**GUIDING PRINCIPLES FOR THE DEVELOPMENT OF LEGISLATION REGULATING THE DOCTOR-PATIENT RELATIONSHIP AND END-OF-LIFE DECISIONS** [1]

**Preface:**

Issues related to the legal treatment of decisions regarding end-of-life care can be effectively resolved only within the framework of the doctor-patient relationship as a whole, and in a manner that safeguards patients' rights to dignity, freedom, and the pursuit of health/well-being and is in keeping with the fundamental dictates of physicians' code of professional ethics. Legislation must establish the objectives, criteria, and limits of medical treatment, define the prerogatives of patients and their physicians, and identify the procedures capable of accommodating and ensuring good clinical practice, thereby providing physicians and patients with an ethical landmark in the framework of legal certainty. The decisions involving end-of-life care considered herein are restricted exclusively to the limitation of treatment and the reorientation of care toward palliative ends; options involving euthanasia have no place in the present proposal.

**1. The doctor-patient relationship and health.**

**1.1.** The goal of the doctor-patient relationship must be the health/well-being of the patient, that is, the best state of physical, mental, and relational well-being that can be attained by the patient under the current conditions.

**1.2.** In practical terms, this goal must be defined not only by the objective criteria suggested by medical science but also in relation to the specificity of the individual being treated. Due consideration must therefore be given to the physical, mental, moral, and relational aspects of the patient's being, the community to which he/she belongs, and his/her conscious choices.

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1. The GUIDING PRINCIPLES FOR THE DEVELOPMENT OF LEGISLATION REGULATING THE DOCTOR-PATIENT RELATIONSHIP AND END-OF-LIFE DECISIONS were elaborated by the Scientific Committee of the Courtyard of the Gentiles Foundation in cooperation with Italian Society of Anesthesia and Intensive Care (SIAARTI) – Study Group on Bioethics

**1.3.** The above concepts are summarized in the principle of *appropriate* treatment as the goal of the doctor-patient relationship and the patient's right. In this context, treatment is considered *appropriate* when it is consistent with scientific knowledge and physicians' code of professional ethics (clinically suitable and proportionate in terms of cost/benefit ratios), in harmony with the patient's perceptions of his/her own wellbeing, and chosen with the patient's consent and with respect for his/her value as an individual.

## 2. Proportionality of treatment

**2.1.** Proportionality is an essential requisite of medical care and therefore a measure of a treatment's legitimacy. Treatment that violates the principle of proportionality is therefore arbitrary and illegitimate/unlawful.

**2.2.** The physician has an obligation to avoid undertaking treatments likely to violate the principle of proportionality and to modify care, interrupting interventions that have been started if they subsequently prove to be incompatible with this principle.

**2.3.** An assessment of proportionality must consider the benefits as well as the suffering that a proposed treatment will cause for the patient in question. From the outset, physicians must consult the patient and/or the person(s) who are supporting the patient's requests (art. 4.2.) and/or have been legally authorized to represent the patient and safeguard his/her rights in case of incapacity.

**2.4.** The principle of proportionality must be respected even in situations of urgency. If the need for medical assistance precludes an adequate assessment of the proportionality of an intervention, the assessment may be deferred. However, it must be undertaken as soon as conditions permit and in a manner compatible with the principles listed in art. 2.2 and 2.3).

## 3. Consent and respect for the patient as an individual.

**3.1.** Given its objective (art. 1.3), the doctor-patient relationship is based by nature on the concept of treatment by consent. The relationship therefore involves the confrontation and concurrence of the physician's medical knowledge and professional responsibilities and the interests of the patient.

**3.2.** Consent must be constructed and implemented in an ongoing process, which accompanies and reinforces the doctor-patient relationship for its duration, from the time of the diagnosis to the choice and implementation of treatment strategies. The process must be planned and carried out in a manner that is commensurate with the patient's ability and willingness to be informed about his/her condition, to assess his/her own state, to make decisions regarding his/her own future, and to assume the responsibility for such decisions. A patient's right to self-determination must be supported even when he/she chooses to delegate responsibility for decisions regarding his care to a trusted party or to the physician caring for

them. In this setting, special attention must be given to persons are legally incompetent and those who are fully or partially incapable of consenting to treatment decisions. This involves exploiting the patient's own residual or partial capacities and regulating the roles played by legal representatives, trustees (v. 4.2), and family members in efforts to safeguard patients' right to care that is appropriate. Owing to physical or mental impairment and/or the emotional fragility that accompanies the end of life and other situations of acute severe illness, a patient may be incapable of making decisions regarding his care. If there is no clearly designated representative or guardian and if the patient's wishes or preferences have not been documented during the process of shared care planning or by means of an advance directive, treatment decisions will be guided by the physician in accordance with criteria of appropriateness and proportionality. If factors or persons subsequently emerge that can shed light on the patient's wishes, the appropriateness of the treatment must be promptly reassessed in light of the new conditions with the aim of ensuring full respect for the patient's wishes and individuality.

**3.3.** The legal instruments used to document the patient wishes cannot be limited to isolated declarations of Instruments are needed that will ensure the construction of consent in a concrete, ongoing process, and such instruments can be obtained by conferring legal value to sound practices that are already in use.

**3.4.** Respect for the individuality of the patient being cared for includes consideration of his/her beliefs, convictions, and preferences.

**4. Legal instruments**

Three instruments are particularly important::

**4.1.** ***Shared care planning.***

**4.1.1.** This process allows patients, with the aid of their physicians, to envision themselves in probable or possible states of health and to identify treatments they would be likely to prefer under those circumstances and those they would probably refuse. It enables patients to project their consent into future scenarios, including those in which they are incapable of making decisions.

**4.1.2.** It should be adopted as the basic form of consent and offered to patients within the framework of doctor-patient relationships, which extend beyond single medical interventions and common treatments of little or no importance.

**4.2.** ***Trustee / Legal guardian.***

**4.2.1.** Patients' rights are completed and guaranteed by the possibility to transfer their right to grant or withhold consent to proposed treatments to trusted individuals, who will support the decisions they make or represent them and defend their rights within the doctor-patient relationship should they become incapable of doing so.

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**4.2.2.** Trustees and guardians are morally and socially bound to carry out the tasks delegated to them by the patient as acts of human solidarity. These individuals also play essential roles in processes aimed at determining the relevance of advance directives elaborated by the patient (art. 4.3.2.).

### 4.3. *Advance directives elaborated by the patient.*

**4.3.1.** This instrument represents the final step in the construction of consent within the doctor-patient relationship. It guarantees respect for patients as individuals and maximizes the chances of equal treatment for persons who are currently capable of making decisions for themselves and those who are not. Advance directives must be regarded not as an obligation but rather as an instrument, which can be used within the doctor-patient relationship to exercise one's right to withhold consent to treatment. The structure of such documents must reflect this function, facilitating freedom of choice regarding their use/non-use. In keeping with the need for certainty and respect for the principles underlying the doctor-patient relationship, patients must also be free to limit the declarations contained in the directive to those dictated by their own individual needs and convictions.

**4.3.2.** Declarations regarding hypothetical situations set in the future must be interpreted, updated, and implemented in a manner that ensures the fullest possible respect for the convictions, preferences, and wishes of the declarant in the actual situation. This type of mediation must be undertaken jointly by the physician and a trustee or guardian designated by the patient (or in the absence of the latter, a person appointed by the court --in Italian, *un amministratore di sostegno ad hoc*), in a process that recapitulates as faithfully as possible the original doctor-patient relationship.

**4.3.3.** This approach allows space not only for declarations of will/volition but also for manifestations of the beliefs, convictions, and preferences that characterize the patient as an individual. It also assigns value to adequately documented private expressions of preference (such as a hand-signed letter given to the physician or other guarantors) and clinical documents such as shared care plans, information recorded in the patient's medical chart, videotaped declarations, and for severely disabled patients, assisted manifestations of will.

## 5. Refusal of treatment.

**5.1.** In this context, the right of the patient to refuse treatment is inherent in the concepts of treatment by consent and treatment appropriateness measured in terms of the benefits perceived and sought by the patient. The final decision on the appropriateness of an intervention must be made by the patient himself (unless such decisions are precluded by incapacitating illness). This principle applies even when the decision involves ending the battle to prolong survival by stopping current treatments and redirecting care toward palliative ends.

**5.2.** Refusal of treatment must occur within the doctor-patient relationship for the following reasons: a) the patient must be provided with information (commensurate with his/her level of understanding) on the consequences of such a decision and on alternative forms of treatment that are available, and b) provisions must be made, which render the health-care staff and the health-care facility itself responsible for ensuring that the treatment plan is revised accordingly, that continuity of care is maintained, and that therapeutic abandonment of the patient is avoided at all costs.

**5.3.** Conscientious objection by a physician is admissible when his/her intervention is required for the withdrawal of life-supporting treatment. In this case, physicians may refuse to carry out an act that is in conflict with their own convictions, while continuing to fulfill their moral duties to ensure continuity of care and arrange for a substitute who will carry out the interventions in question. In the face of legitimate refusal of care that violates the criterion of proportionality, physicians have an ethical and legal duty to withhold or withdraw the treatment in question.

## 6. Legal implications of withholding and withdrawal of treatment.

When treatment is legitimately refused or violates the principle of proportionality, physicians are bound by law and by their code of professional ethics to withhold or withdraw the treatment in question. They also have an inalienable right to demand legislation that regulates the situations herein considered with clarity and assurances that they will not be subject to civil or criminal sanctions for acting in accordance with this duty and with the dictates of good clinical practice.