

# Guaranteeing Access to Palliative Care between National Law and Emerging International Legal Framework: An Overview of the Italian and Spanish Experiences

Antonietta Elia\*

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## Abstract

According to the World Health Organization's Constitution (WHO), "[h]ealth is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (Preamble, first basic principle). This broader concept of health and the considerable increase in the scientific and technological progress of medical treatments inevitably impact, on one hand, the legal duties of physicians, and on the other hand, the rights of patients. If we consider that the best attainable standard of health that a patient could reach depends on the access to and on the type of treatment that he could receive, it is interesting to analyze if and in what measure any legal provision is due at the national and international level in order to identify the duty of physician to ease the suffering of patients (especially at the end of life), as well as to define and eventually guarantee any existing right of patients to have access to palliative treatments, in accordance with their respective health situation. In other words, is there any existing international legal standard defining "palliative treatments"? Is there a sort of a right to have access to palliative treatments? If yes, under which limitations? The present analysis will try, *inter alia*: to summarize the emerging legal standards at the international level, taking into account any applicable limitations under the United Nations Single Convention on Narcotic Drugs of 1961 and other applicable rules; to analyze and compare the Spanish and Italian experiences, both at the Constitutional and Legislative level, taking into account the relevant territorial distribution of competences in order to assign respective responsibility. We firstly conclude that under international law (especially under international human rights law), States have an obligation to adopt measures to create efficient health systems, including the delivery of palliative health treatment. In the light of the first conclusion and as a consequence, States autonomously regulate the duty of physicians and the system architecture necessary to guarantee effective implementation of the patients' right to have access to palliative treatments.

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\* PhD in International Law and Municipal Law in International Matters (Italy); Senior Associate Research and Teaching Fellow of Public Law, University of Santiago de Compostela (Spain); Visiting Professor of International Law, China Youth University of Political Studies, Beijing (Fall-Winter, 2016-2017); Adjunct Professor of Comparative Constitutional Law, Pontifical University "Comillas", Spain (2015-2016); Former Adjunct Professor of International Law, University of Rome III (Italy); Academic Council on United Nations Member; Spanish Association of International Law Member. Contacts: antonietta.elia@usc.es; antonietta.elia@gmail.com. The present proposal is part of a delivered Lecture Series at the Faculty of Law of University of Santiago de Compostela in 2014.

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## I. Introductory Notes

The emergence of the issues related to palliative care treatments is one of the most relevant questions raised by end-of-life decision-making.<sup>1</sup> These fundamental issues are strictly related to the evolution of society and impose the necessary rethinking of the present time as the “new era of rights.”<sup>2</sup> However, it is important to distinguish at this introduction stage of the present analysis that palliative care must be conceived in a broader sense, including pain treatments of chronic illness that may not necessarily lead to the end of life and are inherent to the health condition of aging persons.<sup>3</sup>

Scientific and technological progress, the new social needs “have generated new threats of human dignity, and consequently new requests pressuring the legal orders.”<sup>4</sup> Furthermore, the contextual multiplication of legal sources of law at the national and international level, such as the corresponding increase of institutional mechanisms of guarantee, generated the need to find a comprehensive response, considering all the relevant concurrent norms.<sup>5</sup> According to the Constitution of the World Health Organization (WHO),<sup>6</sup> “[h]ealth is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”<sup>7</sup> Furthermore, as recalled by the WHO Constitution, “[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”<sup>8</sup>

If we consider such “right to palliative care” only as a part of the general and more

<sup>1</sup> On end-of-life decision-making from a multidisciplinary approach, see S. Negri, ed., *Self Determination, Dignity and End-of-Life Care: Regulating Advance Directives in International and Comparative Perspective* (Leiden, The Netherlands: Brill Publishers, 2011).

<sup>2</sup> M. Cartabia, *The Age of “New Rights,”* Strauss Working Paper, n. 03/2010, <http://nyustrauss.org/index.html>.

<sup>3</sup> Harvard School of Public Health FXB Center for Health and Human Rights, *Health and Human Rights Resource Guide*, chap. 5 at <http://harvardfxbcenter.org> (last visited September 13, 2016).

<sup>4</sup> Cartabia, *The Age of “New Rights,”* 8.

<sup>5</sup> On the importance of methodology for legal scholars in the era of globalization of law, see R. van Gestel, Hans-W. Micklitz, and M. Piores Pessoa Maduro, *Methodology in the New Legal World*, EUI Working Papers LAW 2012/2013, [www.eui.eu](http://www.eui.eu).

<sup>6</sup> Adopted by the International Health Conference in New York on July 22, 1946 and entered into force on April 7, 1948. The text of the WHO Constitution as respectively amended by the World Health Assembly Resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.26 is available on the WHO web site [www.who.int](http://www.who.int) (last visited September 8, 2016).

<sup>7</sup> *Ibid.*, Preamble, first basic principle.

<sup>8</sup> *Ibid.*, Preamble, second basic principle.

ample right to health, we risk adopting a sort of a simplistic approach, denying the specific relevance it can reach in the context of the new social order. Furthermore, this type of approach could carry out a limitation of the effective legal dimension of the eventually existing right. How may we define “palliative care”? Are there “common core standards” at the international level? If palliative care has the legal justification of a right, what is its nature? Is it a fundamental right or could it be subjected to legislative limitations?

In effect, the central point to be retained is the evolution of the same concept of health, as defined by the basic principles in the above mentioned WHO Constitution, such as in international human rights law. On this regard, our view is reinforced by the Committee on Economic, Social and Cultural Rights of the United Nations (the Committee). In its General Comment n. 14 on art. 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Committee extensively elaborated the normative content of the right to health. In its opinion, “[h]ealth is a fundamental human right indispensable for the exercise of other human rights [and] [e]very human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.”<sup>9</sup> It also added that “[t]he right to health is closely related to and dependent upon the realization of other human rights ..., including the rights to ... human dignity, life, non-discrimination, equality [and] the prohibition against torture.”<sup>10</sup> Consequently, the right to health is not understood just as the right of everyone to be healthy, but it necessarily refers to the socioeconomic and biological conditions of individuals.<sup>11</sup>

So far, the present analysis, which is not exhaustive, will be based on the aforementioned normative value of the right to health, intended as the right of the individual to well-being.<sup>12</sup> Furthermore, the present contribution will try to offer a comprehensive approach to the topic. Using a human rights approach, it will try, *inter alia*: to summarize the emerging legal standards at the international level, taking into account any applicable limitations under the United Nations Single Convention on Narcotic Drugs of 1961 and other applicable rules; to analyze and compare the Italian and Spanish experiences, both at the Constitutional and Legislative level, taking into account the relevant territorial distribution of competences in order to assign respective responsibility. So far the first part will be dedicated to the analysis of the existing international legal framework in relation to palliative care; the second one to the national case studies, focusing on the Constitutional framework and the existing legal

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<sup>9</sup> United Nations Committee on Economic, Social and Cultural Rights, *General Comment n. 14: The Right to Highest Attainable Standard of Health, Art. 12 of the International Covenant on Economic, Social and Cultural Rights*, E/C.12/2000/4, (August 11, 2000), para. 1.

<sup>10</sup> *Ibid.*, para. 3.

<sup>11</sup> *Ibid.*, para. 8.

<sup>12</sup> F. G. Pizzetti, *Il diritto a non soffrire: Cure palliative e Costituzione*, [www.personaedanno.it](http://www.personaedanno.it) (last visited August 30, 2012).

provisions at the central level fixing or affecting the essential level of assistance. However, due to the limits of the present work, a detailed analysis of implementation at the regional level is not included.

Finally, we firstly conclude that under international law (especially under international human rights law), States have an obligation to adopt measures to create efficient health systems, including the delivery of palliative health treatment. In the light of the first conclusion and as a consequence, States autonomously regulate the duty of physicians and the system architecture necessary to guarantee effective implementation of patients' right to have access to palliative treatments.

## II. Palliative Care into the International Legal Order

### A. Defining Access to Palliative Care: Between WHO Guidelines, Human Rights Norms and the UN Drug Control System

Considering law as one of the patterns of the globalization process, we must verify the existence of legal obligations for the State and/or the emerging standards under international law, eventually evaluating their impact on the national order.

So far, we should recall that, according to the United Nations Committee on Economic, Social and Cultural Rights, States have the duty to “protect, respect and fulfil the right to health.”<sup>13</sup>

From a normative perspective, the Committee, recalling that the right to health contains both freedom and entitlements and that the “entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health,”<sup>14</sup> affirms and recognizes both the right to have access to an efficient health system and the obligation of the State parties to constitute an organizational

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<sup>13</sup> United Nations Committee on Economic, Social and Cultural Rights, *General Comment n. 14*. According to the first paragraph, “Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The realization of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, or the implementation of health programs developed by the World Health Organization (WHO), or the adoption of specific legal instruments.” About the normative value of the General Comments adopted by the Treaty Bodies System Monitoring of the United Nations (including the ECSCR), see International Commission of Jurists, *Study on the Reform of the United Nations Human Rights Treaty Body System* (Geneva: International Commission of Jurists, 2008), [www.icj.org](http://www.icj.org) (last visited September 12, 2016); C. Blake, *Normative Instruments in International Human Rights Law: Locating the General Comment*, Center for Human Rights and Global Justice Working Paper, n.17 (2008), [www.chrgj.org](http://www.chrgj.org) (last visited on September 12, 2016) 10-12.

<sup>14</sup> *Ibid.* at para. 8.

sanitary structure aiming to effectively guarantee the highest attainable standard of health. It could be noted that, when the individuals concerned are patients at the end of life, the highest level standard of health is also determined by the access to palliative care.

It added that “States [must respect the right to health] by ... refraining from denying or limiting equal access for all persons to ... palliative health services,”<sup>15</sup> defining in particular the access to essential drugs as “part of the minimum core content of the right of the highest attainable standard of health.”<sup>16</sup> Furthermore, it noted that “[o]bligations to *protect* include, *inter alia*, the duties of States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties.”<sup>17</sup>

Consequently, under the Covenant States have the obligation to guarantee access to health care services and palliative care treatments, also by establishing an efficient health system. So, is there a common core minimum standard on “palliative care” at the international level?

The World Health Organisation (WHO) firstly stressed the relevance of palliative care to patients not responsive to curative therapy, but it underlined the need to extend the access to palliative care at the first level of illness.<sup>18</sup> The contribution of the WHO to the definition of minimum core standards has been relevant, even if it defined palliative care as an “approach” and not as an individual right. However, its contribution made palliative care relevant as a public health problem. In fact, it defined the “policy development, education and training, provision of good quality care, and drugs availability as key components of a comprehensive palliative care program.”<sup>19</sup> The WHO plays an important role in the promotion of standards and the definition of a better palliative care program, indicating its main constitutive elements. Some aspects of its guidelines have been included in Italian law n. 38/2010 of March 15 (see *further, para. II.3*), such as the consideration of the health and well-being of the family of the patient or the professional training of specialized medical personnel, conceived as parts of the national organizational system.

With regard to the specific issue of the access to palliative medicines, the WHO tries to promote balanced approaches, taking into account that the majority of these medicines are under control measures because of their nature as narcotic drugs. On such a specific point, WHO works in close collaboration with the international control of narcotic drugs and

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<sup>15</sup> *Ibid.* at para. 34.

<sup>16</sup> *Ibid.* at para. 12.

<sup>17</sup> *Ibid.*

<sup>18</sup> WHO, *Cancer pain relief and palliative care*, WHO Technical Report Series, n. 804 (Geneva: WHO, 1990).

<sup>19</sup> For a more detailed analysis of the role of the WHO, see C. Sepúlveda, A. Marlin, T. Yoshida, and A. Ulrich, “Palliative Care: The World Health Organization’s Global Perspective,” *Journal of Pain and Symptom Management*, 24, no. 2 (2002): 91.

psychotropic substances in the framework of the United Nations Drug Control Conventions.

## **B. Access to Palliative Medicines under the United Nations Conventions on Drug Control System**

Firstly, we must underline that the national systems of control of use of drugs and psychotropic substances included in the present study, respectively in the Italian and the Spanish cases, must comply with the international obligations deriving from the United Nations Single Convention on Narcotic Drugs of 1961 and the United Nations Convention on Psychotropic Substances of 1971.<sup>20</sup>

One of the principal aims of the Convention on Narcotic Drugs of 1961 (hereinafter the 1961 Convention) is to limit the drugs under its control to medical and scientific use (Preamble, 8th paragraph), “recognising that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provisions must be made to ensure the availability of narcotic drugs.”<sup>21</sup>

The 1961 Convention created an international mechanism of control, defining and limiting the production, cultivation, use and trade of narcotic drugs and inserting them into separated schedules. In Article 1, it also distinguishes the use of substances and preparation of medical opium from the other substances.<sup>22</sup> Article 4 of the Convention contains the general obligation of Parties to take all legislative measures “to give effect to the convention ... and to limit exclusively to medical and scientific purposes the production, manufacture, ... distribution of [and] the use ... of drugs.”<sup>23</sup> Until now, if we cannot clearly individuate a positive obligation for the State to guarantee the individual access to palliative medicines, we can at least affirm its obligation to recognize its relevance for medical use.

In effect, it must be considered that the system created by the UN Conventions on Drugs Control, and by the 1961 Convention in particular, confers ample procedural autonomy to the States parties. Consequently and as frequently outlined by the International Narcotics

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<sup>20</sup> United Nations, *Treaty series*, n. 706, p. 105, stating that the United Nations Single Convention on Narcotic Drugs adopted in New York on March 1961, as amended by the Protocol of 1972, entered into force on August 8, 1975; United Nations, *Treaty Series*, Vol. 1019, p. 175, stating that the United Nations Convention on Psychotropic Substances of 1971 entered into force on August 16, 1976; Italy ratified the first Convention on April 14, 1975 and acceded to second one on November 27, 1981. Spain ratified the first Convention on January 4, 1977 and acceded to the second one on July 20, 1973.

<sup>21</sup> International Narcotics Control Board, *Report on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*, 2010, [http://www.unodc.org/documents/southerncone/noticias/2011/03-marco/jife/Report\\_of\\_the\\_Board\\_on\\_the\\_availability\\_of\\_controlled\\_substances.pdf](http://www.unodc.org/documents/southerncone/noticias/2011/03-marco/jife/Report_of_the_Board_on_the_availability_of_controlled_substances.pdf) (last visited September 13, 2016).

<sup>22</sup> United Nations, *Convention on Narcotic Drugs, 1961*, at article 1, para. 1, let. o, [https://www.unodc.org/pdf/convention\\_1961\\_en.pdf](https://www.unodc.org/pdf/convention_1961_en.pdf)

<sup>23</sup> *Ibid.* at para. a and c.

Control Board,<sup>24</sup> the majority of national laws are still severe, seriously blocking the access to drugs for medical use.<sup>25</sup>

This problematic aspect has also been emphasized by the United Nations Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment,<sup>26</sup> who recommended to the States to bear in mind that “given [the] lack of access to pain treatment and opioid analgesics for patients in need might amount cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome ... regulatory, educational and attitudinal obstacles to ensure full access to palliative care.”<sup>27</sup>

The Convention on Psychotropic Substances of 1971 (the 1971 Convention), on the other hand, imposes a series of more specific obligations on States parties. Article 5 states as follows: “1. Each Party shall limit the use of substances in Schedule I as provided in article 7. 2. Each Party shall ... limit by such measures as it considers appropriate the manufacture, export, import, distribution and stocks of, trade in, and use and possession of, substances in Schedules II, III and IV to medical and scientific purposes.”<sup>28</sup> Article 7 established the following obligations towards of States Parties:

- a) Prohibit all use except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them;
- b) Require that manufacture, trade, distribution and possession be under a special license or prior authorization;
- c) Provide for close supervision of the activities and acts mentioned in paragraphs *a)* and *b)*;
- d) Restrict the amount supplied to a duly authorized person to the quantity required for his authorized purpose;
- e) Require that persons performing medical or scientific functions keep records concerning the acquisition of the substances and the details of their use, such records to be preserved for at least two years after the last use recorded therein.<sup>29</sup>

According to the scope of both Conventions, we could identify a series of States obligations: firstly, States have a negative obligation, that is, they must avoid measures aiming

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<sup>24</sup> See e.g., *The Report of the International Narcotics Control Board 2007*, [www.incb.org](http://www.incb.org).

<sup>25</sup> International Narcotics Control Board, *Report on the Availability of Internationally Controlled Drugs*.

<sup>26</sup> Manfred Nowak, *Report of the Special Rapporteur of the United Nations on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, A/HRC/10/44, January 14, 2009, [www.ohchr.org](http://www.ohchr.org) (last visited September 12, 2016).

<sup>27</sup> *Ibid.*, *Conclusions and Recommendations*, para. 74 (e), p. 24; see also *Ibid.* pp. 17, 22-23.

<sup>28</sup> United Nations, *Convention on Psychotropic Substances, 1971*, [https://www.unodc.org/pdf/convention\\_1971\\_en.pdf](https://www.unodc.org/pdf/convention_1971_en.pdf).

<sup>29</sup> *Ibid.*

to limit the medical use of substances under control. Such kind of measures of control must be considered as necessary instruments “to restrict the use [of those substances] to legitimate purposes ... and [they must be not used] to unduly restrict [their availability for medical purposes].”<sup>30</sup> Is there an international legal obligation to make available those medicines composed by those substances and used for palliative treatments? Probably we could find it as an “implicit” obligation for States parties. Despite the recognition of the utility of the drug precursors and other substances for medical use, the whole system continues to block access to medicines composed of substances under control. The former United Nations Special Rapporteur on the Right of Everyone to Enjoyment of the Highest Attainable Standard of Health strongly affirmed that the entire system of the Conventions is still totally focused on the criminalization and the need to regulate the trade-related aspects of the substances. Otherwise, the respect for human rights and the guarantee of the right to health are infringed on by the limitation, *inter alia*, of the access to drugs for medical use.<sup>31</sup>

### III. The National Frameworks: Spain and Italy at a Glance

#### A. Access to Palliative Care Treatments in the Italian Constitutional Framework: Looking for a Foundational Basis

The Italian constitutional order is “profoundly structured”<sup>32</sup> on the fundamental principles listed in Articles 1 to 12, such as on the rights and duties guaranteed by the first part of the Constitution. However, when we discuss the constitutional guarantees of a fundamental right we must take into account both the formal and the material Constitution.

The formal Constitution refers to the constitutional guarantees as formally expressed in the text; the second is the result of the *summa interpretatio* of every disposition developed by the Constitutional Court (hereinafter, the Court) with the aim of both disclosing the relevant norms and, at the same time, giving constitutional protection to emerging new interests and social values. Moving from these preliminary considerations, we should stress

<sup>30</sup> *Ibid*, “Preamble,” paras. 5 and 6.

<sup>31</sup> See A. Grover, *Report of the Special Rapporteur on the Right to Highest Standard of Physical and Mental Health*, A/65/255, <http://www.ohchr.org>, in which she emphasized, *inter alia*, that “palliative care is an approach that seeks to improve the quality of life of patients diagnosed with life-threatening illnesses through prevention and relief of suffering [...]”, adding that “[c]ompliance with procedural requirements [...] creating a barrier to supply to these medications [...],” para. 42-45; see also D. Lohman, R. Schleifer, and J. Amon, “Access to Pain Treatment as a Human Right,” <http://www.biomedcentral.com/1741-7015/8/8> (last visited September 12, 2016).

<sup>32</sup> Italian Constitutional Court, *I diritti fondamentali nella giurisprudenza della Corte Costituzionale*, (March 30-31, 2006), <http://www.cortecostituzionale.it>; See also, *inter alia*, G. Amato and A. Barbera, eds., *Manuale di diritto pubblico*, Vol. I, (Bologna, 1997) 233.



that the whole constitutional order is centred on human beings.

Article 2 of the Italian Constitution (hereinafter, the Constitution) expresses the centrality of human beings, affirming that “[t]he Republic recognises and protects the inviolable human rights of everyone, both as an individual and as into social organization where his personality is developed.”<sup>33</sup>

From this disposition derives the position of priority of human rights among constitutional values. According to a jusnaturalistic approach, the term “recognizes” must be understood as referring to the pre-existence of the rights of a human being in relation to the legal order, while the prevalent literature affirms that Article 2 refers to the values guaranteed by a specific order. According to the Italian Constitutional Court,<sup>34</sup> Article 2 of the Constitution must be considered an open “box”; in other terms it represents a general open clause guaranteeing protection of human rights not expressly enunciated in the Constitution. Consequently and according to a consistent jurisprudential address, Article 2 of the Constitution must be considered a “constitutional instrument” to materially offer constitutional protection to every right felt as inviolable by society, which will be recognized by the legislator.

In the light of these considerations, we must examine the constitutional disposal guaranteeing the right to health, considering: the right to access to medicines as a fundamental part of its effectiveness; the constitutional disposal on the right to health in light of the other relevant and concurrent constitutional disposals; the admissibility of a derived right “to have no pain,” as synonymous with the right to have access to palliative care treatments.

## **B. The Constitutional Guarantee of the Right to Health in the Light of the Complex Nature of Article 32 of the Constitution**

Article 32 of the Constitution has a complex nature.<sup>35</sup> Its first paragraph affirms that the “Republic protects the right to health as a fundamental human right and as a community interest, and it guarantees free available cares to indigents,”<sup>36</sup> while the second

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<sup>33</sup> The original text reads as follows: “La Repubblica riconosce e garantisce i diritti inviolabili dell’uomo, sia come singolo sia nelle formazioni sociali ove si svolge la sua personalità [...]” The translation is unofficial. See A. Celotto, ed., *Costituzione annotata della Repubblica Italiana* (Bologna, 2003); For a more detailed comment, see G. Amato and A. Barbera, eds., *Manuale di diritto pubblico*, Vol. I-III (Bologna, 1997); G. Martines, *Diritto Costituzionale* (Torino, 2006).

<sup>34</sup> Constitutional Court, *Judgment 561/1987*,

<http://www.cortecostituzionale.it>; see also, Constitutional Court, *Judgment 88/1979*, (last visited September 13, 2016), where it defines the health value as one of the “subjective positions” under constitutional protection.

<sup>35</sup> See R. Ferrara, *Salute, (diritto alla)*, in *Digesto delle Discipline Pubblicistiche*, Vol. XIII (UTET) 513.

<sup>36</sup> The English translation is unofficial. For a fundamental analysis of the protection of the right to health into and by the Italian Constitution, see C. Mortati, *La tutela della salute nella Costituzione italiana*, in *Scritti*, II (Milano, 1972), 433; see also B. Caravita di Toritto, *La disciplina costituzionale della salute*, in *Dir. Soc.* (1994) 55.; M. Luciani, *Salute (diritto alla)*, in *Enc. Giur.*, Vol. XXVII (1991) 9.

paragraph strongly recognises that “Nobody can be obliged to any sanitary treatment in the absence of an express legal provision. [In any case] the law cannot violate the limits deriving from the respect for the human person.”<sup>37</sup>

As a direct consequence of its inclusion in the Constitutional Title dedicated to ethical and social relationships, the constitutional norm recognizing the right to health has been for a long time considered to have a programmatic nature rather than a prescriptive significance.<sup>38</sup> However, it must be noted that the Italian Constitution contains and reflects the original formal distinction between categories of rights as a direct expression of multiple instances in the Constituent phase.<sup>39</sup>

Though this paper is not the place to discuss the evolution of the form of the State and the consolidation of the “Social State of Rights,” we should retain the fact that while civil and political rights were originally considered synonymous with “freedoms into the state,” social rights contained only an obligation of scope for public powers.

However, according to the consistent address of the Constitutional Court, the separation of categories of rights must be abandoned, considering that the right to health is one of the inviolable rights of person protected by Article 2 of the Constitution.<sup>40</sup> In this context the right to health is also considered one of the rights to a pretension (*diritto di prestazione*) or a right of the individual to receive a positive intervention by the “Republic,” which makes that right effective. It implies that the effectiveness of the pretension is strictly related to the available financial resources in the State’s budget<sup>41</sup> and to the efficient

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<sup>37</sup> According to the Constitutional text of the article in the original language: “1. La Repubblica tutela il diritto alla salute come fondamentale diritto dell’individuo e interesse della collettività e garantisce cure gratuite agli indigenti. 2. Nessuno può essere obbligato ad un determinato trattamento sanitario se non per disposizione di legge. La legge non può in nessun caso violare i limiti imposti dal rispetto della persona umana.”

<sup>38</sup> About the issue of the programmatic constitutional norms, see Crisafulli, *Le norme programmatiche della Costituzione*, in *La Costituzione e le sue disposizioni di principio* (Milano, 1952) 27 and 51.

<sup>39</sup> See L. Carlassare, *Forma di Stato e diritti fondamentali*, in *Quad. Cost.* (1995) 33. The categorization of rights is evident also at the international level. Despite the comprehensive view of human rights endorsed by the Universal Declaration of Human Rights, adopted by United Nations General Assembly Resolution 217 (III) A, on December 10, 1948, the next two Covenants of 1966 enunciated two separate categories of rights, respectively civil and political rights, and economic, social and cultural rights. Obviously, this distinction between categories of rights were the mirror of the political structure at the international level, profoundly impacting the emergent protection of human rights at this time in the international legal order. The interdependence and indivisibility of all human rights, including economic, social and cultural rights, has been many times strongly emphasized by N. Pillay, Former United Nations High Commissioner for Human Rights. See N. Pillay, *Report to the Human Rights Council*, June 2011, <http://www.ohchr.org> (last visited September 13, 2016); With regard to the protection of the right to health in international law, see M.P. Acconci, *Tutela della salute e diritto internazionale* (Padova, 2010).

<sup>40</sup> See for example the Constitutional Court, *Judgment n. 51/1991*, <http://www.cortecostituzionale.it>, at the Jurisprudence section. More clearly speaking, the right to health must be considered as an absolute subjective right, because its scope is to preserve the physic and mental integrity; see A. Barbera and C. Fusaro, *Corso di Diritto Pubblico* (Bologna, 2006) 161.

<sup>41</sup> The Constitutional Court affirmed that in every case, the essential substance of a (social) right must be guaranteed (for example, *Judgment N. 185/1998* cited in Barbera and Fusaro, *Corso di Diritto Pubblico*, 159).

administrative organisation of the health services both at the national and local level, according to the constitutional distribution of competencies. In the light of these considerations, “[the] action of the State ... must be oriented to equilibrating the distortions and inequalities ... with [*ad hoc*] interventions and politics.”<sup>42</sup>

Looking at the constitutional level, we do not find a specific reference to the constituting elements of the right to health. This is the primary consequence of the open and general significance of the abovementioned constitutional norms, allowing it to be potentially applicable to the new exigencies of society, like the emerging need to guarantee the right to have access to palliative care. To this aim, even if it does not expressly refer to palliative care, the Constitutional Court<sup>43</sup> emphasized that a therapeutic treatment is in the middle of two rights of an ill person, namely the right “to receive efficient care” and the “right to be respected into its personal integrity” at a physical and psychological level, as expressed by Article 32, para. 2 of the Constitution. By this reasoning and according to a part of the doctrine,<sup>44</sup> it is admissible to observe that a material right to have access to a “therapeutic treatment” exists at the Constitutional level.

### **C. The General Palliative Care System under Law 38/2010**

Scientific and technological progress has produced new legal interests<sup>45</sup> to be guaranteed, as well as new social and ethical problems related to them.

The right to access to palliative care is an emerging question raised by end-of-life decision-making, felt by society as a consolidated exigency. According to Article 1, para. 3 of the initial Draft Law concerning the Dispositions in Matter of Therapeutic Alliance, Informed Consent and Advance Treatment Directives, patients at the end of life have the right to receive “an appropriate pain therapy, in accordance with the relevant law in force.”<sup>46</sup> On this point, we could suppose that the abovementioned draft law used the terms “pain therapies” as synonymous of palliative care, taking into account the main object of the same

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<sup>42</sup> R. Ferrara, *Salute, (diritto alla)*, in *Digesto delle Discipline Pubblicistiche*, 517.

<sup>43</sup> Constitutional Court, *Judgment 282/2002*. It stated the definition of competencies between State and Regions in the framework of the guarantee of the right to health, especially mentioned the State’s competency to establishing the essential levels guaranteeing civil and social rights as enshrined by art. 117, para. II, alinea m) of the Constitution.

<sup>44</sup> See F. G. Pizzetti, *Il diritto di non soffrire*. In the author’s opinion, the interdependence between the two paragraphs of art. 32 Const. “underlines the essential elements of freedom and autonomy in the individual health decisions [...]” (original language, Italian).

<sup>45</sup> Just to have a critical but fundamental overview on the new era of rights, see the very interesting analysis carried out by Cartabia, *The Age of “New Rights”*.

<sup>46</sup> *The Draft law n. 2350* has been amended and adopted by the Chamber of Deputies, on July 12, 2011, after the previous adoption by the Senate of the Italian Republic on March 26, 2009. The text is available, *inter alia*, on the website <http://www.biodiritto.it> (last visited September 12, 2016).

draft law.

Apparently, we could attribute to the right to access to palliative care a “legislative” nature, because of its regulation by law, however, as we have just underlined above, its foundational basis remains at the constitutional level.

It is also important to note that the relevance of the right to access to palliative care for the effectiveness of the right to health has been recognized into the National Health Plan only into 2009.<sup>47</sup> Before this date, it was not mentioned as one of the fields where public authorities must guarantee the essential level of assistance.

Reading the National Health Plan, it seems that the “duty of assistance by the sanitary authorities” is considered more relevant than the nature of the individual right to have access to palliative care.

The first law concerning “palliative treatments” is n. 39, adopted on February 26, 1999, which only established the creation of residential structures (hospice) in every Region. However, it did not refer to palliative care in a comprehensive way, nor expressly consider access to palliative care as an individual right.<sup>48</sup> According to the new constitutional framework of the distribution of competencies,<sup>49</sup> the State exercises the exclusive legislative power in the matters listed at paragraph 2 of article 117 of the Constitution. The same article, in particular, attributed to the State the exclusive power “to determine the essential levels [at the all national territory] of the pretensions of the civil and social rights.”<sup>50</sup>

Under this competencies’ framework, on March 15, 2010, the Italian Parliament adopted Law 38/2010, relating to “Dispositions to Guarantee the Access to Palliative Care and to

<sup>47</sup> In fact, since the 2009 National Health Plan, the guarantee of access to palliative care as the consolidation of an efficient system at all levels has been considered as “primary objective.” See the relevant information available at <http://www.salute.gov.it> (last visited September 12, 2016)

<sup>48</sup> Permanent Conference for the Relationships between State, Regions, and the Autonomous Provinces of Trento and Bolzano, *Act n. 239/CSR*, December 16, 2010, <http://www.salute.gov.it>, which affirmed the insufficient level of palliative care in Italy, on the 10 year anniversary of its entry into the force of law 39/1999.

<sup>49</sup> The new framework has been introduced with Constitutional Law n. 3/2001, reforming the Title V of the Constitution related to “Regions, Provinces and Municipalities.”

<sup>50</sup> The translation is unofficial. The original text read as follows: “2. Lo Stato ha legislazione esclusiva nelle seguenti materie: [...] m) determinazioni dei livelli essenziali delle prestazioni concernenti I diritti civili e sociali che devono essere garantiti sul tutto il territorio nazionale. [...]” However, we must underline that the Constitutional Court recognized the existence of some “transversal matters,” as in the health care service, where there is a variety of interrelated interests calling upon competencies differently distributed between Regions and State; see Constitutional Court, *Judgment 103/2003*; see also Constitutional Court, *Judgment 438/2008*, where it recognizes, *inter alia*, the right of the patient to receive all relevant information about the therapeutic treatment and its consequences and effects. This case declared the illegitimacy of the law of the Piemonte region, establishing rules about the access to children’s palliative care, underlining the primary competence of the State to fix the essential level of assistance and guarantee; about the protection of fundamental rights in the light of the new constitutional framework of competencies, see S. Gambino, *Federalismo e Salute*, <http://www.federalismi.it> (last visited March 29, 2012); M. Luciani, *I diritti costituzionali tra Stato e Regioni (a proposito dell'articolo 117, comma 2, let. m) della Costituzione*, in *Politica del diritto*, n. 3 (2002).

Pain Treatment.”<sup>51</sup> The Law consists of 12 articles organized as follows: one part is dedicated to fundamental principles, aims and definitions (articles 1 and 2); the second part regulates the competencies, the relationships and the mutual communication of the institutional structures (articles 3 to 8 and 11); the third one is specifically dedicated to the right to access to palliative medicines (articles 9 and 10); the last one refers to financial aspects (article 12).

In contrast to the assumption made by the abovementioned 2009 National Health Plan, the general aim of the Law 38/2010 is “to guarantee the right of the citizen to access to palliative care and to pain treatment” (art. 1, para. 1). It must immediately be noted as a relevant limit, because the law refers to the right of a “citizen,” excluding dangerously all other individuals from the enjoyment of the right, which does not recognize its universality. However, this limit creates a terminological “contradiction” when examining the rest of article 1 related to the aims of the law and article 2, relating to definitions. According to Article 1, paragraph 2, the law protects and fulfil the right to access to palliative care of an “ill person”, defined by article 2, let. c) as a “person affected by a chronicle and evolutionary pathology for which there are no treatments or ... they are inadequately ... [able] to stabilize the illness or to significantly extend life time expectancy.” This more ample view of the text seems to extend the protection to a vaster group of subjects, under the category of “ill person.”<sup>52</sup>

The access to palliative care is guaranteed in the framework of the essential levels of assistance (contained in the Decree of the President of the Council of Ministers of November 29, 2001).<sup>53</sup> It is important to note that the same paragraph 2 of Article 1 of the Law 38/2010 justifies the insertion into the essential levels of assistance of the right to access to palliative care, because of the scope of the “guarantee of the respect for the human dignity and the personal autonomy, the need for health, the equity of the access to assistance, the quality of care and their conformity with the specific exigencies.”

The law limits the action of the sanitary structures imposing on them the respect for: “the human dignity and the autonomy of the ill person, without any discrimination; the protection and promotion of the quality of life until its end; the adequate sanitary [and social] support to the ill person and its family.”<sup>54</sup> Under the section dedicated to the

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<sup>51</sup> “Dispositions to Guarantee the Access to Palliative Care and to Pain Treatment,” *G.U.*, n. 15 (March 19, 2010).

<sup>52</sup> However, F. G. Pizzetti, *Il diritto a non soffrire* emphasizes the reference to the right to palliative care as a citizen’s right, paying particular attention to the subjective sphere of Law 38/2010. In his view, the entitlement of the ill person to enjoyment of the right to have no pain, as expressed at art. 2, para. 1.c) of Law 38/2010, could be not easily interpreted, because of a lack of clarity in defining the category of “ill person.”

<sup>53</sup> “Decree of the President of the Council of Ministers of November 29, 2001,” *G.U., Supplemento Ordinario*, n. 33 (February 8, 2002).

<sup>54</sup> See respectively article 1, para. 3, lets. a), b) and c) of Law 38/2010.

definitions, we must retain the definition of palliative care by the law, which comprehends the totality of therapeutic, diagnostic and supporting interventions designated both for the ill person and his or her family, aiming to actively give care to patients not responding to basic treatments.<sup>55</sup>

The organizational structure could be summarized as follows. First of all, the Minister of Health defines the guidelines for the promotion, the development and the coordination of the interventions at the regional levels, in accordance with the constitutional distribution of competencies found in Article 3, para. 2. The respect for the guidelines is considered to be a fundamental condition for the Regions to have access to integrative financial support.

Most relevant, the Permanent Committee for the Verification of the Essential Levels of Assistance<sup>56</sup> (*Comitato Permanente Paritetico per la Verifica dei Livelli Essenziali di Assistenza*, hereinafter “the Permanent Committee”) is invested with the remit to annually evaluate the state of execution and application of the law, paying particular attention to the efficient and adequate use of financial resources and its conformity with supporting services found in Article 3 of the law. Secondly, the Minister of Health is entitled by law to create a national mechanism to monitoring the specific palliative services offered in every region and on the respective sanitary structure, with the aim of guaranteeing a “uniform” service on the national territory. The content of functions and the organizational structure of this mechanism will be the object of a separate agreement in the framework of the Conference State-Regions found in Articles 5 and 6 of the law.<sup>57</sup> From another point of view, the law imposes the obligation (for the physician) to include the information about the nature of pain and its evolution into the clinical report of every patient.

At this point of the analysis, it must also be considered that the majority of palliative treatments are constituted (though not only) by the diffusion of medicines prepared with particular substances, many of which are considered illegal outside of medical use, not only by the national relevant laws, but also in the framework of specific international treaties. How is the use of these substances limited and/or admitted to medical treatment? Is it admissible to consider the existence of a right to have access to this type of drugs as a part of the general right to have access to

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<sup>55</sup> *Ibid.* at (article 2, para. 1, al. a).

<sup>56</sup> The Permanent Committee has been created by the Convention State-Regions of March 23, 2005 at the Ministry of Health. It is composed of: 4 representatives of the same Minister (one exercising the function of coordinator); 2 representatives of the Minister of Economy and Finance; 1 member of Department of the Regional Affairs of the Presidency of the Council of Ministers; and 7 representatives of the Regions, designated by the Conference of the Presidents of the Regions and Autonomous Provinces. All information is available at <http://www.ministerodellasalute.it>.

<sup>57</sup> WHO, *National Cancer Control Programmes: Policies and Managerial Guidelines*, 2nd ed. (Geneva, 2002) in which the WHO, from a structural perspective, states that palliative care, *inter alia*: “offers a support system to help patients live as actively as possible until death; offers a support system to help the family cope during the patient’s illness”; see also Sepúlveda et al., *Palliative Care: The World Health Organization’s Global Perspective*, 91.

palliative care? In other terms, is there a right to access palliative medicines?

Following the analysis of national law on palliative care, we find a specific section dedicated to this aim. In particular, Article 10 of Law 38/2010 aims to simplify the existing procedure to have access to medicines used for pain therapies. The article, in fact, introduces a series of modifications and integrations to the General Law in Matter of Discipline of Drugs and Psychotropic Substances (*Testo Unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope*), adopted by Decree of the President of the Republic n. 309/1990 (hereinafter, the DPR). Amending the Decree, Law 38/2010 firstly introduces the need to give priority to therapeutic exigencies in the formulation of the list of substances admitted to medical use.<sup>58</sup> Most relevant, the law deletes the previous reference to “patients affected by severe pain,” substituting it with the reference to “ill persons having access to palliative care according to the laws in force.”

However, from a strictly procedural point of view, the law does not introduce relevant substantial modifications. We should partially conclude that at the national level the law recognizes and guarantees the right to access to palliative care, paying particular attention to access to palliative medicines and referring the relevant articulation of the territorial structure of services to the sanitary regional authorities and financial capacity. It seems to be the case in the recent agreement of September 7, 2016 reached at the level of the State-Regions Conference in relation to the draft proposal of modification of Essential Levels of Assistance presented by the Government. Article 23 of the draft proposal regulates domiciliary palliative care services, while Article 31 distinguishes specific palliative treatments for people at the end of life. With regard to the distribution of medicines, Article 9 introduces the possibility for a different use of medicines in case physicians do estimate that the prescription of medicines at the second stage of clinical experimentation in specific cases and under listed limits is necessary.

#### **D. The Fragmented Spanish Legal Framework: A Sketch**

Similar to the Italian Constitutional experience, the constitutional guarantee of the right to health, as enshrined into Article 43.1 of the Spanish Constitution, has been interpreted by the Spanish Constitutional Court<sup>59</sup> in a broader sense as related respectively to the right

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<sup>58</sup> It is relevant to underline that the system of access to palliative medicines at the national level has been previously emended by Legislative Decree n. 272/2005, converted into Law n. 49/2006, published in the *G.U.*, February 27, 2006. This previous Law modified the classification of substances and medicines as the modalities of prescription and authorization.

<sup>59</sup> For the scope of this present work, the analysis of the relevant case-law only referenced relevant judgments adopted by the Court in accordance to article 53.2 of the Constitution, referring to the procedure of direct access of individuals claiming violations of rights. However, it must be underlined that it is not the object of such a

to life and the right of personal autonomy and integrity. As a matter of example, in Judgement STC 5/2002,<sup>60</sup> the Constitutional Court affirmed that the right of personal integrity as provided by Article 15 of the Constitution included the right to health. From a formal point of view, Article 43 recognizes a positive duty of public authorities to organize and protect public health through preventive measures and the delivery of health care services. With those aims, law 14/1986 of April 25, 1986<sup>61</sup> created the General Health Care System. Considered as basic law in accordance with Article 149.1.16 of the Constitution, its implementation covered the entire national territory.

However, we must bear in mind that the territorial distribution of competencies between the State and the Autonomous Communities, as provided in Title VIII of the Constitution, confers to the latter the power to adopt measures in relation to the organization of the local health system, such as the distribution and delivering of medicines. In the absence of a specific basic law regulating the essential levels of access to palliative treatments at the central level, we can find some references in different laws and regulations. One of the most relevant laws directly related to the access to palliative treatments is the Royal Legislative Decree n. 1/2015 of July 24, 2015,<sup>62</sup> that refunds the law on rational use of medicines and sanitary products. Article 49 of this decree expressly references the United Nations Conventions of 1961 and 1971, underlining in paragraph 2 that psychotropic substances are submitted to controls in order to prevent and comply with international obligations relating to the fighting against traffic of illicit drugs and substances. Article 67 of the same law regulates the guarantee of accessibility and affordability of medicines and Article 92.6 refers to the public financial support to deliver medicines and products for specific cases, despite evidence of the reduced costs for aging people affected by chronic diseases in Article 102 (under specific conditions). At the same time, the Spanish law, as the abovementioned Italian draft Agreement on Essential Level of Assistance, also authorized the use of treatments at an experimental stage or for different conditions and indications, referring to the physician for the entire responsibility of those decisions. However, it must be underlined that such kinds of provisions are strictly related to the obligations derived from the UN Drug Control Conventions System.

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procedure.

<sup>60</sup> See STC 5/2002, <http://www.tribunalconstitucional.es> (last visited September 12, 2016).

<sup>61</sup> In BOE n. 102 of April 29, 1986.

<sup>62</sup> In BOE n. 177 of July 25, 2015.



## **IV. Concluding Remarks**

International society is continuing to evolve, embracing new exigencies of guarantee. Considering the right to health as the right to well-being, we have shortly seen that the international legal framework in relation to access to palliative care is a multiple and complex one, because it is necessarily based on a interconnected variety of norms coming from different international regimes. So far, the international human rights norms relating to the protection of the right to health impacted the obligations of States parties to the UN System of Drugs Control (*see paras. I.1, I.2*). Based on this joint reading, States parties are under the “integrate” obligation to guarantee access to health care services and palliative care treatments, including through establishing an efficient health care system. In this context, the contribution of the WHO to the definition of a “minimum core standards” has been fundamental, despite the fact that it considered palliative care as an approach than an individual right. Though the present short overview does not include an examination of the applicable Spanish regional laws, nor the observation of the effective implementation in Italy under the general legal framework, some conclusions are possible.

With regard to the Italian normative framework, we should underline the fact that at the constitutional level, the general right to health has been interpreted in relation to the general open clause contained in Article 2 of the Italian Constitution, in order to expand its content (*see paras II.1, II.2*). However, and according to the Italian Constitutional Court address, the right to palliative care should be considered as a mid-stage between the right to receive efficient care and the right to personal integrity. Based on such a constitutional framework, the access to palliative care into the Italian Legal Order is regulated by law 38/2010, which offers, at least at a normative level, a general legal background (*see Para II.3*). With regard to the Spanish experience, such a similar central normative framework preventing the differentiation of access to palliative treatments in the territory does not exist, for regulation is left to the legislative autonomy of the *Comunidades Autonomas* (Regional Entities). At a Spanish central level, however, we should reference to a group of legislative norms directly or indirectly affecting the access to palliative care (*see para II.4*).

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