreuung exists (EAPC 2009, p. 281). Compare also Pastrana et al. (2008), p. 712.

[6] The film was later followed by another movie. In this second movie, Die letzte Station—Dreharbeiten in einer Sterbeklinik (The Last Station—Filming in a Dying Clinic), the members of the film crew reflected on their initial work and wondered if they themselves have changed due to their experiences in the London hospice. In 1972, the editorial team of the German state channel ZDF was awarded with the Adolf-Grimme-Prize for the production of this second movie.

[7] Historically, the hospice movement always regarded itself as a counterweight to the so-called euthanasia movement that advocates killing on request. Nevertheless, even prominent scientists perceived the dying clinics (Sterbekliniken) as belonging to the euthanasia movement (see for example: Tröndle 1987, p. 40).

Ministry for Youth, Family and Health made a large-scale survey among churches, charitable organizations, hospital associations, and professional individuals, asking if they advocate the establishment of dying clinics in Germany, according to the English or Swedish model.[8] A total of 23 of 25 official submissions (92 %) were against the proposal,[9] fearing deportation and ghettoization of the seriously ill and dying patients.[10] Because of the clearly negative result, the proposed pilot project was rejected. This had a significant impact on the pace of development, since it also excluded any significant financial support.

While in the 1980s the discussion about active euthanasia and physician-assisted suicide flared up again, the public took little notice of the pioneer activities of the hospice movement and other palliative care providers. One of the key turning points was the acknowledgment of the hospice concept as a positive approach by the previously very sceptical Catholic[11] and Protestant[12] churches.

In spite of a dynamic change, it was not until the 1990s that palliative care services gained considerable public importance. Only a model study of the Federal Ministry of Health, which was conducted in the inpatient sector from 1991 to 1996, stimulated a more positive development of palliative care in practice.[13] However, the outpatient sector remained left to various associations and volunteer groups.

Due to this initial lack of official support, German palliative care structures experienced a specific development creating a two-pillar model. On one side there has been the hospice movement, which primarily consisted of laypersons. Still today it mainly relies on the commitment of its volunteer staff. Parallel to this, health care professionals have increasingly engaged in developing palliative medicine structures, which are dominated by physicians.[14] Those two pillars, hospice care and palliative medicine, have largely developed independently of each other. Still today, those two pillars are recognizable. Their interests are being represented by two separate organizations. The hospice initiatives are being represented by their 16 regional associations (Landesarbeitsgemeinschaften—LAGs) and their federal umbrella organization, Hospice and Palliative Association (Hospiz- und

[8] Godzik (1993), p. 27.

[9] Godzik (1993), p. 27; Oheim (2009), p. 42.

[10] More information with further references: Oheim (2009), p. 42.

[11] Pastoralkommission der Deutschen Bischofskonferenz (1993).

[12] Godzik and Jeziorowski (1989) and Godzik (1992).

[13] The Ministry initially funded 12, later 14, inpatient palliative care hospital wards in order to investigate the possibilities of improving care of dying cancer patients in hospitals. For more information, see further Bundesministerium für Gesundheit (1998).

[14] Nowadays, 60 % of the 3,800 members of the German Society for Palliative Medicine (Deutsche Gesellschaft für Palliativmedizin—DGP) are physicians, almost 30 % are involved in care services, and further 10 % work in other professions (among others are psychology, spiritual welfare, social work, physiotherapy, pharmacology, and law). For more information, see further http://www.dgpalliativmedizin.de. Accessed 23 September 2013.

PalliativVerband e.V.—DHPV).[15] Health professionals, in particular physicians, are being represented by the German Society for Palliative Medicine (Deutsche Gesellschaft für Palliativmedizin—DGP).[16] Besides DHPV and DGP, there are also other important organizations that represent the interests of the patients[17] and, in particular, children.[18] In spite of their organizational separation, the cooperation between the two pillars is steadily increasing.

During the last few years, a similar development was taking place on the European level as well. Several nongovernmental and intergovernmental organizations, like the Council of Europe,[19] WHO Europe,[20] or the EAPC,[21] adopted and published documents aiming to strengthen palliative care all over Europe. A common aim of all these organizations was to draw attention of national policymakers on palliative care since they all were calling for governmental actions. For example, the European Federation of Older Persons (EURAG) launched a campaign Making palliative care a priority topic on the European health agenda in 2004. Central to its approach is the recommendation to the European Commission and European Parliament to acknowledge palliative care as a human right.[22] Nevertheless, despite the powerful symbolic language of these and other documents, evidence of their impact remains unclear. In the case of Germany, they seem to have had no or little impact on the parliamentary debate and the resulting legislation regulating palliative care issues so far.[23] At least the transcripts of parliamentary debates and other accompanying documents contain no indications that these IGO or NGO documents played a crucial role. However,

[15] In 1992, the Federal association representing the interests of the 16 regional hospice organizations of the Länder (Landesarbeitsgemeinschaften—LAGs) was established as Bundesarbeitsgemeinschaft Hospiz (BAG). In 2007, this German umbrella hospice organization has been renamed to Deutscher Hospiz- und PalliativVerband e.V. (DHPV). See further http://www.dhpv.de. Accessed 23 September 2013.

[16] The German Palliative Care Society—Deutsche Gesellschaft für Palliativmedizin e.V. (DGP) was established in 1994, mainly representing physicians. See further http://www.dgpalliativmedizin.de. Accessed 23 September 2013.

[17] The association representing the interests of patients, Deutsche Hospiz Stiftung e.V., was founded in 1995. See further http://www.stiftung-patientenschutz.de. Accessed 23 September 2013.

[18] In 1990, six families with children who had life-shortening diseases joined together and founded the German Children's Hospice Association (Deutscher Kinderhospizverein e.V.). See further http://www.deutscher-kinderhospizverein.de. Accessed 23 September 2013

[19] Recommendation Rec (2003) 24 of the Committee of Ministers to member states on the Organization of palliative care and explanatory memorandum (Adopted by the Committee of Ministers on 12 November 2003 at the 860th meeting of the Ministers' Deputies), available at https://wcd.coe.int/ViewDoc.jsp?id=85719. Accessed 23 September 2013.

[20] Davies and Higginson (2004a, b).

[21] Barcelona Declaration on Palliative Care (1995), p. 15; Poznan Declaration (1998), pp. 61–65.

[22] The European Federation of Older People (EURAG) (2004), p. 16.

[23] Differing opinion regarding the Council of Europe: Rixen (2012), recital 1.

all persons involved in the German parliamentary debate have always referred to similar core values enshrined in the German Constitution (Grundgesetz—GG), in particular human dignity, right to self-determination, right to life, and physical integrity.[24]

3 Levels of Palliative Care

According to the Council of Europe and the European Association of Palliative Care (EAPC), there are three basic levels of palliative care: palliative care approach, general palliative care, and specialized palliative care.[25] All these levels can be provided either in outpatient or inpatient settings.

3.1 Palliative Care Approach (Palliativer Ansatz)

The palliative care approach means that all health care professionals should be familiar with the essential principles of palliative care and must apply these principles appropriately in their practice.[26]

It should be an integral part of the disease management from its early stage. It does not focus only on symptom management but also on communication with the patient, his next of kin, and other persons involved in the individual's care. It focuses on the person, not the disease.[27] This equally applies to settings that are not specialized in palliative care. The aim of this approach is to equip the health care professionals with the knowledge and skills that enable them to care for a person diagnosed with a life-limiting disease, meeting the needs of patients and their next of kin facing progressive illness and bereavement. Therefore, it is necessary to include palliative care into the education curricula for all health care professionals. In order to improve skills and knowledge of German physicians, palliative care has been introduced as a compulsory part of medical education. Starting in 2014, every physician applying for a license to practice medicine in Germany will have to prove basic training in palliative care.[28]

[24] Compare for example: German National Ethics Council (Nationaler Ethikrat) (2006), p. 52 et seq.

[25] Council of Europe, CM 2003, 130 Addendum/15 October 2003, paragraph 53; compare also EAPC (2009), pp. 285–286.

[26] Council of Europe, CM 2003, 130 Addendum/15 October 2003, paragraph 53.

[27] The Scottish Government (2008).

[28] Section 27 I 9 of the Approbationsordnung für Ärzte (ÄApprO).

3.2 *General Palliative Care (Allgemeine Palliativversorgung)*

Some health care professionals, such as general practitioners, primary care professionals, professionals working in general hospital wards or nursing homes, although not engaged exclusively in the practice of palliative care, might have very good basic palliative care knowledge and skills due to additional training and expertise in this field. These persons, such as oncologists, geriatric specialists, or general practitioners and nurses with palliative care skills and knowledge, may provide general palliative care. By alleviating symptoms and meeting the needs of individual patients and their next of kin, the aim of general palliative care is to enhance their quality of life and to enable them to lead a decent life until death at home, in residential care facilities, in inpatient hospices, or in hospital wards.

3.3 *Specialized Palliative Care (Spezialisierte Palliativversorgung)*

Specialized palliative care is provided by services, whose core activity is limited to the provision of palliative care, like it is the case with palliative care hospital wards or specialized outpatient palliative care teams. They are typically involved in the care of patients with more complex and demanding care needs and consequently require a greater degree of training, staff, and other resources.

4 Types of Palliative Care Services

The first legal milestone was made in 1997, when the German Bundestag acknowledged the main goal of the hospice movement to enable terminally ill patients to live with dignity until death and recognized that the hospice concept (Hospizgedanke) has to spread and gain more influence at various levels of society.[29]

After that, several legal reforms have been introduced in order to improve the care of terminally ill patients in Germany.[30] All these regulations on the provision of palliative care generally follow the common differentiation between the inpatient and outpatient health care settings. Accordingly, inpatient providers usually include

[29] Bundestag printed paper no. 13/7264, p. 60.

[30] A comprehensive list of numerous German laws and regulations concerning palliative care is available at http://www.dhpv.de/service_gesetze-verordnungen.html. Accessed 23 September 2013.

<table>
<tr><td colspan="2" rowspan="3"></td><td colspan="3">PLACE OF CARE / PALLIATIVE CARE PROVIDER</td></tr>
<tr><td colspan="1">Outpatient</td><td colspan="2">Inpatient</td></tr>
<tr><td>At home or in other domiciliary setting</td><td>Long-term care facilities / quasi domiciliary setting</td><td>Acute care facilities / institutional setting</td></tr>
<tr><td rowspan="4">LEVEL OF PALLIAITIVE CARE</td><td>Palliative approach</td><td>In particular:
• General practitioners;
• Outpatient nursing services*</td><td>Staff of senior citizens' residential and nursing homes</td><td>Staff of general hospital wards</td></tr>
<tr><td rowspan="2">General palliative care*</td><td colspan="2">• General practitioners with basic palliative care skills and knowledge;
• Resident medical specialists / consultants occasionally treating patients with life-threatening or -limiting diseases with good basic palliative care skills and knowledge</td><td>General hospital specialists occasionally treating patients with life-threatening or -limiting diseases with good basic palliative care skills and knowledge (oncologists, geriatric specialists, etc.)</td></tr>
<tr><td>Outpatient nursing services with basic palliative care skills and knowledge</td><td rowspan="2">• Hospices
• Staff of senior citizens' residential and nursing home with basic palliative care skills and knowledge</td><td rowspan="2">Multi professional palliative care consultancy services (Konsiliardienste)</td></tr>
<tr><td>Specialized palliative care</td><td colspan="2">Specialized outpatient palliative care services / teams</td><td>Palliative care hospital wards</td></tr>
</table>

*preferably in close cooperation with services such as neighborhood assistance groups, religious ministers, social workers, psychologists, house-emergency systems, etc.

Fig. 1 Levels of palliative care and corresponding providers

palliative care hospital wards (Palliativstationen) and hospices (Hospize), and outpatient providers mean outpatient hospice services (ambulante Hospizdienste) and providers of specialized outpatient palliative care (spezialisierte ambulante Palliativversorgung—SAPV).[31] This systematization is considering providers that exclusively treat palliative patients with life-limiting diseases. In addition to them, there are also other health care providers that occasionally treat palliative patients, thus providing general palliative care. However, it is hardly possible to draw a clear dividing line between general and specialized palliative care. For a more comprehensive overview, see Fig. 1.

[31] There are several different types of providers of palliative care, especially in the outpatient sector. For further information, see Bundestag printed paper no. 15/5858, p. 10 et seq.

4.1 Inpatient Providers of Palliative Care: Palliative Care Hospital Wards and Hospices

While in 1996 there were altogether 58 inpatient facilities providing palliative care (30 hospices and 28 palliative care wards), in 2011 their number grew significantly up to 426 (195 hospices and 231 palliative care wards).[32] Currently, there are about 40 beds available per 1 million inhabitants, with large differences between the individual German federal states (Länder).

A *palliative care ward* is a specialist department based in or bound to a hospital.[33] Their aim is to alleviate or stabilize symptoms and—if possible—improve quality of life of patients so that they can be released. In Germany, the first palliative care ward was established in 1983 at the University Hospital of Cologne. They are typical for their multiprofessional teams consisting of appropriately qualified physicians, nurses, social workers, counsellors, psychologists, and other therapists, often supported by volunteers. In contrast to other types of palliative care providers, there are no general and verifiable quality criteria for palliative care wards so far.[34]

The first *inpatient hospice* was opened in Aachen (Haus Hörn) in 1986. Currently, there are approximately 200 hospices (including 12 children's hospices[35]) unequally spread across the different regions.[36] Despite initial obstacles of the German society in the 1960s and 1970s, in 1997 the German legislator finally acknowledged that provision of palliative care is an integral part of death with dignity[37] and introduced a new section 39a SGB V of the Fifth Book of the German Social Code (Sozialgesetzbuch Fünftes Buch—SGB V), establishing the first official financing model for inpatient hospices (Hospize).[38] Accordingly, statutory health insurance (SHI) funds for the first time were obliged to participate in the financing of structures, whose sole task is to meet the needs of terminally ill patients.[39] In the sense of this section, the term hospice means an independent,

[32] The current status of development is recorded in Sabatowski et al. (2013).

[33] An additional form of hospital-based palliative care includes palliative care consultancy services (Konsiliardienste). They are often connected to a palliative care ward. Their financial scheme is still unclear.

[34] For more information on financial schemes for hospital-based palliative care, see Maier (2011).

[35] A detailed list of 12 children's hospices (last updated on 27 August 2013), available at http://www.bundesstiftung-kinderhospiz.de/fileadmin/dokumente/liste.pdf. Accessed 19 June 2013.

[36] For an overview of the development of inpatient hospices and palliative care hospital wards from 1996 to November 2011, see Sabatowski et al. (2013).

[37] German Bundestag printed paper no. 13/7264, p. 60; German Bundestag printed paper no. 16/3100, p. 105.

[38] Federal Gazette 1997, BGBl. I p. 1520; for current full English wording of this section, see Appendix.

[39] According to this new section and the relevant Framework Agreement, which was signed by the Bundesarbeitsgemeinschaft Hospiz (now: DHPV) and the Statutory Health Insurance Funds in 1998, the financing relied on multiple sources. See further Hoffmann et al. (2009).

inpatient, homelike facility providing dignified and compassionate care to terminally ill patients, particularly at the end of life, who do not need hospital treatment but who for different reasons cannot adequately be cared for at home or other accustomed surrounding. Rules on the quality of inpatient hospice care are contained in the associated Framework Agreement[40] signed by the National Association of Statutory Health Insurance Funds (Spitzenverband der Gesetzlichen Krankenversicherung—GKV-Spitzenverband) and representatives of main hospice care providers. In the preamble, it emphasizes the aim of inpatient hospice care: provide care and support that improve quality of life of the dying person, do not violate his dignity, and exclude active euthanasia.

This care is being provided by an interdisciplinary team consisting of members of different medical and nonmedical professions and volunteers. A peculiarity of the German system is that the single hospices usually do not have an in-house doctor but work together with local GPs, of whom an increasing number have participated in a palliative care training course.

The financing scheme is different for hospices for adults and for children. In cases of hospices for adults, insurance funds pay 90 % of the costs. The remaining 10 % must be provided by the hospice itself or its owner, as a rule, through donations. In pediatric hospices, 95 % of the costs are covered by insurance funds. Since the revision in 2009, patients are freed from own contributions.

4.2 Outpatient Providers of Palliative Care: Outpatient Hospice Services and Specialized Outpatient Palliative Care Teams

Even though the Federal government initially was against the idea of financing outpatient palliative care services on a regular basis through the system of SHI,[41] it soon had to change its position. Many outpatient hospice groups were already active in the outpatient setting for years, but the supply was far from being nationwide, even though available data suggested that people wanted to spend their end of life at home and avoid unnecessary hospital admissions. Lack of a secure financial basis had an additional negative impact. Therefore, in 2002 the previously mentioned section 39a of the SGB V was amended.[42] The amendment

[40] Rahmenvereinbarung nach § 39a Abs. 1 Satz 4 SGB V über Art und Umfang, sowie Sicherung der Qualität, der stationären Hospizversorgung from 13 March 1998, in its version from 14 April 2010, available at http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/2009-07-23_RV-stationaer.pdf. Accessed 23 September 2013.

[41] Bundestag printed paper no. 13/11459, p. 37.

[42] Section 2 of the Pflegeleistungs-Ergänzungsgesetz from 14 December 2001 (Federal Gazette BGBl. I 3728); for full English wording of this section, see Appendix; for further explanatory information following the Draft, see Bundestag printed paper no. 14/7473, p. 22.

introduced a cofinancing for personal costs of *outpatient hospice services* (ambulante Hospizdienste) that provide qualified accompaniment by volunteers in patients' households or families.[43] The main task of these services is defined as to provide advice on palliative nursing and to assure hiring, training, coordination, and support of volunteers who are ready to accompany a terminally ill person (section 39a II 2 SGB V). Accordingly, the task of the volunteers is to provide emotional, spiritual, and social, but not medical or nursing, support.[44] Like in the case of inpatient hospices, rules on the quality of outpatient hospice services have been fixed in an associated Framework Agreement.[45] Even though it is probably a nonwritten rule of the hospice movement, it is still interesting to see that this agreement does not include an express rejection of active euthanasia, like the previously mentioned agreement on inpatient hospices. For the moment, there are more than 1,500 outpatient hospice services in Germany (including approximately 80 children's outpatient hospice services) involving more than 80,000 volunteers.[46]

Unfortunately, changing section 39a SGB V and introducing a cofinancing for personal costs of outpatient hospice services were by far not enough to reach the desired goal. Because of insufficient symptom control, largely missing specialist support or the time-consuming care of those patients, the assumed wish of staying and being cared at home until death still remained rarely met. In order to change this, in 2007 the German legislator established a claim on specialized outpatient palliative care (spezialisierte ambulante Palliativversorgung—SAPV) for patients with a noncurable, a progressing, or an already far-progressed disease with a limited remaining life span, who are in need of laborious medical treatment (section 37b SGB V).

As provided in section 37b III SGB V, the Federal Joint Committee (Gemeinsamer Bundesausschuss—G-BA), the most important decision-making body in the German health care system, has introduced guidelines on the full particulars of this kind of treatment.[47] The National Association of Statutory Health Insurance Funds (Spitzenverband der Gesetzlichen Krankenversicherung—GKV-Spitzenverband) has further specified particular requirements

[43] Bundestag printed paper no. 14/7473, p. 13. Since 2009, the same counts for nursing homes, institutions for integration of disabled persons, or children and adolescents.

[44] Bundestag printed paper no. 14/7473, p. 22.

[45] Rahmenvereinbarung nach § 39a Abs. 2 Satz 7 SGB V zu den Voraussetzungen der Förderung sowie zu Inhalt, Qualität und Umfang der ambulanten Hospizarbeit from 3 September 2002, in its version from 14 April 2010, available at http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/amb_rahmen_p39a-sgb5.pdf. Accessed 23 September 2013.

[46] Bundesministerium für Gesundheit (2012), p. 2.

[47] Richtlinie des Gemeinsamen Bundesausschusses zur Verordnung von spezialisierter ambulanter Palliativversorgung (Spezialisierte Ambulante Palliativversorgungs-Richtlinie/SAPV-RL) from 20 December 2007, last amended on 15 April 2010, entered into force on 25 June 2010, available at http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/2010-04-15-SAPV-RL.pdf. Accessed 23 September 2013.

on the organization, quality, and standards of SAPV and its providers (see section 132d II SGB V).[48]

SAPV can be provided with varying degrees ranging from one-off counselling to comprehensive palliative care. It is usually being provided by specialized, multiprofessional palliative care services or teams (PCTs) that have signed relevant individual contracts with SHI funds.[49] This practice is often being criticized because current SAPV contracts substantially differ from each other, which may lead to differences in the quality of palliative care provision.[50] The criticism is justified since it is unacceptable to leave an issue, which deeply impacts sensible health objectives and fundamental rights of the patient, to competition between different lobby groups who are negotiating and signing these contracts. The protection of fundamental rights is a government task and not a matter for pressure group politics.[51]

An additional problem is that only patients, whose insurance companies have signed valid individual SAPV contracts with local PCTs, may claim this right. This raises concerns about equitable access to health care. The insured is not entitled to force his statutory insurance to sign such a contract, even if there is an available local PCT.[52]

Nowadays, 6 years after the SAPV claim was introduced by law, specialized palliative care is still not equally available throughout the country. The initial law draft was based on the calculation that one PCT is needed per 250,000 insured persons.[53] Based on that, estimates showed that 330 teams are needed for a nationwide availability of SAPV. Because of the diversity of concepts and organizational structures of SAPV providers, it is unclear what progress has been made in order to achieve this goal. The only empirically provable information is the number of registered codes, so-called Betriebsstättennummern (BSNR). The National Association of SHI Physicians (Kassenärztliche Bundesvereinigung—KBV) issues such a code to a relevant applicant upon his request if he has signed a valid contract with at least one health insurance fund that is in accordance with § 132d I SGB V. According to KBV, they have issued 252 SAPV-specific BSNR codes unequally spread across the different regions (see Fig. 2).[54] However, their distribution gives no information

[48] Empfehlungen des GKV-Spitzenverbandes nach § 132d Abs. 2 SGB V für die spezialisierte ambulante Palliativversorgung from 23 June 2008 in its version from 5 November 2012, available at http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/Palliativ-Empfehlungen-nach-132d-Abs-2-SGB-V_05-11-20102.pdf. Accessed 23 September 2013.

[49] A list of present model contracts (Musterverträge), listed by individual German federal states (Länder), available at http://www.dgpalliativmedizin.de/allgemein/sapv.html. Accessed 23 September 2013.

[50] Jansky et al. (2011), p. 164.

[51] Wodarg (2008).

[52] LSG Nordrhein-Westfalen, decision from 30 March 2009, no. L 16 B 15/09 KR ER.

[53] Bundestag printed paper no. 16/3100, p. 145.

[54] A detailed list of their distribution and further information available at http://www.kbv.de/vl/36178.html. Accessed 23 September 2013. For more information, see also Dielmann-von Berg (2012).

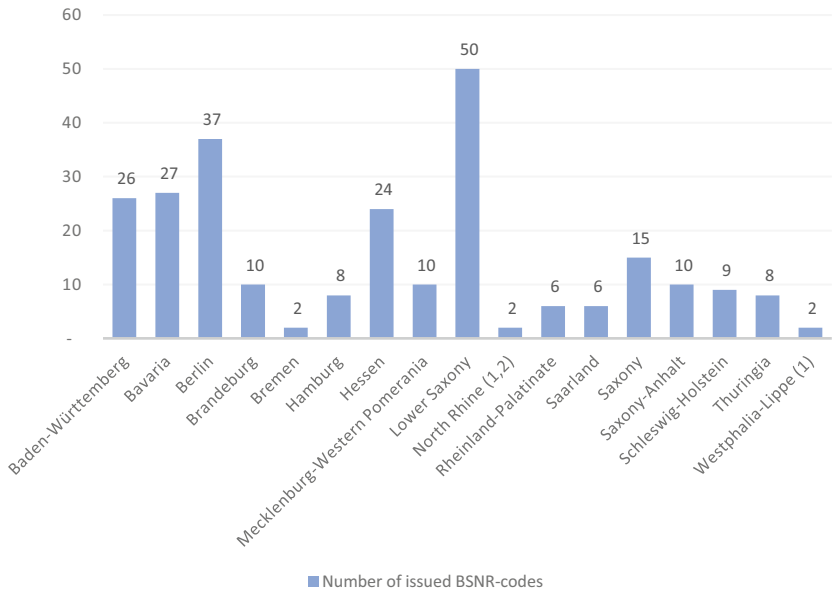

Fig. 2 Regional distribution of registered BSNR-codes for provision of SAPV (last updated: 13 June 2013). Reproduced from National Association of SHI-Physicians (KBV). (1) Regionally specific regulation. (2) Currently 18 palliative care teams are entitled to provide SAPV in the region of North Rhine (status as at 1 January 2013)

about the quality of outpatient palliative care in these regions.[55] In particular, in rural areas the actual implementation of the SAPV claim has hardly made any progress thus far.[56] For several different reasons, availability of SAPV continues to be uneven, although it is growing steadily and spreading to most areas. However, the fact should not be ignored that even if specialized palliative care became fully available in the future, only a relatively small part of the total number of patients with incurable, progressive diseases will benefit from this care.[57]

It is estimated that only 10 % of the incurable, seriously ill, and dying need some form of specialized palliative care.[58] The vast majority of those affected is

[55] While, for example, in Berlin individual physicians who participate in the provision of SAPV have their own individual BSNR codes, elsewhere teams with more than ten physicians have one joint BSNR code. Because of specific regional developments, in the health care region Westphalia-Lippe, no such codes are necessary. In the health care region North Rhine, these codes are being provided by the regional association of SHI physicians (Kassenärztliche Vereinigung Nordrhein—KV Nordrhein). See further Melching (2011).

[56] A detailed map and further information available at Dielmann-von Berg (2012).

[57] Schneider et al. (2010), pp. 66–70

[58] 2.2 II of the Empfehlungen des GKV-Spitzenverbandes nach § 132d Abs. 2 SGB V für die spezialisierte ambulante Palliativversorgung from 23 June 2008 in its version from 5 November 2012, available at http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/Palliativ-Empfehlungen-nach-132d-Abs-2-SGB-V_05-11-20102.pdf. Accessed 23 September 2013.

supposed to be adequately treated within general outpatient palliative care (allgemeine ambulante Palliativversorgung—AAPV). However, there is no official definition of AAPV or a notion of its content. It is only clear that it should be provided by GPs and home care nursing services. However, this artificial division between general and specialized palliative care has triggered many new questions about the quality of life at the end of life.[59]

Persons who exclusively rely on a private insurance for health care (approximately 11 % of the total population) are sometimes also prevented to get appropriate palliative support,[60] even though private insurers have announced to bear the costs for specialized outpatient palliative care.[61]

4.3 Special Case: Health Care Region Westphalia-Lippe

In contrast to the above-mentioned standard practice of individual SAPV contracts, the health care region Westphalia-Lippe has developed a completely different structure of outpatient palliative care services. Their regional association of SHI physicians (Kassenärztliche Vereinigung Westfalen-Lippe—KV Westfalen-Lippe) and SHIs have deliberately decided against individual SAPV contracts and the creation of specialized PCTs.[62] In 2011, after a short test period, they have signed a common permanent contract[63] on the provision of outpatient palliative care in this region. This contract regulates not only the provision of specialized but also general outpatient palliative care. They developed a comprehensive concept that is based on cooperation between resident physicians in general practice (GPs) and specialists and palliative medicine consultancy services (palliativmedizinische Konsiliardienste—PKD), whereas GPs play a very significant role. Therefore, this concept contains no access barriers for GPs. If a GP wants to do so, he may participate in the medical treatment of a particular patient until the end, and it is this physician who decides whether or not to consult or call in a PKD. Westphalia-Lippe has made best progress in developing outpatient palliative care services than any other German health care region. It sounds bizarre that a region that has refused

[59] For further information, see Weihrauch (2012).

[60] For further information, see press releases from the patients' organization IG SAPV '*SAPV und Privatversicherungen*' (28 April 2012) and '*SAPV und Privatversicherungen 2*' (11 June 2012), available at http://www.ig-sapv.de/IG-SAPV/Aktuelles.html. Accessed 23 September 2013.

[61] '*PKV übernimmt Kosten der SAPV*', in: Ärzte Zeitung from 25 June 2009, available at http://www.aerztezeitung.de/praxis_wirtschaft/aerztliche_verguetung/article/554612/pkv-uebernimmt-kosten-sapv.html. Accessed 23 September 2013.

[62] Schlingensiepen (2011).

[63] Vereinbarung zur Umsetzung der ambulanten palliativmedizinischen Versorgung von unheilbar erkrankten Patienten im häuslichen Umfeld, in the health care region Westphalia-Lippe in force since 1 July 2011, available at http://www.palliativ-portal.de/images/pdf/westfalen/sapv-nordrhein.pdf. Accessed 23 September 2013.

individual SAPV contracts and specialized PCTs has the most advanced outpatient palliative care system.

5 Constitutional Basis of Palliative Care Under German Law

Although this is not literally mentioned, it is generally recognized that the right on access to palliative care is based on principles and rights that are guaranteed by the German Constitution. When passing relevant statutory laws on palliative care issues, the German legislator mainly referred to human dignity, right to self-determination, and right to life and physical integrity, as protected under articles 1 I and 2 GG. However, by now German legal scholars have not discussed if the German Constitution is protecting a particular human right to palliative care. Anyway, any discussion on an eventual human right to palliative care needs to make an overall assessment of principles and rights protected by articles 1 I, 2, and 20 I GG.

5.1 Human Dignity and Patient Autonomy

Under the German Constitution, human dignity merits special status distinct from other basic rights or constitutional values. Article 1 I GG reads: Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority.[64] It is considered to be the inherent and inalienable value that belongs to every human being simply by virtue of being human.[65]

There is unanimous consensus that it must be respected and protected also in dying. In this sense, the constitutions of two German states (Länder) are even more concrete, mentioning human dignity in a special context. According to article 8 I 1 of the Constitution of the Land Brandenburg, every person shall have the right to life, physical integrity, and respect for his dignity in dying.[66]

Similar to this, article 1 I of the Constitution of the Free State of Thuringia (Verfassung des Freistaats Thüringen—ThürVerf) reads: Human dignity shall be inviolable. To respect and protect it also in dying shall be the duty of all state authority.

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[64] This norm is directly applicable, and—which is even more important—the German Constitution specifically declares that an amendment affecting basic principles laid down in Article 1 GG is inadmissible (article 79 III GG).

[65] Jacobson (2007), p. 294.

[66] English translation available at http://www.landtag.brandenburg.de/sixcms/media.php/5701/Verfassung_englisch.pdf. Accessed 23 September 2013.

German jurisprudence has hitherto hesitated to determine the normative content of human dignity with a positive approach.[67] Quite the contrary, in their rulings courts primarily decide on when human dignity was violated.[68] When identifying any violations of human dignity, courts first of all follow the so-called object theory (Objektformel). According to it, human dignity as such is affected when a concrete human is degraded to an object, to a mere means, to a dispensable quantity.[69] However, degradation alone does not constitute a violation of human dignity. It is further necessary that either a particular individual is treated in a way that calls into question his quality as a subject or that the treatment in a particular case is showing total disregard of human dignity.[70] It does not take much to realize that such a general concept of human dignity is extremely hard to operationalize.[71] What may compromise it is therefore always a fact-driven analysis of a specific case.[72]

Particularly in the area of care for the vulnerable and the dying, there is an emerging development of different conceptions of human dignity and what is required by respect for it.[73] The possibly most cited attempt at a positive definition comes from the Inquiry Commission Ethics and Law in Modern Medicine, established by the German Bundestag from 2003 until 2005:

> dying with dignity means to be accepted and taken seriously as a human in a surrounding of one's own choice until the end. This means to be accompanied by human and *palliative care*, communication and engagement. Patient's wishes and welfare shall be decisive and binding.[74]

The emphasis of this definition is clearly on patient's right to self-determination, as enshrined in article 2 I in conj. with article 1 I GG. However, by requiring human and palliative accompaniment, communication, and engagement, it simultaneously points out the utmost importance of social responsibility and supportive surrounding, which is necessary in order to enable a patient to exercise his right to self-determination. In its mid-report to the German Bundestag on palliative and hospice care, the Inquiry Commission made several proposals on how to improve quality of

[67] For further information on previous and current attempts of a positive definition, see Herdegen (2013), recital 34 et seq.

[68] In so doing, the courts developed case groups of human dignity violations. For further information on these groups, see Hillgruber (2013), recitals 17-51.1

[69] Dürig (1956), p. 127; Herdegen (2012), recital no. 36. For more information and further references: Will (2011) and Enders (2010).

[70] German Constitutional Court's decision from 15 December 1970, no. 2 BvF 1/69; 2 BvR 629/68; 2 BvR 308/69 = BVerfGE 30, 1 (26).

[71] For a general overview of different conceptions with further references, see Anderheiden (2012), p. 218 et seq. For a comprehensive overview of different worldwide conceptions and, in particular, in care settings, see Jacobson (2007), p. 298 et seq.

[72] German Constitutional Court's decision from 15 February 2006, no. 1 BvR 357/05 = BVerfGE 115, 118 (153) with further references.

[73] For further references, see Jacobson (2007), p. 298 et seq.

[74] Enquete-Kommission des Deutschen Bundestages, Bundestag printed paper no. 15/3700, p. 10.

life and relieve suffering of patients with advanced illness and those close to them.[75] In the report, the Commission rightly emphasized that also at the end of life dignified life is more than self-determined life.[76] It also means recognition, respect, and affection.[77] In this sense, palliative care has been considered to have a strategically important purpose in the broad implementation of the guiding principle of human dignity. Following the Commission's report, the German Bundestag changed the Fifth Book of the German Social Code, introducing a right to specialized outpatient palliative care (section 37b in conjunction with section 132d SGB V).[78] In the explanation of the law draft, it was stressed out that it is a commonly accepted social goal to satisfy human desire to die with dignity, and wherever possible, in one's own familiar domestic surrounding but that this goal was still insufficiently achieved.[79] In this regard, particular attention was paid to pain management and symptom control (section 37b I 1 SGB V).

5.2 *Right to Physical Integrity*

Long before the present German Constitution came into force, German courts have recognized that wrongfully inducing, enhancing, or maintaining pain meets the offense of bodily harm, as defined by section 223 et seq. of the German Criminal Code (Strafgesetzbuch—StGB) and section 823 I of the German Civil Code (Bürgerliches Gesetzbuch—BGB) and that this offense can also be committed by omission and negligence.[80] The same applies to other physical symptoms that may cause unbearable suffering.

No contemporary legal scholar seriously questions that the right to adequate pain and symptom management is a constitutionally protected human right. In this context, it is usually being referred to the right to physical integrity (article 2 II GG).[81] It is considered to be violated in any case when the State takes measures that prevent a disease to be cured or at least alleviated, thus unnecessarily prolonging or maintaining physical suffering.[82] This particularly applies if the State rules out

[75] Enquete-Kommission des Deutschen Bundestages, Bundestag printed paper no. 15/5858, p. 67 et seq.

[76] Ibid., p. 8.

[77] Ibid., p. 8.

[78] For current English translation of this section, see Appendix.

[79] Bundestag printed paper no. 16/3100, p. 105, referring to the mid-report of the Inquiry Commission from 2005 (Bundestag printed paper no. 15/5858, p. 67 et seq.).

[80] BGH decision no. 4 StR 129/95 from 20 July 1995 = NJW 1995, 3194; OLG Hamm decision no. 3 Ss 396/74 from 6 September 1974 = NJW 1975, 604 (605); OLG Düsseldorf decision no. 2 Ss 302/88—266/88 II from 10 January 1989 = NStZ 1989, 269.

[81] Compare for example: Großkopf and Schanz (2005), p. 138; German Federal Administrative Court's decision from 19 May 2005, no. 3 C 17/04 = BVerwGE 123, 352.

[82] German Federal Administrative Court's decision from 19 May 2005, no. 3 C 17/04 = BVerwGE 123, 352.

access to basically available treatment methods aiming at nonnegligible reduction of suffering.[83]

In its report to the UN Human Rights Council from 1 February 2013, the Special Rapporteur on torture and other cruel, inhuman, or degrading treatment or punishment, Juan E. Méndez, for the first time stated that denial of health care might not only essentially interfere with the right to health:

> Medical care that causes severe suffering for no justifiable reason can be considered cruel, inhuman or degrading treatment or punishment, and if there is State involvement and specific intent, it is torture.[84]

In Germany, there is increasing recognition[85] that article 2 II, in conjunction with article 1 I GG, guarantees pain treatment as a particular human right. In this sense, former Federal judge Klaus Kutzer was one of the first jurists who back in the 1990s[86] highlighted the legal importance of pain relief for dignified life: treatable, unbearable suffering must be relieved for the sake of human dignity.[87] He rightly pointed out that severe pain, which a patient might perceive as unbearable, can destroy the personality of that patient and violate his dignity by degrading him into a mere object and disabling him to accept his suffering.[88] Referring to his opinion, the German Federal Court of Justice (Bundesgerichtshof—BGH) later judged that the legal interest of enabling death with dignity and freedom from pain in accordance with the declared or presumed will of a patient is of higher value than the prospect of having to live a bit longer, suffering most difficult, especially so-called excruciating pain.[89] This aspect is of particular importance in the context of palliative care.

5.3 Welfare State Principle (Sozialstaatsprinzip)

Article 2 II GG and the welfare state principle (article 20 I GG) oblige the State to provide access to vital medical care to everyone regardless of age and income.[90]

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[83] Ibid.

[84] Report of the Special Rapporteur (2013), p. 9.

[85] For example: Zenz and Rissing-van Saan (2011), p. 384; Kutzer (2010).

[86] See for example: Kutzer (1991), p. 55; Kutzer (1994), p. 115.

[87] In the years before that, German criminal courts have of course many times recognized that wrongfully inducing, enhancing, or maintaining pain meets the offense of assault, which can also be committed by omission and negligence. However, they usually discussed it in the context of the criminal and tort law and not referring to human dignity as contained in article 1 I of the German Constitution.

[88] Kutzer (1994), p. 115; Kutzer (1991), p. 55.

[89] BGH decision from 15 November 1996, no. 3 StR 79/96 = BGHSt 42, 301 (305), referring to Kutzer (1994), p. 115. See also: German Federal Administrative Court's (Bundesverwaltungsgericht = BVerwG) decision from 19 May 2005, no. 3 C 17/04 = BVerwGE 123, 352.

[90] Steiner (2011), recital 5, referring to judgments of the German Constitutional Court = BVerfGEn 115, 25 (43); 123, 186 (242).

This also applies at the end of life. Within the welfare state concept of the German Constitution, protection of an individual in cases of illness is deemed to be a core responsibility of the State.[91] The legislator meets this task primarily by introducing and regulating the SHI. However, this task to provide vital medical care does not mean that SHI funds are obliged to cover each possible measure.[92] They are allowed to decide subsequently to an economic evaluation (section 12 SGB V—Wirtschaftlichkeitsgebot/efficiency principle),[93] but economic reasoning shall not cancel the core of basic human rights.[94] In cases near the end of life, this may cause severe conflicts between patients and their insurance funds. In 2005, the German Constitutional Court (Bundesverfassungsgericht—BVerfG) had to decide if a SHI fund of a patient, who was suffering from a life-limiting illness, had to meet the costs of a previously nonapproved treatment. In the particular case, the plaintiff (born in 1987) was suffering from Duchenne's muscular dystrophy, which usually significantly influences life expectancy and quality of life. From 1992 to 1994, he was treated by a specialist in general medicine, who was not an SHI-accredited doctor. For this treatment, he used certain procedures that are not accepted in the traditional medical science, such as the use of high-frequency vibrations (bioresonance therapy). In spite of the fact that the real and perceived impact of the treatment on the plaintiff's medical condition was positive, his health insurance fund rejected his application to reimburse the costs. It held that the therapeutic success of the used methods has not been scientifically proven.[95]

The Court decided in favor of a constitutional complaint of the patient. According to the Court's decision, it is not compatible with fundamental rights that are guaranteed under article 2 I, in conjunction with article 1 I GG (right to self-determination), the welfare state principle, and article 2 II GG (right to life and physical integrity), to reject reimbursement of a treatment that has been chosen by an insured patient and applied by a physician, if there is some noticeable prospect of cure or positive influence on the disease process.[96] What counts is the effect that a treatment has in each individual case.[97] This reimbursement rule only counts for

[91] Ibid.

[92] BVerfG decision from 6 December 2005, no. 1 BvR 347/98 = BVerfGE 115, 25 with further references.

[93] Compare also BVerfG decision no. 1 BvL 28/95/1 BvL 29/95/1 BvL 30/95 from 17 December 2002 = BVerfGE 106, 275 (277, 303, 308).

[94] Compare '*Ökonomie darf das Menschenrecht auf Schmerzfreiheit nicht aushebeln*', in: Medical Tribune Kolloquium no. 3/2010, pp. 6–7.

[95] BVerfG decision no. 1 BvR 347/98; from 6 December 2005. For further information on the case, see: Bohmeier and Penner (2009), pp. 65–77.

[96] Ibid.

[97] Ibid.

patients for whose life-limiting or usually fatal disease there is no other generally accepted treatment that meets the medical standards.[98]

Serious objections to the Court's criteria have been expressed by medical and legal experts who contend that the Court has disregarded patients' protection against unknown risks and 'quackery', as well as the incalculable financial effects on the community of insured.[99]

In 2010, BVerfG passed another important judgement, stating that article 1 I, in conjunction with article 20 I GG, guarantees every needy person the material conditions that are indispensable for his physical existence and for a minimum participation in social, cultural, and political life.[100]

It, therefore, guarantees a particular basic right to a subsistence minimum (Existenzminimum) that is in line with human dignity. According to the Court's decision, this individual right is violated when a person lacks the necessary financial resources for the aforementioned minimum participation. According to the prevailing opinion, this subsistence minimum also includes provision of a vital medical subsistence minimum, whereas some authors additionally deduce this from article 2 II GG, but with the same result.[101]

5.4 Palliative Care as a Human Right?

According to the Federal Health Ministry, nowadays there is a broad consensus, crossing all party lines, on the request to develop needs-based palliative care in Germany.[102] However, hitherto legal rules on the provision of palliative care and the accompanying organizational models often were introduced following the bottom-up principle. Especially at the beginning of the legislative process, the German Bundestag did not really act in an anticipatory way but was rather gradually reacting to the already existing structures, especially of the lay hospice movement. Meanwhile, the German legislator passed several simple laws regulating different aspects of palliative care and thus strengthened its legal basis. The above-mentioned constitutional rules and requirements have step-by-step been

[98] Following this decision, in 2011 the G-BA changed its guidelines for medical diagnosis and treatment methods (Gemeinsamer Bundesausschuss (G-BA) 2011b); for further information, compare also BVerfG decisions no. 1 BvR 2496/07 from 29 November 2007 (supplementary to the BVerfG-decision from 6 December 2005, no. 1 BvR 347/98) and no. 1 BvR 3101/06 from 6 February 2007 (specifying the time proximity of the beginning of a life-threatening condition).

[99] Burkhard (2006), p. 181, with further references.

[100] BVerfG decision from 9 February 2010, no. 1 BvL 1/09, 1 BvL 3/09, 1 BvL 4/09 = NJW 2010, 505. See also the accompanying English press release no. 5/2009 of 9 February 2010, concerning this judgment, available at http://www.bundesverfassungsgericht.de/en/press/bvg10-005en.html. Accessed 23 September 2013.

[101] Neumann (2006), p. 393, with further references.

[102] Bundesministerium für Gesundheit (2012) p. 2.

specified in several, already mentioned, simple law provisions, in particular within the Fifth Book of the German Social Code. In spite of numerous laws regulating palliative care issues, the German legislator never discussed the existence of a particular human right on palliative care.

However, this question is gaining more importance since several influential international NGOs[103] are currently promoting the Prague Charter,[104] aiming to urge governments to introduce or change regulations in order to relieve suffering of patients with life-limiting or terminal illnesses and ensure access to palliative care. One of the main objectives of the Prague Charter is the acknowledgment of palliative care as a human right. German key associations, like the DGP or DHPV, also promote it, advocating the existence and acknowledgment of a particular human right on palliative care.

By now, German scholars have not discussed if the German Constitution contains a particular human right on palliative care. However, any future discussion on this issue must consider the aforementioned rulings of the German Constitutional Court.

Some scholars already argue that article 1 I, in conjunction with the welfare state principle (article 20 I GG) and article 2 II GG, also guarantees a particular constitutional right to pain treatment.[105] In this sense, they refer to the aforementioned decision from 2010, guaranteeing every individual a right to a minimum participation in social, cultural and political life.[106] As they rightly point out, pain treatment is an essential part of the subsistence minimum. It is indeed impossible to have a minimum participation in social, cultural and political life if somebody is suffering unbearable pain caused by a life-limiting disease. This applies all the more in cases when patients wish to die in order to escape unbearable suffering, although the level of suffering could be alleviated.[107] Since unbearable suffering might also be caused by other, in particular physical, symptoms, this notion of a right to a subsistence minimum should be extended to these states of suffering and not only to the physical symptom of pain.

Nevertheless, what does this mean for palliative care? An eventual basic right on pain relief or symptom management cannot automatically be equated as a right on palliative care. Palliative care is more than pain management and symptom control, since it also contains psychological, spiritual, and emotional aspects. Therefore, it

[103] European Association for Palliative Care (EAPC), International Association for Palliative Care (IAHPC), Worldwide Palliative Care Alliance (WPCA), and Human Rights Watch (HRW) are working together to advocate for access to palliative care as a human right. Full text of the Charter and further information available at http://www.eapcnet.eu/Themes/Policy/PragueCharter.aspx. Accessed 23 September 2013.

[104] Compare also the Declaration of Montréal that Access to Pain Management Is a Fundamental Human Right from 2010, available at http://www.iasp-pain.org/Content/NavigationMenu/Advocacy/DeclarationofMontr233al/default.htm. Accessed 23 September 2013.

[105] Kutzer (2010), p. 12; Penner and Bohmeier (2011), pp. 526–535.

[106] Ibid.

[107] Penner and Bohmeier (2011), pp. 526–535

would be wrong to reduce palliative care to pain relief and symptom management. Opponents of such an equation rightly object that this would only be a reduction to one of its parts, thus possibly leading to a medicalization of death. It is a legitimate question whether palliative medicine itself (unintentionally) contributes to a medicalization of end of life by focusing on pharmacological measures for pain control and symptom management in its research projects. The German Government also raises this question in its Sixth Report on the Elderly.[108]

Having in mind the goal of palliative care, it is reasonable to ask if article 1 I, in conjunction with the welfare state principle (article 20 I GG) and article 2 II GG, guarantees not only a particular right to pain treatment but also a particular human right to palliative care. The above-mentioned decision from 2005[109] might be an argument in favor of the existence of such a particular right. By obliging SHIs to bear the costs for procedures that are not even accepted in the traditional medical science, the Court has significantly strengthened the rights of insured patients. Thus, it gave primacy to individual's quality of life over strictly scientific reasoning. As already mentioned, the Court stated that in cases of life-limiting or usually fatal diseases, particular treatment costs must be reimbursed for the sake of fundamental rights that are guaranteed under article 2 I in conjunction with article 1 I GG (right to self-determination), the welfare state principle and article 2 II GG (right to life and physical integrity), if there is no other generally accepted treatment that meets the medical standard and if the patient feels noticeable prospect of cure or positive influence on his disease process.

6 Controversial Medical Measures

6.1 Artificial Nutrition and Hydration

Only rarely an issue is discussed as emotionally as admissibility of withdrawing or withholding artificial nutrition and hydration at the end of life. Deciding about these medical measures is particularly challenging when a patient cannot communicate his current wishes due to a terminal illness, advanced dementia, or persistent vegetative state. Legal representatives, family members, or other persons affected often agonize over this question, since they intuitively perceive withdrawing or withholding of nutrition and hydration as letting someone starve or die of thirst.[110]

[108] Bundestag printed paper no. 17/3815, p. 178. See further: Goh (2012).

[109] BVerfG decision from 6 December 2005, no. 1 BvR 347/98 = BVerfGE 115, 25.

[110] May (2001), p. 257 et seq.; Friedrichsen (2009), pp. 52–54, with further references. For further information, see also the BtPRAX online lexicon, containing a comprehensive list of important judicial decisions regarding the withdrawal or withholding of nutrition and hydration and other end-of-life issues, available at http://www.bundesanzeiger-verlag.de/betreuung/wiki/Sterbehilfedokumente. Accessed 23 September 2013.

Decisions on their provision bear additional conflict potential, since many religious traditions consider provision of food and water, in whatever form, as basic care, thus suggesting that the provision of such care to patients who are incapable to eat and drink on their own should be considered mandatory. This is also Vatican's traditional position, having strong influence on the Italian legislative branch considering end-of-life issues. On this issue, the situation in Germany is different. Here, too, it is mandatory to provide the patient with basic care,[111] which may include dignified lodging, attention, grooming, relief of pain, dyspnoea, and nausea, as well as alleviation of hunger and thirst. However, the latter means careful feeding by hand and not by artificial nutrition and hydration, which is considered to be a medical intervention. Like any other medical intervention, it may only be conducted if there is a medical indication for its provision and if the physician obtains patient's valid consent. If a competent patient refuses, or if a legal representative refuses on behalf of an incompetent patient, the physician must withhold or stop its provision. Moreover, except in some extremely rare cases, German palliative care professionals strongly oppose the use of artificial nutrition and hydration in the terminal phase,[112] in cases of advanced dementia or persistent vegetative state. In this regard, the opinion of Borasio and de Ridder has become generally accepted: patients who are in the terminal phase usually feel no thirst or hunger that would justify provision of artificial feeding or hydration.[113] Quite the opposite: there seems to be strong evidence that in the terminal phase those measures are rather harming than alleviating.[114] In cases of advanced dementia, artificial nutrition and hydration lack medical indication: Available studies have provided no evidence that the aspired goals can be achieved with this medical measure. They found no differences in terms of life prolongation, improvement of the nutritional status, quality of life, better wound healing, or decrease of the suffocation risk.[115]

Nevertheless, every year, approximately 140,000 patients receive a PEG tube in Germany. Most of them, more than 70 %, are in senior citizens' residential and nursing homes in cases of patients suffering dementia,[116] thus minimizing nursing care requirements. In this context, a general improvement of palliative care skills and knowledge of all staff groups is necessary.

[111] BÄK (2011), p. A 346.

[112] Ibid., p. A 347.

[113] Borasio (2009) and de Ridder (2009).

[114] Müller-Busch (2004a), pp. 107–112; Müller-Busch (2004b), pp. 369–377; Strätling et al. (2005), pp. A-2153/B-1814/C-1718, with further references.

[115] Borasio (2009).

[116] Strätling et al. (2005), p. A-2153, with further references.

6.2 Palliative Sedation

Nowadays, comprehensive palliative care has been accepted as the most appropriate standard of care for relief of suffering near the end of life. Its supporters even believe that proper palliative care makes active euthanasia and physician-assisted suicide unnecessary. However, it must be noted that the dividing line is sometimes blurry. This is particularly the case when physicians strive to alleviate severe suffering at the end of life by conducting palliative sedation—maybe the most controversial aspect of palliative care. In the context of palliative medicine, palliative (or therapeutic) sedation is defined as the monitored use of medications intended to induce a state of decreased or absent awareness (unconsciousness) in order to relieve the burden of otherwise intractable suffering in a manner that is ethically acceptable to the patient, family, and health care providers.[117]

Indeed, critically ill patients with severe refractory symptoms may be alleviated effectively with this medical measure. This is also the reason why hospices, palliative care services, and palliative and intensive care hospital wards throughout the world commonly practice it. However, there is a gray area in end-of-life care between treatments administered to relieve pain and suffering and those intended to hasten death,[118] especially if sedation is being conducted at the same time as cutting off other medications or removing a patient's feeding tubes.

In recent years, several documents containing procedural guidelines or recommendations on the use of palliative sedation have been published in order to highlight its importance and limits in palliative care and avoid undesirable developments.[119] According to them, there are basically three levels of sedation:

- Intermittent (partial), reversible, low sedation;
- Continuous, reversible, low sedation;
- Continuous, irreversible, deep sedation.[120]

The level of sedation should be the lowest necessary to provide adequate relief of suffering. The last form should only be considered if the prior two levels were ineffective and when the patient is in the very terminal stages of his illness with an expected prognosis of hours or days at most. Only exceptionally it may be selected first in the setting of an end-of-life catastrophic event. For example:

EAPC requirements are: (1) the suffering is intense; (2) the suffering is definitely refractory; (3) death is anticipated within hours or a few days; (4) the patient's wish is explicit and (5) in the setting of an end-of-life catastrophic event such as massive hemorrhage or asphyxia.[121]

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[117] Cherny et al. (2009), p. 581; EAPC (2010), p. 342.

[118] Sprung et al. (2008).

[119] For example: Cherny et al. (2009) and Neitzke et al. (2010).

[120] Neitzke et al. (2010), p. 141.

[121] Cherny et al. (2009), p. 586.

Regarding its legal permissibility under German law, it must be stated that the same requirements apply to palliative sedation as to any other medical measure. As such, it follows the same legal rules. First and foremost, the physician must evaluate and decide if this measure is medically indicated. In the second step, he must obtain the patient's valid consent.[122] If it is the desire of a severely suffering patient, then it is legally necessary and legitimate to give absolute priority to pain relief and symptom management, even if it is clear that this kind of treatment is likely to hasten death. The absolute limit of any pain and symptom treatment desired by the patient is the provision of § 216 of the German Penal Code, concerning killing on request. Especially, the last form of continuous, irreversible, deep sedation raises concerns about its legal permissibility due to its high potential of misuse. After all, it is being provided with the intention to keep it up until death occurs. For this reason, it is justifiable to use the term terminal rather than palliative sedation for this form. Due to its lethal outcome, it is highly questionable if this form of sedation is ever indicated.[123] The physician at least risks to be accused of killing on request or even murder.[124] In this context, it must also be emphasized that some medical professionals criticize the legal discussion on so-called indirect euthanasia. In contrast to earlier views, they point out that opiates (e.g. morphine) or benzodiazepines, if properly administered, do not hasten but rather slightly postpone death. However, many still acknowledge the existence of cases of indirect euthanasia but consider it to be extremely rare, if medication is being administered properly.

7 Future Developments and Challenges

In April 2012, German media reported of a case of a 73 year-old woman who was suffering from lung cancer.[125] She was residing in a nursing home, which was informed that a local specialized palliative care service has been providing her on-site palliative care for quite some time. Being fully aware of her life-limiting disease, she anticipated her treatment preferences. Therefore, her nursing home medical record contained a remark that in case of emergency, she refused any replacement to a hospital and wanted the local outpatient palliative care service to be contacted. One night, the woman experienced acute breathlessness, and the night nurse did not call the above-mentioned service but rather contacted the general medical emergency service (Ärztlicher Notdienst), thus intentionally ignoring the

[122] For further information, compare also Beckmann (2009) and Salkic and Zwick (2012).

[123] Same doubt raised by Holtappels and Behringer (2012), p. 20.

[124] The German physician Mechthild Bach committed suicide in 2011 after being charged of murder in several cases. '*Internistin Mechthild Bach ist tot – Suizid*', in: Ärzte Zeitung online 24 January 2011. http://www.aerztezeitung.de/panorama/article/638048/internistin-mechthild-bach-tot-suizid.html. Accessed 23 September 2013

[125] Schlingensiepen (2012) and Augstein (2012).

remark in the medical record. The doctor correctly identified that she was in the terminal delirium and prescribed the right medication, leaving her in the nursing home according to her anticipated will. She died 2 h later having a good symptom control. Even then the night nurse did not call the palliative care network but the ambulance. Despite a telephone conversation with his palliative care colleague, the emergency doctor called the police, arguing that he could not know what had been administered to the patient.[126] The prosecutor's office initiated a death investigation procedure and the body was not released for burial, which was an additional shock to the relatives. Only a day after, the body was returned to the family.

This recent case from the German city of Witten is a prime example that in spite of the numerous legal changes during the last few years, even persons who work in the health care system still lack basic legal and professional knowledge regarding palliative care and the correct treatment of dying patients, thus causing unnecessary suffering. In many other cases, treatment often ends with unwanted hospital admissions.

In spite of numerous legal changes, there is still a long way to go until palliative care becomes available to every patient who needs it.[127] Germany's palliative care development continues to be uneven,[128] even though the number of adequate services has increased significantly. This case also urgently emphasizes how important it is to achieve broad acceptance of palliative care not only in the political arena but also in society and—most of all—in health care branches that are not particularly specialized in palliative care. In 2010, in order to change this and promote the possibilities and access to palliative care, DGP, DHPV, and the German Medical Association (Bundesärztekammer—BÄK) have initiated the Charter for the Care of the Critically Ill and the Dying in Germany.[129] It is Germany's contribution to the Budapest Commitments, a European and international framework for palliative care development, which several professional palliative care organizations[130] have launched at the EAPC Budapest Congress in June 2007.[131] The aim is to encourage national associations to commit themselves for one or several achievable goals in the development of palliative care in the respective countries.[132]

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[126] Augstein (2012).

[127] Müller-Busch (2009), p. 308.

[128] Compare also Martin-Moreno et al. (2008).

[129] Charta zur Betreuung schwerstkranker und sterbender Menschen in Deutschland, available at http://www.charta-zur-betreuung-sterbender.de/tl_files/dokumente/Charta_Broschuere.pdf. Accessed 23 September 2013; for further information, see Nauck and Dlubis-Mertens (2011), pp. 176–178.

[130] It is a collaboration between the EAPC, the International Association for Hospice and Palliative Care (IAHPC), and the World Palliative Care Alliance (WPCA).

[131] European Association for Palliative Care (EAPC), International Association for Hospice and Palliative Care (IAHPC), Worldwide Palliative Care Alliance (WPCA) 2007: Budapest commitments—a framework for palliative care development. http://www.eapcnet.eu/Themes/Policy/Budapestcommitments.aspx. Accessed 23 September 2013.

[132] Budapest Commitments at the EAPC Congresses. Report from Trondheim, 29–31 May 2008, available at: http://www.eapcnet.eu/Themes/Policy/Budapestcommitments/BCatEAPCcongresses.aspx. Accessed 19 June 2013.

Following this goal, 50 relevant German health care and sociopolitical institutions and organizations consensually approved and initiated the mentioned Charter. By mid-September 2013, 680 institutions[133] and 3,567 individuals[134] have signed the Charter.

Like in many other countries, in Germany palliative care is mainly being provided to cancer patients (and their families). Meanwhile, there is unanimous agreement that it shall be extended to other patient groups.[135] Especially older people with progressively evolving disabilities or dementia are often being neglected, even though they are in urgent need of palliative care. Even though the state is particularly obliged to protect the dignity of people who are in vulnerable situations, primarily determined by age-related disease and disability,[136] the reality is somewhat different. Acknowledging that in nursing homes for the elderly and home care patients rarely receive palliative or spiritual care for the dying, the Robert Bosch Foundation started its program Palliative Care for Senior Citizens.[137] It also includes an educational initiative for nursing home staff (caregivers, nurses, and head of nursing staff) and general practitioners, focusing on improving palliative care in Germany for people with dementia.[138] It is currently being implemented countrywide.

Moreover, the modern palliative approach goes beyond the actual phase of death and includes also earlier stages of chronic diseases. In Germany, this new conceptual approach must gain much higher recognition in general practice. Article 8 of the Charter of Rights for People in Need of Long-Term Care and Assistance (Pflege-Charta),[139] first published in 2007 by the German Federal Ministry of Family Affairs, Senior Citizens, Women, and Youth and the German Federal Ministry of Health, is only one step made into that direction. Under the heading Palliative Support, Dying and Death, it states that everyone in need of long-term care and assistance has the right to die in dignity.[140]

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[133] A comprehensive list of institutions that have signed the Charter available at: http://www.charta-zur-betreuung-sterbender.de/tl_files/dokumente/Charta-Unterstuetzer-Institutionen.pdf. Accessed 19 June 2013.

[134] A comprehensive list of institutions that have signed the Charter available at: http://www.charta-zur-betreuung-sterbender.de/tl_files/dokumente/Charta-Unterstuetzer-Einzelpersonen.pdf. Accessed 19 June 2013.

[135] '*Sechster Bericht zur Lage der älteren Generation in der Bundesrepublik Deutschland – Altersbilder in der Gesellschaft*' (Bundestag printed paper no. 17/3815, p. 178 et seq.).

[136] BVerfG decision from 3 April 2001, no. 1 BvR 2014/95 = BVerfGE 103, 197 (221).

[137] More information on this program available at http://www.bosch-stiftung.de/content/language2/html/6780.asp. Accessed 19 June 2013.

[138] Robert Bosch Foundation. Palliative care curriculum 2010, http://www.bosch-stiftung.de/content/language2/html/13157.asp. Accessed 23 September 2013

[139] English wording available at http://www.pflege-charta.de/fileadmin/charta/pdf/Die_Charta_in_Englisch.pdf. Accessed 19 June 2013.

[140] Ibid.

The acceptance of this Charter is steadily growing. Several regional or federal explanatory memoranda to the legislation refer to it.[141] In addition, it was one of the reference documents for the European Charter of the Rights and Responsibilities of Older People in Need of Long-term Care and Assistance, which was developed in the context of the EU project A European Strategy to Combat Elder Abuse (EUSTACEA).[142]

Additionally, it is of particular importance and challenging to answer the question on how to ensure social cohesion and access to palliative care to individuals who have fallen out of the system of SHIs or who have never been part of it, like travellers, homeless, people who were excluded from the SHI for not paying, etc. Due to the fast growth of palliative care structures and definitive trend towards formalizing the role and tasks of all persons involved in palliative care services—including hospice volunteers—the financial scheme gains additional importance. The absence of specific reimbursement provides a disincentive for palliative care providers to take care of these extremely vulnerable members of society. This is highly problematic when one considers that provision of palliative care often means enabling death with dignity, like in cases of excruciating pain or otherwise unbearable suffering.

Finally, achieving the best possible quality of life for children with life-threatening conditions and their families remains highly challenging. Every year 3,500 children die in Germany due to severe illness.[143] In spite of that, in 2011, SHI funds financially supported only 267 children and adolescents with specialized outpatient palliative care services.[144]

At present, there are 12 inpatient children's hospices and 108 outpatient children's hospice services that provide support for children and their families at home or in other familiar settings.[145] Generally, the same legal regulations apply to children's palliative care providers as for adults. In the applicable legal provisions, it is only stressed out that due attention is to be paid to special children's needs.[146] One such special need is the early integration in palliative care. Pediatric palliative care indeed differs from palliative care for adults. According to the WHO definition, palliative care for children is the active total care of the child's body, mind, and spirit and also involves giving support to the family. It begins when illness is diagnosed and continues regardless of whether or not a child receives treatment directed at the disease. Health providers must evaluate and alleviate a child's physical, psychological, and social distress. Effective palliative care requires a

[141] A detailed list with further references available at http://www.pflege-charta.de/umsetzung-der-pflege-charta/gesetzliche-bezugnahmen-auf-die-pflege-charta.html. Accessed 19 June 2013.

[142] For more information and further references, see http://www.pflege-charta.de/en/about-the-charter.html. Accessed 23 September 2013.

[143] Führer (2011), pp. 583–596.

[144] Gemeinsamer Bundesausschuss (G-BA) (2011a).

[145] In Germany, the first inpatient children's hospice was founded in 1998. Detailed lists of existing children's hospices and hospice services is available at http://www.deutscher-kinderhospizverein.de/verein/kinderhospizarbeit-in-deutschland/. Accessed 19 June 2013.

[146] See section 39a I 5 SGB V (inpatient children's hospices), section 39a II 8 SGB V (outpatient hospice services) and section 37b I 6 SGB V (specialized outpatient palliative care—SAPV).

broad multidisciplinary approach that includes the family and makes use of available community resources; it can be successfully implemented even if resources are limited. It can be provided in tertiary care facilities, in community health centers, and even in children's homes.[147]

In Germany, early integration is also specified in the already mentioned corresponding framework agreements on hospices[148] and outpatient hospice services[149], as well as the recommendations on specialized outpatient palliative care.[150] The latter, for example, includes the possibility that SAPV teams for adults also support children who are in need of specialized palliative care. The only prerequisite is to hire at least one pediatrician and one pediatric nurse who have specialization in palliative care (point 5.5 of the recommendations). There are considerable doubts if such mixed teams can fulfill the special needs of children with life-limiting diseases and their families.[151]

However, especially specialized outpatient services face problems that threaten their existence. Due to their special needs, comprehensive support of these children and their families causes annual costs of approximately 500,000 euros per team.[152] But the finances are lacking, which is why the current children's palliative care teams have to compensate several hundred thousand euros with the help of donations every year. One of the problems seems to be that SHI funds have put their emphasis on services for adults, since children's care is not profitable.[153] In June 2013, relevant stakeholders have adopted joint recommendations on the arrangement of SAPV concepts for children and adolescents in order to improve the currently deficient palliative care service for this group of patients.[154]

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[147] World Health Organization (1998), p. 8.

[148] Preamble and section 2 I c of the Framework Agreement (Rahmenvereinbarung nach § 39a Abs. 1 Satz 4 SGB V über Art und Umfang, sowie Sicherung der Qualität, der stationären Hospizversorgung) from 13 March 1998, in its version from 14 April 2010, available at http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/2009-07-23_RV-stationaer.pdf. Accessed 23 September 2013.

[149] Rahmenvereinbarung nach § 39a Abs. 2 Satz 7 SGB V zu den Voraussetzungen der Förderung sowie zu Inhalt, Qualität und Umfang der ambulanten Hospizarbeit from 3 September 2002, in its version from 14 April 2010, available at: http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/amb_rahmen_p39a-sgb5.pdf. Accessed 23 September 2013.

[150] Empfehlungen des GKV-Spitzenverbandes nach § 132d Abs. 2 SGB V für die spezialisierte ambulante Palliativversorgung from 23 June 2008 in its version from 5 November 2012, available at: http://www.dhpv.de/tl_files/public/Service/Gesetze%20und%20Verordnungen/Palliativ-Empfehlungen-nach-132d-Abs-2-SGB-V_05-11-20102.pdf. Accessed 23 September 2013.

[151] More on this: Gottschling (2012), p. 1.

[152] DGP (2011).

[153] Dielmann-von Berg (2013).

[154] Empfehlungen zur Ausgestaltung der Versorgungskonzeption der Spezialisierten ambulanten Palliativversorgung (SAPV) von Kindern und Jugendlichen from 12 June 2013, available at: http://www.dgpalliativmedizin.de/images/stories/Empfehlungen_zur_Ausgestaltung_der_Versorgungskonzeption_der_Spezialisierten_ambulanten_Palliativversorgung_von_Kin.pdf. Accessed 23 September 2013.

8 Conclusion

There are not that many countries in Europe where official policymaker paid so much attention to strengthening and establishing palliative care in order to improve the quality of life of the severely or chronically ill or dying, as in Germany. Since 1997, necessary laws and regulations have been discussed and introduced. Parliamentary documents and debate transcripts prove that human dignity has been and still is one of the major considerations and motives applied throughout the process of passing and/or debating legal provisions on end-of-life issues. Yet, it seems that the stakeholders never really engaged in a discussion about the dignity itself. Rather, it appears to have been accepted as an intuitively clear concept—at least in the field of end-of-life care.

Essential legal points have been set. However, there is still a long way to go before palliative care is available to all who need it. Now, the practical impact of the introduced legal regulations must be empirically evaluated in order to determine to what degree the targeted objectives have been achieved and if they need to be changed or further improved, which is very likely—at least in the field of outpatient palliative care.

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End-of-Life Care and the Economics of Living Wills

Marcus Oehlrich

Abstract Living wills are not only of legal and bioethical interest; they may also foster the costs of the health care system in the event that they exclude a refusal of end-of-life-treatment. Whereas in Germany and Italy the economic aspects of living wills have been widely neglected so far, in the US there exists a huge body of controversial literature. However, cost arguments in favor of the legal institution of living wills are not corroborated by empirical findings. In contrast, as health economic research shows, an effective living will enhances the utility of the individual, his family, and even the society by underpinning the right of self-determination. In comparison of the three countries, it was shown that the valuation of this right is open to cultural and religious arguments. This study recommends accounting for the necessity of the correct drafting of an individual living will. There are several alternatives to deal with the resulting problems, which are handled differently in Germany, Italy, and the US.

Contents

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1 Introduction

The public debate on health and health care in Germany, as in many other countries, is currently dominated by two major issues: bioethics and medical care under resource scarcity. But while in bioethics[1] soon after the development of appropriate capabilities in biomedical research some workable compromises based on a broad public discussion of their effects have been made, the question how scarce resources should be allocated within the health care system is still unresolved. In contrast to organ transplantation,[2] where a decision on the micro-allocation of transplants obviously must be taken instantly, decisions on the macro-allocation, i.e. the allocation of the available financial resources within the health care system, were mostly delegated to the discretion of the physicians. These are in turn set by cost-containment legislation under an acute pressure to reduce costs. Patients and physicians alike are suffering under the effects of this allocation mechanism. Patients see themselves exposed to a restriction of medical services that conflicts with their needs and may in part be even unlawful. Physicians are in turn placed into a situation in which cost reductions may conflict with medical and ethical standards.

Living wills,[3] however, encompass both topics. They do not only foster bioethical discussion but also influence costs to the health care system. The increase in the

[1] With the Ethics Council Act of 16 July 2007, the German Ethics Council was established as the successor of the National Ethics Council. Its purpose is to pursue the questions of ethics, society, science, medicine, and law and the probable consequences for individual and society that result in connection with research and development, in particular in the field of the life sciences and their application to humanity.

[2] The allocation of organs in Germany is organized by Eurotransplant, which is responsible for the allocation of donor organs in Austria, Belgium, Croatia, Germany, Luxembourg, the Netherlands, and Slovenia. Its allocation system is objective, transparent, reproducible, and valid. It is designed to make the best match possible given the circumstances.

[3] Instead of living wills, also other advance directives could have been investigated. As is laid down in the economic analysis (see infra Sect. 5), only living wills due to their instructional nature can be analyzed in such a way. Thus, noninstructional directives such as proxy directives will be excluded henceforth.

percentage of old people inevitably leads to a further cost explosion in health care because the older people and those towards the end of life account for a considerable proportion of health care costs. Especially in the field of end-of-life treatments, it is often pointed out that patients may see themselves confronted with the refusal of life-sustaining measures due to social pressure and increased financial expenses for an upcoming treatment. This may apply, particularly, because the health benefit of treatment at the end of life, besides palliative care, is often very doubtful.

In particular, the debate on the economic benefits and a burden on the health care system through the provision of legal instruments, which prevent the utilization of medical resources to sustain life, are seen as a taboo. The discussion, thus, is generally hovering around the ethical and moral stance that such decisions are not open to economic arguments. As Ash and Arons state:

> [s]ome people find it unpleasant, even morally offensive, to contemplate how the economics of health care policy might affect end-of-life care, holding that money should not matter when life and death are on the line and that any form of health care 'rationing' may convey a disrespect for human life.[4]

This explains why even in the debate on living wills and the legislation process was far from an argument that is consistent with economic considerations. The German jurists, the medical association, or the political parties did not make this explicit position. Instead, they warned of the use of living wills for cost reduction in the health care system, in conjunction with the advice that doctors should not be guided by cost considerations and should decide taking into account the welfare of the patient.

On the other hand, this does not mean a contradiction, since the likely cause for the institution of living wills is not the reduction of health care costs but patient empowerment because changes in end-of-life care may reduce low productivity, i.e. futile[5] medical treatment. Thus, reallocating scarce resources to other uses could result in an increase in total welfare. Health economics has developed on the basis of microeconomic theory schemes to assess competing medical interventions in order to enable the allocation of scarce resources in health care. Economic evaluation is nowadays particularly interesting for innovative treatments that frequently increase overall treatment costs considerably—as do many beneficial medical interventions. However, due to the general resource constraints in health care, not all interventions that are clinically effective are worth 'doing' either from a payer, provider, or patient perspective. Economic evaluation is a useful tool for making the difficult decisions concerning new interventions in an environment of scarce resources. In contrast to mere discussions on the 'value' of medical interventions, which are often arbitrary, it follows a clear methodology in comparing different programs and in making proposals for the allocation of limited resources. While such evaluations are intended to rationalize by identifying medical

[4] Ash and Arons (2009), p. 306.

[5] See Arons and Wisniewski (2006).

interventions to decrease costs and/or increase consequences, they have not been applied to abstract legal provisions in health care yet but rather for singular interventions.

In comparison with other countries, the latest developments of legislation and legal research on living wills in Germany can be placed in the middle of a continuum of an exhaustive debate. Although the legal institution has been enacted following a fierce and extensive political debate, empirical findings and, especially, economic reasoning have been excluded. On the other hand, in Italy the bill[6] on advance directives encompassing also living wills has just recently been passed only in the Chamber of Deputies (Camera dei Deputati) and, thus, not yet came into force. For an exhaustive discussion of the economic effects of living wills, it does not suffice to include only Germany and Italy. In order to insure this broader type of analysis, a jurisdiction must be included in which also a consideration of the economic perspective has been taken place. Therefore, the situation in the US will be analyzed because there is not only the legal institution of living wills and other advance directives; also their economic effects have been discussed fiercely on a broad basis of empirical data. These empirical findings can be applied to the current state of discussion in Germany and Italy, where such empirical data on the economic effects of living wills do not exist. Furthermore, it is of interest to compare these three countries because they are characterized by ethical and religious arguments. Suffice to note the similarities of the legal and legislative proceedings in the Schiavo (US) and the Englaro (IT) cases.[7]

The aim of this essay will be to provide an overview on the economic effects of living wills. The main issue under question is whether living wills may not only be in the interest of the patient but also result in decreasing or reallocating costs. For the vast majority of people, this question should not even be asked. However, the economic effects of living wills are in the following to be handled not by prescriptive but positive analysis. Economic theory is, therefore, not intended to overturn medical, legal, or ethical arguments. It is rather the case that the effects have not been scrutinized yet. Compared to the US, where the recent legislation on living wills was accompanied by a fierce discussion about its economic reasons, these were completely passed over by the draft bill on living wills in Germany.

Up to now, there has been no study published on the economic effects of living wills in Germany and Italy. Initially, the legislation in the US and Germany is described emphasizing the economic effects widening the view to the situation in Italy. After that, a more general discussion of key principles of economic analyses of living wills is conducted henceforth. Particular emphasis is placed on the selection of appropriate types of evaluations, the viewpoint, and the required data. This essay concludes with a summary.

[6] Bill No. 2350 'Dispositions in matter of therapeutic alliance, informed consent, and advance treatment directives', Disposizioni in materia di alleanza terapeutica, di consenso informato e di dichiarazioni anticipate di trattamento).

[7] See infra Sects. 2 and 4, respectively.

2 Situation in the United States

2.1 The Political Debate on the Advanced Care Planning Consultation Provision for Drafting Living Wills

The bioethical discussion about advance care planning in the US became nationwide at the latest with the fate of Theresa Marie Schiavo, who at the age of 26 suffered from a heart attack resulting in a persistent vegetative state (PVS). Ultimately, the court held Ms. Schiavo's state to be "without hope of ever regaining consciousness".[8] Ensuing, Ms. Schiavo's husband and her parents fought over 5 years for or against the discontinuation of her artificial nutrition and hydration.[9] Even federal and state legislators tried to overrule judicial orders to remove Ms. Schiavo's feeding tube.[10]

The public debate reverted to living wills during the health care reform under the Obama Administration.[11] Its aim was to reform the private insurance system and to introduce a ban on refusals of patients with preexisting conditions and an improvement in the supply of medicines. The law came eventually into force after long negotiations in 2010.[12] One of the many points of contention was Section 1233 of the bill, which was aimed to introduce the so-called advanced care planning consultation to provide Medicare[13] reimbursement for consultations regarding life-sustaining treatment. The first initiative for this amendment of Section 1861 of the Social Security Act enjoyed bipartisan support and was introduced to the House of Representatives on April 2, 2009, as 'Life Sustaining Treatment

[8] In re Guardianship of Schiavo, No. 90-2908GD-003, 2000 WL 34546715, at *4 (Fla. Cir. Ct. Feb. 11, 2000).

[9] In re Guardianship of Schiavo, 780 So. 2d 176, 177–78 (Fla. Dist. Ct. App. 2001). See also Annas (2005), pp. 1710–1715.

[10] Perry (2006), pp. 553–630. See also Schiavo ex rel. Schindler v. Schiavo, 357 F. Supp. 2d 1378 (M.D. Fla. 2005); Schiavo ex rel. Schindler v. Schiavo, 403 F.3d 1223 (11th Cir. 2005), reh'g en banc denied, 403 F.3d 1261 (11th Cir. 2005); Schiavo ex rel. Schindler v. Schiavo, 358 F. Supp. 2d 1161 (M.D. Fla. 2005); Schiavo ex rel. Schindler v. Schiavo, 403 F.3d 1289 (11th Cir. 2005).

[11] For the legal context of palliative care in the US, see Washington v. Glucksberg, 521 U.S. 702 (1997); Vacco v. Quill, 521 U.S. 793 (1997); Gonzales v. Oregon, 546 U.S. 243, 262 (2006). See also the commentary in Burt (1997). However, due to the arbitrariness of the Fifth and Fourteenth Amendment regarding this matter, federal and state laws are divergent. For example, several states such as Oregon and Washington introduced state laws to approve physician-aided dying.

[12] Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2010) (enacted); Health Care and Education Affordability Reconciliation Act of 2010, H.R. 4872, 111th Cong. (2010) (enacted).

[13] Medicare is the federal health insurance for people 65 or older, people under 65 with certain disabilities, or people of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant).

Preferences Act of 2009' (House Bill 1898).[14] The preliminary provisions laid down in House Bill 1898 were incorporated into section 1233 of House Bill 3200, 'America's Affordable Health Choice Act',[15] by July 14, 2009. The final version of this act was House Bill 3962, which passed the House of Representatives on November 7, 2009. It was accompanied by the 'Patient Protection and Affordable Care Act' (House Bill 3590), which passed the Senate on December 24, 2009, and the House of Representatives on March 21, 2010, and was eventually signed by President Obama on March 23, 2010. The 'advanced care planning consultation' was ultimately not included in the final legislation. However, it was implemented indirectly, since it was included in a new Medicare fee schedule for various medical treatments. Thus, the advanced care planning consultation will be included as part of a regular health check.

The mandatory content to be included in these advance care or end-of-life voluntary consultations to be amended in section 1861 of the Social Securities Act was set forth in detail:

(A) An explanation by the practitioner of advance care planning, including key questions and considerations, important steps, and suggested people to talk to.
(B) An explanation by the practitioner of advance directives, including living wills and durable powers of attorney, and their uses.
(C) An explanation by the practitioner of the role and responsibilities of a health care proxy.
(D) The provision by the practitioner of a list of national and State-specific resources to assist consumers and their families with advance care planning, including the national toll-free hotline, the advance care planning clearinghouses, and State legal service organizations (including those funded through the Older Americans Act of 1965).
(E) An explanation by the practitioner of the continuum of end-of-life services and supports available, including palliative care and hospice, and benefits for such services and supports that are available under this title.
(F) (i) Subject to clause (ii), an explanation of orders regarding life sustaining treatment or similar orders, which shall include—

(I) the reasons why the development of such an order is beneficial to the individual and the individual's family and the reasons why such an order should be updated periodically as the health of the individual changes;
(II) the information needed for an individual or legal surrogate to make informed decisions regarding the completion of such an order; and
(III) the identification of resources that an individual may use to determine the requirements of the State in which such individual resides so that the treatment wishes of that individual will be carried out if the individual is unable to communicate those wishes, including requirements regarding the designation of a surrogate decisionmaker (also known as a health care proxy).

(ii) The Secretary shall limit the requirement for explanations under clause (i) to consultations furnished in a State—

[14] H.R. 1898, 111th Cong. (2009). The sponsors of the Bill were Charles Boustany (Republican, LA), Geoff Davis (Republican, KY), Patrick Tiberi (Republican, OH), Ron Kind (Democrat, WI), John Yarmuth (Democrat, KY), and Earl Blumenauer (Democrat, OR).

[15] H.R. 3200, 111th Cong. § 1233 (2009).

(I) in which all legal barriers have been addressed for enabling orders for life sustaining treatment to constitute a set of medical orders respected across all care settings; and
(II) that has in effect a program for orders for life sustaining treatment described in clause (iii).

(iii) A program for orders for life sustaining treatment for a States described in this clause is a program that—

(I) ensures such orders are standardized and uniquely identifiable throughout the State;
(II) distributes or makes accessible such orders to physicians and other health professionals that (acting within the scope of the professional's authority under State law) may sign orders for life sustaining treatment;
(III) provides training for health care professionals across the continuum of care about the goals and use of orders for life sustaining treatment; and
(IV) is guided by a coalition of stakeholders includes representatives from emergency medical services, emergency department physicians or nurses, state long-term care association, state medical association, state surveyors, agency responsible for senior services, state department of health, state hospital association, home health association, state bar association, and state hospice association.

Within the 'advanced care planning consultation', the patient should be advised by his physician, nurse practitioner, or physician assistant about the design of medical treatment at the end of life encompassing an explanation of medical interventions of the continuum of care. This consultation should include living wills, powers of attorney, and the access to possible advice centers for affected persons and their families. It will be accessible for patients in a 5-year cycle. In the event of a change in the state of health such as the diagnosis of a chronic disease, a life-threatening injury, or admission to a nursing home, the consultation can take place outside the 5-year intervals. The costs of the consultation are borne by Medicare, an insurance program of the government that takes care of Americans over 65. As part of the consultation, the patient should be given the opportunity to draft a declaration on the refusal of life-sustaining treatment. In this case, the patient can select from full coverage to the exclusion of some or all of the treatment. This includes, e.g., the waiver to be taken to a hospital or to receive antibiotics.

The bill came especially under fierce criticism from the Republicans. Republican Betsey McCaughey, who already opposed to the Clinton health care reform, spoke of a "vicious attack on the elderly" with the intention to shorten their life. Strikingly, she expressed the opinion that the government would show the elderly how they "can end their lives sooner". She criticized that the scheme creates an intrusion into the privacy of the affected persons. McCaughey's misconception was that the consultation shall be mandatory. Instead, the text of Section 1233 only provisioned voluntarily consultations. Sarah Palin, Vice Presidential candidate in the 2008 elections, claimed that "Obama's death panel"[16] would decide who should die and who is worthy to live.[17] So it was left to the bureaucrats who gets medical

[16] MacGillis (2009), at A01.

[17] Posting of Sarah Palin to Facebook, Statement on the Current Health Care Debate, http://www.facebook.com/note.php?note_id=113851103434 (August 7, 2009, 13:26).

care. John A. Boehner, Republican leader of the House of Representatives, spoke in this context, even from government-supported euthanasia. The President of LifeTree,[18] Elizabeth D. Wickham, criticized that the patient "would lose by section 1233 the ability to control the treatment at the end of his life". In general, the opponents of Medicare reimbursement for the advance care planning consultation portrayed its economic reasoning for living wills as government-promoted euthanasia in order to save money.[19] Even the rhetorical Nazi comparison was quoted by some opponents.[20]

On the other hand, the bill had many advocates. Jon Keyserling, head of the national hospice and palliative organization, emphasized that the law did not urge older people to end their lives but provided them with appropriate advice on important decisions in their lives. He was supported by Jim Dau, a spokesman for AARP,[21] an organization representing the interests of people over 50, stating that the law should ensure that people "make the right decision". Whether they opt for or against life-sustaining treatment is in the hands of the affected persons. The original sponsor of the bill, Congressman Earl Blumenauer, defended the regulation as "a step in the right direction", which gives patients more control over the treatment received. It is designed to bring about regulation that physicians and patients see consultations as integral part of health care so that important decisions were not delayed until one is forced to. The advocates of the provision also emphasized that it was important to decide early on how one wishes to be treated at the end of life in the event that the capacity of the person to decide about such issues decreases, or is even lost at some point in time.

2.2 *Economic Reasoning in Favor of the Advanced Care Planning Consultation*

Although several studies have demonstrated that the Medicare patients who die each year account for a considerable proportion of the program's cost,[22] a consensus, at least in the medical literature, has developed that cost reductions through

[18] LifeTree, Inc., is a 501(c)(3) pro-life Christian educational ecclesiastical ministry. LifeTree's original mission has been expanded into an educational effort to raise awareness throughout North Carolina about the need to protect life, from its earliest beginnings to natural death.

[19] For an overview on the discussion, see MacGillis (2009), p. A01. See also Perry (2006), Perry (2010).

[20] Smith (2009), Hastings (2009).

[21] AARP is a nonprofit, nonpartisan organization with a membership that helps people aged 50 and over have independence, choice, and control in ways that are beneficial and affordable to them and the society as a whole, ways that help people 50 years old and over improve their lives.

[22] Barnato et al. (2004). Zhang et al. (2009).

changes in practices at the end of life (e.g., advance directives, hospice care, and the elimination of futile care) are illusionary.[23] However, President Obama stated that

> [T]he chronically ill and those toward the end of their lives are accounting for potentially 80 % of the total health care bill. [T]here is going to have to be a conversation that is guided by doctors, scientists, ethicists. And then there is going to have to be a very difficult democratic conversation that takes place. It is very difficult to imagine the country making those decisions just through the normal political channels. And that's part of why you have to have some independent group that can give you guidance. It's not determinative, but I think [it] has to be able to give you some guidance.[24]

Zhang et al. explored the differences in the use of life-sustaining medical interventions of cancer patients in the final week of life, depending on whether a previous advance care planning consultation has taken place.[25] The study shows that patients who had previous consultation are more likely to receive palliative care instead of life-sustaining treatment. This resulted also in a cost decrease of over 35 % compared with those who had no previous advance care planning consultation. In addition, the study emphasizes the value of increasing communication between end-stage cancer patients and their physicians leading to a higher quality of life during the final weeks. It is even questioned whether these more intensive and expensive treatments do not only worsen the quality of life but also have any significant result on mean survival.[26] Furthermore, the communication of the desires, needs, and intentions of the individual should begin early and needs to be memorialized in the form of a living will.[27] This communication is, however, undervalued and underfunded by the health care system.[28]

Therefore, if curative end-of-life treatment is more expensive, the refusal of futile interventions by drafting a living will may result in lower costs. As the advance care planning consultation was integrated into Medicare and most authors quote the widely available Medicare data, these data will be investigated in the following. Taking into account all terminal diseases, health care expenditures in the last year of life to be borne by Medicare constitutes about one-quarter of the entire program's cost. Medicare spent $13,316 per elderly insured, while total health care costs per insured accounted for app. $29,300.[29] Although these figures were ascertained in 1988, the proportions remained stable, leading to the stylized fact that 27 % of Medicare costs refer to only those 5 % of Medicare recipients who die

[23] Emanuel and Emanuel (1994), Ash and Arons (2009), Emanuel (1996).

[24] David Leonhardt, After the Great Recession, N.Y. TIMES SUNDAY MAG., May 3, 2009, at 36, available at http://www.nytimes.com/2009/05/03/magazine/03Obama-t.html?pagewanted=1&_r=1.

[25] Zhang et al. (2009).

[26] Id.

[27] Ash and Arons (2009).

[28] Id.

[29] Emanuel and Emanuel (1994).

within 1 year.[30] The criticism of the optimistic assumption that there are substantial cost savings by reallocating from curative to palliative care, however, can be summarized according to Emanuel and Emanuel in five points:

(1) the straightforward error of extrapolating the twenty-seven to thirty percent of Medicare to a similar share of all medical expenditure;
(2) selection bias in observational demonstrations of the low cost of alternative end-of-life care;
(3) the high cost of high-quality alternatives (e.g., hospice based end-of-life care);
(4) the unpredictability of death and the difficulty in advance identification of 'futile' care- in particular using retrospective data; and
(5) the widespread adoption of DNR orders, which limit the application of futile but highly expensive services at the very end of life, may mean that the low-hanging fruit of end-of-life cost savings has already been picked and marginal switching from aggressive to palliative care will yield smaller savings.[31]

There is reasonable evidence that these five points draw a true picture of cost saving opportunities. In general, it is not possible to extend the Medicare figures to the whole population because Medicare recipients die at much higher rates than do the general population.[32] Therefore, the end-of-life expenditure in the national health care bill is substantially lower. Comparing the costs associated with hospice care, there is, however, no clear picture. While one case–control study estimated the cost savings to be at $5000 for Medicare recipients who die in hospice (mainly due to lower ICU usage),[33] other studies have shown even higher costs.[34]

3 Situation in Germany

3.1 The Legislative Process Leading to the Living Will Act

The institution, its compulsory nature, and the reach of living wills have been the subject of a controversial legal review and public discussion, which culminated in the '3rd Act Changing the Custodianship Law (Living Will Act)'.[35,36] Before that, the Federal Court of Justice (Bundesgerichtshof) and the Federal Constitutional Court (Bundesverfassungsgericht) established a general hierarchy of criteria in the

[30] Emanuel (1996), Scitovsky (1994).
[31] Ash and Arons (2009), pp. 316–317.
[32] Emanuel and Emanuel (1994), pp. 540–544.
[33] Morrison et al. (2002), pp. 1783–1790.
[34] Raphael et al. (2001), pp. 458–461.
[35] Drittes Gesetz zur Änderung des Betreuungsrechts, v. 29. Juli 2009 (BGBl. I S. 2286).
[36] See for details the contribution of J. Taupitz in this publication.

event that the patient lost the capability to participate in his health care decisions.[37] In September 2006, the 66th Association of German Jurists voted by a large majority for the promotion of the legal regulation of euthanasia and the binding nature of advance directives.[38]

Furthermore, at least within the last decade before the enactment of the 'Living Will Act', a controversial discussion began.[39] The German Ethics Council has intensively discussed the issues involved in dealing responsibly with dying. It has perused a large volume of material, obtained expert opinions, consulted with doctors and other medical specialists, and held several meetings at which it exposed itself to public debate.[40] Finally, three separate bills were introduced in the Bundestag in order to form the 'Living Will Act', with a wide variation of scope and different levels of requirements for a valid living will. Although none of those quoted economic reasons for introducing the act, they will be analyzed regarding their economic effects in the following discussions.

The so-called Stünker-Draft[41] proposed to introduce living wills in sec. 1901 a Civil Code. These living wills are binding even if they provide for a discontinuation of life-sustaining treatment without limitation of reach to terminal and irreversible diseases. The living will must be in writing and signed personally without requiring a former consultation of a physician or certification of a notary. The Stünker-Draft did not provide for economic reasons besides budgetary effects, which have to be stated in every draft bill. These costs were estimated to stay the same as under the "preliminary" ruling of the Federal Court of Justice.[42] For other parties or consumer prices, no results were expected from the bill. Moreover, the Stünker-Draft did not provide for any financial assistance regarding the costs of drawing up a living will in the event that the individual does not have the financial resources.

The so-called Bosbach-Draft[43] proposed to introduce proxy directives in sec. 1901 a and living wills in sec. 1901 b Civil Code. In comparison with the Stünker-Draft, the reach of living wills was, however, limited by sec. 1901 b (2),(3) Civil Code, which requires for the binding refusal of life-sustaining treatments the former consultation with a physician, the certification of a notary, and a renewal of the

[37] BGH 1 StR 357/97—decision from 13 Sept 1994 = BGHSt 40, 257. BverfG – 1 BvR 618/93—decision from 2 Aug 2001 = NJW 2002, 206. BGH – XII ZB 2/03—decision from 17 March 2003 = BGHZ 154, 205.

[38] Beschlüsse des 66. Deutsche Juristentags. Stuttgart 19 to 22 September, 2006.

[39] See, e.g., Taupitz (2000a, b).

[40] The outcome is enshrined in the Opinion "Self-determination and care at the end of life", published in 2006. Self-determination and care at the end of life continues the examination of the themes addressed in the Opinion "The advance directive", published in June 2005.

[41] This Bill was drafted by the members of parliament Joachim Stünker, Michael Kauch, Dr. Lukrezia Jochimsen, and Jerzy Montag. See Bundestags-Drucksache 16/8442.

[42] See Bundestags-Drucksache 16/8442, p. 12.

[43] The bill was named after its sponsors Wolfgang Bosbach, René Röspel, Katrin Göhring-Eckhardt, Dr. Harald Terpe, Josef Philip Winkler, Otto Fricke, Gerda Hasselfeldt, Dr. h.c. Wolfgang Thierse, Volker Kauder, and Renate Künast. See Bundestags-Drucksache 16/11360.

living will in a 5-year cycle. Written living wills that do not fulfill these requirements are only binding in the event of a terminal and irreversible disease. Furthermore, the bill provided for an amendment of Social Security Code 5 in order to entitle the insured individuals for a medial consultation to be chargeable to the social security system[44]:

§ 24 c Consultation for a Living Will

> In order to establish a living will insured are entitled to a medical consultation on diseases, possibilities of their treatment, and consequences of the discontinuation or the failure to adopt measures of treatment. The consultation encompasses also the documentation of the scope of the consultation and its result by the physician.

Although the bill proposed this free-of-charge medical consultation to draw up a living will consistent with sec. 1901 b (2) 1 Civil Code, the reasoning of the bill does not consider for the costs to be borne by the social security system.

The so-called Zöller-Draft[45] aimed to introduce living wills in sec. 1901 b Civil Code. This draft was limited to regulate only what is strictly necessary. A further modified version of the draft, which also contained provisions for the form of advance directive and criteria to determine the patient's wishes, was introduced in the Bundestag on 18 December 2008.

After a hearing of experts in the Legal Committee of the Bundestag, the second and third readings of all proposals took place on 28 May 2009. On 18 June 2009, it was voted on the three then present draft bills, as well as on an application of a small group of members of parliament, which suggested not legislating living wills. With a majority of 317 votes to 233 no votes and 5 abstentions, the parliament finally adopted the bill, which based on the Stünker-Draft.

3.2 Economic Effects of the Living Will Act on Social Security

Due to the fact that the then enacted Stünker-Draft did not provide for any economic reasons besides budgetary effects, which have to be stated in every draft bill, living wills cannot result in any direct cost for the social security system. Therefore, any economic effect may stem from indirect results to social security or results outside the social security system.

The indirect results from living wills may be based on the refusal of futile interventions within the living will. This may lead to lower costs for the social security system. As was discussed in the US case based on empirical data from Medicare, however, other alternative interventions (e.g., hospice-based end-of-life care or palliative care) may result in even higher costs.

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[44] According to Bundestags-Drucksache 16/11360, as translated by the author.

[45] The bill was named after its sponsors Wolfgang Zöller, Dr. Hans Georg Faust, Dr. Herta Däubler-Gmelin, and Monika Knoche. See Bundestags-Drucksache 16/11493.

The economic effects outside the social security system are even harder to investigate. For example, there are other economic consequences for patients and the families. Moreover, there may be even economic effects in other sectors such as private nursery at home as a part of palliative care.

However, none of these possible effects has been discussed in Germany as economic reasoning is still seen as a taboo ("human life is not open to economic arguments"). Therefore, the analysis of economic effects of the German living will act is far more complex than of amendment in section 1861 of the US Social Securities Act. On the other hand, in totally neglecting economic arguments, also the opportunities of living wills are being undervalued in Germany. This is underpinned by the fact that none of the then three bills for enacting a living will act did provide for any financial assistance for drafting up a living will. Even the Bosbach-Draft neglected the costs to the social security system.

It seems that the taboo of considering economic arguments in the field of living wills—in contrast to the US—leads in the end to a quite surprising result: whereas in the US the costs for medical consultation before drafting a living will are borne by Medicare, in Germany the costs have to be paid by the individual without any financial assistance. Because medical consultation for drafting a living will has to be paid according to the payment scheme for the so-called private insured patients (Gebührenordnung für Ärzte, GOÄ), these costs can be deemed to be prohibitive. However, the drawing up of a living will without any medical knowledge may lead to perverse provisions that are open to ambiguity or even harm the interest of the patient because they are contrary to his then real intention. The ministries of health and justice are trying to limit these detrimental effects. It is, however, questionable whether predefined templates downloadable from the internet are able to deal with these very individual beliefs and states of health.

4 Situation in Italy

4.1 Legislative Process Leading to Bill No. 2350

In Italy, the draft bill on advance directives has been passed recently only in the Chamber of Deputies. Very similar to the US, there was also in Italy an individual case (Eluana Englaro) that gained nationwide attention and prompted a fierce debate involving political parties, as well as the Catholic Church.[46] As in the US, the Prime Minister (Presidente del Consiglio dei Ministri) tried to overrule judicial review leading to a derogation of the separation of powers.

As a reaction to the Englaro case, a bill was introduced in the Italian parliament in order to regulate therapeutic alliance between the patient and the physician,

[46] See, for details, the contribution of V. Ivone in this publication.

informed consent, and advance directives (Bill No. 2350, 'Dispositions in matter of therapeutic alliance, informed consent, and advance treatment directives'[47]—**Disposizioni** in **materia di alleanza terapeutica**, **di consenso informato e di dichiarazioni anticipate di trattamento**).[48]

> Article 3.
> (Content and limits of the advance treatment directive)
> 1. In an advance directive, the declarant, being fully competent and in possession of complete medico-clinical information, with regard to a possible future permanent loss of mental capacity, expresses orientations [directions] and information useful for the physician as to the medical treatments to be performed in conformity with the present law.
> 2. The advance treatment directive may contain an express renunciation of any or some specific kinds of therapeutic treatments of disproportionate or experimental nature.

In contrast to Germany, the bill prohibits to state the discontinuation of artificial nutrition and hydration in an advance directive (art. 3, para. 4, Bill No. 2350). Moreover, in order for an advance directive to be valid the bill requires it to be written after the provision of complete and exact medical information, dated and signed by the individual and the physician (art. 4, para. 1, Bill No. 2350). The advance directive must be renewed in a 5-year cycle in order to be valid. However, it does not bind the physician to the explicit will of the patient. Rather, it is aimed to form a therapeutic alliance between the patient and the physician.

4.2 Effects of the Living Will Act on Social Security

Bill No. 2350 does not explicitly provide for any reimbursement for the costs of medical consultation before drafting a living will. Costs for palliative care are, however, regulated by Law No. 38, 15 March 2010 ('Dispositions to guarantee the access to palliative care and relief of pain'—Disposizioni per garantire l'accesso alla cure palliative e alla terapia del dolore). According to this Act, the Ministry of Health (Ministero della Salute) is authorized to introduce an information campaign on palliative care because recent research carried out by the patient organization Cupido showed that the knowledge within the population about the mere existence of the law is as low as 30 %.[49] According to article 1 of Law No. 38, all terminally ill patients shall have the right to access palliative care and pain therapy. It does not, however, create the legal institute of a living will. In contrast, it establishes networks of palliative care and pain management.

[47] Henceforth, an unofficial English translation by Stefania Negri is being used.

[48] The bill was approved by the Senate of the Italian Republic (Senato della Repubblica) on 26 March, 2009, as amended and approved by the Chamber of Deputies (Camera dei Deputati) on 12 July, 2011.

[49] Spizzichino M. Implemetation status of Law 38 of March 15th, 2010, presentation 31 May 2012.

According to recent data, the usage of strong opiods in Italy is substantially lower than in the rest of Europe.[50] Whereas the consumption per capita in Germany was at 9.08 Euro, it was only 1.07 Euro in Italy. The European average was at 4.47 Euro. This underpins regional differences in the usage of strong opiods, which is more widespread in northern Europe, as well as in the north of Italy. Therefore, the implementation of an intensified palliative care will lead to higher costs to the Italian health care system. On the other hand, also the quality of life of patients treated with palliative medication is improved as the main goal of palliative care is quick pain relief.

5 Economic Analysis of Living Wills

5.1 Types of Economic Evaluations

In analyzing the economic effects of living wills, both costs and consequences must be identified, measured, valued, and compared with alternative legal provisions being considered. This is especially true because the preliminary assumption of replacing futile and expensive care with low cost palliative care is falling short. Moreover, it is merely not possible to identify in advance those patients for which curative effort is futile.[51] Due to the fact that economic literature on living wills is nearly inexistent, in the following some introductory notes are to be made.

The major economic analytic techniques cost-effectiveness analysis (including cost-minimization analysis), cost-utility analysis, and cost-benefit analysis measure consequences in different units (Table 1).

Generally, economic evaluations are used to investigate a specific intervention, i.e. the application of specific type of surgery or the administration of a specific drug. However, as the living will is an advance directive in order to regulate possible interventions in the future in the event that the patient does not have the capability to state his will at that time, the basis of the evaluation is far more complex. Not only is there a cluster of medical interventions, but also it is not known in advance whether, when, and which medical interventions will be necessary and chosen. Therefore, the economic analysis should also consider probabilities. Thus, instead of the generally used term ‘intervention’, ‘living will’ as a cluster of interventions with different probabilities is used henceforth.

A cost-effectiveness analysis compares the costs of a living will, valued in money terms, to its consequences in the natural units of effectiveness (e.g. life years gained). Therefore, it can only be used to compare alternative living wills that produce the same ‘type’ of consequences. It cannot be used, however, to compare

[50] Spizzichino M. Implemetation status of Law 38 of March 15th, 2010, presentation 31 May 2012.
[51] Ash and Arons (2009), p. 317.

Table 1 Measurements of costs and consequences in economic evaluation

Analytic technique	Measure of costs	Measure of consequences
Cost-Effectiveness Analysis (CEA)	Money units	Physical units (effects)
Cost-Utility Analysis (CUA)	Money units	Quality-adjusted life years (or equivalent)
Cost-Benefit Analysis (CBA)	Money units	Money units

Cost-minimization analysis is implied in cost-effectiveness analysis when consequences are identical in all relevant respects
Modified from Drummond et al. (1997)

different types of consequences at the same time unless a common unit measuring consequences is established. This common unit can be achieved in two different approaches, leading to cost-utility analysis by preference weighting and cost-benefit by value-weighting analysis. Therefore, this type of evaluation is only suitable to compare living wills that have homogeneous outcomes and where dominant outcome of primary interest can be identified. Although this prerequisite is in most cases quite restrictive, it may be reasonable to focus on life years gained as the common measure of effect. However, even this is problematic if any of the alternative living wills have a multidimensional effect on quality of life, as well as on quantity of life.[52] Moreover, in end-of-life treatment, not only the 'mere' survival but also the types, frequencies, and severity of side effects and the absence of pain are interesting outcomes. Therefore, a cost-effectiveness analysis of living wills is not feasible.

A cost-benefit analysis values the consequences in monetary units most frequently by asking how much individuals would be willing to pay to obtain the consequences (willingness to pay or contingent valuation) and is, therefore, considered to be the 'best' economic evaluation.[53] Because both the costs and the consequences of a living will are measured in money units, a decision can be made upon the difference between benefits and costs. If benefits exceed the costs, a positive net benefit is generated and the living will itself is worth doing. If several different regulations on living wills are being compared, the one with the highest difference should be chosen. The attribution of monetary terms allows even the comparison of regulations that produce different consequences, although practical difficulties in measuring the preferences using willingness to pay must be overcome.[54] However, it is not feasible to apply this type of analysis to living wills.

A cost-utility analysis measures the consequences in quality-adjusted life years (QALYs) reflecting both the quantity and the quality of life years resulting from the legal regulation on living wills.[55] A possible alternative measure is the healthy-year equivalent (HYE).[56] Eventually, alternative regulations on living wills are

[52] Spilker (1990).

[53] Johannensson and Jonsson (1991), pp. 1–23.

[54] Robinson (1993), pp. 924–926.

[55] Raisch (2000), pp. 906–914, Gold et al. (1996a), pp. 82–134.

[56] Mehrez and Gafni (1989), pp. 142–149; Gafni and Birch (1993), pp. 325–339.

compared in respect of cost per QALY gained. Quality-adjusted life years are calculated by multiplying the number of life years gained from a living will weighted with the individual perception of health-related quality of life ('utility') for that period on a scale of 0 (immediate death) to 1 (perfect health). In fact, the living will might not result in a prolongation of life in comparison to the alternative but enhance quality of life as it is aimed at in palliative care. In contrast to cost-effectiveness analysis, different consequences can be captured by cost-utility analysis. Despite several analytical issues that arise in dealing especially with palliative care, it is the only type of analysis that is applicable to living wills.

5.2 Viewpoint

A further decision has to be made on the viewpoint of the economic evaluation of living wills. This is important because it determines the types of costs included, the cost of each resource unit, and, in some instances, the measures of outcomes, i.e. the positive and negative effects are included. Most generally, the costs of living wills can be classified into the categories health care resources, patient and family resources, and resources from other sectors. The societal viewpoint is the most comprehensive perspective, in which all costs and all effects are considered regardless of who incurs the costs or who realizes the consequences from the living will. For public sector decision-making, this perspective is considered to be the most relevant, although it is frequently deemed to be too difficult and too expensive to measure costs other than direct medical costs.[57] Therefore, applying different viewpoints reveals which groups will favor the investigated provisions for establishing living wills for economic reasons. The results from economic evaluations depend on the selected viewpoint. It is clear that in analyzing the economic effects of living wills not only the budgetary effects—as discussed within the parliamentary committees of the Bundestag—are relevant. Moreover, living wills may lead to the refusal of medical interventions and may, thus, shift costs from curative medical treatment to palliative care.

Particularly, when dealing with different types of living wills, the measurement and valuation of costs and consequences depend on the selected viewpoint of the evaluation. Economic evaluations of living wills from a payer or provider perspective, i.e. hospital, physician, regularly include only direct medical costs incurred by the corresponding provider (e.g., Medicare or the German public health insurance) rather than all health care resources consumed. In end-of-life treatment, especially supportive care is given outside the hospital and might not be attributable to the hospital. Therefore, these costs are not included in studies analyzed from a hospital or health system perspective. Generally, the various costs and consequences can be assembled as depicted in Fig. 1.

[57] Gold et al. (1996b).

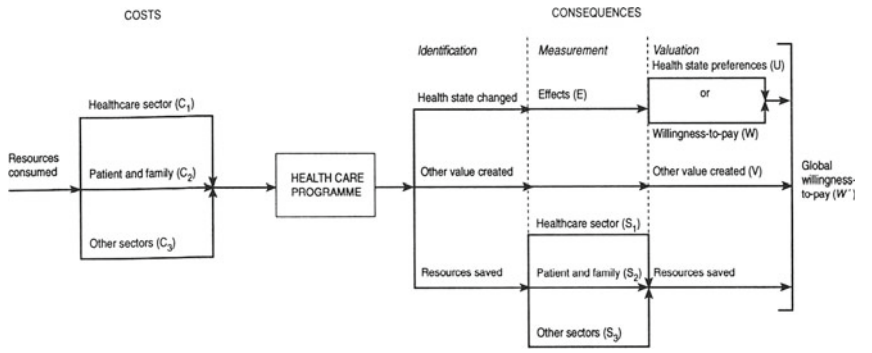

Fig. 1 Components of economic evaluation. *Source*: Drummond et al. (1997)

The costs resulting from living wills can be attributed to three sectors: the health care sector (C_1), patient and family (C_2), and other sectors (C_3). Total cost is calculated by multiplying the quantities of resources consumed (e.g., drugs, equipment used, hospital days, physician visits) by the corresponding unit costs or prices.

However, as the aforementioned research on the economics of living wills in the US shows, there is no clear evidence on the attributable costs:

> The distribution of the full costs of health care across providers requires significant new research. Basics of use, such as the rates of use of hospice and other palliative care-within hospitals, in freestanding facilities, or at home-and the sociodemographic distribution of care, are unknown. Similar questions remain about rates of creation and application of advance directives. These basics need to be examined before we can move to policy-analytic questions such as the economic factors or disincentives that account for low rates of utilizing palliative care in these hospice settings, or whether changes in the incentive structure (Medicare, private insurers, hospitals) would change the use or quality of palliative or hospice care.[58]

In order to identify the costs of living wills, it must be distinguished between current costs for writing down the living will and future costs that are incurred when decision-making capacity is lost. Besides out-of-pocket expenses in traveling, various copayments, expenditures, time for care, and nursing, support at home is the most important resource of patients and their families consumed during treatment. Resources consumed in other sectors include costs in the social services sector for providing services to ill individuals.

The consequences can either arise in savings of resources in the health care (S_1), patient and family (S_2), or other sectors (S_3) and in health effects (E). While an end-of-life-treatment can save resources in the health care sector by avoiding the need for other costly medical interventions (e.g., surgery, radiation), patients and their families might have the benefit of reduced travel and time costs, and other sectors might benefit, e.g., through reduced compensation and disability costs.

[58] Ash and Arons (2009), p. 320.

Particularly for living wills, which direct costs in the remote future, special attention has to be made to time preference. Costs and benefits must, thus, be discounted if they occur on a longer time horizon so that all values compared refer to the same time period. A variety of approaches can be used for this adjustment, and the selection of an 'adequate' discount factor might have significant effects on the result of the evaluation.

5.3 Summary of Findings and Discussion

In summarizing the costs and consequences of living wills, the findings from the empirical studies from the US, as well as the current state of research in Germany and Italy, can be arranged as depicted in Table 2.

The most surprising result is that living wills through the use of palliative care do not lead to lower costs in the health care sector. Although there are some studies with contradicting results, these do not stand up to close scrutiny. Of course, the use of palliative care according to the living will of the patient leads to lower medical costs. The difficulty with this view is, however, that it totally neglects the costs in other parts of the health care sector such as nursing or costs for palliative care at home. In addition, the above-mentioned empirical findings stem from nonexperimental studies that are critical for two reasons:

> First, hospice participants are self selected and may likely have used fewer resources in the conventional care setting had they not opted for hospice. This selection bias leads to overestimates of the savings from hospice care. Second, entrance into hospice may be associated with the realization that further curative efforts are futile, while the hospice nonusers had the potential for realizing gains from continuing curative effort.[59]

On the other hand, there are several positive consequences of living wills besides the nonexistent cost advantages. First and foremost, a living will results in a higher quality of life for the patient and also his family if all medical interventions are arranged according to his actual will. The possibility to draft a living will also raises the awareness of palliative care as an alternative to intensified medical interventions. For the health care sector, even in the case of increased costs, a living will ameliorates the allocation of ICU usage. ICU resources can be freed for patients who have stated their will to the treatment of high intensive medical care. Moreover, living wills also underpin the right of self-determination, although it cannot be valued in monetary terms.

[59] Ash and Arons (2009), p. 317.

Table 2 Costs and consequences of living wills

Costs of living wills	
Health care sector (C_1)	Higher
	Very high (if the living will is being drafted by the individual alone)
Patient and family (C_2)	Higher (drafting a living will)
	Care at home
Other sectors (C_3)	Higher because of social services outside the health care sector
Consequences of living wills	
Health state preference	Increased quality of life, decreased quality of life in the event that the living will does not represent the actual will of the patient
Other value created	Awareness of palliative care
Health care sector (S_1)	ICU and other capacities freed for other patients
	Accurate allocation of medical and nursing resources
Patient and family (S_2)	Right of self-determination (individual)
Other sectors (S_3)	Right of self-determination

6 Conclusion

The discussion showed that cost arguments in favor of the legal institution of living wills are not corroborated by empirical findings. In contrast, an effective living will enhances the utility of the individual, his family, and even the society by underpinning the right of self-determination. In comparison of the three countries, it was shown that the valuation of this right is open to cultural and religious arguments. A positive analysis of the economic effects of living wills, thus, only describes the consequences but is not intended to prescribe the legislative body the creation of a specific legal institution. This study can, however, recommend accounting for the necessity of the correct drafting of an individual living will. As was pointed out, the living will is often drafted long time before its use by a medical layman. Therefore, it may contain provisions that do not represent the actual will of the patient at the time of application of the document. There are several alternatives to deal with the resulting problems, which also influence the economic effects of living wills. The German legislator, in contrast to the bill in Italy, did not vote for a necessity of a medical consultation prior to drafting the living will.[60] The authorities tried to limit the harmful effects of "wrong" living wills drafted by laymen through preformulated specimen. In contrast, in the US at least for some patients, the costs of a medical consultation for drafting the living will are borne by the health care system. Even in Italy, where the law on living wills is not yet in effect, there has been an information campaign on the possibilities of palliative care. From all this, it follows that the economic effects of living wills are positive, although this should be investigated by empirical studies also in Germany and Italy.

[60] Taupitz (2010), pp. 155–177.

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Appendix
Constitution of the Italian Republic[1]

Article 2

The Republic recognises and guarantees the inviolable rights of the person, as an individual and in the social groups within which human personality is developed. The Republic requires that the fundamental duties of political, economic and social solidarity be fulfilled.

Article 13

Personal liberty is inviolable. No form of detention, inspection or personal search nor any other restriction of personal freedom is admitted, except by a reasoned measure issued by a judicial authority, and only in the cases and the manner provided for by law.

In exceptional cases of necessity and urgency, strictly defined by the law, law enforcement authorities may adopt temporary measures that must be communicated to the judicial authorities within forty-eight hours. Should such measures not be confirmed by the judicial authorities within the following forty-eight hours, they shall be revoked and deemed null and void.

Any act of physical and moral violence against a person subjected to restrictions of personal liberty shall be punished.

The law shall establish the maximum period of preventive detention.

[1] Official translation of the Constitution provided by the Chamber of Deputies, available at http://en.camera.it/4?scheda_informazioni=23.

S. Negri et al. (eds.), *Advance Care Decision Making in Germany and Italy*, 257
Veröffentlichungen des Instituts für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim 41,
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Article 32

The Republic shall safeguard health as a fundamental right of the individual and as a collective interest and shall guarantee free medical care to the indigent.

No one may be forcefully submitted to medical treatment unless provided for by law. In no case may the law violate the limits imposed by respect for the human being.

Italian Draft Bill: "Dispositions in Matter of Therapeutic Alliance, Informed Consent and Advance Treatment Directives"[2]

Article 1 (Protection of Life and Health)

1. In consideration of the principles enshrined in articles 2 [protection of inviolable rights], 3 [principle of equality], 13 [protection of personal freedom], and 32 [protection of the right to health] of the Italian Constitution, the present law:
   a) Recognizes and protects human life as an inviolable and indisposable right, guaranteed also in the terminal phase of life and in case the person is no longer competent, until death is verified according to the law;
   b) Recognizes and protects the dignity of every person as a priority over the interest of society and of the applications of technology and science;
   c) Prohibits under articles 575 [murder], 579 [murder by consent] and 580 [aiding or abetting suicide] of the Italian criminal code every form of euthanasia, assistance and aid to suicide, considering that medical activities and assistance to patients are exclusively aimed to protect life and health and to relieve suffering;
   d) Mandates doctors to inform patients of the most appropriate medical treatments – except for what is provided in article 2, paragraph 4 – and of the prohibition on every form of euthanasia, recognizing as a priority the therapeutic alliance between the doctor and the patient, which is of particular significance at the end of life;
   e) Recognizes that no medical treatment can be performed without informed consent as provided in article 2, considering that health must be protected as an individual fundamental right and as a collective interest, and that nobody can be compelled to receive a specific medical treatment except under a

[2] Draft Bill passed by the Senate of the Italian Republic on 26 March 2009 and approved with amendments by the Chamber of Deputies on 12 July 2011; the Bill was never enacted as law due to the dissolution of the Italian Parliament in December 2012. Unofficial English translation by Stefania Negri.

S. Negri et al. (eds.), *Advance Care Decision Making in Germany and Italy*, Veröffentlichungen des Instituts für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim 41,
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mandatory provision of law and with the limits imposed by the respect for the human person;

f) Guarantees that in case of patients at the end of life or for whom death is imminent, doctors shall abstain from medical treatments that are extraordinary and disproportionate with respect to the patient's clinical conditions or to healing objectives.

2. The present law guarantees, within the framework of those interventions already provided by the legislation in force, social and economic policies aimed at taking care of patients, in particular of those who are mentally incompetent – be they citizens, foreigners or stateless persons – and of their families.
3. Patients mentioned in subparagraph 1.*f)* are entitled to receive appropriate pain therapies in accordance with the relevant law in force and in conformity with palliative care protocols.

Article 2 (Informed Consent)

1. Except for cases provided by law, every medical treatment must be performed after informed consent is expressly, freely and consciously given by the patient.
2. The expression of informed consent shall be preceded by correct and comprehensible information provided by the attending physician to the patient as to the diagnosis, prognosis, scope and nature of the proposed medical treatment, foreseeable benefits and risks, possible side effects, as well as possible treatment alternatives and the consequences of refusal of treatment.
3. The therapeutic alliance built within the doctor-patient relationship according to paragraph 2, can be expressed, whenever the doctor deems it necessary and the patient so requests, in a document on informed consent, signed by the patient and the doctor. This document is included in the medical record upon request of the doctor or of the patient.
4. The patient retains the right to refuse in whole or in part the information he is entitled to receive. Such refusal may occur at any time and must be expressed in a document, signed by the interested subject, which becomes an integral part of the medical record.
5. Informed consent to medical treatment shall always be fully or partially revocable. The revocation shall be recorded in the medical record.
6. In the case of a disqualified person, informed consent is given by the legal custodian, who signs the document. In the case of an incapacitated person or emancipated minor, informed consent is given jointly by the guardian and the interested person. Whenever an administrator has been appointed by court, and the court's decree statues that assistance and representation shall also be provided in health-related situations, informed consent is given also by the administrator, or by the administrator alone. The decision of these subjects also encompasses the provisions of article 3 and it is taken with the sole aim of protecting the health and life of the incapacitated person.

7. Informed consent to medical treatment of children is given or refused by those who exercise parental or guardian authority after having heard the wishes and requests of the child. The decision of these subjects is taken with the sole aim of protecting the life and the psycho-physical health of the child.
8. With respect to all disqualified or incapacitated persons, lacking any declaration of advance treatment directives, the health personnel shall always act with the sole aim of protecting the life and health of the patient.
9. Informed consent to medical treatment is not required where, in case of emergency, there is a real and immediate risk to the patient's life.

Article 3 (Contents and Limits of the Advance Treatment Directive)

1. In an advance treatment directive, the declarant, who is fully mentally competent and has received complete medical information, with regard to a possible future permanent loss of mental capacity, expresses his directions and useful information as to the medical treatments he wishes to receive, in conformity with the provisions of the present law.
2. The advance treatment directive may contain an express renunciation of any or of some specific therapeutic treatment of disproportionate or experimental nature.
3. The advance treatment directive shall not contain instructions corresponding to the crimes proscribed by articles 575, 579, and 580 of the Criminal Code.
4. Also in compliance to the United Nations Convention on the Rights of Persons with Disabilities, signed in New York on 13 December 2006, artificial nutrition and hydration, in the various forms that science and technology can provide, must be maintained until the end of life, except in cases where they are no longer efficacious in providing the patient with the nutritional elements necessary for the essential physiological functions of the body. They shall not be the object of an advance treatment directive.
5. The advance treatment directive is activated when the subject is in a state of permanent incompetence – due to an assessed absence of integrative cortical-subcortical brain activity – and cannot understand information on medical treatment and its consequences, so that he cannot make decisions about himself. Such assessment is certified by a medical board composed, without additional or new costs for the public finances, of an anaesthetist-intensivist, a neurologist, the attending physician and the specialist in the disease affecting the patient. With the exclusion of the attending physician, these doctors are appointed by the directive board of the medical facility where the patient is hospitalised or by the relevant local health authority.

Article 4 (Form and Duration of the Declaration of Advance Treatment Directives)

1. Advance treatment directives are not binding, they are redacted in writing, dated and signed by the interested fully competent adult after the provision of appropriate and exhaustive medical information, and they are collected only by the general practitioner, who simultaneously signs them.
2. Advance treatment directives shall be made in full freedom and consciousness, and signed with an autograph signature. Any declaration of intent or direction expressed in ways different from the forms and modalities provided by the present law have no value and shall not be used to reconstruct the patient's will.
3. Unless the subject has become mentally incompetent, the advance treatment directive is valid for 5 years starting from the date of the drafting of the act according to paragraph 1, after which term it is no longer valid. The advance treatment directive can be renewed several times in the same form and modalities as provided in paragraphs 1 and 2.
4. The advance treatment directive can be revoked or modified at any time by the interested person. Revocation of the advance treatment directive, even partially, must be signed by the interested person.
5. The advance treatment directive must be included in the medical record from the moment it is activated from a clinical point of view.
6. In case of emergency or when the subject is in immediate peril of life, the advance treatment directive does not apply.

Article 5 (Assistance to Subjects in a Vegetative State)

1. In order to grant and guarantee equitable access to assistance and quality of care, the assistance to subjects in a vegetative state represents an essential level of health care, in accordance with the modalities provided in the Decree of the President of Ministers of 29 November 2001, as published in the ordinary supplement of the *Gazzetta Ufficiale* n. 33 of 8 February 2002. Healthcare assistance to persons in vegetative state or affected by other neurological conditions is provided through hospital, residential and home care, according to the modalities provided in the above mentioned Decree and the agreement between the Ministry of Health, the Regions and the Autonomous Provinces of Trento and Bolzano on the Guidelines for assistance to persons in a vegetative state and minimally conscious states, as approved on 5 May 2011 by the Unified Conference provided by article 8 of the legislative decree no. 281 of 28 August 1997 and following amendments. Home care is as a rule provided by the local health authority with territorial jurisdiction over the place where the subject in a vegetative state is.

Article 6 (Proxies)

1. In the advance treatment directive, the declarant can appoint an adult mentally competent proxy, who accepts the appointment by signing the directive.
2. The declarant who has appointed a proxy may substitute him according to the same modalities followed for his appointment, at any time and without any obligation to give reasons for such a decision.
3. The appointed proxy is the sole subject who is legally authorized to interact with the doctor with regard to the content of the advance treatment directive and he undertakes to act exclusively in the best interests of the patient, always and solely in accordance with the wishes legitimately expressed by the subject in his advance treatment directive.
4. The proxy is entitled to ask and receive from the doctor every information on the state of health of the declarant.
5. The appointed proxy undertakes to ensure that the patient is administered the best available palliative treatments, avoiding any situation of therapeutic futility or therapeutic abandonment.
6. The appointed proxy undertakes to verify carefully that no situation amounting to the crimes proscribed by articles 575, 579, and 580 of the Criminal Code affects the patient.
7. The trustee can renounce the appointment in writing, communicating his renunciation to the declarant or, if he is mentally incompetent, to the doctor who is responsible for the medical treatment.
8. In case no proxy has been appointed, the tasks provided in paragraphs 2, 3 and 4 above are undertaken by the relatives indicated by the Civil Code in Book II, title II, headings I and II.

Article 7 (The Role of the Doctor)

1. The directions expressed by the declarant in the advance treatment directive are taken into consideration by the attending physician, who, after having heard the proxy, writes down in the medical record the reasons why he does or does not follow them.
2. In case the attending physician decides not to follow the directions expressed by the patient in the advance treatment directive, he has to consult the proxy or the patient's relatives, as indicated by the Civil Code in Book II, title II, headings I and II, and give detailed reasons for his decision, which has to be written down and signed in the medical record or in a separate document annexed to the advance treatment directive.
3. The doctor cannot take into consideration directions which are meant to cause the death of the patient or are in conflict with the law or medical deontology. After having heard the trustee, the doctor evaluates the instructions according to science and conscience, and applying the principles of the inviolability of human

life and the protection of health and life, according to the principles of precaution, proportionality and prudence.

Article 8 (Final Provisions)

1. A Registry of advance treatment directives is created within a single national information archive. The subject entitled to the processing of data inserted in this archive is the Ministry of Health.
2. By regulation to be adopted according to article 17, paragraph 3, of Law No. 400 of 23 August 1988, within 120 days from the date of entry into force of the present law, the Ministry of Health, after having heard the Guarantor for the protection of personal data, shall provide the technical rules and the modalities of access, conservation and consultation of the Registry sub paragraph 1. The decree shall also establish the terms and forms according to which the interested persons will be able to draft the advance treatment directive at the general practitioner's office, as well as those concerning registration and conservation at the local health authority, and telematics transmission to the Registry mentioned in paragraph 1 above. Every information concerning the possibility to draft an advance treatment directive are made available on the website of the Minister of Health.
3. [. . .]
4. [. . .]

Italian Criminal Code[3]

Article 575 (Murder)

Whoever causes the death of a person shall be punished with imprisonment for not less than twenty-one years.

Article 579 (Murder by Consent)

Whoever causes the death of a person with his/her consent shall be punished with imprisonment from six to fifteen years.

The aggravating circumstances set out in Article 61 do not apply.

The provisions relating to murder apply if the offense is committed:

1) Against a person under the age of eighteen years;
2) Against a person who was mentally disabled, or in a state of mental deficiency, because of another illness or of abuse of alcoholic or narcotic substances;
3) Against a person whose consent was extorted by the offender by violence, menace or suggestion, or obtained by deception.

Article 580 (Aiding or Abetting Suicide)

Whoever abets someone to commit suicide, or reinforces someone's intent to commit suicide, or in any way facilitates its execution, shall be punished, if the suicide occurs, with imprisonment from five to twelve years. If suicide does not occur, he/she shall be punished with imprisonment from one to five years provided

[3] Unofficial translation.

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that the attempt to commit suicide results in a serious or very serious personal injury.

The sentence is increased if the instigated, abetted or aided person finds him/herself in one of the conditions specified in numbers 1 and 2 of the preceding article. Nonetheless, if the person is under the age of fourteen years or is otherwise incompetent, the provisions relating to murder apply.

Italian Civil Code[4]

Article 5

Acts of disposition of one's body are prohibited when they cause a permanent diminution of physical integrity or are otherwise contrary to law, public policy or morality.

[4] Unofficial translation.

S. Negri et al. (eds.), *Advance Care Decision Making in Germany and Italy*, Veröffentlichungen des Instituts für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim 41,
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Constitution of the Federal Republic of Germany[5]

Article 1 [Human Dignity–Human Rights–Legally Binding Force of Basic Rights]

(1) Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority.
(2) The German people therefore acknowledge inviolable and inalienable human rights as the basis of every community, of peace and of justice in the world.
(3) The following basic rights shall bind the legislature, the executive and the judiciary as directly applicable law.

Article 2 [Personal Freedoms]

(1) Every person shall have the right to free development of his personality insofar as he does not violate the rights of others or offend against the constitutional order or the moral law.
(2) Every person shall have the right to life and physical integrity. Freedom of the person shall be inviolable. These rights may be interfered with only pursuant to a law.

[5] Basic Law for the Federal Republic of Germany (Grundgesetz für die Bundesrepublik Deutschland—GG) of 23 May 1949 (Federal Law Gazette, p. 1), in the revised version published in the Federal Law Gazette, part III, class. No. 100-1, as last amended by Article 1 of the Law of 21 July 2010 (Federal Law Gazette, part I, p. 944). Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_gg/index.html (accessed: 29 March 2012).

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Article 4 [Freedom of Faith and Conscience]

(1) Freedom of faith and of conscience, and freedom to profess a religious or philosophical creed, shall be inviolable.
(2) The undisturbed practice of religion shall be guaranteed.
(3) No person shall be compelled against his conscience to render military service involving the use of arms. Details shall be regulated by a federal law.

Article 6 [Marriage–Family–Children]

(1) Marriage and the family shall enjoy the special protection of the state.
(2) The care and upbringing of children is the natural right of parents and a duty primarily incumbent upon them. The state shall watch over them in the performance of this duty.
(3) Children may be separated from their families against the will of their parents or guardians only pursuant to a law, and only if the parents or guardians fail in their duties or the children are otherwise in danger of serious neglect.
(4) Every mother shall be entitled to the protection and care of the community.
(5) Children born outside of marriage shall be provided by legislation with the same opportunities for physical and mental development and for their position in society as are enjoyed by those born within marriage.

German Criminal Code[6]

Section 13 (Omissions)

(1) Whosoever fails to avert a result which is an element of a criminal provision shall only be liable under this law if he is responsible under law to ensure that the result does not occur, and if the omission is equivalent to the realisation of the statutory elements of the offence through a positive act.
(2) The sentence may be mitigated pursuant to section 49 (1).

Section 32 (Self-Defence)

(1) A person who commits an act in self-defence does not act unlawfully.
(2) Self-defence means any defensive action that is necessary to avert an imminent unlawful attack on oneself or another.

Section 34 (Necessity)

A person who, faced with an imminent danger to life, limb, freedom, honour, property or another legal interest which cannot otherwise be averted, commits an act to avert the danger from himself or another, does not act unlawfully, if, upon weighing the conflicting interests, in particular the affected legal interests and the degree of the danger facing them, the protected interest substantially outweighs the

[6] Criminal Code (Strafgesetzbuch—StGB) of 15 May 1871, in the version promulgated on 13 November 1998 (Federal Law Gazette, part I, p. 3322), last amended by Article 5 (3) of the Law of 24 February 2012 (Federal Law Gazette, part I, p. 212). Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_stgb/index.html (accessed 29 March 2012).

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one interfered with. This shall apply only if and to the extent that the act committed is an adequate means to avert the danger.

Section 49 (Special Mitigating Circumstances Established by Law)

(1) If the law requires or allows for mitigation under this provision, the following shall apply:

1. Imprisonment of not less than three years shall be substituted for imprisonment for life.
2. In cases of imprisonment for a fixed term, no more than three quarters of the statutory maximum term may be imposed. In case of a fine the same shall apply to the maximum number of daily units.
3. Any increased minimum statutory term of imprisonment shall be reduced as follows: a minimum term of ten or five years, to two years; a minimum term of three or two years, to six months; a minimum term of one year, to three months; in all other cases to the statutory minimum.

(2) If the court may in its discretion mitigate the sentence pursuant to a law which refers to this provision, it may reduce the sentence to the statutory minimum or impose a fine instead of imprisonment.

Section 211 (Murder Under Specific Aggravating Circumstances)

(1) Whosoever commits murder under the conditions of this provision shall be liable to imprisonment for life.
(2) A murderer under this provision is any person who kills a person for pleasure, for sexual gratification, out of greed or otherwise base motives, by stealth or cruelly or by means that pose a danger to the public or in order to facilitate or to cover up another offence.

Section 212 (Murder)

(1) Whosoever kills a person without being a murderer under section 211 shall be convicted of murder and be liable to imprisonment of not less than five years.
(2) In especially serious cases the penalty shall be imprisonment for life.

Section 213 (Murder Under Mitigating Circumstances)

If the murderer (under section 212) was provoked to rage by maltreatment inflicted on him or a relative, or was seriously insulted by the victim and immediately lost self-control and committed the offence, or in the event of an otherwise less serious case, the penalty shall be imprisonment from one to ten years.

Section 216 (Killing at the Request of the Victim; Mercy Killing)

(1) If a person is induced to kill by the express and earnest request of the victim the penalty shall be imprisonment from six months to five years.
(2) The attempt shall be punishable.

(Model) Professional Code for Physicians in Germany[7]

Art. 16 (Support for the Dying)

Physicians must support the dying while preserving their dignity and respecting their wishes. They are forbidden to kill patients upon their request. They may not perform assisted suicide.

[7] MBO-Ä 1997—The Resolutions of the 114th German Medical Assembly 2011 in Kiel. Unofficial English translation available at http://www.bundesaerztekammer.de/page.asp?his=4.3569.

S. Negri et al. (eds.), *Advance Care Decision Making in Germany and Italy*, 275
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German Social Code[8]

Section 37b SGB V (Specialized Outpatient Palliative Care)

(1) [1]Insured persons with a non-curable, progressing and an already far progressed disease and a limited remaining life-span, who are in need of laborious care, have the right to claim specialized outpatient palliative care. [2]The service has to be prescribed by a SHI-accredited physician or a hospital physician. [3]Specialized outpatient palliative care includes medical and nursing services and their coordination, particularly for pain relief and symptom control, and aims to provide the care from sentence 1 to insured persons in their familiar home or home-like surrounding; this, for example, includes facilities of individual case support for handicapped persons as well as child and youth services. [4]Insured persons, who are admitted to an inpatient hospice, have a right to claim the necessary medical part of the specialized outpatient palliative care. [5]This only applies, if and as far there are no other providers who are obliged to provide the particular services. [6]Thereby, the special needs of children are to be considered.

(2) [1]Insured persons, who are residing in inpatient nursing homes, as defined by section 72 subsection 1 of the Eleventh Book [*of the German Social Code*], also have a right to specialized palliative care as defined in subsection 1. [2]Contracts under section 132d subsection 1 [of the Fifth Book of the German Social Code] determine, if services from subsection 1 have to be provided by SHI-contractual partners within the nursing home or by staff of the nursing home; section 132d subsection 2 applies accordingly.

(3) The Federal Joint Committee [*Gemeinsamer Bundesausschuss – G-BA*] determines by guidelines, as defined in section 92 [of the Fifth Book of the German Social Code], the full particulars of the services, especially

1. the demands on the diseases under subsection 1 sentence 1 as well as the demands on the insured's special supply needs,

[8] Unofficial English translation by Amina Salkić as of 5 November 2013.

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2. content and scope of the specialized outpatient palliative care including its relation to other outpatient health care services and [content and scope] of cooperation of providers [of specialized palliative care] with already existing outpatient hospice services and inpatient hospices (integrative approach); the already existing care structures have to be respected,
3. content and scope of cooperation between the prescribing physician and the provider of specialized palliative care.

Section 39a SGB V (Inpatient and Outpatient Hospice Services)

(1) [1]Under contracts as defined by sentence 4 [of this subsection], insured persons who are in no need of a hospital treatment, have a right to a subvention for services in inpatient or partially inpatient hospices that provide palliative *medical* treatment, if outpatient health care cannot be provided in the insured's home or family. [2] Taking into account the subventions according to the Eleventh Book [of the German Social Code], the relevant SHI-fund bears 90 % (95% for children's hospices) of the eligible costs from sentence 1. [3] The daily subvention must not fall below 7 % of the monthly reference figure stated in section 18 subsection 1 of the Fourth Book [of the German Social Code] and must not exceed the actual daily costs according to sentence 1, taking into account the subventions of other social care providers. [4] The National Association of Statutory Health Insurance Funds comes to an agreement with key-organizations representing the interests of inpatient hospices about the nature and scope of service under sentence 1. [5] Special needs of children's hospices have to be met sufficiently. [6] The National Association of SHI-Physicians has to be given the opportunity to comment. [7] The contracts concerning the details of the service under sentence 1 must contain a provision for an independent arbiter, who will be pointed out by the parties, to set the content of the contract in the case that a settlement cannot be reached between the parties. [8] If the parties cannot agree on an arbiter, the controlling authority of the contracting SHI-fund will point out an arbiter. [9] The costs of the arbitral procedure will be split between the parties of the contract.

(2) [1]For insured persons, who do not need hospital treatment or inpatient or partially inpatient care in a hospice, the SHI-fund has to support outpatient hospice services (*ambulante Hospizdienste*), which provide qualified voluntary end-of-life care (*Sterbebegleitung*) that is carried out at the persons' homes, within their families, in inpatient nursing care facilities, in facilities for social integration assistance for disabled persons or child and youth services. [2]The subvention moreover requires that the outpatient hospice service

1. cooperates with nursing care providers and physicians that are experienced in palliative medicine and

2. is carried out under the professional responsibility of a nurse or any other professionally qualified person who has several years of experience in palliative medical care or an equivalent vocational training and who is skilled as responsible care-giver or can prove leadership qualification.

[3]The outpatient hospice service provides palliative nursing consultation by appropriately qualified staff and guarantees the acquisition, training, coordination and support of volunteers who are ready to accompany dying patients.[4] Subvention under sentence 1 is accomplished through an appropriate subsidy to the necessary personnel costs. [5] The subsidy refers to service indices which are composed by the number of qualified volunteers in relation to the number of patients who were supported at the end-of-life. [6] The expenses of the health insurance company for the support under sentence 1 are 11 % of the monthly reference figure under section 18 subsection 1 of the Fourth Book per service index point, but it must not exceed the eligible personnel costs of the hospice service. [7] The National Association of SHI-Funds comes to an agreement with the key-organizations representing the interests of outpatient hospice services about the details of the support requirements and the content, quality and the scope of outpatient hospice care. [8] Special needs of children's outpatient hospice care have to be met sufficiently.

Section 132d SGB V (Specialized Outpatient Palliative Care)

(1) [1]Where necessary for an adequate provision the SHI funds conclude contracts with suitable facilities or persons about the provision of specialized outpatient palliative care, including the remuneration and its billing, taking into account the guidelines under section 37b [of the Fifth Book of the German Social Code]. [2] The contracts have to additionally set out in which way the care provider is also engaged in consultative functions.

(2) With the involvement of the German Hospital Association [*Deutschen Krankenhausgesellschaft – DKG*], the Associations of Care Institutions' Sponsors at Federal Level, the key-organizations of hospice services and palliative care as well as the National Association of SHI-Physicians, the National Association of SHI-Funds issues joint and integrative recommendations on

1. factual and personnel requirements of the care providers,
2. measures for quality assurance and further professional education,
3. standards for need-based provision of specialized outpatient palliative care.